

**DECISION MEMORANDUM—
INDIVIDUAL SANITARY MEASURE
Denmark**

Daniel Oestmann and Priya Kadam
David Smith and Kevin Gillespie

EQUIVALENCE REQUEST:

Denmark requested an equivalence determination for an alternative post-mortem inspection i.e. visual inspection instead of palpation and incision of lung and liver and their associated lymph nodes of slaughtered market hogs. For purposes of determining equivalence, Danish market hogs are of the 220-240 pounds /six months of age range; the alternative post-mortem inspection procedure is not applicable to sows, boars, and roaster pigs.

BACKGROUND:

On December 16, 2008 in an FSIS-Denmark bilateral meeting a team of FSIS experts met and reviewed Denmark's Supply Chain Inspection system, and presentations by Danish officials. The Supply Chain Inspection system allows inspection of market hogs raised under an integrated quality control program coupled with an on-site verification at slaughter establishments of visually inspected carcasses and organs to ensure that passed carcasses and parts are wholesome and not adulterated. As a part of this inspection system, on December 24, 2008, FSIS approved Denmark's use of an alternative post-mortem inspection procedure omitting the incision of mandibular lymph nodes for market hogs used to detect granulomatous lymphadenitis which is mitigated through on-farm controls that are assessed and reported through government oversight when hogs come to slaughter.

As a part of this Supply Chain Inspection system, in April 2010, Denmark proposed another alternate visual only post mortem inspection procedure, omitting the palpation of mesenteric lymph nodes of slaughtered market hogs used to detect granulomatous lymphadenitis is mitigated through on-farm controls that are assessed and reported through government oversight when hogs come to slaughter. After reviewing a risk assessment supporting this alternate procedure, FSIS approved it on February 29, 2012.

On September 13, 2013 Denmark proposed an additional visual post-mortem inspection procedure to omit the palpation of lung and liver and their associated lymph nodes of slaughtered market hogs used to detect granulomatous lymphadenitis, which is mitigated through on-farm controls that are assessed and reported through government oversight when hogs come to slaughter. At slaughter, FSIS inspectors observe the ventral and dorsal surfaces of the liver and lung surfaces and the associated lymph nodes for abnormalities. This visual observation of the liver and lungs in conjunction with the visual observation of other viscera and discretionary incisions of the mandibular lymph nodes as proposed by the Danes are expected to be sufficient to detect abnormalities such as pneumonia, visible abscesses, and lymphoma that may be seen domestically. As

Denmark's proposal was already in compliance with FSIS' inspection procedures there was no equivalence determination necessary. The following evaluation is for this inspection procedure. Granting equivalence for this alternate post mortem inspection will result in visual inspection in the entirety of the finisher pigs from controlled housing to the slaughter house.

Additionally, Denmark provided a risk assessment that was conducted in three Danish establishments from October to November 2012. The sample size of this assessment was 3,000 market hogs that were exclusively raised indoors. This risk assessment provided a comparison of visual post-mortem inspection with traditional post-mortem inspection. This risk assessment was independently evaluated by the Technical University of Denmark

Denmark's risk assessment identified the most common pathologies that have the potential to be overlooked with a visual only mode of inspection. These were embolic pneumonia in the lungs and liver abscesses.

Denmark conducted an exposure assessment to assess the intended use of the tissues (lungs, livers), and estimate the amount of exposure the consumer would have to them. This assessment concluded that the risk of food safety exposure related to the lungs and livers is negligible because:

- 1) Lungs from market hogs are inedible in Denmark, and the bacteria causing embolic pneumonia are not found in muscle;
- 2) The prevalence of liver abscesses is very low, and likely to be detected during visual observation. Additionally, most livers are used for pet food in Denmark. There are some livers that are used for human food, but in these cases the livers will undergo a manual inspection and abscesses would be detected;
- 3) Denmark's data indicate that if 18 million market hogs are slaughtered in a year (which they typically do) then it could be expected that 5,400 (0.03%) cases of embolic pneumonia and 234 (0.0013%) cases of liver abscesses can occur.
- 4) Using the comparative study of visual only versus traditional inspection and the sample size of 3,000 hogs it was determined that one out of three cases of embolic pneumonia was missed by traditional inspection, and that one out of five cases were missed by visual only inspection. Using these figures, it can be assumed that 1,800 cases of embolic pneumonia would be missed by traditional inspection, and 1,080 cases of embolic pneumonia would be missed by visual only inspection in a year.
- 5) There were only two livers with abscesses found during the data collection period, and they were both detected visually. The low number of abscesses collected help to support the claim of a low prevalence, and that in the expected 234 cases to be seen in a year, the vast majority can probably be detected with visual inspection.

Through data collection Denmark has identified that the greatest foodborne risk is related to the presence of *Salmonella* spp. and *Yersinia enterocolitica* and the cross contamination that comes from palpation. Denmark has had a *Salmonella* surveillance-

and-control program in place since 1995. *Yersinia* is most effectively controlled through hygienic slaughter practices. The food safety risk associated with both of these identified pathogens can be greatly reduced through the implementation of a visual only inspection model.

The risk assessment also took zoonotic diseases that are of a particular concern with swine into consideration although the risk of exposure to hogs that are raised exclusively indoors is very low. The specific diseases that were considered included:

Tuberculosis (TB) – Denmark has been free of TB since 1980,

Foot and Mouth Disease (FMD) – Denmark is recognized by the OIE as being free of FMD with its last case being observed in 1983,

African Swine Fever (ASF) – ASF has never been reported in Denmark,

Classical Swine Fever (CSF) – Denmark is free of CSF with its last case being reported in 1933,

Aujeszky's Disease – Denmark has been free of Aujeszky's disease since 1991,

Brucellosis - Denmark has been recognized as free of Brucellosis by the EU since 1979,

Trichinellosis – *Trichinella* has not reported in Denmark since 1930,

Porcine Reproductive and respiratory Syndrome (PRRS) – PRRS is endemic in Denmark, but is a notifiable disease. It is unlikely that PRRS could be detected at post-mortem, but is more likely at the farm. Omitting the incision/palpation of the lungs and livers would not affect the ability to detect PRRS

Denmark's conclusion to their risk assessment, and confirmed by the Technical University of Denmark, is that there is no risk to food safety if the visual post-mortem inspection of market hogs raised exclusively indoors replaces traditional post-mortem inspection.

FSIS FOOD SAFETY MEASURE:

The purpose of post-mortem inspection of livestock is to protect the public health by ensuring that carcasses and parts that enter commerce are wholesome and not adulterated. To achieve this goal, in swine slaughter establishments operating under traditional inspection or in those establishments operating under the HACCP-Based Inspection Models Project (HIMP), FSIS inspectors perform ante-mortem and post-mortem inspection procedures to detect diseases, abnormalities, and contamination of livestock carcasses and parts.

In establishments operating under HIMP, FSIS requires that the establishment implement ante-mortem and post-mortem sorting procedures and present to FSIS only normal and healthy-appearing animals and carcasses and parts that are wholesome and free of defects. HIMP also requires additional FSIS verification procedures to ensure that the establishment produces only safe, wholesome products.

OBJECTIVE OF THE FOOD SAFETY MEASURE:

FSIS inspectors conduct ante-mortem inspection of live swine and post-mortem inspection of carcasses and parts on a carcass by carcass basis. In market age swine, FSIS performs inspection under either the traditional inspection system or under the HIMP inspection system. In both cases, inspection procedures are intended to identify and remove unwholesome and adulterated carcasses and parts from the food supply.

EQUIVALENCE CRITERIA:

The criteria used for making an equivalence determination for an alternative post-mortem inspection procedure for market-age hogs are set forth below:

1. The government inspection service administers an inspection program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass.
2. The government inspection system requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market hog carcasses presented for inspection.
3. The incidence of diseases in market hogs, such as TB, is not higher than the incidence in the United States.
4. The market swine must be born and raised in the country.
5. The government inspection service must implement a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects).

EQUIVALENCE EVALUATION:

The government inspection service administers an inspection program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass.

This criterion is met. As per Denmark's Supply Chain Inspection system, Denmark uses a combination of pre-slaughter data collection and post-mortem inspection to ensure the identification and removal of diseased carcasses and parts from the food supply. Pre-slaughter data must be presented to the slaughter establishment prior to slaughter of the swine. The Official Veterinarian at the slaughter establishment will verify that this information is supplied to the slaughter establishment. Without this information, swine will not undergo slaughter. This system allows for full traceability of swine and provides the health information of all swine prior to slaughter. Ante-mortem inspection occurs in

the same way as conducted by FSIS. The proposed alteration to post-mortem inspection is related to the visual inspection instead of palpation of the lung and liver and their associated lymph nodes of slaughtered market hogs. Denmark has conducted, and submitted to FSIS, a risk assessment¹ which focused on the areas of swine carcass inspection that will be altered under their “Supply-Chain Inspection” proposal. This risk assessment was conducted on the visual inspection of the lungs and liver and their associated lymph nodes instead of palpation of slaughtered market hogs.

Denmark conducted a study on comparing visual and traditional inspection (palpation) of the lungs and liver. A sample size of 3000 was assessed. Embolic pneumonia in lungs and liver abscesses were identified as the lesions that might be overlooked if visual inspection was conducted because of their small size and location behind the backside of the organ.

The outcome of this risk assessment study was that the changes proposed:

1. Did not have a significant impact on food safety. Neither did it have a negative impact on the assessment of animal health as well as the assessment of the welfare of the pigs.
2. According to the slaughter house statistics embolic pneumonia in lungs and liver abscesses lesions occur at a low prevalence.
3. Denmark typically slaughters about 18 million finisher pigs. The risk assessment found that one of three cases of embolic pneumonia was missed when conducting visual inspection. It was estimated that, in a worst case scenario, 1800 cases of embolic pneumonia will be missed per year.
4. The study concluded that the risk of human exposure related to the hazards identified in embolic pneumonia were negligible because:
 - a. lungs are not considered edible tissue
 - b. meat from pigs with embolic pneumonia that escape detection seems low, because the bacteria are normally not present in the muscle tissue and if present it is in low numbers, and these bacteria are not food borne
 - c. low numbers of abscesses present in the carcasses associated with pyaemia are most likely found during cutting
 - d. hazards found in relation to the embolic pneumonia did not have a significant zoonotic potential and do not show up in the human statistics – hence they do not seem to have a relevance for food safety

¹ Assessment of risk associated with a change in meat inspection- Is mandatory palpation of the liver and lungs a necessary part of meat inspection of finisher pigs? By Pacheco Goncalo, Amanda Brinch Kruse, Lis Alban, and Jesper Valentin Petersen. Danish Agricultural & Food Council and University of Copenhagen, Denmark. Translated into English February 28, 2013

5. The study concluded that the risk of human exposure related to the liver abscesses is very low because:
 - a. prevalence of liver abscesses is very low
 - b. will most likely be identified during meat inspection. Livers that are intended for human consumption undergo manual inspection; therefore abscesses or any other lesions of the liver would be found.

Therefore, there is only a negligible risk involved in visual inspection of lungs and liver and their associated lymph nodes. This assessment covers only finisher pigs that originated in controlled housing farms where the animals were raised under controlled conditions. Thus this alternate post-mortem inspection is effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain. There is a separate criterion below that requires that the swine be market age hogs that are raised under controlled housing so an equivalence determination of this inspection procedure would require that this condition be met.

The government inspection system requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market hog carcasses presented for inspection.

This criterion is met. As described above, Denmark uses a combination of pre-slaughter data collection and post-mortem inspection to ensure the identification and removal of diseased carcasses and parts from the food supply. This information includes but is not limited to: feed, pathogen testing, medical treatments, etc., exchanged between primary producers, the slaughterhouses and the competent authority. Pre-slaughter Supply Chain Information data must be presented to the official inspector, and any information that may cause health concerns must be presented to the official veterinarian prior to ante-mortem inspection of the swine. The Official Veterinarian at the slaughter establishment will verify that this information is supplied to the slaughter establishment. Without this information, swine will not undergo slaughter. Official veterinarians at the slaughter establishment are allowed to use their own professional opinion in deciding if the herd of swine should be allowed to undergo visual inspection or traditional inspection. Any findings that would affect the inspection method (visual vs. traditional) will become historical data connected to the supplying farm, and will be presented as Supply Chain Information for the next herd of swine arriving at the slaughter establishment from that farm. This system allows for full traceability of swine and provides the health information of all swine prior to slaughter.

The incidence of diseases in market hogs, such as Tuberculosis (TB), is no higher than the incidence in the United States.

This criterion is met. Denmark has been recognized as free of *Mycobacterium bovis* (bovine tuberculosis) since 1980. A large-scale surveillance program in cattle in Denmark is in place ensuring a constant documentation of the free status. Denmark has acknowledged the rare occurrence of *Mycobacterium avium*. Because it is known that *M. avium* can be spread by bedding material EU countries require that bedding material

(traditionally peat) be heat treated to mitigate this risk. If the bedding is not heat treated it is not allowed to be used.

The market hogs must be born and raised in the country.

This criterion is met. In order to qualify for this program, the producer must demonstrate that the market hogs are of Danish origin. Only swine that have been raised indoors since weaning, and are raised under controlled circumstances are eligible for this inspection procedure. There is complete segregation of the swine from other species while on the farm, during transport to the slaughter establishment, during lairage and slaughter.

The government inspection service must implement a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects).

This criterion is met. In 2008 the Danish Veterinary and Food Administration (DVFA) submitted performance standards for verifying inspection for the removal of both food safety and non-food safety defects. These standards were introduced for all market hog slaughterhouses on January 1, 2009. The standards include: 1) not more than 5% non-compliances for inspection tasks (palpation, incision and hygienic behavior), 2) not more than 6% cumulative non-compliances for pathological findings (2% for the carcass, 2% for the plucks and 2% for other organs), and 3) for hygienic slaughter not more than 2% non-compliances for contamination in general and 0% fecal contamination. The quality of the meat inspection is conducted by the official veterinarian by checking 100 carcasses including organs per line per shift after post mortem inspection. If non-compliances exceed the performance standards then additional instructions are given to the staff and the frequency of checks is increased.

In 2011 the DVFA revisited the standards and made changes.

Main changes in the new performance standards:

- The standard is covering the overall performance monitoring of the whole meat organization, however the daily check of the official auxiliaries is not part of this standard. Their performance continues to be checked daily by the official veterinarian, but it is no longer considered a performance standard.
- Greater focus on evaluation and corrective actions
- Key performance indicators to compare between slaughterhouses
- New sample frequencies according to the principles in DS/ISO 2859-1
- New procedures for supervision

Number of samples:

- Number of samples is statistically calculated and depends on the number of pigs slaughtered at a particular slaughterhouse. One sample consists of 'one animal' i.e. ante-mortem, post-mortem (carcasses, plucks, intestines, etc.) inspection and inspection on the rework platform.

- At a minimum 5 procedures for each sample. The supervisor makes an inspection of the procedures (palpation, incision, behavior), and the supervisor makes an ordinary inspection of carcasses which have already been through post-mortem control to make sure the right decisions are made by the inspectors.
- If food safety is compromised there will be an immediate correction. Furthermore there will be a monthly evaluation. At the monthly evaluation a 3% differentiation is accepted without changing sample size. If more than 3% the frequency will go up. Focus will be on follow-up to make sure the right corrective actions are made.

Other verification procedures:

- The absence of visible fecal contamination is monitored on a daily basis. The inspection is done after post-mortem inspection but before the carcasses enter the chilling room.
- Evaluation of individual staff members takes place every third year and is used as a tool for development of the individual staff member. *This does not pertain to slaughter establishments so it plays no role in a determination of equivalence for this program. It is only relevant to small food businesses, i.e., restaurants.
- The official veterinarian checks the work of official auxiliaries on a daily basis.

Denmark has observed that these performance standards have been a viable tool to supervise and assess the quality of the meat inspection at each slaughterhouse. There are no changes in the verification programs and this was verified by e-mail correspondence on January 17, 2014.

The Danish risk assessment verified that when an official inspector finds ingesta and/or bile on one organ it is linked to other organs (other pluck and visceral offal) and the carcass. This could cause concern regarding generalized sanitary dressing procedures. In this case the food business operator and the official inspectors heighten their focus on the dressing procedures. Corrective actions and preventive measures will be implemented as needed, and will be verified by the official inspector.

FSIS asked Denmark if DVFA provides for inspection during processing, and if the official personnel are trained to identify pathology of the liver during further harvesting procedures. Denmark responded that the meat inspection is sufficient and meets all relevant requirements. The standards and verification procedures that Denmark has implemented are viable tools to assess the meat inspection and secure food safety. There is an on-going and monthly evaluation of the Key Performance Indicators with focus on corrective actions.

Denmark has implemented a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects. Therefore, this criterion meets FSIS requirement.

RECOMMENDATION:

FSIS has determined that Denmark's request for an equivalence determination for an alternative post-mortem inspection i.e. visual inspection instead of palpation of lungs and liver and their associated lymph nodes of slaughtered market hogs meets the established criteria. Therefore, Denmark's equivalence request should be granted.

CONCURRENCE/OPPD:



10/7/15

Daniel Engeljohn

Date

Assistant Administrator

OPPD, FSIS



UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
OFFICE OF INTERNATIONAL AFFAIRS
INTERNATIONAL EQUIVALENCE STAFF
WASHINGTON, DC 20250



DENMARK EQUIVALENCE DETERMINATION FOR THE “SUPPLY CHAIN INSPECTION – THE DANISH WAY”

December, 2008

FILE ASSURANCE CHECKLIST

CERTIFICATION STATEMENT

The contents of this file have been reviewed in accordance with the Equivalence Management Controls established by the International Equivalence Staff as certified by the Senior Equivalence Officer assigned to the file and reviewed by the Director, International Equivalence Staff (IES), Office of International Affairs.

COUNTRY

DENMARK

TYPE OF FILE

- ☒ ON-GOING EQUIVALENCE DETERMINATION
- ☐ INITIAL EQUIVALENCE DETERMINATION
- ☐ ANNUAL ON-SITE AUDIT
- ☐ OTHER:

CERTIFIED BY



EQUIVALENCE OFFICER, IES

DATE:

12/18/08

REVIEWED BY



DIRECTOR, IES

DATE:

12/19/08



**UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
OFFICE OF INTERNATIONAL AFFAIRS
INTERNATIONAL EQUIVALENCE STAFF
WASHINGTON, DC 20250**



**DENMARK EQUIVALENCE DETERMINATION
FOR THE "SUPPLY CHAIN INSPECTION – THE DANISH WAY"**

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United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

Dr. Jan Mousing
Chief Veterinary Officer
Danish Veterinary and Food Administration
Mørkhøj Bygade 19
DK-2860 Søborg

Dear Dr. Mousing,

I am writing to inform you of the equivalence determination made by this office with regard to your request for the use of an alternative post-mortem inspection procedure for market hogs. In the submission, Denmark requested an equivalence determination for:

- Supply Chain Inspection – The Danish Way

As part of the equivalence determination process, the Food Safety and Inspection Service (FSIS) establishes criteria for determining whether an alternative sanitary measure will ensure the same level of public health protection as the FSIS requirement. Accordingly, FSIS has established the following criteria for making equivalence determinations for an alternative post-mortem inspection procedure for market hogs:

- The government inspection service administers an inspection program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass.
- The government inspection system requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market hog carcasses presented for inspection.
- The incidence of diseases in market hogs, such as Tuberculosis (TB), is no higher than the incidence in the United States.
- The market hogs must be born and raised in the country.
- The government inspection service must implement a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects).

Based on the information submitted by the government of Denmark, FSIS has determined that this alternative post-mortem inspection procedure for market hogs meets the established criteria. Therefore, FSIS is granting the government of Denmark approval to use the supply chain inspection for the purposes of post-mortem inspection of meat products exported to the United States.

If you have any questions, please contact me at telephone number 202-720-3781, facsimile number 202-690-4040, or by e-mail at internationalequivalence@fsis.usda.gov.

Sincerely,

A handwritten signature in cursive script that reads "Sally White JD". The signature is written in black ink and is positioned above the printed name and title.

Sally White
Director
International Equivalence Staff
Office of International Affairs

CC:

Steve Huete, Agricultural Attaché, American Embassy, The Hague
Anders Klôcker, Minister Counselor, Royal Danish Embassy
Bernard Van Goethem, Director, Directorate E, European Commission, Brussels
Wolf Maier, Counselor, Food Safety and Consumer Affairs, EC
Ghislain Marechal, EC, DG SANCO - Directorate General for Health and Consumers
Alfred Almanza, Administrator, FSIS
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David Young, Europe Area Director, FAS
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Office of Science and Technical Affairs, FAS
Country File

FSIS:OIA:IES:DSMITH:720-3395:DK SCI:12/18/08

DECISION MEMORANDUM

ISSUE:

Denmark has developed a system for inspection of market hogs which puts more emphasis on ante-mortem animal disease detection on-farm rather than post-mortem inspection for gross lesions at slaughter.

BACKGROUND:

Denmark has implemented a Supply Chain Inspection system. This system allows inspection of market hogs raised under an integrated quality control program coupled with on-site verification at the slaughter establishment for checking the accuracy of visually inspected carcasses and organs to ensure that passed carcasses and parts are wholesome and not adulterated.

A team of FSIS experts met and reviewed Denmark's Supply Chain Inspection system, Denmark's reference materials, and information presented by Danish officials during a FSIS-Denmark bilateral meeting on December 16, 2008. The FSIS team conducted the review using the following criteria:

FSIS FOOD SAFETY MEASURE:

The purpose of post-mortem inspection of livestock is to protect the public health by ensuring that carcasses and parts that enter commerce are wholesome and not adulterated. To achieve this goal, in swine slaughter establishments operating under traditional inspection or in those establishments operating under the HACCP-Based Inspection Models Project (HIMP), FSIS inspectors perform ante-mortem and post-mortem inspection procedures to detect diseases, abnormalities, and contamination of livestock carcasses and parts.

In establishments operating under HIMP, FSIS requires that the establishment implement ante-mortem and post-mortem sorting procedures and present to FSIS only normal and healthy-appearing animals and carcasses and parts that are wholesome and free of defects. HIMP also requires additional FSIS verification procedures to ensure that the establishment produces only safe, wholesome products.

OBJECTIVE:

FSIS inspectors conduct ante-mortem inspection of live swine and post-mortem inspection of carcasses and parts on a carcass by carcass basis. In market age swine, FSIS performs inspection under either the traditional inspection system or under the HIMP inspection system. In both cases, inspection procedures are intended to identify and remove unwholesome and adulterated carcasses and parts from the food supply.

EQUIVALENCE CRITERIA AND EVALUATION:

Criteria used to determine whether an alternative post-mortem inspection procedure for market age hogs is equivalent to the U.S. inspection procedure for market age hogs are set forth below:

1. The government inspection service administers an inspection program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass.
2. The government inspection system requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market hog carcasses presented for inspection.
3. The incidence of diseases in market hogs, such as TB, is no higher than the incidence in the United States.
4. The market swine must be born and raised in the country.
5. The government inspection service must implement a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects).

Application of Equivalence Criteria for an Alternative Post-Mortem Inspection Procedure for Market Age Hogs.

The government inspection service administers an inspection program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass.

This criterion is met. Denmark uses a combination of pre-slaughter data collection and post-mortem inspection to ensure the identification and removal of diseased carcasses and parts from the food supply. Pre-slaughter data must be presented to the slaughter establishment prior to slaughter of the swine. The Official Veterinarian at the slaughter establishment will verify that this information is supplied to the slaughter establishment. Without this information, swine will not undergo slaughter under the proposed program. This system allows for full traceability of swine and provides the health information of all swine prior to slaughter. Ante-mortem inspection occurs in the same way as conducted by FSIS. The proposed alteration to post-mortem inspection is related to the omission of mandibular lymph node incision.

Denmark has conducted, and submitted to FSIS, a peer reviewed risk assessment which focused on the areas of swine carcass inspection that will be altered under their "Supply-Chain Inspection" proposal. This risk assessment was conducted on the omission of incising the mandibular lymph nodes as well as the omission of incising the hearts. The heart incision aspect is not pertinent to this review because FSIS does not perform this task. The outcome of this risk assessment was that the changes proposed could potentially

improve food safety by reducing cross contamination of microorganisms such as *Salmonella*.

The government inspection system requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market hog carcasses presented for inspection.

Denmark has adopted a sanitary measure that is *same as* the FSIS requirement. No equivalence determination is needed. Denmark requires establishments to conduct generic *E. coli* testing. In addition, Danish authorities conduct *Salmonella* performance standard testing per the FSIS requirements.

The incidence of diseases in market hogs, such as Tuberculosis (TB), is no higher than the incidence in the United States.

This criterion is met. Denmark has been recognized as free of *Mycobacterium bovis* since 1980. A large-scale surveillance program in cattle in Denmark is in place ensuring a constant documentation of the free status.

The market hogs must be born and raised in the country.

This criterion is met. In order to qualify for this program, the producer must demonstrate that the market hogs are of Danish origin. Only swine that have been raised indoors are eligible for this inspection procedure, and there is complete segregation of the swine from other species while on the farm, during transport to the slaughter establishment, during lairage and slaughter.

The government inspection service must implement a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects).

This criterion is met. Effective January 1, 2009, the Danish Veterinary and Food Administration will establish a performance standard for meat inspection for all pig slaughterhouses. The performance standard is monitored daily by the Official Veterinarian. The Official Veterinarian verifies that the Official Auxiliaries are properly conducting their inspection activities.

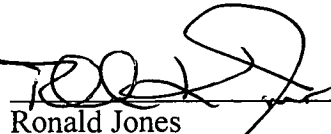
RECOMMENDATION:

FSIS has determined that the alternate post-mortem procedure for market age hogs submitted by Denmark is equivalent to the FSIS post-mortem procedure for market age hogs. Therefore, Denmark's equivalence request should be granted.

DECISION CONFIRMATION AND APPROVAL:

 12/20/08
Sally White, Director
International Equivalence Staff
Office of International Affairs, FSIS

CONCURRENCE:

 12-23-08
Ronald Jones
Acting Assistant Administrator
Office of International Affairs

EQUIVALENCE CRITERIA:

The criteria used by FSIS to determine whether the Netherlands' alternative post-mortem inspection procedure is equivalent to the FSIS post-mortem procedure are set forth below:

- The government inspection service administers an inspection program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass.
- The government inspection system requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market hog carcasses presented for inspection.
- The incidence of diseases in market hogs, such as Tuberculosis (TB), is no higher than the incidence in the United States.
- The market hogs must be born and raised in the country.
- The government inspection service must implement a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects).

**EQUIVALENCE DETERMINATION
DOCUMENT REVIEW MEETING MINUTES
DENMARK – Alternative Inspection Procedure
Visual Inspection of Swine Carcasses
December 8, 2008**

PARTICIPANTS:

Dr. Bob Ragland, PAF, OPPD
Dr. David Smith, International Equivalence Staff, OIA
Dr. Natasha Shinn, International Equivalence Staff, OIA
Todd Furey, International Equivalence Staff, OIA

DOCUMENTS REVIEWED:

- FSIS Correspondence to the Netherlands [July 16, 2008]
- Denmark – Equivalence Submission for visual inspection of swine carcasses [November 21, 2008]

EQUIVALENCE REQUEST:

On November 21, 2008, the Food Safety and Inspection Service (FSIS) received an equivalence determination request from Denmark regarding an alternative inspection procedure. In the request, Denmark wishes to cease the routine palpation and incision into the major mandibular lymph nodes and cease the routine opening of the heart.

Based on the work instructions outlined in FSIS Directive 6100.2 (9/17/07), the FSIS inspector shall incise and observe the mandibular lymph nodes. However, FSIS does not incise the heart.

The equivalence criteria used for this review were established during the review of the Netherlands request.

FSIS FOOD SAFETY MEASURE:

The purpose of post-mortem inspection of livestock is to protect the public health by ensuring that carcasses and parts that enter commerce are wholesome and not adulterated. To achieve this goal, in market hogs slaughter establishments operating under traditional inspection or in those establishments operating under HIMP, FSIS inspectors perform ante-mortem and post-mortem inspection procedures to detect diseases, abnormalities, and contamination of livestock carcasses and parts.

In establishments operating under HIMP, FSIS requires that the establishment implement ante-mortem and post-mortem sorting procedures and present to FSIS only normal and healthy-appearing animals and carcasses and parts that are wholesome and free of defects. HIMP also requires additional FSIS verification procedures to ensure that the establishment produces only safe, wholesome products.

OBJECTIVE:

For market hogs slaughtered in the United States, FSIS requires that ante-mortem inspection of live market hogs and post-mortem inspection of carcasses and parts be conducted on a carcass-by-carcass basis. In market hogs, FSIS performs post-mortem inspection under the traditional inspection system or the HIMP inspection system. Post-mortem inspection

procedures under traditional inspection include incision, observation and palpation, as applicable, of the head, viscera and carcass. Under HIMP, FSIS post-mortem inspection procedures involve only a visual inspection, with no incisions or palpation. In both cases, inspection procedures are intended to identify and remove unwholesome and adulterated carcasses and parts from the food supply.

EQUIVALENCE CRITERIA:

The criteria used by FSIS to determine whether the Netherlands' alternative post-mortem inspection procedure is equivalent to the FSIS post-mortem procedure are set forth below:

- The government inspection service administers an inspection program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass.
- The government inspection system requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market hog carcasses presented for inspection.
- The incidence of diseases in market hogs, such as Tuberculosis (TB), is no higher than the incidence in the United States.
- The market hogs must be born and raised in the country.
- The government inspection service must implement a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects).

EVALUATION:

The government inspection service administers an inspection program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass.

This criterion is met. Denmark uses a combination of pre-slaughter data collection and post-mortem inspection to ensure the identification and removal of diseased carcasses and parts from the food supply. This data must be presented to the slaughter establishment prior to slaughter of the swine. The Official Veterinarian at the slaughter establishment will verify that this information is supplied to the slaughter establishment. Without this information, swine will not undergo slaughter under the proposed program. This system allows for full traceability of swine and provides the health information of all swine prior to slaughter. Ant-mortem inspection occurs in the same way as conducted by FSIS. The proposed alteration to post-mortem inspection is related to the omission of mandibular lymph node incision.

Denmark has conducted, and submitted to FSIS, a peer reviewed risk assessment which focused on the areas of swine carcass inspection that will be altered under their "Supply-Chain Inspection" proposal. This risk assessment was conducted on the omission of incising the mandibular lymph nodes as well as the omission of incising the hearts. The heart incision aspect is not pertinent to this review because FSIS does not perform this task. The outcome

of this risk assessment was that the changes proposed could potentially improve food safety by reducing cross contamination of microorganisms such as *Salmonella*.

The government inspection system requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market hog carcasses presented for inspection.

Denmark has adopted a sanitary measure that is *same as* the FSIS requirement. No equivalence determination is needed. Denmark requires establishments to conduct generic *E. coli* testing. In addition, Danish authorities conduct *Salmonella* performance standard testing per the FSIS requirements.

The incidence of diseases in market hogs, such as Tuberculosis (TB), is no higher than the incidence in the United States.

This criterion is met. Denmark has been recognized as free of *Mycobacterium bovis* since 1980. A large-scale surveillance program in cattle in Denmark is in place ensuring a constant documentation of the free status.

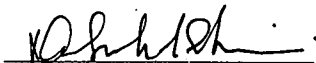
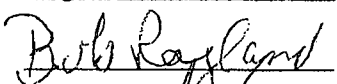
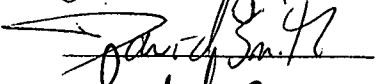
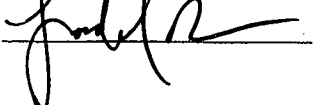
The market hogs must be born and raised in the country.

This criterion is met. In order to qualify for this program, the producer must demonstrate that the market hogs are of Danish origin. Only swine that have been raised indoors are eligible for this inspection procedure, and there is complete segregation of the swine from other species while on the farm, during transport to the slaughter establishment, during lairage and slaughter.

The government inspection service must implement a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects).

This criterion is met. Effective January 1, 2009, the Danish Veterinary and Food Administration will establish a performance standard for meat inspection for all pig slaughterhouses. The performance standard is monitored daily by the Official Veterinarian. The Official Veterinarian verifies that the Official Auxiliaries are properly conducting their inspection activities.

MINUTES OF REVIEW, REVIEWED AND APPROVED

Name	Signature	Date
Dr. Natasha Shinn, IES, OIA		<u>12/18/08.</u>
Dr. Bob Ragland		<u>12/18/2008</u>
Dr. David Smith, IES, OIA		<u>12/18/08</u>
Todd Furey, IES, OIA		<u>12/18/2008</u>

Smith, David

From: Anders Klöcker [andklo@um.dk]
Sent: Wednesday, November 26, 2008 1:31 PM
To: Furey, Todd
Cc: Smith, David; fransisco.gonzales1@fsis.usda.gov
Subject: Summary of telephone conference November 14th, 2008

Attachments: referattelefonmøde14nov2008.doc



referattelefonmøde
14nov2008.do...

Dear Todd,

Attached please find our summary of the telephone conference November 14th, 2008.

Best regards,

Anders

ANDERS M. KLOCKER / ANDKLO@UM.DK
MINISTER COUNSELLOR / FOOD, AGRICULTURE AND FISHERIES DIRECT +1 (202) 797-5341 / CELL
(202) 390-0846/ FAX (202) 328-1470 ROYAL DANISH EMBASSY / MINISTRY OF FOREIGN AFFAIRS OF
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Ministry of Food, Agriculture and Fisheries

Danish Veterinary and Food Administration



FSIS

DIVISION FOR MICROBIOLOGICAL
FOOD SAFETY, HYGIENE
AND ZONOSSES CONTROL

20.11.2008

File: 2008-20-23-02391/CHVI

Summary

Visual inspection of fattening pigs – Conference call 14 November 2008

Participants FSIS, USA:

- Todd Furey, FSIS, OIA (TF)
- Francisco Gonzales (FG)
- David Smith, FSIS, OIA (DS)

Participants, Denmark:

- Charlotte Vilstrup, DVFA (CHVI)
- Lise Lykke Steffensen, DMA (LST)
- Lis Alban, DMA (LIA)
- Susanne J. Jensen, DMA (SJJ)
- Birthe Steenberg, DMA (BSB)

Participants, The Royal Danish

Embassy, Washington, DC

- Anders M. Klöcker (AMK)

Agenda:

1. Introduction of participants in the conference call
2. Follow up from the conference call – September 30
3. Status on the project:
 - The risk assessment
 - Supply Chain Meat Inspection:
 - a. Preconditions
 - b. Enforcement procedures and prerequisites
4. Questions and comments from FSIS
5. Next step.
6. Any other business

Re 1. Introduction of participants in the conference call

Each person participating in the conference call gave a short presentation. It was agreed upon that after the meeting a summary including discussions issues and conclusion will be provided to all participants.

Re 2 Follow up from the conference call on September 30

LIA: The Risk assessment has been sent to external review. Comments are expected within two weeks and will be included in the final version.

TF: Their comments are important – please, send us the final version when that is completed

Re 3 Status on the project

The Risk Assessment

CHVI: New name – please notice – trying to separate it from the Dutch programme by adding *The Danish Way* and stated that status of the project would be given according to the “Overview Document “ on the Supply Chain Meat Inspection as forwarded by email 14 November 2008.

Supply Chain Meat Inspection

Going through the overview Supply Chain Meat Inspection – the Danish Way

With respect to the prerequisites and productions system of pigs in Denmark a number of questions were raised:

TF: How old are the pigs?

CHVI: 5 months

TF: How many pigs are expected to be included in the program per year?

CHVI: 90 % - 21. millions

BSB: It will be ensured, that pigs raised outdoor etc. will undergo traditional meat inspection.

LST: Do you have all the information you need about the Danish system?

TF: Pictures to describe the Danish systems would be nice!

FG: Does a slaughterhouse slaughter both finishers and sows and boars?

CHVI: No – the slaughterhouses in question are only slaughtering finishers.

TF: More detail about the audit of the Food Chain Information would be nice

TF: On the farm – what are you looking for?

TF: Are there some written description about participation in the program both with respect to the slaughterhouse and the farmers?

CHVI: We will try to explain more precisely what prerequisites is required if finishers shall undergo supply chain inspection

FG: Indoor / outdoor access – what do you mean?

CHVI: We want to emphasise that only pigs raised indoor in integrated production systems can undergo visual inspection as part of supply chain meat inspection

TF: Some additional information on the Salmonella program would be useful

AK: Maybe we can use some of the information Henning Petersen (FVST) have sent in connection with poultry and the Salmonella control programme.

TF: Concerning performance standards on the PM inspection: Is it a tool to control the inspection – or is it a tool to control the establishment?

CHVI: Primarily, the aim of the performance standards is to control the meat inspection

FG: From the draft of the performance standards – monitoring on performance – if performance standards are not met – which corrective actions will be made?

CHVI: We will try to clarify the description

FG: How do you ensure that the staff is properly trained for the new situation – is there a description of training of the personal?

CHVI: We will include that in description

Ad 4 Questions and comments from FSIS / Ad 5 Next step

TF: What is the expectation in terms of timing?

CHVI: As quickly as possible

LST: What is your time schedule? – We will try to deliver the follow up version at the end of next week

TF: A meeting in Washington would be good – delegation from Denmark – both governmental and the commercial side. Could perhaps be held in the middle of December this year

CHVI: You just have to say when ...

FG: Concerning biosecurity ... which requirements do you have? – Will there be a need to alter the housing of the animals?

CHVI: We shall describe the production system we have for pigs, including Quality Standards for pig production in Denmark and Code of practice.

Yours faithfully

Charlotte Vilstrup

Senior veterinary officer, DVM

Direct tel. +45 33956275

E-mail chvi@fvst.dk

Ministry of Food, Agriculture and Fisheries

Danish Veterinary and Food Administration



Food Safety and Inspection Service
Office of International Affairs

DIVISION FOR MICROBIOLOGICAL
FOOD SAFETY, HYGIENE
AND ZOOSES CONTROL

10.10.2008
File: /CHVI

RESUME

Visual inspection of fattening pigs – Conference call September 30, 2008

Participants FSIS, USA:

- Bill James, FSIS, OIA (BJ)
- Todd Furey, FSIS, OIA (TF)
- David Smith, FSIS, OIA (DS)
- Natacha Chen, FSIS, OIA (NC)

Participants, the Royal Danish Embassy, Washington, DC:

- Anders M. Klöcker (AMK)

Participants, Denmark:

- Charlotte Vilstrup, DVFA (CHVI)
- Lise Lykke Steffensen, DMA (LST)
- Lis Alban, DMA (LIA)
- Susanne J. Jensen, DMA (SJJ)
- Birthe Steenberg, DMA (BSB)

Agenda:

1. Introduction of participants in the conference call
2. Presentation of status on the risk assessment of visual inspection of fattening pigs in Denmark
3. Questions and comments from FSIS
4. Discussion of the project plan. Next step.
5. Any other business

Re 1 Introduction of participants in the conference call

AMK began with establishing the aim of the telephone conference. Denmark consults FSIS in all phases of a project aimed at, ultimately, a transition of the meat inspection into visual meat inspection based on food chain information. This is to sort out any concerns and prevent that technical issues will arise at a later stage, as FSIS is requested by Denmark to grant the equivalency approval of the new system.

After the meeting, a summary including the discussion issues and conclusions will be sent to all participants in order to establish this file.

CHVI introduced the Danish participants and TF introduced the American participants.

Re 2 Presentation of status on the risk assessment of visual inspection of fattening pigs in Denmark

LIA stated that the risk assessment (that was sent out electronically prior to the meeting) not only is based on analysis of own collected lymph nodes and hearts – but on all data available from relevant laboratories, statistics and the international literature.

Regarding lymph nodes

Information about the role of *M. avium* has been collected. Unfortunately, we only today discovered relevant information from the OIE: according to Resolution No. XXVI adopted by the International Committee of the OIE during its 73rd General Session, 22 - 27 May 2005 *M. avium* is deleted from the list of diseases that OIE finds of relevance. The reason for de listing is cited in the following and can be found in Appendix XXVIII of the same report:

“Avian tuberculosis – It is ubiquitous and has no significance for international spread. The morbidity and mortality are not significant in birds. Human infections may occur under exceptional circumstances, but natural infection in humans is rare. It should be deleted from the list”

The report can be downloaded from http://www.oie.int/tahsc/eng/en_reports.htm

According to this resolution, changes to the Terrestrial Animal Health Code Chapter 2.1.1. have been implemented – as suggested by the Code Commission in Appendix VI in Report of the Meeting of the OIE Terrestrial Animal Health Standards Commission, 17 - 28 January 2005.

The decision of the OPIE is in line with the international prevailing opinion that *M. avium* is not food-borne.

BJ agreed that it makes sense not to inspect/control carcasses for hazards which have been eradicated. However there is a need for some kind of monitoring.

CHVI commented that based on risk assessment DK intend to continue traditional meat inspection of sows, boars and finishers not held indoor since weaning. It was also stated that all mandibular and mesenterial lymph nodes from carcasses at the Danish slaughterhouses are used for pet food.

Regarding hearts

The hazards related to the pig heart are not considered foodborne but occupational. This implies that they are primarily a problem for the slaughterhouse workers.

If you stop opening the hearts – the exposure to the slaughterhouse workers of these hazards are lowered.

Sample sizes

The prevalence of mandibular lymph nodes with granulomatous processes is very low, and we have, therefore, some problems collecting 100 lymph nodes. Therefore, we prefer to use other data as well e.g. data from the laboratories which makes laboratory investigation of poultry and pigs suspected of having tuberculosis. This approach is in line with the Australian epidemiologists Tony Martin and Angus Cameron in their recommendation on how to document freedom from disease. The only difference is, that we do not claim that we are free from *M. avium*, but that the prevalence is very low. This is supported from the data from the laboratories analysing the suspect cases.

- Poultry: 0-3 cases per year are seen consisting of old hens from backyards producers as well as birds from zoological gardens
- Pork: 0-2 cases per year

BJ was confident in DK's capacity to produce a scientifically based risk analysis and stated that it is up to DK to decide upon the appropriate size of a sample as long as confidence intervals are appropriately accounted for.

Re 3 Questions and comments from FSIS

BJ: Do you have an ongoing programme for measuring Bovine TB in DK?

LIA stated that the programme is described in section 6.3.1 in the Risk assessment. For further information see: <http://gl.foedevarestyrelsen.dk/FDir/Publications/2007090/rapport.pdf>

TF: *Do you have a surveillance of where zoonosis occur from?*

An Annual report from the Danish Zoonosis Centre is made and can be obtained at:

<http://www.vet.dtu.dk/Default.aspx?ID=9606>

NC *Are the hazards covering all the way from stable to table.*

Yes, since real assessment deals with what you find in the live animal, exposure assessments with what you as a consumer or a slaughterhouse worker are exposed to in the meat – we will describe this clearer in the risk assessment.

Re 4 Discussion of the project plan. Next step.

BJ stated that Denmark needs a strong enforcement programme. It must be described how identified risks will be handled and the process must be followed closely.

LIA stated that it will be possible to make use of the hygiene data (E. coli) – before and after introduction of visual inspection.

AMK asked FSIS about the exact requirements for documentation included in the pending, official Danish request for equivalence approval by FSIS. AMK referred to the equivalence approval by FSIS of the – by and large identical – Dutch system in July, 2008 and assumed that in the case of Denmark a scientifically based risk analysis combined with an exhaustive description of the regulatory enforcement mechanisms being implemented to continuously enforce the new procedures and to monitor the stipulated performance of the system would fulfil the requirements of FSIS.

TF and DS in general agreed to this point and referred to the basic principles by which FSIS determines the equivalence of an alternative post-mortem inspection procedure for market hogs. The principles were described as follows:

- The government inspection service administers an inspection program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass.

- The government inspection system requires the use of prerequisite programs that reduce the incident of food borne pathogens in market hog carcasses presented for inspection.
- The incidence of diseases in market hogs, such as TB, is no higher than the incidence in the United States.
- The market swine must be born and raised in the country.
- The government inspection service must implement a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects).

Based on this discussion it was agreed upon that Denmark:

1. Finalises the risk assessment
2. Submits to FSIS a draft description of the intended government verification program
3. Upon submission of this draft, another telephone conference will be held
4. Next and final step will be for Denmark to officially submit the final request for equivalence approval by FSIS of the new inspection method

The Danish participants informed FSIS that it will be considered to label the new inspection method not as visual inspection but rather in an alternative way that better reflects the fact that the method is based on veterinary health data from stable to slaughter house.

Ministry of Food, Agriculture and Fisheries

Danish Veterinary and Food Administration



FSIS

DIVISION FOR MICROBIOLOGICAL
FOOD SAFETY, HYGIENE
AND ZOOSES CONTROL

02.07.2008

File: 2008-20-23-02391/CHVI

RESUME

30. juni 2008

BSB

Visual inspection of fattening pigs – Telephone conference 23 June 2008

Participants FSIS, USA:

- Todd Furey, FSIS, OIA (TF)
- David Smith, FSIS, OIA (DS)
- Andreas Keller, FSIS, OIA (AK)
- Maritza Colón-Pullano, FSIS, OP (MKP)

Participants, The Royal Danish Embassy, Washington, DC

- Anders M. Klöcker (AMK)
- Signe Hoff (SH)

Participants, Denmark:

- Charlotte Vilstrup, DVFA (CHVI@fvst.dk)
- Søren Aabo, National Food Institute (SAA@food.dtu.dk)
- Lis Alban, DMA (LIA@danishmeat.dk)
- Susanne J. Jensen, DMA (SJJ@danishmeat.dk)
- Birthe Steenberg, DMA (BSB@danishmeat.dk)

Agenda:

- 1 Introduction of participants in the conference call
- 2 Description of project on visual inspection of fattening pigs
- 3 Questions from FSIS

- 4 Discussion of any further steps needed to ensure compliance with USA/FSIS requirement
- 5 Any other business

Ad 1 Introduction of participants in the conference call

AMK began with establishing the aim with the telephone conference. Denmark involves the US in this early phase of a project aimed at, ultimately, a transition into visual meat inspection in order to prevent that any technical issues will arise as FSIS, at a later stage, is requested by Denmark to grant the equivalency approval of the new system. Therefore, it is very important for Denmark to facilitate an exhaustive technical discussion and to establish a file covering the questions covered step by step. This in order to prevent technical recourse at a later stage.

After the meeting a summary including the discussion issues and conclusions will be sent to all participants in order to establish this file.

When the risk assessment is finished, the Americans have the possibility to raise more questions, and give recommendations before the final approval of the next part of the project.

CHVI introduced the Danish participants and TF introduced the American participants.

Ad 3 Description of project on visual inspection of fattening pigs

Time table (CHVI).

Traceability (SJJ)

Study 1 – Status for heart and lymph node study (CHVI)

Tuberculosis (LIA)

Study 2 - Pilot study (CHVI)

Performance standards (CHVI)

Traditional inspection versus visual inspection (CHVI)

Status and further process (CHVI)

Ad 4 Questions from FSIS

a. FSIS asked whether the hogs are registered individually or by herd and what is the size of an average herd in Denmark?

Denmark replied that at the farm they are registered by herd – but at the abattoir the pigs are individually numbered.

A medium-sized finisher herd produces around 1000 -3000 pr. year

b. FSIS raised the question whether traditional and visual inspection will be performed at the same time during the pilot study (study 2)?

Referring to results of earlier studies – in particular the large scale study in Horsens; Denmark in the 1990'ies, it is not the intention to carry out both visual inspection and traditional inspection at the same time. Denmark will introduce the changes on two slaughterhouses to follow the process and the changes closely.

The objective of study 1 is to investigate whether food safety is jeopardized when omitting the routine incision of the heart and the submandibular lymph nodes. If this is not the case, we intend to introduce these two changes. The performance will be measured by comparing historical data and current data.

And to take seasonality into account, data from one year before, and one year after the changes will be evaluated.

Performance standards must be met with traditional meat inspection as well as with visual inspection.

c. FSIS asked if there will be only indoor raised pigs in the project?

Denmark confirmed that only indoor raised pigs will be part of the project. This is in accordance with changes in the EU legislation as of 1st of January 2006, which make it possible to carry out visual meat

inspection of finisher pigs. The possibility is restricted to fattening pigs housed under controlled housing conditions in integrated production systems since weaning¹.

d. FSIS asked with relation to Food Chain information (FCI) how far in advance the information about the herd arrives at the abattoir?

Denmark answered that according to the EU legislation the Food Chain information (FCI) must be present 24 hours in advance. Until end of 2009 the FCI can arrive at the latest together with the pigs they concern. The FCI needs to be evaluated by the slaughterhouse prior to the slaughter of the animals regardless of the time of arrival of the FCI.

Danish farmers have a contract with an abattoir. Hence they deliver to the same abattoir week after week (month after month).

Supplementary, FSIS asked about details in the food chain information system and in particular *which other information is collected including E. coli and salmonella sampling.*

Denmark told that data are exchanged between the producer and the slaughterhouse prior to slaughter – but the information is generated for the entire production chain; from stable to table. As for Salmonella, meat juice samples as well as carcass swab samples are taken in relation to slaughter. And E.coli process control samples are taken due to both US and EU-legislation.

It was agreed to add *E.coli and Salmonella sampling* on the figures on **Traceability – stable and table.**

d. To the question from FSIS on what happens if the information is not there, Denmark said that no visual inspection will be carried out.

¹. (Annex I, section IV, Chapter IV, point 2 B in Regulation (EC), No 854/2004 of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption).

e. FSIS asked if Denmark plans to use serology on TB?

The question by FSIS was returned back to FSIS by Denmark by asking whether an animal on 6 months will be able to produce a serological response and is avian TB meat-borne ? Those are two questions that need to be addressed.

Denmark explained that it has not been possible to get detailed information from Netherland about this test. Of particular interest is the positive and negative predictive value associated with the test. Furthermore, avian TB is not considered meat-borne by the experts Denmark has talked to. Hence, it is questionable whether it makes sense to survey for avian TB in finisher farms. FSIS agreed to this.

f. FSIS asked whether the test is intradermal?

Yes for Cattle – but for hogs we use meat inspection, was the answer from Denmark

Denmark wanted to know how the test is carried out in USA. FSIS answered that for cattle the test is intradermal.

The answer was followed by a question from Denmark on what is going on in US-regions free of TB ? FSIS promised to examine and return with a reply !

g. Denmark clarified that performance standards will be conducted as follows:

- 100 carcasses incl. organs inspected after PM-inspection per line / shift / day

h In relation to study one and the sampling of lymph nodes, the FSIS needed clarification on how many pigs have been slaughtered during the project period (mid March through 11 June ; 11 lymph nodes out of how many pigs – and traditionally inspected?

Denmark answered that the annual number of pigs slaughtered in Denmark is approximately 22 million. The data collection began in the middle of March (3 months) ~5 million pigs slaughtered in that period. *All* pigs are inspected traditionally.

i. FSIS asked about the Prevalence of M. avium in pigs?

Denmark answered that so far we have found 11 lymph nodes with gross morphological changes indicating TB. Among these, 7 were bacteriological negative, 3 were due to *Rhodococcus Equi* and one is waiting for final result. If this last sample is due to *M. avium* and the population it came from consisted of 2 mio. finishers, the prevalence is $1/2 \text{ mio.} = 0,00005\%$

j. Denmark asked whether FSIS consider M. avium a meat borne zoonosis?

FSIS replied that this is not the case in the USA.

Ad 5 Discussion of any further steps needed to ensure compliance with USA/FSIS requirement

All agreed on the importance of having an ongoing dialogue. A telephone conference was considered a good idea, and CHVI also invited the Americans to make a visit to Denmark.

Ad 6 Any other business

Denmark asked whether FSIS had any follow-up questions to the answers from Denmark given by letter dated May 8th, 2008.

FSIS answered that this is not the case.

Yours faithfully

Charlotte Vilstrup
Senior veterinary officer, DVM
Direct tel. +45 33956275
E-mail chvi@fvst.dk

Visual inspection of fattening pigs

Conference call June 23, 2008 between:

- Food Safety and Inspection Service
- Danish Veterinary and Food Administration
- Danish Meat Association

Agenda

1. Introduction of participants in the conference call
2. Election of chairman of meeting and keeper of minutes
3. Description of project on visual inspection of fattening pigs
4. Questions from FSIS
5. Discussion of any further steps needed to ensure compliance with USA/FSIS requirement
6. Any other business

Participants from Denmark

- Charlotte Vilstrup
 - DVM, Senior Veterinary Officer, DVFA
- Søren Aabo
 - DVM, Ph.D., Research leader, Senior Scientist, National Food Institute
- Lis Alban
 - DVM, Ph.D., Dipl. ECVPH, DMA
- Birthe Steenberg
 - DVM, Senior Specialist, DMA
- Susanne Jensen
 - Food Scientist, Specialist, DMA

Time table

Study of design: investigations and evaluation of possible risk discontinuing incisions of hearts and submandibular lymph nodes

Pilot study: Testing Visual Inspection on two selected slaughterhouses (Tican, Thisted and Danish Crown, Søby)

2008												2009	
January	February	March	April	May	June	July	August	September	October	November	December	January	February
Preparation of Study, as: - Project plan - Inspections - Literature studies													
Test period for hearts and lymph nodes													
Preparing risk assessment and processing statistical data													
Preparation of pilot study including on-site visits to slaughterhouses													
Presentation of risk assessment													
Development of plan for pilot study - Testing Visual Inspection and risk off coverings with slaughterhouses and competent authorities													
Pilot study at Tican, Thisted and Danish Crown, Søby													
Evaluation of pilot study													
Ongoing dialogue/discussion with FSIS													
January	February	March	April	May	June	July	August	September	October	November	December	January	February
2008												2009	

Traceability in the danish pig production

A precondition for our meat inspection

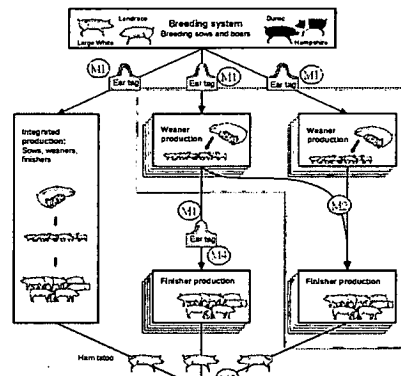
- Covered by a registration, marking and documentation system including:
 - All pig herds are registered with a herd number (**CHR-number**) in the Central Register of Domestic Animals
 - Information is exchanged in all parts of the chain (**food chain information**) from producer to slaughterhouse (mandatory requirement within EU)
 - Standard recording of detected lesions during post mortem inspection (conducted for more than ten years)

Food chain information

Relevant information provided:

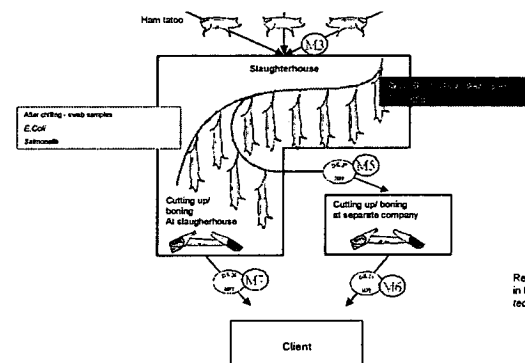
- Status of the herd (e.g. indoor/outdoor)
- Animal health status
 - e.g. Salmonella status at herd level
- Veterinary medical products used
- Results of other samples taken
 - In the framework of monitoring and control of zoonoses and residues relevant to public health
- Name and address of veterinarian attending herd

Traceability - Stable



Ref: Madec, F. (2001). – Traceability in the pig production chain. *Rev. sci. tech. Off. Int. Epiz.*, 20 (2)

Traceability - Table



Ref: Madec, F. (2001). – Traceability in the pig production chain. *Rev. sci. tech. Off. Int. Epiz.*, 20 (2)

Ministry of Food, Agriculture and Fisheries
Danish Veterinary and Food Administration

Collection of hearts and lymph nodes - Status by June 11

- Lymph nodes with gross morphological changes
 - 11 samples
 - 7 negative (no bacteriological findings)
 - 4 positive (3 *Rhodococcus equi* + 1 waiting for result)
- Hearts
 - 28 samples with endocarditis (cases)
 - All bacteriologic positive* (Streptococcus & Erysipelothrix)
 - 32 control samples (no endocarditis)
 - All bacteriologic negative

*: Identification by DNA sequence not yet accomplished

Ministry of Food, Agriculture and Fisheries
Danish Veterinary and Food Administration

Bovine Tuberculosis – Denmark officially free of Bovine TB since 1980

- Surveillance based on:
 - Clinical findings by practitioners
 - Meat inspection of all slaughtered animals
 - Intra-cutane TB test of cattle
 - Export samples
2,000-3,000 cattle tested per year
 - Before admittance to semen collection centers
550 – 600 bulls tested per year

Ministry of Food, Agriculture and Fisheries
Danish Veterinary and Food Administration

Avian Tuberculosis

- Cases sporadically seen in HIV patients and young children
 - Not considered meat-borne
- In Ireland where bovine TB is present in cattle, a double intra-cutane test is used
 - If reaction only towards avian TB is seen, animal is considered TB negative and no further actions taken
- How is avian TB in pigs dealt with in the US ?

Ministry of Food, Agriculture and Fisheries
Danish Veterinary and Food Administration

Pilot study – visual inspection of fattening pigs

- Based on our studies on lymph nodes and hearts, a risk assessment will be made assessing the impact on food safety of the two suggested changes
- If food safety is not jeopardized, we will introduce the visual inspection on two slaughterhouses (pilot study)
- Here we will need performance standards
 - A part of quality assurance of meat inspection data
 - Will ensure the quality of meat inspection



Performance standards

Criteria to be met

- Inspection tasks (palpation etc.): 5%
- Inspection decisions:
- Pathological findings : 6%
 - 2% on the carcass
 - 2% on the hearts
 - 2% on other organs
- Hygienic slaughter: 2%
 - 2% contamination in general
 - 0% fecal contamination



Performance standards cont.

- Verification:
 - To check the quality of the meat inspection
 - The official veterinarian must check 100 carcasses incl. organs per line per shift *after* PM-inspection
 - In case of *non-compliance* with the performance standard:
 - Follow up by documentation and reestablishing the standard



Traditional inspection versus visual inspection

A comparison of the two systems will be conducted during the pilot study by use of

- Meat inspection results:
 - Comparison of historical meat inspection results with meat inspection results from visual inspection
- Slaughterhouse monitoring data on carcasses
 - Salmonella performance standard
 - E. coli



Visual inspection – Status and further process

- Study 1
 - Continued collection of lymph nodes and hearts
 - Risk assessment expected to be made by mid-September
- Study 2
 - Planning has started and includes visits to the two selected slaughterhouses
 - Intention to introduce visual inspection at two slaughterhouses ultimo 2008

Following is a detailed description of the verification procedure on the performance of the official staff (veterinarians and auxiliaries):

Introduction

The traditional meat inspection is carried out on the slaughter line at the line speed at each slaughter house.

The meat inspection is carried out by official veterinarians and auxiliaries all employed by the Danish Veterinary and Food Administration. The auxiliaries work under the responsibility and the supervision of the official veterinarian.

On the line the post mortem (PM) inspection is most commonly performed by auxiliaries. If no abnormalities are observed the carcass and the organs are accepted as fit for human consumption. In case of abnormalities found here the carcass and the organs are sent to the rework platform, where the abnormalities are removed (by the slaughter house staff), and the pathology is evaluated more closely by auxiliaries or by the official veterinarian. This evaluation leads to a decision whether to accept or condemn the carcass and the organs.

According to the EU regulation² the official veterinarian must regularly check the work of official auxiliaries. The Danish Veterinary and Food Administration will ensure that this criteria is met by the use of performance standards.

The verification procedure on the quality of the PM-inspection

From January 1st 2009 the performance standard for the meat inspection will be introduced for all slaughter houses for pigs, the standard being as follows (monitored daily in each slaughter house);

- Inspection tasks (palpation, incision and hygienic behavior):

Not more than 5% non-compliance

The PM-inspection has to be performed in compliance with Regulation (EC) 854/2004. The verification is made on the inspection platform. The size of the random sample is determined by \sqrt{n} (n being the number of animals slaughtered per day in the slaughter house).

See Annex 2 for sample size considerations.

The official veterinarian carries out the verification.

- Pathological findings:

Not more than 6 % non-compliance

- 2% non-compliance on the carcass
- 2% non-compliance in plucks
- 2% non-compliance in other organs

² Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004, annex I, section III, chapter 1 point 3

In Regulation (EC) 854/2004, annex I, section II, chapter V the pathological abnormalities that result in meat being declared unfit for (animal or human) consumption is listed. The standard is set for 6% non-compliance i.e. the auxiliaries can miss only 6% of pathological abnormalities in the random sample. The 6% is a cumulative standard (consisting of a 2% standard for the carcass, 2% standard for the plucks and 2% standard for the other organs). See annex 2 for sample size considerations.

- Registration of hygienic slaughter:

Not more than 2% non-compliance for registering of contamination and 0% non-compliance for fecal contamination.

Fecal contamination is a CCP for which the slaughterhouse is responsible.

In addition the standard for the carcass for contamination is 2% and 0% for fecal contamination.

For sample size considerations see Annex 2.

Monitoring of performance

The draft formula to be filled out, when the official veterinarians monitor the performance of the meat inspection is as listed in the Annex 1 (p.t. only in Danish).

How to use the performance standards

The guideline for the official veterinarians includes a description of action that needs to be taken to ensure that the standard is met. If the performance standard is not met, the guideline also describes how the official veterinarian must ensure correction of the performance of the meat inspectors, so that the standard is observed.

The performance standards must be met, and if not, corrective action should be taken right away. If the standards are not observed, the official veterinarian must increase the number of monitoring of the performance standards to twice per day until the standards are again observed.

It is the responsibility of the chief veterinarian on each slaughter plant to ensure that the performance standard is met.

5. Implementing – plan

a. Precondition for implementation:

- i. The risk assessment has concluded that there is no excess risk for humans. The risk assessment has been accepted by the competent authorities in Denmark and abroad.
- ii. Own check procedures on quality of the post mortem inspection is in place

- iii. Own check procedure on opening of the hearts prior to the hearts being sold in detail to remove blood coagula and to condemn any hearts with abnormalities.
- iv. Any necessary changes to the platforms, light etc are in place.

b. Plan – preliminary schedule

The Supply Meat Chain Inspection will be implemented initially at two selected medium-sized slaughterhouses – Danish Crown, Holstebro and Tican, Thisted.

In November and December 2008, a dialogue takes place between the competent authorities and the plants. Hereby, the necessary adjustments are prepared.

Pending on acceptance of the suggested changes to the Danish Meat inspection system by the end of 2008, the revised post mortem inspection can begin in January 2009.

c. Evaluation and verification

The performance on the two selected plants will be followed closely both by the competent authority and the plants themselves.

Besides evaluation of the performance standards for meat inspection we will focus on the process criteria for E. coli, Total Viable Count and Salmonella. A decline in the prevalence of these contaminants might be connected to an improvement of performance of the post mortem inspection in the new system.

d. Time schedule for implementation:

To follow the implementation of the new system closely and to adjust on an ongoing basis, it has been decided to implement the Supply Meat Chain Inspection stepwise. An introduction period of two months at the two selected plants is considered acceptable before the system can be introduced to other plants.

Annex 1

Standard of meat inspection

Date and time: _____ Slaughterline: _____

Sample size: _____ Official veterinary signature.: _____

Inspection tasks - maximum 5% non-compliance³

	OK	Not OK Describe non-compliance	Follow-up action	
Inspection of head				
Incision of the mandibular lymph nodes				
Inspection of the mouth, fauces and tongue				
Carcass inspection				
Inspection of both internal and external surfaces of the carcass?				
Intestine inspection				
Is the entire set of intestines inspected?				
Palpation of the mesenteric lymph nodes				
Inspection of the spleen?				
Inspection of gastric lymph nodes				
Pluck inspection				
Visual inspection of lungs, trachea and mediastinal lymph nodes?				
Palpation of the lungs and lymph nodes				
Inspection of the pericardium and incision of the heart				
Inspection of the liver and lymph nodes				
Inspection of the kidneys?				
Pathological decisions - maximum 6 % non-compliances²				
Inspection of head				
Is pathological lesion diagnosed correctly?				
Is pathological lesion registered correctly?				
Carcass inspection				
Is pathological lesion diagnosed correctly?				

³ Palpation, incision and hygienic behaviour maximum 5% non-compliance

² Maximum 6% accumulated non-compliance (2% on the carcass, 2% on hearts, 2% in pluck)

Is pathological lesion registered correctly?				
Inspection of intestines				
Is pathological lesion diagnosed correctly?				
Inspection of plucks				
Is pathological lesion diagnosed correctly?				
Is pathological lesion registered correctly?				
For registration of hygienic slaughter maximum 2% non-compliance³				
Hygiene (for all inspection locations)				
Is contamination registered correctly?				
Is fecal contamination registered correctly?				
After control/rework platform – auxiliary				
Is the slaughterhouse staff removing the right parts (incl.regional lymph nodes)?				
Presentation of removed parts for inspection?				
Registrations changed correctly?				
Inspection of the plucks in connection with the carcass?				
After control area/rework platform (OV):				
Is pathological lesion diagnosed correctly?				
Is registration correctly conducted?				
Retained plucks and intestines inspected before final inspection decision is made?				

³ 0% non-compliance for fecal contamination

Kontrol med kontrollen

Dato og klokkeslæt: _____

Slagtelinie: _____

Antal: _____

Udført af dyrlæge: _____

Kontrol af inspektionens opgaver højst 5% fejl⁴

	OK	Ikke OK - beskriv det observerede	Opfølgning	
Hovedkontrollør:				
Foretages opbladrning af de mandibulære lymfeknuder?				
Inspiceres hoved og svælg?				
Kropskontrollør:				
Inspiceres slagtekroppens indvendige og udvendige flader inkl. brysthinde og				
Tarmkontrollør:				
Inspiceres hele tarm-sættet?				
Palperes krøslymfeknuder?				
Inspiceres milt?				
Foretages milten ved "Rød seddel"?				
Inspiceres mavens lymfeknuder?				
Pluckskontrollør:				
Inspiceres lunger, luftrør, spiserør, mellemgulv?				
Palperes lunger og lymfeknuder?				
Inspiceres hjerte og hjertesæk og åbnes til begge hjertekamre				
Inspiceres lever og leverlymfeknuder				
Inspiceres nyrer – er nyrerne decapsuleret?				
Kontrol af patologiske forandringer højst 6 % fejl²				
Hovedkontrollør:				

⁴ fx palpation, indsnit og hygiejnisk opførsel: må der højst være 5% afvigelser.² Højst fejl i 6 % af bedømmelserne (2% på kroppen, 2% på hjerter, 2% på organer)

Bedømmes sygdomme korrekt?				
Indtastes sygdomme korrekt?				
Kropskontrollør:				
Bedømmes sygdomme korrekt?				
Indtastes sygdomme korrekt?				
Tarmkontrollør:				
Bedømmes sygdomme korrekt?				
Pluckskontrollør:				
Bedømmes sygdomme korrekt?				
Udrenses og opmærkes korrekt				
For registrering af hygiejnisk slagtning højst 2% fejl³				
Hygiejne (gælder for alle pladser):				
Registreres kontamination korrekt?				
Registreres fækal forurening korrekt?				
EK – TT plads:				
Kontrolleres lokal udrensning korrekt – herunder udrensning af regionale lymfeknuder?				
Præsentation af udrenset materiale?				
Indtastes ændringer korrekt?				
Kontrolleres og opmærkes plucks korrekt?				
EK- Dyrlæge:				
Bedømmes korrekt?				
Registreres korrekt på sygeliste/terminal?				
Kontrolleres fratagne tarme og plucks på kontrolplatform før endelig bedømmelse?				

³ Højst 2% fejl for registrering af kontamination og 0% fejl for fækal kontamination.

SAMPLE SIZE EVALUATIONS

A. Prevalence estimation

Table 1

Sample size (n) based on the number of finisher pigs slaughtered in a day as well as precision of prevalence estimate divided according to expected prevalence (6% or 2%)

N	10	20	40	80	100	200	400	600	800	1,000	2,000	4,000	6,000	8,000	10,000	12,000
N	3	4	6	9	10	14	20	24	28	32	45	63	77	89	100	110
6%	0.27	0.22	0.19	0.16	0.15	0.13	0.11	0.10	0.09	0.08	0.07	0.06	0.05	0.05	0.05	0.05
2%	0.16	0.13	0.11	0.09	0.09	0.07	0.06	0.06	0.05	0.05	0.04	0.04	0.03	0.03	0.03	0.03

The aim is to identify the prevalence by use of a sample. The precision of such a result depends on the sample size (n) ; the higher the sample size, the more precise is the resulting prevalence estimate. The precision also depends on the expected prevalence of the condition of interest; here set to 2% or 6% and the confidence level is 95%.

N= Number of pigs slaughtered during a slaughter day

n= Number of pigs in a sample determined as the square root of N – as suggested by The Netherlands

The precision, L, is estimated based on the following formula:

$$L = (4 * pq / n)^{0.5}$$

This is valid for large populations, e.g. N>200. For population sizes <200, the precision listed in Table 1 is underestimated (the result of the investigation of the sample is closer to the true prevalence than shown in the table)

Example: If 2000 finisher pigs are slaughtered in a day, 45 carcasses should be included in the sample. If a prevalence of 6% is expected, then the precision is 4%; with other words the true prevalence lays $\pm 4\%$ from the result of the sample (in 95 out of 100 times). If 3 out of the 45 investigated carcasses were positive, then the estimated prevalence of the condition in the population consisting of the 2,000 carcasses is $3/45 \pm 4\% = 7\% \pm 4\% = 95\%$ confidence interval: 3-11%

B. Documentation of absence of a condition (fecal contamination)

Table 2
Sample size required to estimate maximum prevalence P_{\max} by use of sample n in population of size N . The entire sample is examined and found negative

N	10	20	40	80	100	200	400	600	800	1,000	2,000	4,000	6,000	8,000	10,000	12,000
n	6	9	13	18	20	28	40	49	57	63	89	126	155	179	200	219
Diseased	3	4	7	11	13	19	27	34	40	45	64	92	113	131	147	161
P_{\max}	0.26	0.22	0.18	0.14	0.13	0.09	0.07	0.06	0.05	0.04	0.03	0.02	0.02	0.02	0.01	0.01

The aim is to document absence of a condition e.g fecal contamination of a carcass. The larger the sample analysed and found negative, the more confident are we that the condition is not present or low-prevalent. We measure this as the maximum prevalence that could “hide” in the population, despite of the negative sample.

N = number of finishers slaughtered in a day

n = sample size = $2 \cdot N^{0.5}$ – as suggested by The Netherlands

The maximum prevalence that could “hide” in the population is determined by the following formula:

Max number of diseased = $(1 - (0.05)^{(1/n))}(N - (n - 1)/2)$

P_{\max} = Max number of diseased / N

Example: if 2,000 finisher pigs are slaughtered in a day, 89 should be examined. If all these are found negative, then we are 95% confident that true prevalence of the condition of interest is less than 3%.

Reference for formulas used in Section A and B:

Martin, S.W., Meek, A.H., Willeberg, P., 1987. Veterin

ary Epidemiology – Principles and Methods. Iowa State University. Ames, Iowa. 22-47.

Ministry of Food, Agriculture and Fisheries
Dutch Veterinary and Food Administration

Performance standards

Criteria to be met

- Inspection tasks (palpation etc.): 5%
- Inspection decisions: 6%
- Pathological findings :
 - 2% on the carcass
 - 2% on the hearts
 - 2% on other organs
- Hygienic slaughter: 2%
- 2% contamination in general
- 0% fecal contamination

Ministry of Food, Agriculture and Fisheries
Dutch Veterinary and Food Administration

Performance standards cont.

- Verification:
 - To check the quality of the meat inspection
 - The official veterinarian must check 100 carcasses incl. organs per line per shift *-after PM-inspection*
- In case of *non-compliance* with the performance standard:
 - Follow up by documentation and reestablishing the standard

Ministry of Food, Agriculture and Fisheries
Dutch Veterinary and Food Administration

Traditional inspection versus visual inspection

A comparison of the two systems will be conducted during the pilot study by use of

- Meat inspection results:
 - Comparison of historical meat inspection results with meat inspection results from visual inspection
- Slaughterhouse monitoring data on carcasses
 - Salmonella performance standard
 - E. coli

Ministry of Food, Agriculture and Fisheries
Dutch Veterinary and Food Administration

Visual inspection – Status and further proces

- Study 1
 - Continued collection of lymph nodes and hearts
 - Risk assessment expected to be made by mid-September
- Study 2
 - Planning has started and includes visits to the two selected slaughterhouses
 - Intention to introduce visual inspection at two slaughterhouses ultimo 2008

Smith, David

From: Smith, David
Sent: Tuesday, July 08, 2008 12:06 PM
To: Furey, Todd; White, Sally
Subject: RE: FOR REVIEW - Response to Denmark Qs

Attachments: Response to 20080702 Questions.doc



Response to
0080702 Questions.

David Smith, DVM, MS
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From: Furey, Todd
Sent: Tuesday, July 08, 2008 12:00 PM
To: White, Sally; Smith, David
Subject: FOR REVIEW - Response to Denmark Qs

<< File: Response to 20080702 Questions.doc >>

Todd M. Furey
USDA, FSIS
Office of International Affairs

Denmark Questions

7/2/08

Q: Will an animal less than 6 months of age be able to produce a serological response?

FSIS does not collect any data on this subject.

*Q: Does FSIS consider *M. avium* a meat borne zoonosis?*

There is no definitive linkage in the scientific literature that implicates *M. avium* as a pathogen capable of spreading disease through a food-borne route. Therefore, FSIS does not consider *M. avium* to be a disease of public health significance.

Q: Does USDA conduct intradermal tuberculin in swine?

FSIS does not perform this test. However, within USDA, the Animal and Plant Health Inspection Service will conduct intradermal testing of swine when deemed necessary.

How to ensure continuous freedom from bovine tuberculosis in fischer pigs when changing meat inspection?

Denmark is officially free from bovine tuberculosis. A risk assessment of Danish finisher pigs shows that there is no added value related to the cutting into the mandibular lymph nodes during meat inspection. A precondition is that the pigs originate from integrated production systems, where the pigs are kept in-door.

The aim of meat inspection is to ensure that the meat we consume is savoury and safe. Meat inspection was designed 100 years ago when people in Denmark became ill among others from bovine tuberculosis (TB). Since, bovine TB has been eradicated from Denmark. Nowadays, other hazards fill up the statistics. In particular, Salmonella and Campylobacter are resulting in a larger number of human cases. The rules for meat inspection should be updated to take into account the hazards that are most important at a given point in time. This is the philosophy behind changes in 2006 to the legislation of the European Community that made it possible for the competent authority to decide that finisher pigs under certain conditions can undergo a modernised meat inspection.

There are three requirements, which should be fulfilled:

- A risk assessment should be undertaken and demonstrate that the suggested changes do not jeopardise food safety
- Relevant only for finishers from integrated production systems, where pigs are kept in-door since weaning
- Food chain information should be exchanged between the herd owner and the slaughterhouse prior to slaughter

The proposal was only to cut into the mandibular lymph node on carcasses where pathological changes are observed, because omission of the routine cutting might reduce the spreading of Salmonella and Yersinia bacteria for the benefit of the consumer.

A risk assessment was undertaken in collaboration between University of Copenhagen (the former Royal Veterinary and Agricultural University), the Danish Veterinary and Food Administration and Danish Meat Association (DMA). The aim was among others to assess the impact on the suggested changes on food safety.

Risk of bovine TB is the reason for cutting into the mandibular lymph node. If a cow or a pig is infected with bovine TB then the lymph node will look like gritty cheese on the inside (called granulomatous lesions), however other bacteria might also cause this altered look. According to the Danish slaughterhouse database the prevalence of granulomatous lymph nodes is very low among Danish finisher pigs (0.01-0.02%).

Samples were collected from ten Danish slaughterhouses. No TB bacteria were found in any of the samples. Bovine TB was found in farmed deer in Denmark previously. No free-living deer have ever been found TB-positive in Denmark. In fact, Denmark is recognised by the EU as being officially free from bovine TB since 1980.

To ensure continuous freedom from bovine TB an extensive surveillance program is in place.

The surveillance program consists of:

- Examination of cattle during meat inspection
- Testing of bulls before they enter a semen collection centre
- Testing of cattle before export
- Testing of pigs exported to certain countries that require testing for TB

Denmark only imports a limited number of cattle and pigs, and requirements for testing and quarantine are in place. Hence, if bovine TB should enter the country, there is a high probability that it will be found during quarantine.

Moreover, we will continue to cut into the mandibular lymph nodes of sows and boars as well finishers from herds that do not fulfil the criteria for being subjected to Supply Chain Meat Inspection. These groups of pigs are expected to be at higher risk than in-door reared finishers which only live for five months without any contact to other animals than their pen mates.

Conclusively, the surveillance program in place continuously documents freedom from bovine TB. Hence, there is no risk of bovine TB associated with the omission of the routine cutting of the mandibular lymph nodes. On the contrary, unnecessary palpation and cutting will increase the risk of spreading bacteria such as Salmonella and Yersinia.

As a part of a quality control, the risk assessment has undergone a peer-review process where comments from three independent professors from Great Britain and Norway were incorporated. The risk assessment can be found on the homepage of the Danish Veterinary and Food Administration on <http://www.foedevarestyrelsen.dk/forside.htm> and DMA <http://www.danishmeat.dk/Forside.aspx>

day to ensure that the performance standards are met. For organs and plucks the standard frequency is two times 40 carcasses are checked.

In case of non-compliance (the standard is not met), additional instruction will be given to the staff and the frequency will be increased. If more than 2% deviations occur on a day, additional checks will be performed the following day.

If the performance standard is exceeded in more than two cases per week, the frequency of checks will be increased to five checks per day (5 x 40 carcasses) for a full week. For plucks and organs the frequency will be increased to three checks per day for a period of one week.

c. Opening of the hearts?

The hearts will be opened, preferably separately from the carcass to remove blood clots present. Findings of any abnormalities will result in the condemnation of the heart itself.)

4. Enforcement procedures – competent authorities

a. Procedures on audit – HACCP system and in general

The Danish Veterinary and Food Administration carries out audits on the HACCP systems on all EU approved slaughterhouses and slaughterhouses approved for export to the USA.

The Official Veterinarian (OV) carries out the official inspection tasks in the slaughterhouses in accordance with Regulation (EC) 854/2004.

The inspection includes all relevant issues of the regulations including; audit of good hygiene practises and HACCP-based procedures.

Food Chain Information

According to Regulation (EC) 854/2004 the relevant FCI (as described in the risk assessment (pp 5 and 6) should be sent to the slaughterhouse prior to the animals being transported to the slaughterhouse. This enables the slaughterhouse to take appropriate measures concerning logistics and meat inspection. In Denmark, electronic recording systems which cover the requirements regarding exchange of FCI between the herd owner and the slaughterhouse are in place (Fig. 1). One example is the Central Husbandry Register ([http://www.glr-chr.dk/pls/glrchr/chrmenu\\$.menu](http://www.glr-chr.dk/pls/glrchr/chrmenu$.menu)) and the central recording of the use of veterinary medication called VetStat (<http://www.vet.dtu.dk/Default.aspx?ID=9205>) as well as the Zoonosis Register, which contains information about the Salmonella status in the herd. The consumer will receive information through television, radio, or newspaper if meat sold on the market has to be recalled. Such recalls occur through the rapid alert system (http://ec.europa.eu/food/food/rapidalert/index_en.htm).

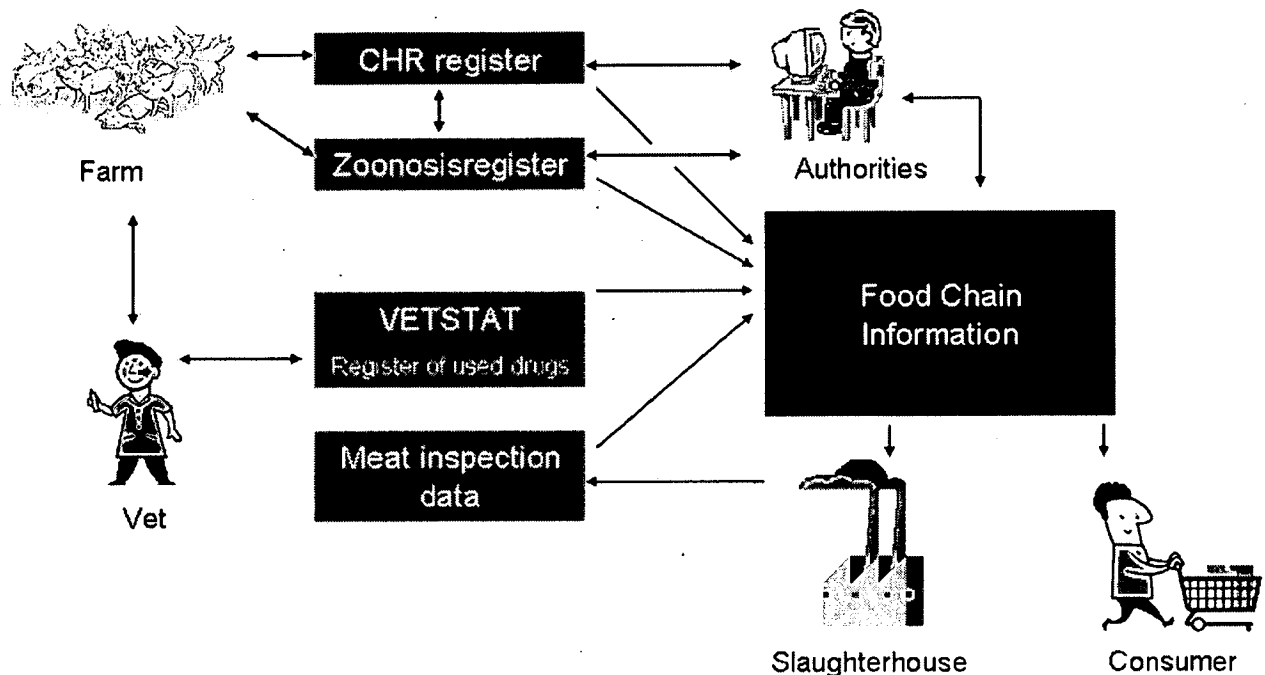


Figure 1

Description of the connection between collection of food chain information during animal production and the slaughterhouse, Denmark, 2008

The OV checks the Food Chain information to ensure that the slaughterhouse requests, receives, checks and acts upon it in compliance with regulation. The procedures are verified by audit by the OV.

In addition to the general FCI, it is mandatory that the slaughterhouses for finishers receive information stating whether the finishers have been held indoor since weaning if the animals are intended for supply chain inspection. The OV checks that as part of the inspection of FCI and the animals received for slaughter can only undergo visual inspection as part of supply chain inspection if this information is present before the slaughter of the animals. If the information is not available or the animals have had access to outdoor areas since weaning, the animals must undergo traditional meat inspection. The procedures are verified by audit by the OV.

b. Verification – performance standards for meat inspection

In addition to the audits on the food chain information system verification of the quality of the post mortem inspection is performed

Smith, David

From: Anders Klöcker [andklo@um.dk]
Sent: Friday, October 10, 2008 2:28 PM
To: James, William
Cc: White, Sally; Smith, David; Furey, Todd
Subject: Visual Inspection in Denmark, Next Step and Resume of Telephone Conference Sep. 30, 2008

Attachments: Resume tel-conference Sep 30 2008.doc

Dear Bill,

On behalf of my colleagues in Copenhagen I would like to thank you and your staff for a very fruitful telephone conference September 30th, 2008.

The project concerning visual inspection (pending a new and more precise title) is of very high importance to Denmark and we therefore appreciate the priority given by FSIS to our questions and considerations.

Attached please find our resume of the meeting.

Based on the positive outcome of the meeting we will now focus on drafting a government verification program. We expect to have a draft ready for discussion with FSIS by late October. I will update you later in October – with the hope to be able to schedule another telephone conference soon after the draft is ready.

Best regards,

Anders

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12/18/2008

Ministry of Food, Agriculture and Fisheries

Danish Veterinary and Food Administration



FSIS

DIVISION FOR MICROBIOLOGICAL
FOOD SAFETY, HYGIENE
AND ZOOSES CONTROL

02.07.2008

File: 2008-20-23-02391/CHVI

RESUME

30. juni 2008

BSB

Visual inspection of fattening pigs – Telephone conference 23 June 2008

Participants FSIS, USA:

- Todd Furey, FSIS, OIA (TF)
- David Smith, FSIS, OIA (DS)
- Andreas Keller, FSIS, OIA (AK)
- Maritza Colón-Pullano, FSIS, OP (MKP)

Participants, The Royal Danish Embassy, Washington, DC

- Anders M. Klöcker (AMK)
- Signe Hoff (SH)

Participants, Denmark:

- Charlotte Vilstrup, DVFA (CHVI@fvst.dk)
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- Susanne J. Jensen, DMA (SJJ@danishmeat.dk)
- Birthe Steenberg, DMA (BSB@danishmeat.dk)

Agenda:

- 1 Introduction of participants in the conference call
- 2 Description of project on visual inspection of fattening pigs
- 3 Questions from FSIS

- 4 Discussion of any further steps needed to ensure compliance with USA/FSIS requirement
- 5 Any other business

Ad 1 Introduction of participants in the conference call

AMK began with establishing the aim with the telephone conference. Denmark involves the US in this early phase of a project aimed at, ultimately, a transition into visual meat inspection in order to prevent that any technical issues will arise as FSIS, at a later stage, is requested by Denmark to grant the equivalency approval of the new system. Therefore, it is very important for Denmark to facilitate an exhaustive technical discussion and to establish a file covering the questions covered step by step. This in order to prevent technical recourse at a later stage.

After the meeting a summary including the discussion issues and conclusions will be sent to all participants in order to establish this file.

When the risk assessment is finished, the Americans have the possibility to raise more questions, and give recommendations before the final approval of the next part of the project.

CHVI introduced the Danish participants and TF introduced the American participants.

Ad 3 Description of project on visual inspection of fattening pigs

Time table (CHVI).

Traceability (SJJ)

Study 1 – Status for heart and lymph node study (CHVI)

Tuberculosis (LIA)

Study 2 - Pilot study (CHVI)

Performance standards (CHVI)

Traditional inspection versus visual inspection (CHVI)

Status and further process (CHVI)

Ad 4 Questions from FSIS

a. FSIS asked whether the hogs are registered individually or by herd and what is the size of an average herd in Denmark?

Denmark replied that at the farm they are registered by herd – but at the abattoir the pigs are individually numbered.

A medium-sized finisher herd produces around 1000 -3000 pr. year

b. FSIS raised the question whether traditional and visual inspection will be performed at the same time during the pilot study (study 2)?

Referring to results of earlier studies – in particular the large scale study in Horsens; Denmark in the 1990'ies, it is not the intention to carry out both visual inspection and traditional inspection at the same time. Denmark will introduce the changes on two slaughterhouses to follow the process and the changes closely.

The objective of study 1 is to investigate whether food safety is jeopardized when omitting the routine incision of the heart and the submandibular lymph nodes. If this is not the case, we intend to introduce these two changes. The performance will be measured by comparing historical data and current data.

And to take seasonality into account, data from one year before, and one year after the changes will be evaluated.

Performance standards must be met with traditional meat inspection as well as with visual inspection.

c. FSIS asked if there will be only indoor raised pigs in the project?

Demark confirmed that only indoor raised pigs will be part of the project. This is in accordance with changes in the EU legislation as of 1st of January 2006, which make it possible to carry out visual meat

inspection of finisher pigs. The possibility is restricted to fattening pigs housed under controlled housing conditions in integrated production systems since weaning¹.

d. FSIS asked with relation to Food Chain information (FCI) how far in advance the information about the herd arrives at the abattoir?

Denmark answered that according to the EU legislation the Food Chain information (FCI) must be present 24 hours in advance. Until end of 2009 the FCI can arrive at the latest together with the pigs they concern. The FCI needs to be evaluated by the slaughterhouse prior to the slaughter of the animals regardless of the time of arrival of the FCI.

Danish farmers have a contract with an abattoir. Hence they deliver to the same abattoir week after week (month after month).

Supplementary, FSIS asked about details in the food chain information system and in particular *which other information is collected including E. coli and salmonella sampling.*

Denmark told that data are exchanged between the producer and the slaughterhouse prior to slaughter – but the information is generated for the entire production chain; from stable to table. As for Salmonella, meat juice samples as well as carcass swab samples are taken in relation to slaughter. And E.coli process control samples are taken due to both US and EU-legislation.

It was agreed to add *E.coli and Salmonella sampling* on the figures on **Traceability – stable and table.**

d. To the question from FSIS on what happens if the information is not there, Denmark said that no visual inspection will be carried out.

¹.(Annex I, section IV, Chapter IV, point 2 B in Regulation (EC), No 854/2004 of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption).

e. FSIS asked if Denmark plans to use serology on TB?

The question by FSIS was returned back to FSIS by Denmark by asking whether an animal on 6 months will be able to produce a serological response and is avian TB meat-borne ? Those are two questions that need to be addressed.

Denmark explained that it has not been possible to get detailed information from Netherland about this test. Of particular interest is the positive and negative predictive value associated with the test. Furthermore, avian TB is not considered meat-borne by the experts Denmark has talked to. Hence, it is questionable whether it makes sense to survey for avian TB in finisher farms. FSIS agreed to this.

f. FSIS asked whether the test is intradermal?

Yes for Cattle – but for hogs we use meat inspection, was the answer from Denmark

Denmark wanted to know how the test is carried out in USA. FSIS answered that for cattle the test is intradermal.

The answer was followed by a question from Denmark on what is going on in US-regions free of TB ?

FSIS promised to examine and return with a reply !

g. Denmark clarified that performance standards will be conducted as follows:

- 100 carcasses incl. organs inspected after PM-inspection per line / shift / day

h In relation to study one and the sampling of lymph nodes, the FSIS needed clarification on how many pigs have been slaughtered during the project period (mid March through 11 June ; 11 lymph nodes out of how many pigs – and traditionally inspected?

Denmark answered that the annual number of pigs slaughtered in Denmark is approximately 22 million. The data collection began in the middle of March (3 months) ~5 million pigs slaughtered in that period. *All* pigs are inspected traditionally.

i. FSIS asked about the Prevalence of M. avium in pigs?

Denmark answered that so far we have found 11 lymph nodes with gross morphological changes indicating TB. Among these, 7 were bacteriological negative, 3 were due to Rhodococcus Equi and one is waiting for final result. If this last sample is due to M. avium and the population it came from consisted of 2 mio. finishers, the prevalence is $1/2 \text{ mio.} = 0,00005\%$

j. Denmark asked whether FSIS consider M. avium a meat borne zoonosis?

FSIS replied that this is not the case in the USA.

Ad 5 Discussion of any further steps needed to ensure compliance with USA/FSIS requirement

All agreed on the importance of having an ongoing dialogue. A telephone conference was considered a good idea, and CHVI also invited the Americans to make a visit to Denmark.

Ad 6 Any other business

Denmark asked whether FSIS had any follow-up questions to the answers from Denmark given by letter dated May 8th, 2008.

FSIS answered that this is not the case.

Yours faithfully

Charlotte Vilstrup
Senior veterinary officer, DVM
Direct tel. +45 33956275
E-mail chvi@fvst.dk

Ministry of Food, Agriculture and Fisheries
Danish Veterinary and Food Administration

Visual inspection of fattening pigs

Conference call June 23, 2008 between:

- Food Safety and Inspection Service
- Danish Veterinary and Food Administration
- Danish Meat Association

Ministry of Food, Agriculture and Fisheries
Danish Veterinary and Food Administration

Agenda

1. Introduction of participants in the conference call
2. Election of chairman of meeting and keeper of minutes
3. Description of project on visual inspection of fattening pigs
4. Questions from FSIS
5. Discussion of any further steps needed to ensure compliance with USA/FSIS requirement
6. Any other business

Ministry of Food, Agriculture and Fisheries
Danish Veterinary and Food Administration

Participants from Denmark

- Charlotte Vilstrup
 - DVM, Senior Veterinary Officer, DVFA
- Søren Anbo
 - DVM, Ph.D., Research leader, Senior Scientist, National Food Institute
- Lis Alban
 - DVM, Ph.D., Dipl. ECVPH, DMA
- Birthe Steenberg
 - DVM, Senior Specialist, DMA
- Susanne Jensen
 - Food Scientist, Specialist, DMA

Ministry of Food, Agriculture and Fisheries
Danish Veterinary and Food Administration

Time table

Sketch of design for registration and evaluation of possible risk (contaminating) incidents of food and non-food commodity (preparation)

Flowchart illustrating the process of registration and evaluation of possible risk (contaminating) incidents of food and non-food commodity (preparation).

The flowchart details the steps from initial registration to final evaluation and reporting. It includes boxes for 'Registration of risk in Central Register', 'Evaluation of risk in Central Register', and 'Evaluation of risk in Central Register'. It also mentions 'Reporting of risk to the public' and 'Reporting of risk to the public'.

Ministry of Food, Agriculture and Fisheries
Danish Veterinary and Food Administration

Traceability in the danish pig production

A precondition for our meat inspection

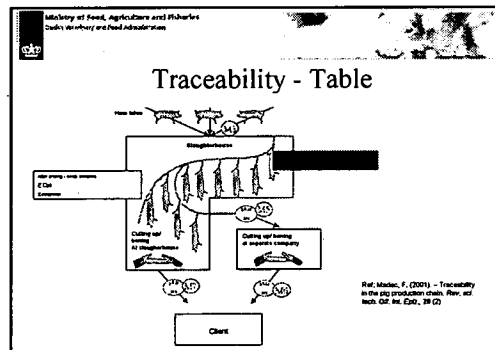
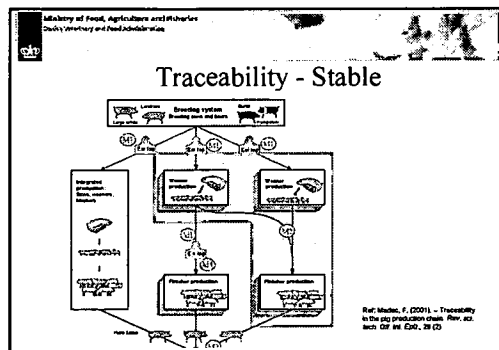
- Covered by a registration, marking and documentation system including:
 - All pig herds are registered with a herd number (*CHR-number*) in the Central Register of Domestic Animals
 - Information is exchanged in all parts of the chain (*food chain information*) from producer to slaughterhouse (mandatory requirement within EU)
 - Standard recording of detected lesions during post mortem inspection (conducted for more than ten years)

Ministry of Food, Agriculture and Fisheries
Danish Veterinary and Food Administration

Food chain information

Relevant information provided:

- Status of the herd (e.g. indoor/outdoor)
- Animal health status
 - e.g. Salmonella status at herd level
- Veterinary medical products used
- Results of other samples taken
 - In the framework of monitoring and control of zoonoses and residues relevant to public health
- Name and address of veterinarian attending herd



- Ministry of Food, Agriculture and Fisheries
Danish Veterinary and Food Administration
- ### Collection of hearts and lymph nodes - Status by June 11
- Lymph nodes with gross morphological changes
 - 11 samples
 - 7 negative (no bacteriological findings)
 - 4 positive (3 *Rhodococcus equi* + 1 waiting for result)
 - Hearts
 - 28 samples with endocarditis (cases)
 - All bacteriologic positive* (*Streptococcus* & *Erysipelothrix*)
 - 32 control samples (no endocarditis)
 - All bacteriologic negative
- *: Identification by DNA sequence not yet accomplished

- Ministry of Food, Agriculture and Fisheries
Danish Veterinary and Food Administration
- ### Bovine Tuberculosis – Denmark officially free of Bovine TB since 1980
- Surveillance based on:
 - Clinical findings by practitioners
 - Meat inspection of all slaughtered animals
 - Intra-cutane TB test of cattle
 - Export samples
 - 2,000-3,000 cattle tested per year
 - Before admittance to semen collection centers
 - 550 – 600 bulls tested per year

- Ministry of Food, Agriculture and Fisheries
Danish Veterinary and Food Administration
- ### Avian Tuberculosis
- Cases sporadically seen in HIV patients and young children
 - Not considered meat-borne
 - In Ireland where bovine TB is present in cattle, a double intra-cutane test is used
 - If reaction only towards avian TB is seen, animal is considered TB negative and no further actions taken
 - How is avian TB in pigs dealt with in the US ?

- Ministry of Food, Agriculture and Fisheries
Danish Veterinary and Food Administration
- ### Pilot study – visual inspection of fattening pigs
- Based on our studies on lymph nodes and hearts, a risk assessment will be made assessing the impact on food safety of the two suggested changes
 - If food safety is not jeopardized, we will introduce the visual inspection on two slaughterhouses (pilot study)
 - Here we will need performance standards
 - A part of quality assurance of meat inspection data
 - Will ensure the quality of meat inspection

a. Specific procedures – E.coli, Total Viable Count and Salmonella
As part of the EU requirements and requirements for export of pig meat to the US procedures for monitoring E. coli, Total Viable Count and Salmonella have been in place since 1997/1998 and will under the supply meat chain inspection system continue as usual.

3.2. Verification procedures - slaughterhouse responsibility

As part of the supply chain meat inspection system procedures and verification of the food chain information is of specific importance. As a result of changing the meat inspection a new procedure on quality control of post mortem inspection will be implemented.

a. Food chain information

Before accepting the animals for slaughter, the slaughterhouse must check the information about the herd. This is done when the owner of the herd signs in for slaughtering the animals and it is checked within the database of the slaughterhouse.

In case of non-compliance, the animals will be marked specifically. These animals may be slaughtered and the carcass will be retained until the required information is obtained and/or any suspicion is confirmed or rejected.

The system is audited by the slaughterhouse checking up a fixed part (minimum 1%) of the owners to check if the required information is present and valid.

As part of the Code of Practice the owner of the herd will be audited by the slaughterhouse.

b. Performance standards –quality control of PM-inspection

In general the post mortem inspection is performed by the official auxiliaries (OA). In case of any deviation the carcasses is marked by the OA. This includes presence of fecal contamination or digestive tract contamination. Carcasses with remarks are detained for extended examination before final judgement.

A part from this standard procedure, verification of the performance of handling and correction of all defects on the rework station by the slaughterhouse will be introduced under the Supply Meat chain Inspection System. The overall aim is to improve the performance of the meat inspection and to continue the reduction and/or elimination the defects that passes through traditional inspection

The performance standard is set at compliance levels at 98% a day and 98% a week of the checked carcasses to meet the specification. Four times 40 carcasses are checked every

Smith, David

From: Anders Klöcker [andklo@um.dk]
Sent: Wednesday, December 17, 2008 1:38 PM
To: Smith, David
Cc: Jones, Ronald; White, Sally; Furey, Todd
Subject: Summary of TB risk in relation to Supply Chain Meat Inspection
Attachments: Pixie engelsk_TB.doc

Dear David,

Thank you for a very productive meeting yesterday. The Danish delegation appreciated the opportunity to present the Danish project concerning supply chain meat inspection and we now look forward to a decision enabling us to implement the new procedures.

Based on the questions from especially Office of Policy regarding TB we have produced a short summary which might be helpful in relation to possible dialogue with external constituents.

As mentioned earlier please do not hesitate to return to me immediately in case of any further questions.

Best regards,

Anders

ANDERS M. KLOCKER / ANDKLO@UM.DK
MINISTER COUNSELLOR / FOOD, AGRICULTURE AND FISHERIES
DIRECT +1 (202) 797-5341 / CELL (202) 390-0846/ FAX (202) 328-1470

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3200 WHITEHAVEN ST., N.W. / WASHINGTON, D.C. 20008
PHONE +1 (202) 234-4300 / WWW.DENMARKEMB.ORG

12/18/2008

Adams, Susan

From: White, Sally
Sent: Thursday, December 04, 2008 11:52 AM
To: Adams, Susan
Cc: Furey, Todd; Smith, David
Subject: Fw: Supply Chain Meat Inspection - Final Risk Assessment

Attachments: Modernisation of Meat Inspection_DK.pdf

Please log in. This is a rush

Sent from my BlackBerry Wireless Device

-----Original Message-----

From: Anders Klöcker <andklo@um.dk>
To: White, Sally; Furey, Todd; Smith, David; Gonzalez, Francisco
Sent: Thu Dec 04 11:34:38 2008
Subject: Supply Chain Meat Inspection - Final Risk Assessment



Modernisation of
Meat Inspecti...

Dear all

Here comes – attached – the final version of our risk assessment. Now also including the comments from the external review (appendix B).

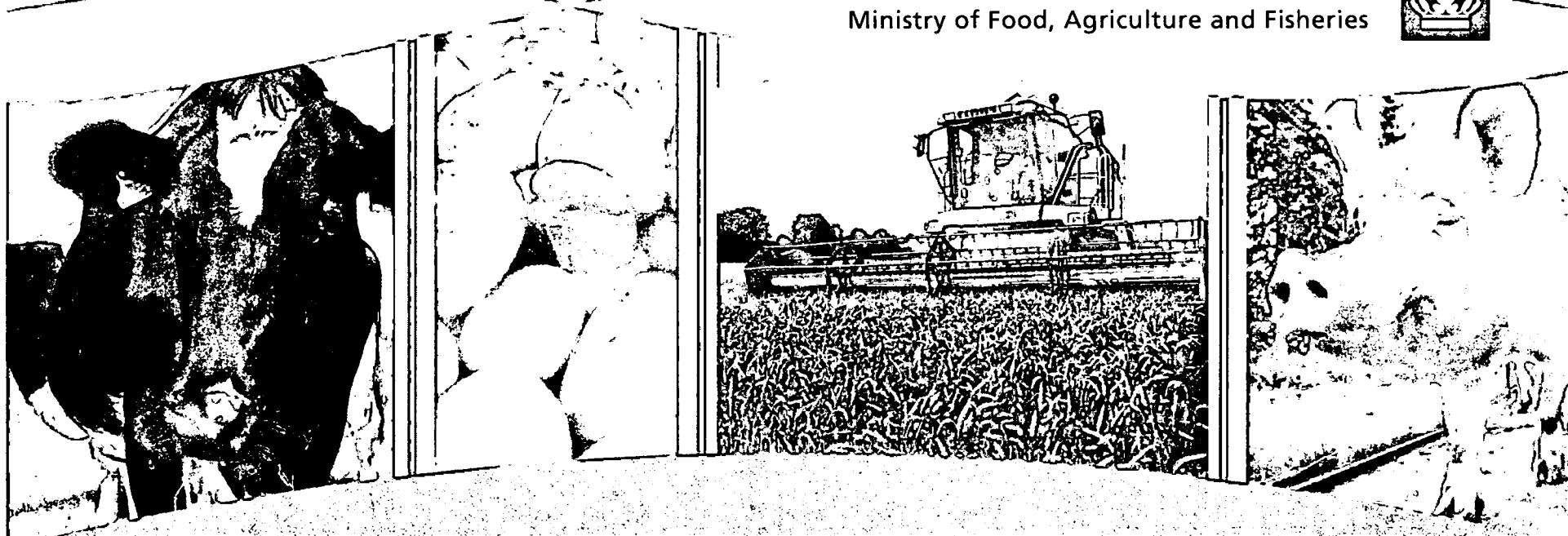
Best regards,

Anders

ANDERS M. KLOCKER / ANDKLO@UM.DK <mailto:ANDKLO@UM.DK> MINISTER COUNSELLOR
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How will Meat Inspection change?

Charlotte Vilstrup,
Senior Veterinary Officer, DVM
DVFA

		INSPECTION SYSTEMS	
	Subject	Traditional meat inspection	Supply chain meat inspection
	Animal health and zoosanitary status	Denmark is officially free from TB	
	Origin of the pigs	Born and raised in Denmark	
Prerequisites	Delivery of pigs for slaughter	All pigs + sows and boars	Only finishers from integrated production systems <u>and</u> kept indoor since weaning
Preconditions – for delivery and slaughtering pigs	Food Chain Information (Required information have for years been registered and kept in databases (VETSTAT, CHR, Zoonosis Register) and exchanged between slaughterhouse and primary producer as part of a Code of Practice From 1 January 2008 mandatory for pigs within the EU	General information on · Animal health status, incl. name and address of the owner of the herd · Salmonella status · treatment on veterinary drugs · any relevant reports from previous ante- and post mortem inspection · name and address of the private veterinarian	General information on · Animal health status, incl. name and address of the owner of the herd · Salmonella status · treatment on veterinary drugs · any relevant reports from previous ante- and post mortem inspection · name and address of the private veterinarian · information on indoor/outdoor-access
	The Danish Salmonella surveillance and control programme	Main elements in the surveillance and control programme •Feed •Breeder and multiplier herds •Finisher herds •Sow herds •Fresh meat	



	Subject	Traditional meat inspection	Supply chain meat inspection
Meat inspection according to Regulation 854/2004 on official control on products of animal origin	Ante-mortem inspection	All pigs are inspected by the Official Veterinarian	All pigs are inspected by the Official Veterinarian
	Post-mortem inspection	Routine inspection includes: Visual, palpation and incisions of lymph nodes and opening of hearts. Inspection leads to either approval or further inspection before final approval and/or condemnation	Routine inspection includes: Visual inspection and palpation. No incisions of lymph nodes and opening of hearts. Inspection leads to either approval or further inspection before final approval and/or condemnation
Process control – hygienic slaughter	Fecal contamination	Zero tolerance - CCP	Zero tolerance – CCP
	Process control criteria – carcass testing	E. coli + Total viable count according to EU and US-requirement modified under equivalence agreement between US and DK Enforcement procedures and statistical calculating methods are used	E. coli + Total viable count according to EU and US-requirement modified under equivalence agreement between US and DK Enforcement procedures and statistical calculating methods are used



Enforcement programs - government	Audit procedures	Audit of the HACCP system including audit of the Food Chain Information	Audit of the HACCP system including audit of the Food Chain Information including information on indoor/outdoor access
	Salmonella testing	<p>FSIS requirements are adopted and followed due to equivalence agreement</p> <p>On going sampling program – set of 55</p> <p>Performance standard an enforcement procedures are followed</p> <p>Sample verification testing is performed by official veterinarian</p>	<p>FSIS requirements are adopted and followed due to equivalence agreement</p> <p>On going sampling program – set of 55</p> <p>Performance standard an enforcement procedures are followed</p> <p>Sample verification testing is performed by official veterinarian</p>
	<i>Standardized government verification program of the quality of the post mortem inspection – performance standard</i>	<p><i>Introduced from January 1 2009</i></p> <p><i>Ensuring the performance for inspection tasks as well as pathological findings by the official meat inspection</i></p>	<p><i>Introduced from January 1 2009</i></p> <p><i>Ensuring the performance for inspection tasks as well as pathological findings by the official meat inspection</i></p>



Verification programs - government	Procedures in general	Verification of Food Chain Information process control criteria	Verification of Food Chain Information, including information on indoor/outdoor access process control criteria
	Procedures on performance standard	Verification and evaluation of the performance of handling and correction of all defects on the rework station	Verification and evaluation of the performance of handling and correction of all defects on the rework station
Enforcement and verification program - establishment	Verification of the performance at the rework platform	Will be introduced in the beginning of 2009 and stepwise at all pig slaughterhouses	
Implementing plan	<ul style="list-style-type: none"> - Precondition - Preliminary Schedule - Evaluation and verification 	<p><i>Precondition</i></p> <p>Risk assessment terminated – concluding no risk for human in omission of the routine incisions of lymph nodes and hearts, and</p> <ul style="list-style-type: none"> - Accepted by National competent authority and FSIS, USA - Enforcement and verification programs in place including practical arrangements <p><i>Preliminary Schedule</i></p> <ul style="list-style-type: none"> - Implementing stepwise – starting with two selected slaughterhouses – January 2009 ? - Stepwise at other slaughterhouses <p><i>Evaluation</i></p> <ul style="list-style-type: none"> - Close follow up on the performance in the two selected slaughterhouses 	



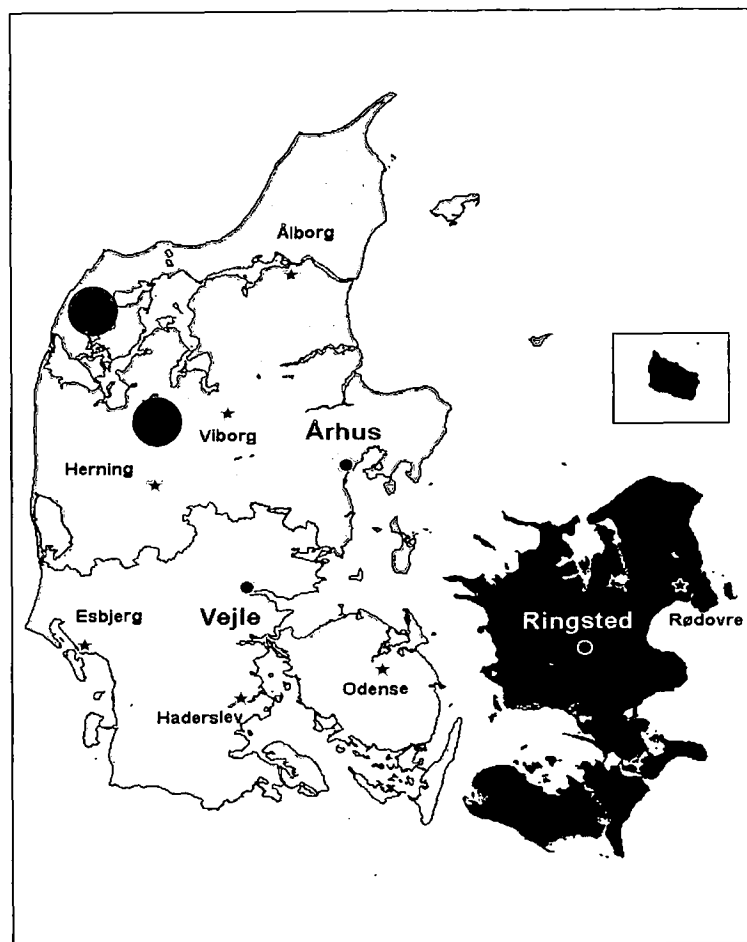
Implementation plan

Preconditions

- Risk assessment approved
- Exchange of Food Chain Information on each slaughterhouse in place
- Instruction and training of staff (auxilliaries and Official Veterinarians)
- Necessary adjustments of the working facilities (approved by DVFA)

Implementation

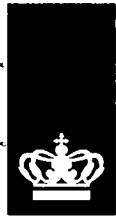
- At two selected medium-sized slaughterhouses: Danish Crown, Holstebro and Tican, Thisted meat inspection will be changed



Tican Thisted



DC Holstebro



Evaluation and verification by DVFA

First two months

- Intensified check on Food Chain Information incl. indoor/outdoor acces (10% of deliveries of pigs on each slaughterhouse)
- Performance standards of the meat inspection evaluated
- Process control criteria for E.coli total viable count and salmonella evaluated

Ongoing

- Verification of FCI-procedures in place by regular frequency audits
- Performance standards for meat inspection
- Check for indoor/outdoor acces for the finishers as part of official check on farm level (carried out by health unit in local control and enforcement units)



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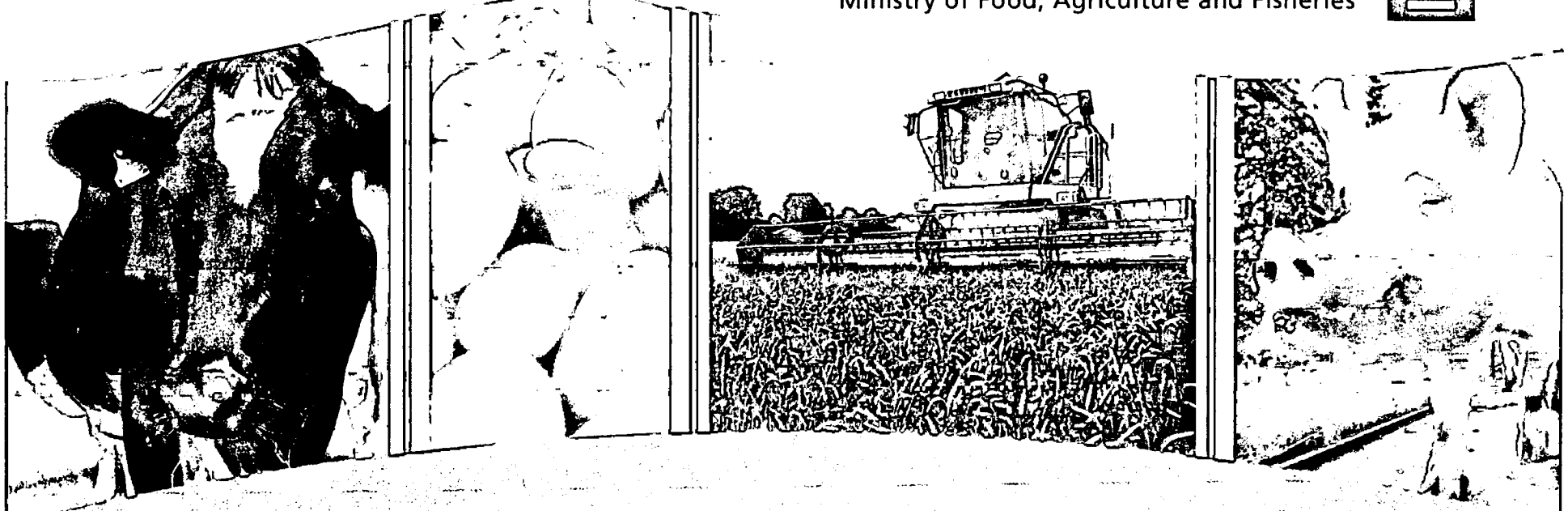
Questions

Assessment of risk for humans associated
with Supply Chain Meat Inspection
- The Danish Way



December 2008

Ministry of Food, Agriculture and Fisheries



Supply Chain Meat Inspection – the Danish Way

Annelise Fenger, Deputy Director General, Danish Veterinary and Food Administration



Meeting on December 16 th 2008

Participants from Denmark

- Mrs. Annelise Fenger, Deputy Director General, Danish Veterinary and Food Administration
- Mrs. Charlotte Vilstrup, Senior Veterinary Officer, DVM, Danish Veterinary and Food Administration
- Mr. Erik Bisgaard Madsen, Deputy CEO, DVM, PhD, Danish Meat Association
- Ms. Lis Alban, Chief Scientist, DVM, PhD, Dipl. ECVPH, Food Department, Risk Analysis Group, Danish Meat Association



Agenda

1. Introduction of supply chain meat inspection - the Danish way (Annelise Fenger, DVFA)
2. The Danish pig production system (Erik B. Madsen, DMA)
3. Supply chain meat inspection - risk assessment (Lis Alban, DMA)
4. How will the meat inspection change? Comparing traditional and supply chain inspection (Annelise Fenger, Charlotte Vilstrup, DVFA)
5. Questions and comments from FSIS



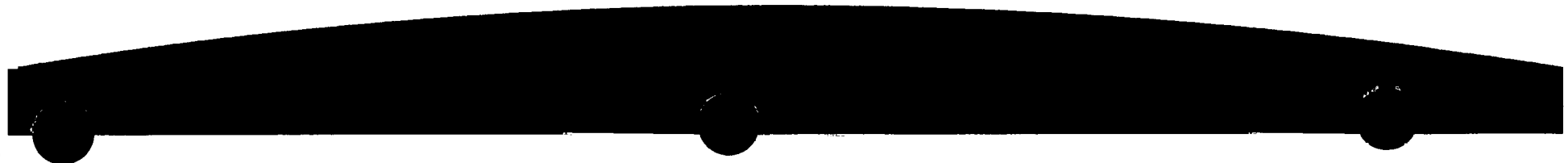
DVFA in overview

Head Office

- Formation of rules and regulations concerning food and animal health issues
- Coordination of official controls regarding food, animal health issues and animal welfare issues

Regional Offices *3 regions*

- Official controls regarding food, animal
- Health and animal welfare incl. Slaughterhouses
- Approval of food business operators





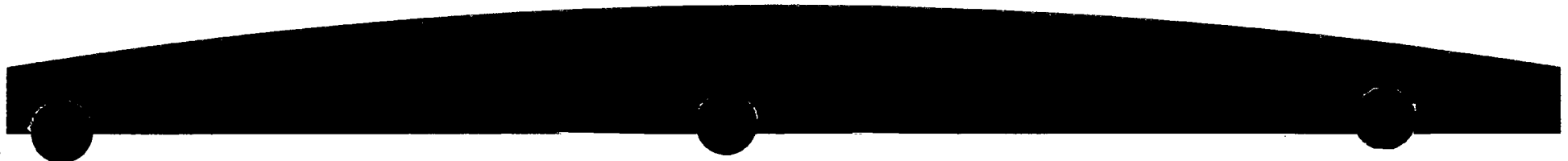
DVFA responsibilities

- Food and veterinary legislation
- Food and veterinary control
- Animal diseases
- Animal welfare control
- Nutritional information



Background for Supply Chain Meat Inspection

January 2006 the EU-regulation was changed, making it possible for the competent authority to decide that fattening pigs housed under controlled housing conditions in integrated production systems need only undergo visual inspection...

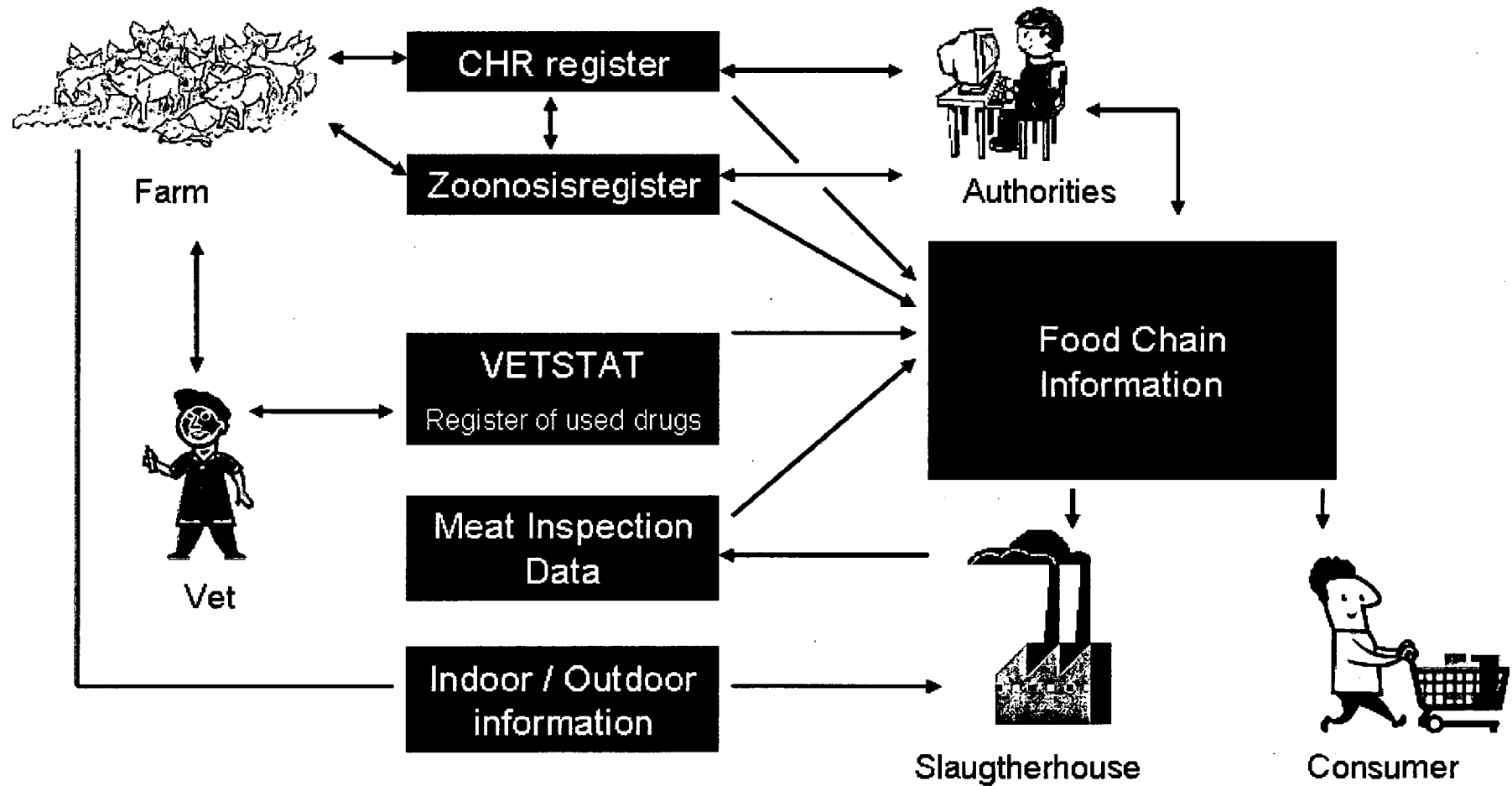




Background

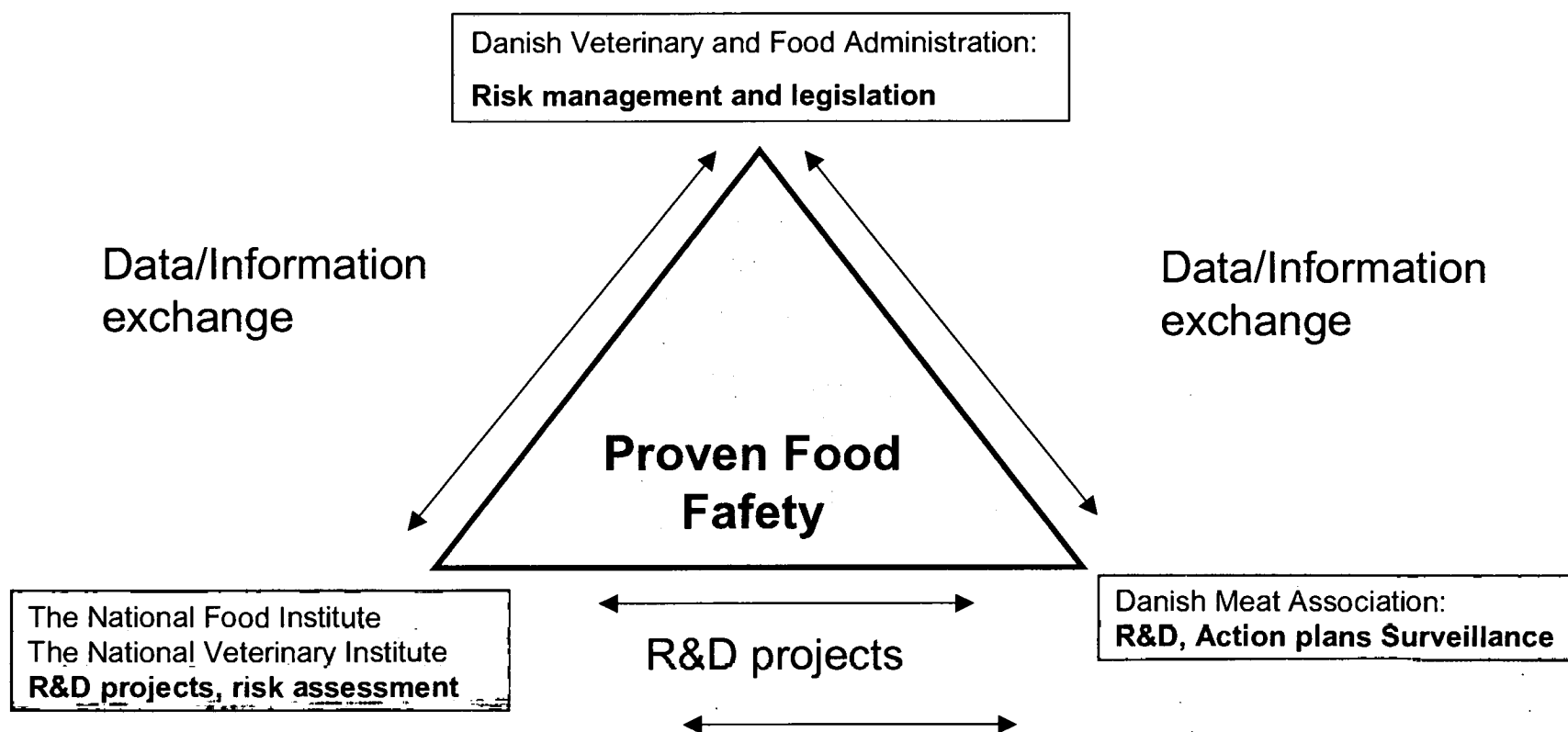
- In 2007 the Danish Parliament decided on a modernization of meat inspection - should be effective, ensure a high level of food safety, ensure a high zoosanitary standard and have a good working environment for the meat inspectors
- Focusing on the hazards on food safety without jeopardizing animal or human health
- The zoosanitary situation in DK is an important factor in a risk-based-approach to meat inspection
- Production of finishers in DK is a very standardized production and covered by a thorough registration from stable to table in databases

Ministry of Food, Agriculture and Fisheries





High Food Safety Standards





Supply Chain Inspection – the Danish Way

- The approach to a risk based meat inspection has been made in a cooperation between DVFA and DMA
- A project group was set up consisting of experts from the industry, the University of Copenhagen and DVFA
- A risk assessment was made (including data collection of hearts and lymphnodes on pig slaughter houses in DK, a literature study as well as expert opinions)



Supply Chain Inspection – the Danish Way

- A transparent and dialogue-based relation to FSIS
- Changes in meat inspection will only be made if the changes can be accepted by FSIS
- Upon acceptance of the suggested change. Meat inspection will be changed to supply chain meat inspection on 2 slaughterhouses. The process will be followed closely by the DMA and DVFA. Supply chain meat inspection can then be introduced stepwise on pig slaughterhouses in DK

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Ministry of Food, Agriculture and Fisheries
Danish Veterinary and Food Administration



END

Assessment of risk for humans associated
with Supply Chain Meat Inspection
– The Danish Way



December 2008

Supply Chain Meat Inspection Danish Pig Production - Stable to Table

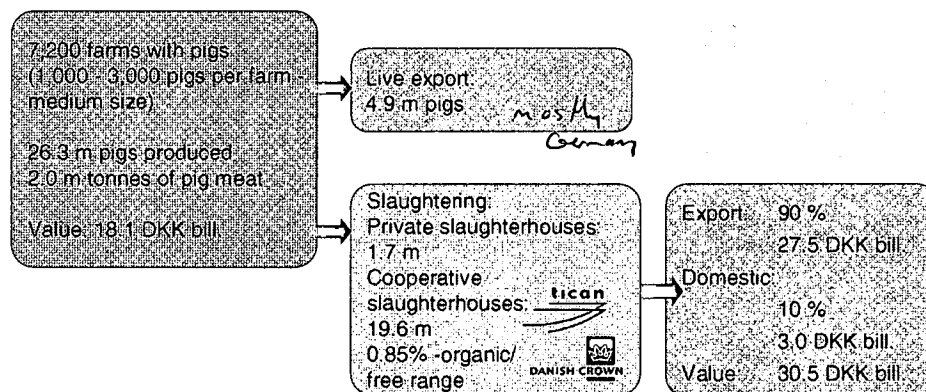
Erik Bisgaard Madsen
Deputy Director General, DVM, PhD
Danish Meat Association



15 Dec. 2008

Danish Pigmeat Industry

2007



15 Dec. 2008

Pig Production System in Denmark

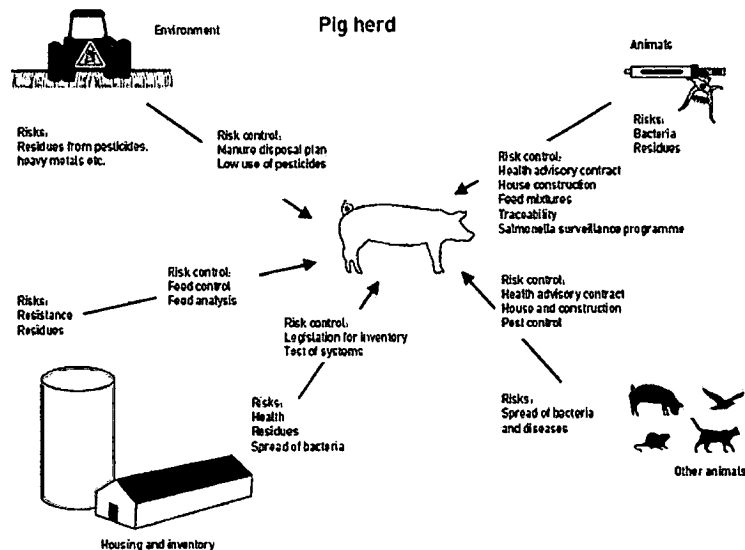


- Pig identification and traceability
- Regulation of feedstuffs
- Use of prescribed medicine
- Treatment of diseased pigs
- Housing and equipment
- Management
- Delivery of pigs



15 Dec. 2008

Pig Production System in Denmark



15 Dec. 2008

Traceability in the Danish pig meat production



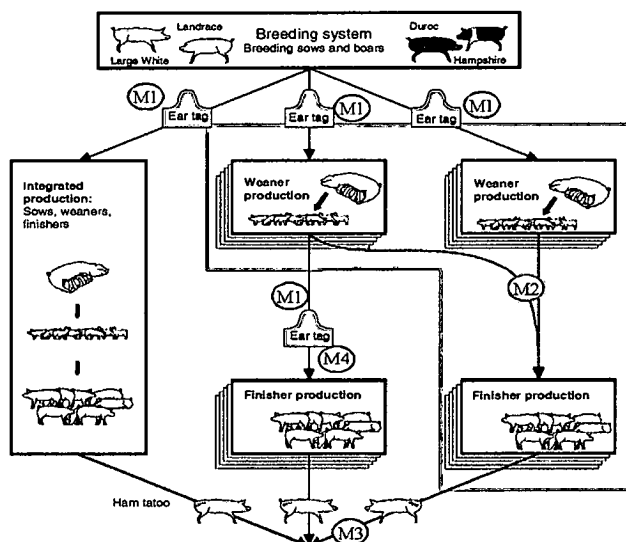
- Important for food safety
- Important documentation of the quality of the meat
- Required by European Law*
- Makes it possible to trace the meat through the production chain



*EC/178/2002

15 Dec. 2008

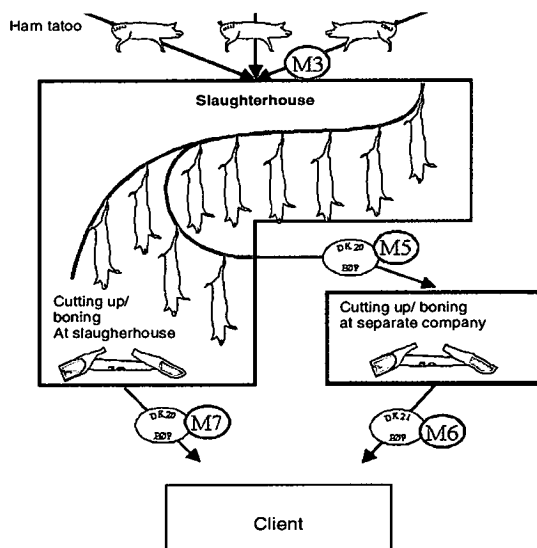
Traceability – Stable to table (1)



Ref: Madec, F. (2001). – Traceability in the pig production chain. *Rev. sci. tech. Off. Int. Epiz.*, 20 (2)

15 Dec. 2008

Traceability – Stable to table (2)



Ref: Made, F. (2001). – Traceability in the pig production chain. *Rev. sci. tech. Off. Int. Epiz.*, 20 (2)

15 Dec. 2008

Traceability – Danish pig production



CHR-number

- Registration of all pig herds with a specific herd number – Central Register of Domestic Animals
- The register is used for all contact between the herd and the competent authorities

Food chain information

- Exchange of information in all parts of the chain from primary producer to slaughterhouse – mandatory requirements within EU



15 Dec. 2008

Food Chain Information



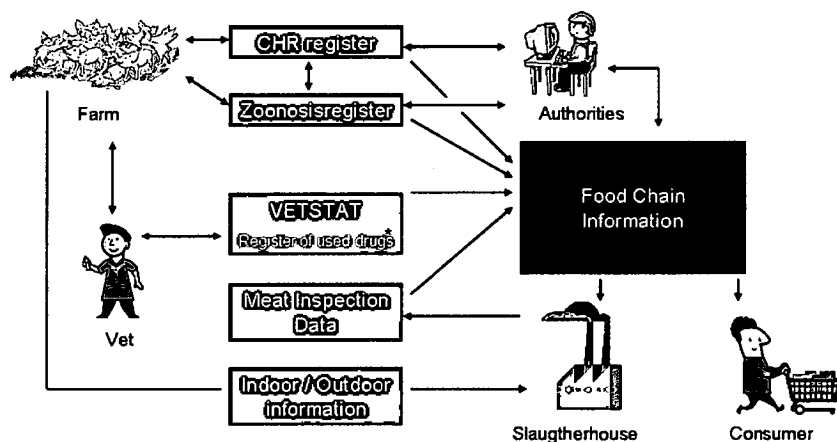
Relevant information to be provided, e.g.:

- Status of the holding of origin
- Animal health status, e.g. Salmonella status at herd level
- Veterinary medicine
- Results of samples taken within the framework of the monitoring and control of zoonoses and residues
– to protect public health
- Name and address of the veterinary practitioner



15 Dec. 2008

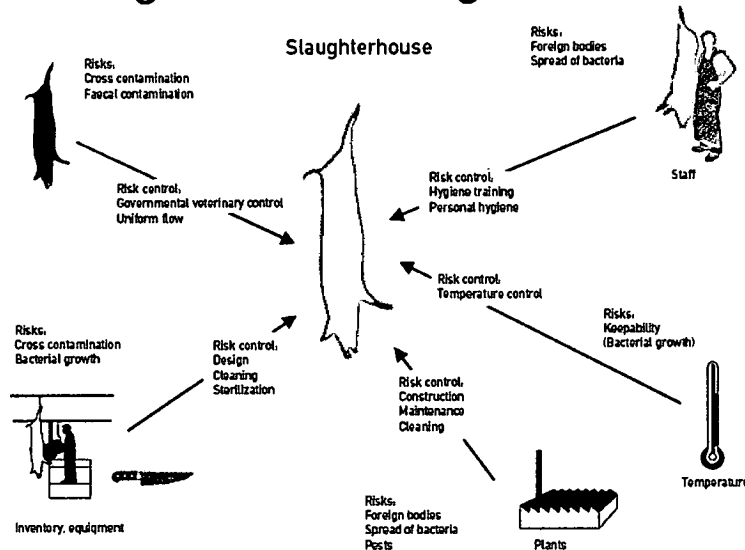
Food Chain Information The Danish Way



* Prescribed medicine

15 Dec. 2008

Handling of risk at slaughterhouses



15 Dec. 2008

The Danish Salmonella Control Program

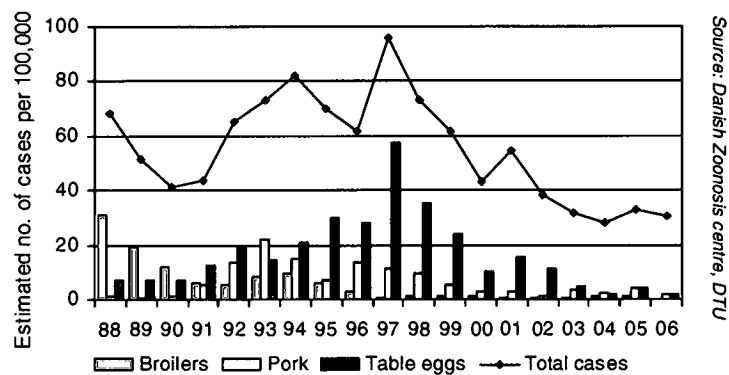


- National, mandatory control scheme since 1995
- Constantly adjusted and improved – based on science and data
- Coordinated efforts between government, research institutions, and industry
- Stable-to-table program
- Monthly assessments of herds and slaughterhouses by testing of antibodies and bacteriological samples



15 Dec. 2008

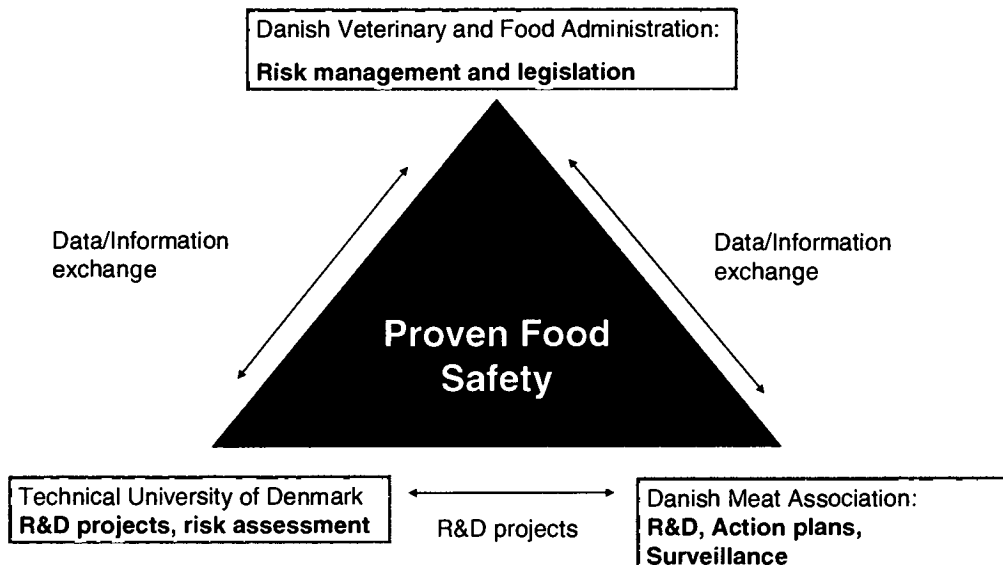
Salmonella control program – Number of human cases in Denmark



Figures for 2007 not released yet. Further decline demonstrated

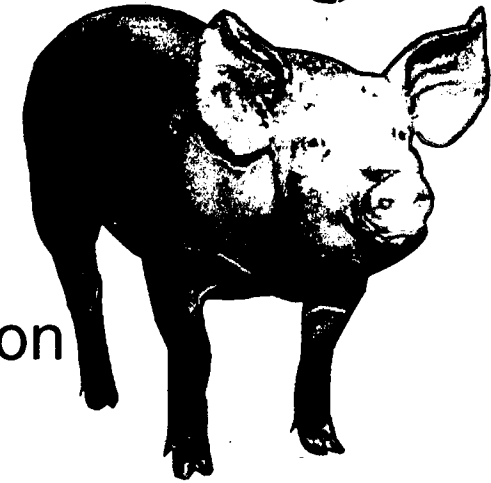
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High Food Safety Standards – The Danish Way



15 Dec. 2008

Conclusion



- No risk for humans associated with omission of routine incision into mandibular lymph nodes and hearts of finisher pigs
- This is valid for
 - Finisher pigs from integrated production systems reared under controlled housing conditions
 - Reared in-door since weaning
 - Where food chain information is exchanged
- We call this Supply Chain Meat Inspection – The Danish Way

Risk for humans associated with Supply Chain Meat Inspection

Lis Alban

Chief Scientist for Risk Assessment

DVM, PhD, Dipl. European College of Veterinary
Public Health

Danish Meat Association



Introduction

- Recent changes in EU legislation enable introduction of modifications to meat inspection
 - Only for finisher pigs and calves from integrated production systems reared under controlled housing conditions since weaning
- It requires that a risk assessment is undertaken and that this shows that the changes do not jeopardize human health



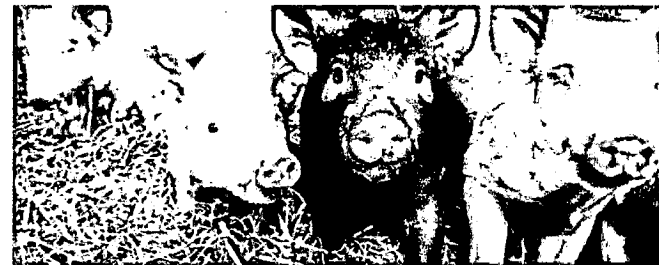
Requirements by EU legislation

- Integrated production system
 - Feed and rearing
 - Pigs should be in-door reared since weaning
 - Bedding and access to premises
 - Garbage dumps, pest management and control of sewage
- Food Chain Information
 - Should be exchanged between producer and slaughterhouse prior to slaughter



Aim

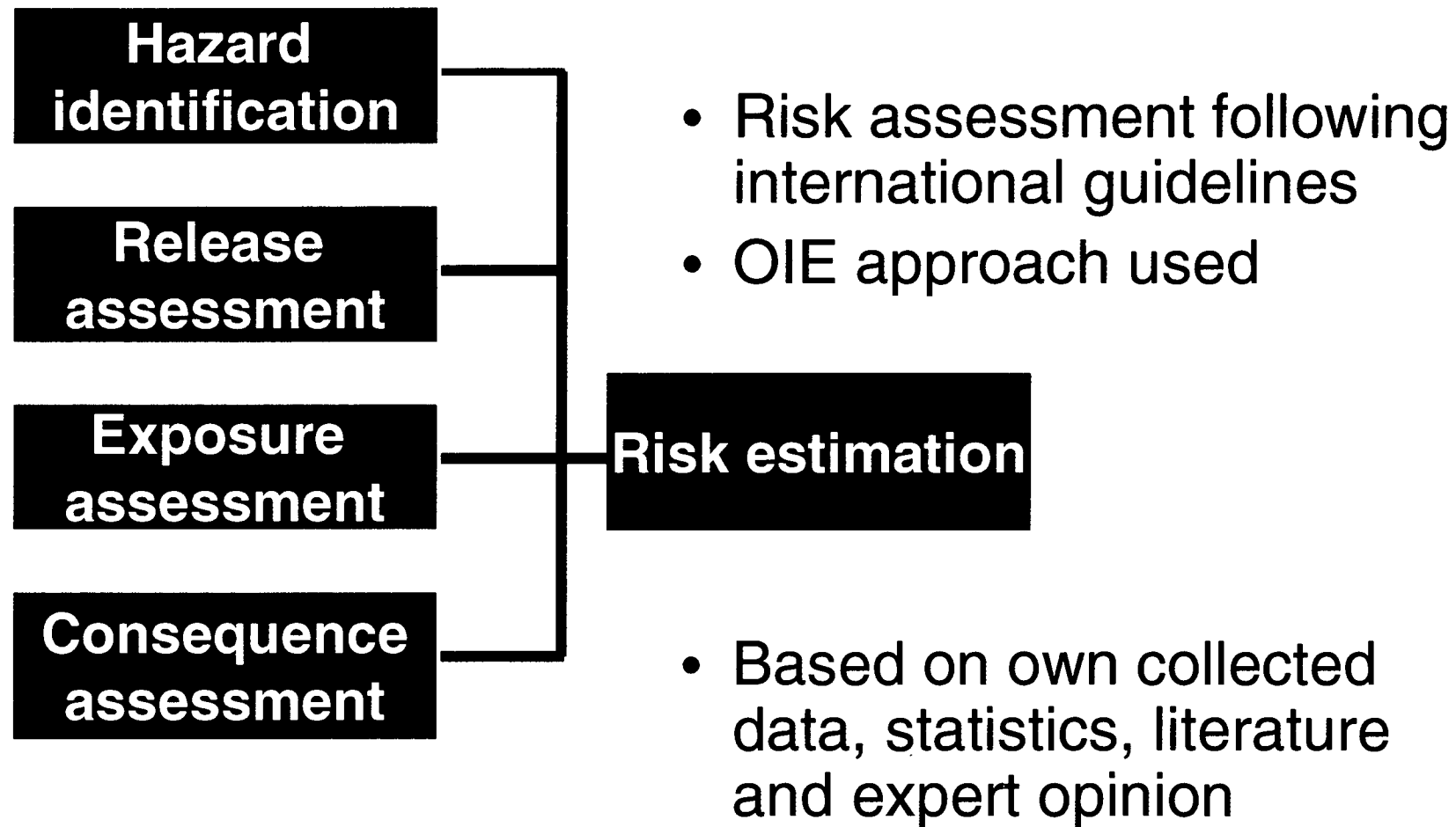
- Assess risk associated with omission of routine incision into mandibular lymph nodes and hearts of finisher pigs
 - Might lower spreading of food safety hazards like *Salmonella* and *Yersinia*
- Risk interpreted as risk for food safety, zoo-sanitary status and working environment
 - Only results for food safety presented here
 - The other issues are covered in the report



Process

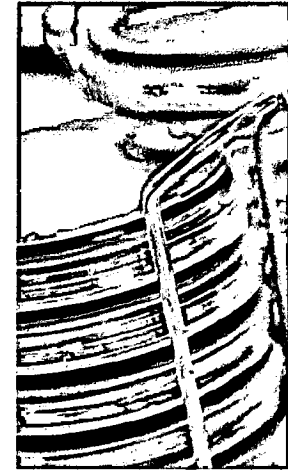
- Group work between experts from
 - Faculty of Life Sciences, University of Copenhagen
 - Danish Meat Association, Department of Food
 - Danish Veterinary and Food Administration
- External review of report by three professors
 - Katharina Stärk, Royal Veterinary College, London
 - Truls Nesbakken, Norwegian School of Veterinary Science, Oslo
 - Eystein Skjerve, Norwegian School of Veterinary Science, Oslo
 - Comments incorporated into report

Method



Results - Lymph nodes

- Bovine tuberculosis (TB) main hazard
 - Denmark has free status since 1980
- TB-like lesions in 0.01% to 0.02% of lymph nodes
 - Primarily due to *Rhodococcus equi*
- Avian TB occasionally observed in Denmark
 - Wild birds, but also zoo-birds and backyard-birds
 - Very low prevalence in pigs
- Mandibular lymph nodes is used for pet food (heat-treated)
- Avian TB and *Rhodococcus equi* are not considered meat-borne, according to the literature



Risk estimate for lymph nodes

Meat inspection circular

- Lesions found in other lymph nodes than mandibular and mesenteric => carcass subjected to extended inspection
- If avian TB found => condemnation of carcass

Risk estimate

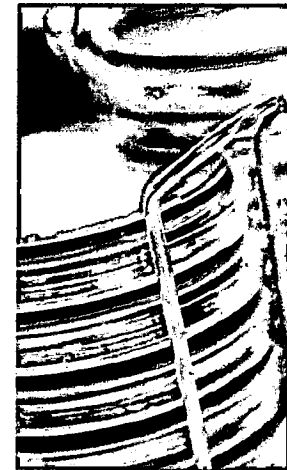
- Very low probability of release of avian TB and *Rhodococcus*
- Hardly any exposure of consumers
- No consequences of exposure

=> No risk



Results - Hearts

- Endocarditis main lesion of interest
 - Found in 0.01% of hearts
- Primarily because of infection with *Streptococcus suis* and *Erysipelothrix rhusiopathiae*
 - These hazards are not meat-borne but occupational
 - Implies that e.g. slaughterhouse workers are at risk of infection in already existing wounds
 - Occurs so seldom that it is not considered a risk by the Danish slaughterhouse worker's union



Risk estimate for hearts

Meat inspection circular

- If other lesions are found on carcass
 - Carcass subjected to extended meat inspection
 - Decision about carcass depends on results of inspection

Hearts will be opened by slaughterhouse workers

- If endocarditis is found, the heart will be condemned

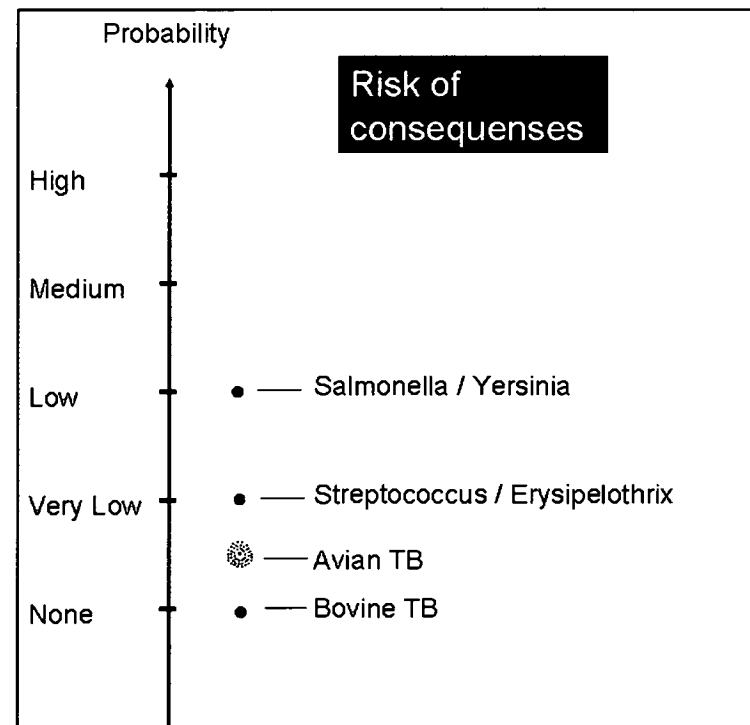
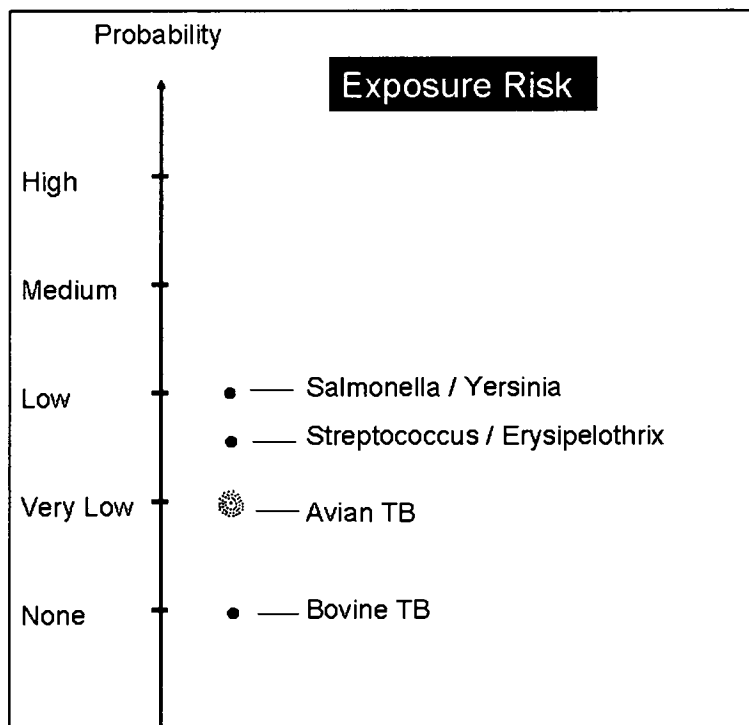
Risk estimate

- Low probability of release of bacteria
- Very low exposure of consumers
- No consequences of exposure

=> No risk



Summing up



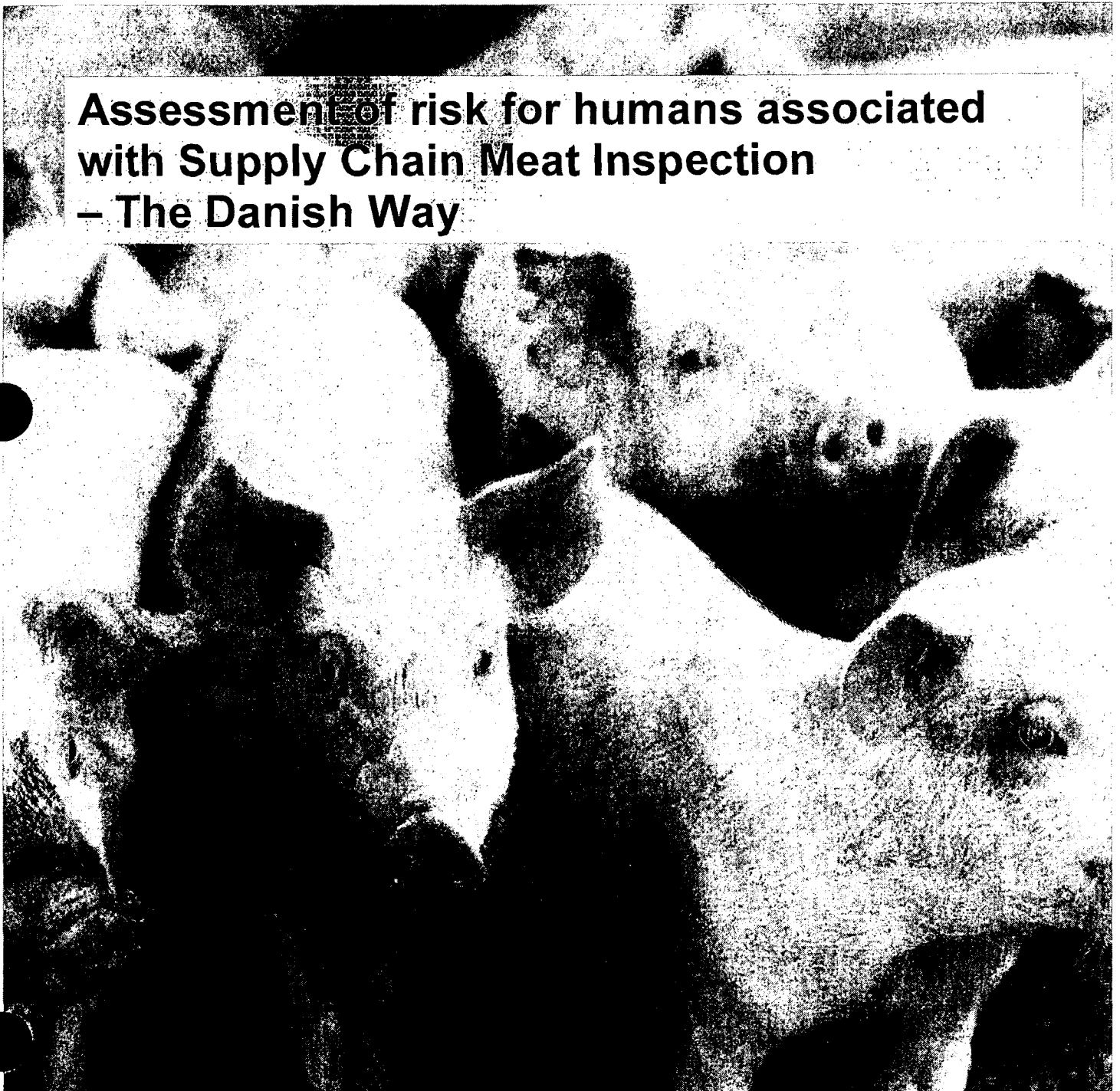
- = High certainty linked to estimate of probability
- = Some uncertainty linked to estimate



Ministry of Food, Agriculture and Fisheries
Danish Veterinary and Food Administration



Assessment of risk for humans associated with Supply Chain Meat Inspection – The Danish Way



December 2008

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Preface

In 2007, the Danish Parliament decided that a modernisation of meat inspection should be initiated. As a part of the modernisation three institutions – The Danish Veterinary and Food Administration (DVFA), Department of Veterinary Pathobiology, Faculty of Life Science, University of Copenhagen (KU-Life) and Danish Meat Association (DMA) - in collaboration undertook a project regarding meat inspection of finisher pigs, housed under controlled conditions. The intention of the project was to identify how meat inspection could be modernised without jeopardising human health.

The objective of meat inspection is to focus on the hazards that constitute a risk for food safety. Moreover it should be ensured that the control of finisher pigs conducted ante- and post mortem is performed in a way that results in a high level of food safety.

When changing the meat inspection it must be ensured, that not just food safety but also the zoo-sanitary standards are not affected negatively.

The Danish pig meat production system is covered by a thorough registration, marking and documentation which makes a tracing of the meat through the production chain possible. This is in line with the mandatory requirement within the European Union that so-called food chain information from all parts of the food chain should be exchanged prior to sending animals for slaughter. This includes the primary producer, the slaughterhouse and the competent authority.

We suggest that two specific inspection procedures will be omitted from the routine meat inspection: the opening and incisions of the heart and the incisions and palpation of major mandibular lymph nodes. A carcass with visually observable pathological findings will still have its hearts and mandibular lymph nodes palpated and incised.

We combine this approach with the food chain information which is being exchanged between the herd and the slaughterhouse and we call the entire approach Supply Chain Meat Inspection – The Danish way. This modernisation of meat inspection will only apply to finisher pigs from integrated production systems.

Prior to initiating such a change, we undertook a risk assessment to identify if there was a risk for humans or for the zoo-sanitary status. We followed international guidelines for how to conduct risk assessments. To ensure the quality of the risk assessment, we asked three independent, internationally recognised as experts in food safety to act as external reviewers. Their reviews – and our response to the issues raised - have been included in an appendix to the risk assessment. The experts were:

- 1) Katharina Stärk, Professor, Veterinary Public Health, the Royal Veterinary College, London,
- 2) Truls Nesbakken, Professor, Food Safety, the Norwegian School of Veterinary Science, Oslo,
- 3) Eystein Skjerve, Professor, Epidemiology of Food-borne Diseases, the Norwegian School of Veterinary Science, Oslo.

The risk assessment is public and can be obtained either upon request or directly on the home page of our institutions www.danishmeat.dk and www.fvst.dk. The risk assessment acts as decision support for the Danish Meat Association. Just as importantly, it constitutes a documentation of why the changes suggested are safe for both humans and animal health. This is of importance for both our trading partners as well as the Danish consumers.

The authors

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Abstract

Recent changes in the legislation of the European Union enable the introduction of modifications of the traditional meat inspection of finisher pigs and calves from integrated production systems. Denmark intends to make use of this possibility, initially for finisher pigs and later on for calves. Based on an analysis of the pig-pork chain, two issues came up: what is the food safety value of the routine palpation and incision into the major mandibular lymph nodes as well as the routine opening of the heart? To address the impact on food safety when omitting these incisions, a risk assessment was conducted following international guidelines. To generate input data, two studies were conducted on ten Danish slaughterhouses. Study 1 included the collection of 43 lymph nodes with granulomatous lesions. Study 2 comprised the collection of 88 hearts with macroscopic changes indicating presence of endocarditis. Microbiological and pathological examinations were conducted. Moreover, relevant data from slaughterhouse and laboratory statistics as well as information from the literature and expert opinion were included in the risk assessment.

If lymph nodes are not opened routinely, lymph nodes with lesions might pass the meat inspection unnoticed. Among the different lesions possibly observed in lymph nodes, granulomatous lesions are the most important with respect to food safety, because these might be a result of infection with bovine tuberculosis. A very low prevalence of granulomatous lesions in lymph nodes is observed in Denmark (0.01-0.02%) and only a part of these lesions are found in the mandibular lymph nodes. Study 1 showed that all lymph nodes examined were negative for *Mycobacterium* spp. *Rhodococcus equi* was most commonly found (63%). In one case (2%) *Nocardia farcinica* was found, and the remaining 35% of the samples were culture-negative. Avian tuberculosis is occasionally found in backyard poultry, zoological gardens and pigs. There is no risk that consumers should acquire bovine tuberculosis from eating Danish pork because Denmark is officially free from this disease since 1980. There is a low risk of exposure to avium tuberculosis from pork, because of the low prevalence and because the mandibular lymph nodes are entirely used as pet food after adequate heat-treatment. Moreover, the prevailing opinion in the literature is that avian tuberculosis is not pork-borne. There is a very low exposure risk of *Rhodococcus equi* but this organism is not considered pork-borne either. It should be noted, that routine palpation and opening of lymph nodes in the head area might result in spreading of food safety hazards like *Salmonella* and *Yersinia*.

If hearts are not opened routinely, a case of endocarditis might pass the meat inspection unnoticed. A very low prevalence of endocarditis is generally observed in Danish finisher pigs (0.01%). Study 2 showed that endocarditis was primarily associated with *Streptococcus* spp. (51%), secondly by *Erysipelothrix rhusiopathiae* (32%), *Lactobacillus* (5%) and *Arcanobacterium pyogenes* (1%). The remaining samples were either awaiting identification (6%) or culture-negative (6%). The agents found in the hearts are primarily occupational hazards and not meat-borne. This implies that you do not get ill from consuming meat contaminated with these micro-organisms. To reduce exposure of the consumers to these occupational hazards, we suggest that the hearts are opened after meat inspection by slaughterhouse workers and prior to sales. This will reduce the spreading of these hazards from the heart to the carcass and further on to slaughterhouse personnel and consumers.

In conclusion, it was found that omitting the incisions into the mandibular lymph nodes as well as omitting the routine opening of the heart do not seem to be associated with an increased risk for human health. Likewise, the suggested changes seem to have a positive effect on the working environment, and there is no negative effect on the zoo-sanitary status.

Keywords: Pigs, Meat inspection; Risk-based; Food safety; Granulomatous lesions; *Mycobacterium* spp; Endocarditis; *Streptococcus* spp.; Supply Chain; Traceability

1. Introduction

1.1 Background

The objective of meat inspection is to ensure safe and savoury meat for human consumption. Meat inspection has been conducted for more than 100 years. During that time period, the hazards have changed. However, the current meat inspection is to a large extent based on the hazards of the past. This implies that in some countries resources are spent on looking for *Mycobacterium bovis* even though this kind of tuberculosis was eradicated decades ago. Moreover, the hazards of today, like *Salmonella* and *Yersinia*, are not addressed adequately because they cannot be found macroscopically. That results in a number of people getting ill. A part of these cases could have been avoided, if meat inspection was adjusted to the hazards of today.

With the creation of the internal market in 1992 in the European Union (EU), several directives in the area of food hygiene were adopted. This has resulted in a high level of food safety, whilst ensuring free circulation of commodities. The directives cover food of animal origin on the one hand, and food of non animal origin on the other hand, reflecting a difference in approach. For food of animal origin a set of very detailed and product-specific rules has been developed.

For the EU Commission there was a legal obligation to examine the relationship between the different Community food hygiene rules. This resulted in The White Paper on Food Safety (Anon., 1999) which introduced the principles of risk-based approach, the farm-to-table principle, the prime responsibility of food business operators, and the supervising role of the competent authority. Moreover, according to EU regulation (EC) No. 852/2004, the primary responsibility for food safety rests with the food business operator (Anon., 2004a). Those basic principles are the cornerstones in the EU-legislation on food hygiene.

In reality, no inspection can remove all hazards, but correctly conducted, meat inspection will lower the risk of humans becoming ill. To increase effectiveness, meat inspection should focus on the most important hazards found in the population of interest. It should here be taken into account that the hazards might vary due to variations over the years as well as between geographical areas and production types. According to this line of thinking, meat inspection should be risk-based. The risk-based approach to meat inspection was endorsed by the Ruwenberg World Congress on Meat and Poultry Inspection in 1997 (Anon., 1998). Since then several countries have worked with a modernisation of meat inspection (See section 1.3 for a wider description).

In 2000, the EU Scientific Committee on Veterinary Measures relating to Public Health published its opinion on revision of the meat inspection procedures (Anon., 2000). This report evaluated the effect of traditional meat inspection compared with the effect of a visual meat inspection. The conclusion was among others that post-mortem inspection for finishers in itself assists little in improving food safety with regards to microbiological and chemical hazards. Moreover, the report found that not all lesions were best detected in a traditional system, and the pattern of which lesions were detected with the highest sensitivity in the visual or traditional system varied. The report also listed requirements for which animals that could undergo visual inspection.

This report formed the basis for the relatively new EU regulation (EC) No 854/2004 which specifies how meat inspection of finisher pigs in the EU should be conducted. The regulation has opened up for introduction of modifications of the traditional meat inspection of finishers from integrated production systems reared under controlled housing conditions, if a risk assessment can show that such changes will not jeopardize human health. A list of requirements to controlled housing conditions and integrated production systems can be found in an appendix to Annex VIb of Regulation (EC) No 1244/2007 (Anon., 2007a). The list includes requirements to feed, in-door/out-door rearing, bedding, access to premises, garbage dumps, pest management, and sewage.

Tailored to the new legislation is the requirement that farmers should register all health-related problems observed in the herd. This is called food chain information (FCI) and more details can be found in Regulation (EC) No 853/2004 (Anon., 2004b), Regulation (EC) No 854/2004 (Anon., 2004c), Regulation (EC) No 2074/2005 (Anon., 2005a), Regulation (EC) No 2076/2005 (Anon., 2005b). The FCI should be sent to the slaughterhouse prior to the animals being transported to the slaughterhouse. This enables the slaughterhouse to take appropriate measures concerning logistics and meat inspection.

In Denmark, electronic recording systems which cover the requirements regarding exchange of FCI between the herd owner and the slaughterhouse are in place (Fig. 1). One example is the Central Husbandry Register ([http://www.glr-chr.dk/pls/glrchr/chrmenu\\$.menu](http://www.glr-chr.dk/pls/glrchr/chrmenu$.menu)) and the central recording of the use of veterinary medication called VetStat (<http://www.vet.dtu.dk/Default.aspx?ID=9205>) as well as the Zoonosis Register, which contains information about the Salmonella status in the herd. This programme ensures e.g. that finishers from herds with an unacceptable high seroprevalence for *Salmonella* are subjected either to sanitary slaughter or hot-water decontamination after slaughter.

The consumer will receive information through television, radio, or newspaper if meat sold on the market has to be recalled. Such recalls occur through the rapid alert system (http://ec.europa.eu/food/food/rapidalert/index_en.htm).

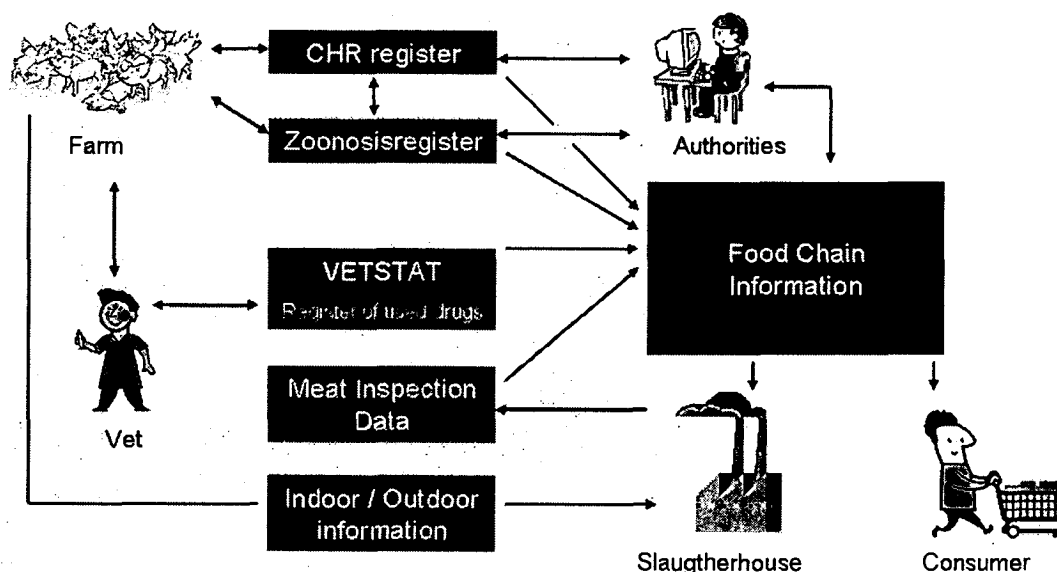


Figure 1

Description of the connection between collection of food chain information during animal production and the slaughterhouse, Denmark 2008

1.2 Identification of relevant modifications to the meat inspection

To identify which changes to evaluate, an analysis of the entire meat chain was conducted. As part of such analysis, discussions were taken among others with slaughterhouse personnel including meat inspectors.

Any modification of the meat inspection will have an effect on not just food safety but often also on other aspects like the working environment. Ideally, a modification will result in the following:

- a) improvement of food safety,
- b) more cost-effective,
- c) no adverse effect on zoo-sanitary standard, and
- d) improvement of the working environment.

Through such discussions in Denmark, it was revealed that it was questionable whether two specific routine procedures had any positive impact on food safety. The first dealt with palpation and incision of the mandibular lymph nodes; the second with the opening of the heart. Berends & Snijders, (1997) recommended that the incisions of lymph nodes and palpation of the carcass should be replaced by visual inspection to reduce the potential for further carcass contamination. Moreover, Olsen et al. (2001) found that leaving the tongue in the intact head was associated with a reduction in the prevalence of *Salmonella* positive carcasses. Hence, omission of these cuts might lower the contamination and cross-contamination of the carcasses with common food safety hazards like *Salmonella* and *Yersinia*. The effect might not be statistical significant as found by Hamilton et al. (2002). This is probably because the slaughterhouse workers are also touching the carcass when trimming it.

Finishers from integrated production systems that are kept in-door since weaning have less variation in disease pattern than finisher pigs from other types of production e.g. outdoor-reared pigs. Moreover, exchange of food chain information will ensure that all relevant information reaches the abattoir prior to slaughter. For herds that fulfil these criteria we suggest that the routine incisions into the mandibular lymph nodes and into the heart are omitted. Finishers that do not fulfil these requirements should be subjected to traditional meat inspection. In line, if anything abnormal is observed, then the carcass will go to extended control during meat inspection. We call this way of inspection "Supply Chain Meat Inspection – The Danish Way" to acknowledge the similarities with the kind of meat inspection conducted in The Netherlands but also to distinguish it from this because there are some minor differences (The Dutch system will be described later on in this section).

When conducting Supply Chain Meat Inspection, the meat inspectors neither touch nor cut the lymph nodes or the hearts as a routine action, but only when required. Another term for this is visual inspection. Several studies have compared the effect of visual inspection with the traditional inspection (Hamilton et al., 2002; Mousing et al., 1999; Mousing et al., 1997). These studies have shown that more or less the same pathological findings are found when visual inspection is conducted compared to traditional inspection of finisher pigs. In line, studies carried out in a Danish slaughterhouse have shown that visual inspection of the head of finisher pigs reduced the prevalence of food safety bacteria such as *Salmonella* on the carcass (Sørensen & Petersen, 1999; Petersen et al., 2002).

Supply Chain Meat Inspection is not a 100% visual inspection. The only change compared to traditional meat inspection is that the mandibular lymph nodes and the heart are not opened routinely as a part of the meat inspection.

1.3 Risk-based meat inspection in other countries

Several countries have looked into how an efficient and modern meat inspection should be conducted. Recently, a Scandinavian working group published a common report, in which it was pointed out that there is a need to make the official meat inspection more risk-based and that the use of resources should be optimised (Tema Nord, 2006).

In Sweden, a project on visual inspection of pigs was initiated in the beginning of 2007. The overall aim of the project is to examine to which extent visual inspection is able to reduce contamination of the meat with food-borne pathogens. The project does also focus on how changes in the performance of the meat inspection influence the physical activities and ergonomics for the inspection personnel and the possibility to increase cost efficiency of the meat inspection. The project has been worked out

in close cooperation between the competent authorities in Sweden and the meat industry organisation. In line with the Danish system, a precondition for pigs to undergo visual inspection is the fulfilment of the mandatory requirements on food chain information as well as the pig should be part of an integrated production system. A second phase of the project was started in the early spring 2008 and the project has not yet been concluded upon (V. Larsson, personal communication; Å. Rutegard, personal communication).

In Denmark, a comparative study of the frequency of lesions, detected by visual and traditional inspection of slaughter pigs was conducted from January to July 1993 at a Danish export slaughterhouse. The study included 183,383 slaughter pigs which were first subjected to a visual inspection and then to traditional meat inspection procedures (incision and palpation), as per current rules, by two different inspection teams (Mousing et al., 1997). The conclusion of the study was that more or less the same pathological findings are found when visual inspection was conducted compared to traditional inspection of finisher pigs. Please see section 6.2 for a wider description of the results of the project.

In The Netherlands, a revised meat inspection system has been developed called "The Pork Supply Chain Meat Inspection". The system is based on exchange of food chain information available at the slaughterhouse prior to slaughter. Moreover, a risk profile on farm level with regards to *Mycobacterium avium* is made available based on serology, performed on a routinely basis. This risk profile should be neutral or low for pigs that are intended for visual meat inspection. The system is audited and verified by the competent authorities. At the slaughterhouse level, the system is supervised by the official veterinarian. The supervision includes a check of the performance of the official auxiliaries as well as a monitoring of the establishment operators on slaughter defects and pathological observations just before cooling, where a certain set of performance standards are to be met (Jelsma, 2008). The inspection of the mandibular lymph nodes and hearts are performed visually in the Dutch inspection system, which was approved by the USA in July 2008 (FSIS, 2008a)

Outside the EU, the Australian meat inspection system is an example of both a risk-based and integrated meat inspection system. Personnel employed by the slaughterhouses carry out the ante- and post-mortem inspection. The competent authority demands that the meat inspection system is based on implementation of an official risk-based quality assurance system, which is audited / revised by the official veterinarian (Anon., 2003). In Australian exporting abattoirs, excision of the sub-maxillary and cervical lymph nodes is performed on a routinely basis by the abattoir company (Anon., 1997a). The excision procedure is considered a quality control point under the company's HACCP-based Quality Assurance system. Specific requirements from an importing country may indicate additional or alternative procedures. The routine task on examination of hearts is visual with additional palpation of the external surfaces of the heart (Anon., 1997b).

The meat inspection system of slaughter pigs in USA is another example of placing greater responsibility on the industry for the production of safe food. Since 1996, the Food Safety and Inspection Service (FSIS) is conducting a project called HACCP-based Inspection Models (HIMP). The models are based on data collected on five slaughterhouses. The aim is to determine the current food safety and other consumer protection achievements related to the traditional inspection systems. Based on this, performance standards have been developed. As part of HIMP, FSIS has conducted a verification inspection to assure compliance with the standards both ante-mortem and post mortem. A cornerstone of this project is that establishments must take more responsibility for independently identifying and removing minor dressing defects and abnormal conditions that could pose a threat to the consumer. Furthermore, carcasses and viscera that have passed inspection must meet finished product standards, established by the FSIS (FSIS, 2008b). When conducting routine inspection of pig carcasses in the US, the inspection program personnel are required to incise and observe the mandibular lymph nodes, while the heart is only visually inspected (Anon., 2007b).

On Iceland, post-mortem inspection of lambs are performed solely visual according to an equivalence agreement between Iceland and the USA (S.Ö. Hansson, personal communication).

1.4 Aim

The aim of the present study was to assess the food safety risk associated with discontinuing the following two routine procedures in the meat inspection of Danish finisher pigs originating from farms which are a part of an integrated production system:

- a) The incision and palpation of the major mandibular lymph nodes
- b) The opening and incision of the heart

Moreover, the impact on the zoo-sanitary standard was thoroughly dealt with, while the impact on the working environment was dealt with in brief.

Summary of section 1: Recent changes in the legislation of the European Union enable the introduction of modifications of the traditional meat inspection of finisher pigs and calves from integrated production systems. Denmark intends to make use of this possibility initially for finisher pigs and later on for calves. Based on an analysis of the pig-pork chain, two issues came up: what is the food safety value of the routine palpation and incision into the major mandibular lymph nodes as well as the routine opening of the heart? To address the impact on food safety when omitting these incisions, a risk assessment was conducted. Moreover, the impact on the zoo-sanitary standard was thoroughly dealt with, while the impact on the working environment was dealt with in brief.

2. Materials and Methods

2.1 Description of risk assessment

Risk assessment is an internationally recognised process that enables an objective, transparent, data-based evaluation of risks associated with a given act; in this case two proposed changes in the meat inspection of Danish finisher pigs. A risk assessment can be qualitative or quantitative depending among others on the question raised and the data availability. This risk assessment is primarily qualitative and it is based on the general approach described by OIE (OIE, 2004). This approach differs only in the order of the elements from the guidelines described by Codex Alimentarius. Hence, the following elements were included:

1. Hazard identification
2. Release assessment
3. Exposure assessment
4. Consequence assessment
5. Risk estimation

In the hazard identification (step 1) we judged which agents could be associated with a risk for humans and if so how (occupational hazard or food safety hazard). This was based on information from the literature.

In the release assessment (step 2) the probability of the hazards (identified in step 1) in/on the live animals or the carcass was assessed both based on our two studies as well in-house statistics, the literature, report from official laboratories and expert opinion.

In the exposure assessment (step 3) we estimated the prevalence of the exposure of consumers to the relevant hazards.

In the consequence assessment (step 4) the consequences related to the unwanted outcome were described, based on data from the literature. The unwanted outcome was first seen as a person becoming ill due to exposure to the hazards. Furthermore, the number of people becoming ill was assessed. Data from official statistics as well as expert opinion were used here.

Then we compared the two ways of conducting meat inspection (traditional versus Supply Chain Meat Inspection). Here, we used data from a large scale side-by-side study conducted in Denmark in 1993 (Mousing et al., 1997).

Next, the impact on the national zoo-sanitary status was evaluated based on data from the literature as well as expert opinion. Finally, the impact on the working environment was dealt with in brief.

In Risk estimation (step 5) the conclusions from the previous sections were integrated in an overall risk estimate. Here, focus was on the difference between traditional and Supply Chain Meat Inspection.

2.2 Data collection

The Danish Meat Association (DMA) is an organisation which represents a number of abattoirs accounting for 92% of the pigs slaughtered in Denmark in 2007. A central meat inspection database is run by DMA. Meat inspectors (official veterinarians and auxiliaries) on the slaughterhouses associated with DMA are obliged to report abnormal findings to the database. The database has been in place for more than 10 years. This implies that the prevalence of specific conditions is known even though that reporting might vary slightly from slaughterhouse to slaughterhouse.

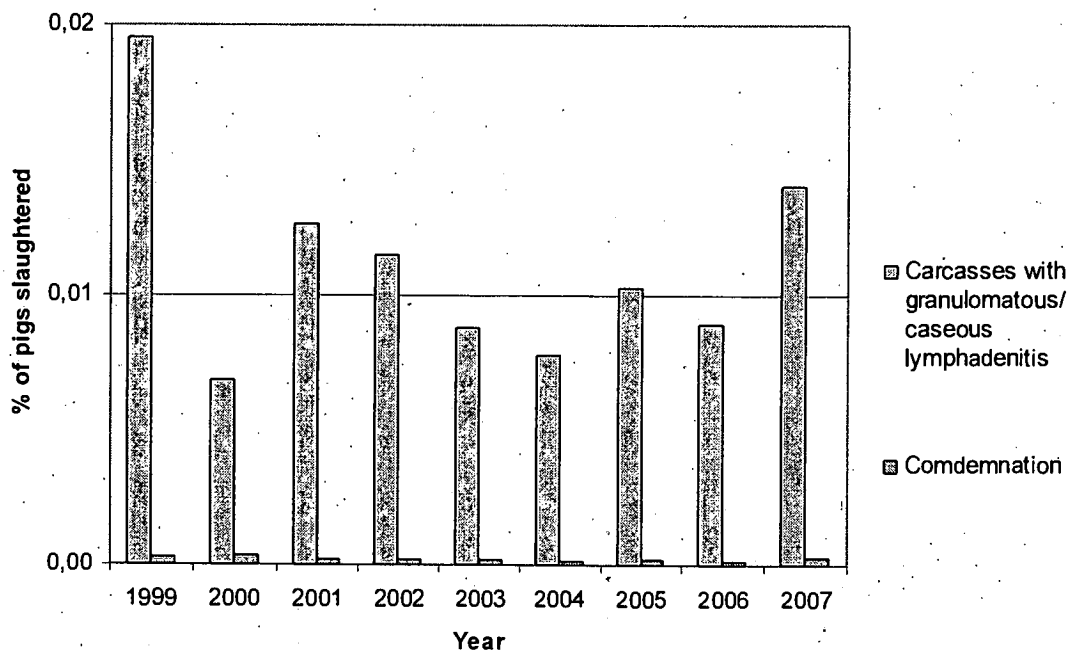


Figure 2

Prevalence of pig carcasses with granulomatous/caseous lymphadenitis and prevalence of condemnation as result of these lesions. Denmark, 1999-2007. Source: Danish Meat Association

The prevalence of granulomatous lymphadenitis in Danish finisher pigs is very low: varying from less than 0.01% to 0.02%. Only a minor part of these findings results in condemnation of the carcass (Fig. 2).

Likewise, the prevalence of endocarditis in Danish finisher pigs is very low; slightly lower than 0.01% in all years from 1999 to 2007. However, around 89% (ranging between years from 85%-92%) of these carcasses are condemned (Fig. 3). Please see section 6.1 for a more detailed description of the meat inspection circular describing when a carcass should be condemned.

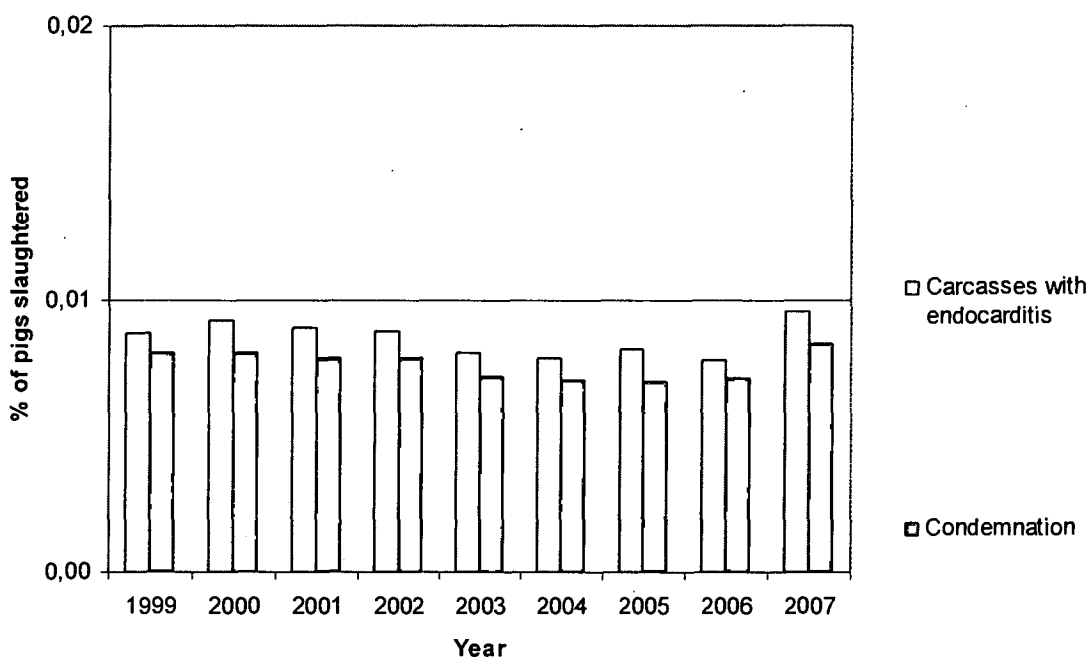


Figure 3

Prevalence of pig endocarditis and the prevalence of condemnation as a result of this finding. Denmark, 1999-2007. Source: Danish Meat Association

As an input to the risk assessment we sampled 43 mandibular lymph nodes with granulomatous lesions. Furthermore, we collected 88 hearts with endocarditis and 57 normal hearts (acting as controls). This took place during normal slaughter operations at ten modern DMA slaughterhouses from March to November 2008. The sample size considerations as well as the design of the study are explained in detail in Appendix A. Sampling was intended to be a 100% sampling (all mandibular lymph nodes with lesions indicative of tuberculosis corresponding to granulomatous/caseous lesions observed in one million finishers). However, the sampling was associated with difficulties; the prevalence was very low and we were only interested in lesions in the mandibular lymph nodes. In several cases the slaughterhouse workers had cleaned out the lymph nodes before the carcass reached the meat inspector.

To ensure a wider basis of information than data from our studies alone, data from the official Danish laboratories and the literature as well as expert opinion were included in the risk assessment. According to Martin et al. (2007a) the confidence to a statement about disease occurrence increases if several kinds of surveillance data are combined and that these are in line and cover a longer time period than one time period only.

Summary of section 2: The risk assessment was conducted following international guidelines. To generate input data, two studies were conducted on ten Danish slaughterhouses. Study 1 included the collection of 43 lymph nodes with granulomatous lesions. Study 2 comprised the collection of 88 hearts with endocarditis. Microbiological and pathological examinations were conducted. Moreover, relevant data from slaughterhouse and laboratory statistics as well as information from the literature and expert opinion were included in the risk assessment.

3. Hazard identification

3.1 Mandibular lymph nodes

According to the EU regulation, traditional meat inspection includes incision of the major mandibular lymph nodes (*Ln mandibulares*). These lymph nodes are in some countries called the submaxillary lymph nodes. Lymph nodes serve as organs that can clear infection from the organism. Several hazards can be present in these organs. Some hazards have or might have a zoonotic impact by being meat-borne or occupational hazards, whereas others are not considered pathogenic at all.

Tuberculosis is the main hazard of interest that can be found in the mandibular lymph node. Infection with tuberculosis might result in development of granulomatous lesions in the lymph nodes. This is seen macroscopically as half-transparent, greyish processes. Often necrosis is present (caseous lymphadenitis) and / or mineralization (Jensen, 2006).

3.1.1 Tuberculosis

Tuberculosis is caused by *Mycobacterium* spp. When dealing with livestock, two types of tuberculosis are of interest: *Mycobacterium bovis* (bovine tuberculosis) and *Mycobacterium avium* subsp. *avium* (in the following called *M. avium* or avian tuberculosis).

Mycobacterium bovis can infect both humans and animals. Humans are infected through meat, milk, fresh cheese or contact. The agent is present in several countries like the United Kingdom. However, Denmark is officially free from bovine tuberculosis since 1980. A large-scale surveillance programme in cattle in Denmark is in place ensuring a constant documentation of the free status (see section 7.1 for a description of the surveillance programme).

Mycobacterium avium can infect birds and animals like pigs and cattle. However, it is only potentially pathogenic to humans. According to Bauer (1999) the clinical presentation of humans infected with *M. avium* complex (MAC) can be largely divided into three groups: 1) pulmonary infections in patients with pre-existing lung disease, 2) lymph node infections in the throat of otherwise healthy, small children, and 3) disseminated infection in severely immune-compromised patients. During the HIV-pandemic the latter group became very important in the 1980s and 1990s. However, due to improvements in treatment of HIV patients, this group is decreasing (Stout & Hamilton, 2006). In HIV/AIDS patients the infection is probably acquired via the gastrointestinal tract. This is contrary to persons without HIV/AIDS, where the most common site of MAC infection is the respiratory tract (Stout & Hamilton, 2006). Identical strains from human and pigs have been shown, reflecting either animals, like pigs, as a source of infection or a common reservoir for human and animals (Bauer, 1999; Komijn, 1999;

Tirkkonen et al., 2007). According to Bauer (1999) the most prevailing opinion is that the source of human infections with *M. avium* is unlikely to be animals, and that the source should be found in the environment. Other possible reservoirs for *M. avium* infection in humans have been reported to be tap water (Von Reyn et al., 1994), hard cheese (Horsburgh et al., 1994), cigarettes (Eaton et al., 1995), and peat (Bauer, 1999).

Outside Denmark, generalized tuberculosis in pigs is uncommon and in most cases a result of infection with *M. bovis* (Jepsen, 1968). The frequent occurrence of *M. avium* in lesions limited to the cervical and mesenteric lymph nodes in naturally infected pigs indicates that infection usually occurs by ingestion (Thoen, 2006). A study by Janetschke (1963 – cited from Thoen, 2006) revealed that the pulmonary route of infection was noted in only 2.7% of the cases, as indicated by involvement of the bronchial lymph node. However, the presence in the bronchial lymph nodes might also be a result of haematogenous spread. Hence, infection in pigs is primarily alimentary.

According to Thoen (2006), infection in a pig is a result of exposure to *M. avium* through 1) use of peat that has not undergone sufficient heat-treatment, 2) soil-contaminated wood shavings, or 3) contact to wild birds or poultry production (or offal from such productions). Previously, the practice of feeding pigs offal from poultry or cattle plants was a risk factor for the introduction of tuberculosis to pigs (Thoen, 2006). This infection route is negligible in the EU today because swill feeding has been prohibited for several years (Anon., 2002).

3.1.2 Other agents

When granulomatous lesions are observed at slaughter, several organisms might be the cause.

According to the literature, the predominant cause of granulomatous lymphadenitis is *Rhodococcus equi*. The lesions associated with infection with *R. equi* cannot be differentiated from those of tuberculosis unless bacteriology is performed (Taylor, 2006). *R. equi* is primarily a soil resident but it is also a transient in the intestinal tract of many species including pigs. Some pig isolates resemble those from humans; however it is not known whether this is because some human cases maybe of porcine origin or it is a result of a common source of exposure. There seem to be no incentive nowhere to institute control measures for *R. equi* (Taylor, 2006). A study by Ottosen (1945 – cited from Thoen, 2006) showed that *R. equi* occurred more frequently in the soil of hog pens than elsewhere. However, newer studies suggest that *R. equi* is less common today (Takai et al., 1996 – cited from Taylor, 2006). It might be speculated that modern in-door pig production systems do not favour the survival of a soil resident like *R. equi*. Humans are also occasionally infected with *R. equi*. The bacterium has been described as a contact zoonosis, and it is not known for being food-borne. In immunosuppressed humans infection might be more severe and in rare cases even life-threatening. Most cases are secondary to HIV infection (Esteves et al., 2007; Linder, 1997) but transplantation patients might also be at risk (Cronin et al., 2008).

M. avium paratuberculosis has also been associated with lesions in lymph nodes in pigs from a pig herd with close contact to a cattle herd infected with Johne's disease (Thoen, 2006). Parasites might occasionally be present as a result of visceral larvae migrans (Valli & Parry, 1993). Neoplasm and fungi can also be found (Jensen et al., 2006).

3.2 Hearts

As part of the traditional meat inspection, the heart is opened and inspected. The most important lesions in the heart of pigs from integrated production systems - that is recorded to the meat inspection database – are pericarditis, epicarditis, apostematous myocarditis (abscess in the heart) and endocarditis.

Most of the bacterial agents which can be found in the pericardium and epicardium are not zoonotic with the exception of *S. suis* which will be dealt with in the following (Leps & Fries, 2008). Moreover, pericardial and epicardial lesions will often be detected without incision because they are usually visible from the outside of the heart. Myocardial lesions might consist of abscesses (e.g. due *Arcanobacterium pyogenes*) (unpublished results).

The lesions in the myocardium might also be caused by parasites like *Echinococcus granulosus/multilocularis* or *Cysticercus cellulosae* (Leps & Fries, 2008). However, infection with *C. cellulosae* can be detected during meat inspection in the masseter muscle, tongue, diaphragm and intercostal muscles of the slaughtered animal (Jensen et al., 2006). *C. cellulosae* has not been observed in Danish finisher pigs since the 1930s (J. Boes, personal comment). Echinococcosis results in the development of cysts in the lung tissue (hydatidosis) (Jensen et al., 2006). The last case of echinococcosis was observed in 1996 (Anon., 2008a). In conclusion, parasitic infections in the myocardium will most likely be diagnosed during meat inspection of other parts of the carcass.

Endocarditis is usually bacterial in cause, the exceptions being an occasional parasitic or mycotic lesion. The lesions are usually primary on the valves. In the pig, *Streptococcus* spp. are the most commonly found organism followed by *Erysipelothrix rhusiopathiae* (Robinson & Maxie, 1993). Other organisms which can be found in association with endocarditis in pigs are among others *Arcanobacterium pyogenes* og *Staphylococcus* spp. (Taylor, 2006). These pathogens are mainly considered occupational hazards and not food-borne. This implies that people at risk are those that are getting regularly into contact with live animals (farmers, veterinarians) fresh carcasses or excretes from the slaughter process (slaughterhouse workers and meat inspectors). Infection is opportunistic and results from the invasion of skin or mucous membranes. Infection requires predisposing factors such as wound in the skin; infection is therefore often secondary.

In particular, *Erysipelothrix rhusiopathiae* is known for being an occupational hazard (Reboli & Farrar, 1989; Wood & Henderson, 2006). Most cases occur via scratches or puncture wounds of the skin. The most common manifestation in humans is a skin infection called erysiploid. In rare occasions, septicaemia associated with endocarditis is seen (Reboli & Farrar, 1989). According to Fries (1999 - cited from Leps & Fries, 2008) heat-treatment inactivates the bacteria. This might explain why food-borne cases are not reported despite of a non-negligible prevalence of hearts with lesions are exposing consumers to *E. rhusiopathiae* regularly.

Streptococcus suis is also mainly considered an occupational hazard. The first case of *S. suis* infection in humans was reported from Denmark in 1968 by Perch. Since then, nearly 200 human cases have been reported world-wide (Statens Serum Institut, 2005). So, *S. suis* infections in humans are considered a rare event. The infection produces meningitis in humans, but other conditions like endocarditis, cellulites, and arthritis have been reported too (Higgins & Gottschalk, 2006). During 1996-1999, only one case of meningitis due to infection with *S. suis* was observed in Denmark, and that was in a pig farmer (Statens Serum Institut, 2000). However, in Hong Kong *S. suis* has been reported as one of the major causes of meningitis in adults (Statens Serum Institut, 2005; Higgins and Gottschalk, 2006). The diseased people all had contact to pigs (Staten Serum Institut, 2005). It is currently being investigated why *S. suis* apparently behaves more aggressively in Hong Kong than elsewhere. Despite of the low number of human cases, Leps & Fries (2008) do not exclude food as a carrier of *S. suis* and mention that consumption of raw or undercooked pork or pork blood might be considered as a source of human infection. This is in line with Berends et al. (1993) who noted that food-borne illness caused by *Streptococcus* might occur as a result of contamination of a meal or meat prepared in advance and stored incorrectly.

Staphylococcus aureus is widely distributed in the environment and is seen on both animals and humans. Strains are exchanged between individuals and across species. *S. aureus* multiplies on damaged mucosal surfaces or skin and can invade to cause bacteraemia. Usually, infection leads to formation of abscesses (Taylor, 2006). A special strain of *S. aureus* which is methicillin-resistant (MRSA) has

attracted attention in recent years. Although infection with MRSA in humans is mainly a problem on hospitals and nursing homes, six cases related to contact with pigs was observed in Denmark in 2007 (Statens Serum Institut, 2008). Food-borne intoxication as a result of presence of *S. aureus* might also occur but is a result of the development of an enterotoxin related to inadequate storage and cooling of e.g. meat products (Berends et al., 1993; Sutherland & Varnam, 2002).

Arcanobacterium pyogenes is common on the mucous membranes of the upper respiratory tract and the genital tract of several animal species including pigs. Disease is therefore a result of endogenous infection and is sporadic, requiring some predisposing events, such as trauma to initiate the process. Infection is often secondary (Taylor, 2006).

Summary of section 3: If lymph nodes are not opened routinely, lymph nodes with lesions might pass the meat inspection unnoticed. Granulomatous lesions are the most important with respect to food safety, because this might be a result of infection with bovine tuberculosis. Other hazards might be present to. Among these, avian tuberculosis and *Rhodococcus equi* are of greatest importance.

If hearts are not opened routinely, a case of endocarditis might pass meat inspection unnoticed. The most important hazard are here *Streptococcus* spp. and *Erysipelothrix rhusiopathiae*. A pig with endocarditis might also have lesions in other organs.

4. Release assessment

4.1 Prevalence of relevant hazards in the mandibular lymph node

The result of Study 1 is presented in Table 1. It is noted that all lymph node samples were negative for *Mycobacterium* spp. since they were acid-fast negative by Ziehl-Neelsen stain. Moreover, in 63% of the samples *Rhodococcus equi* was found. One sample contained *Nocardia farcinica*. Even though no samples were positive for *M. avium*, the limited sample size makes it impossible to conclude much about the prevalence of *M. avium* in Danish finisher pigs. In the following other data will support the findings in Table 1 and show that the prevalence is probably very low.

The cut surface varied in size from 1-10 mm.

Table 1

Distribution of different organisms found in a study on 43 mandibular lymph nodes with granulomatous lesions and or caseous necrosis in finisher pigs, Denmark 2008

Organism	Number of samples (%)
Negative* for <i>Mycobacterium</i> spp.	43 (100)
<i>Rhodococcus equi</i>	27 (63)
<i>Nocardia farcinica</i>	1 (2)
Culture-negative	15 (35)
Total	43 (100%)

* Acid-fast negative by Ziehl-Neelsen stain

In The Netherlands, a significant increase in the incidence of granulomatous lesions in lymph nodes from finisher pigs was seen in the late 1990s. This prompted a large-scale investigation in five slaughterhouses. A total of 856 out of 158,763 pigs (0.5%) had granulomatous lesions either in the submaxillary or the mesenteric lymph nodes. A follow-up study on 402 affected lymph nodes revealed that around half of these lesions were caused by *M. avium* (Komijn et al., 1999). A more recent investigation in The Netherlands again revealed a relatively high prevalence of lesions in the submaxillary lymph nodes in finisher pigs (Komijn et al., 2007). More than 2 million pigs were examined, and 0.75% of these had lesions in the submaxillary lymph node. Infection was clustered within herds and in the nine farms with the highest prevalence, 2.3-5.7% of the animals were found with lesions. Lesions in the submaxillary lymph nodes were 77 times more common than in the mesenteric lymph nodes. A total of 99 lymph nodes with granulomatous lesions were cultured for *M. avium*. However *M. avium* could not be isolated from these 99 lymph nodes. *Rhodococcus equi* was found in 45% of the samples. The two Dutch studies indicate that the prevalence of *M. avium* has strongly decreased over the last decade.

The findings from The Netherlands are in line with the Danish situation; in the second half of the 1990s the prevalence of pigs with *M. avium* was higher than today. Today, the prevalence of avian tuberculosis in Danish pigs is very low. The official laboratory at the Veterinary Institute receives carcasses where more than one lymph node with granulomatous lesions is observed for mandatory laboratory investigation. According to this laboratory, only one to three submissions per year are received, and each submission includes one or two pigs. *M. avium* is sometimes found, but not each time (S.B. Giese, personal communication).

Tuberculosis is not seen in commercial poultry in Denmark, but occasionally in backyard farms with older hens or in birds from zoological gardens (S. Kabell, personal communication). A total of one to seven cases of avian tuberculosis in poultry have been found annually at the official laboratory during 1999-2005 (Anon., 2007c). No cases were found in 2006 and 2007 (Anon., 2008a). In 2008, one bird from a zoological garden was found positive. So, the poultry cases are restricted to backyard poultry or zoological gardens. Moreover, three to four cases are found in wild birds in Denmark annually (S. Kabell, personal communication). The very low prevalence of avian tuberculosis observed in backyard poultry is probably a result of an occasional spill-over from wild birds. The increased industrialisation and separation between poultry and pig production will most likely reduce this exposure further.

In the USA, a similar development in the prevalence of avian tuberculosis has been observed. Data from inspections at US abattoirs have revealed a constant decline since 1922, and data from 1995 shows that in 0.2% of all carcasses, lesions indicating tuberculosis are observed. Only 0.003% of these carcasses are – however – condemned as a result of evidence of generalized tuberculosis (Thoen, 2006).

The figures from The Netherlands and the USA indicate a higher prevalence of granulomatous lesions in lymph nodes than observed in Denmark where only 0.01-0.02% of the finisher pigs are observed with these lesions (see Fig. 2).

4.2 Prevalence of relevant hazards in the heart

The microbiological results of Study 2 on hearts with and without endocarditis are presented in Table 2. It is noted that the most commonly found microorganism was *Streptococcus suis* (46%), followed by *Erysipelothrix rhusiopathiae* (32%) and beta-hemolytic *Streptococci* (6%). The remaining samples consisted of a number of different pathogens, awaited identification, or the sample was sterile (6%) (Table 2). For the hearts without endocarditis, most were culture-negative (79%). Only in 4% of the hearts without endocarditis a pathogen was found. In the remaining cases, the sample had been contaminated (including findings of *Proteus*).

The endocarditis cases found varied in size from a few mm to several cm.

The meat inspectors were asked to record other lesions found on the carcasses where endocarditis had been found. Unfortunately, it was not the impression that the meat inspectors recorded/reported all such lesions. In 20 out of 75 hearts (28%) with endocarditis (and where information was available) other lesions were observed as well. These included: embolic pneumonia, chronic peritonitis, infarct in the kidney, lung stasis, purulent myocarditis, tail biting, osteomyelitis, chronic arthritis, or abscess in the brain. Sometimes more than one of these conditions was present. The presence of these conditions requires that the carcass being subjected to extended meat inspection. All these carcasses were condemned. Please see section 6.2.2 for a discussion of this issue in particular with respect to how this will be dealt with in the Supply Chain Meat Inspection.

Table 2

Distribution of organisms found in a study of 88 pig hearts with endocarditis and 57 pig hearts without endocarditis found at the slaughter line, Denmark 2008

Organism	No. of hearts with organism (%)	
	With endocarditis	Without endocarditis
<i>Streptococcus suis</i> like	40 (45.5)	
<i>Erysipelothrix rhusiopathiae</i>	28 (31.8)	
Beta-hemolytic <i>Streptococci</i> *	5 (5.7)	
Mixed culture with <i>Streptococcus</i>		2 (3.5)
<i>Lactobacillus garvieae</i>	4 (4.5)	
<i>Proteus</i>		1 (1.8)
<i>Arcanobacterium pyogenes</i>	1 (1.1)	
Isolates awaiting identification	5 (5.7)	
Culture-negative	5 (5.7)	45 (78.9)
Contaminated		9 (15.8)
Total	88 (100.0)	57 (100.0)

* Awaiting final laboratory identification.

In a Danish study, Pedersen et al. (1984) reported that the organism most often found in slaughter pigs with endocarditis was *Erysipelothrix rhusiopathiae* (64%, N=147). This is contrary to the findings of the present study where *Streptococcus* spp. were the most commonly found organism (Table 2), however, our findings are in line with Robinson & Maxie (1993). The world-wide development within pig production towards a more industrialised housing and management - with little if any contact to the outdoor environment - might change the distribution of the organisms.

Summary of section 4: Denmark is officially free from bovine tuberculosis since 1980. A very low prevalence of granulomatous lesions in lymph nodes is observed in Denmark (0.01-0.02%) and a part of these lesions are found in the mandibular lymph nodes. Study 1 showed that all lymph nodes examined were negative for *Mycobacterium* spp. In 63% *Rhodococcus equi* was found. In one case (2%) *Nocardia farcinica* was found, and the remaining 35% of the samples were culture-negative. In Denmark, avian tuberculosis is occasionally found in backyard poultry, zoological gardens and pigs.

There is a very low prevalence of endocarditis in Danish finisher pigs (0.01%). Study 2 showed that endocarditis was primarily associated with *Streptococcus* spp. (51%), secondly *Erysipelothrix rhusiopathiae* (32%), *Lactobacillus* (5%) and *Arcanobacterium pyogenes* (1%). The remaining samples were either unidentified (6%) or culture-negative (6%).

5. Consequence assessment

5.1 Assessment of impact of disease on the individual

As shown in the previous section, several organisms present in or on a pig might result in disease in humans either as a result of a food-borne infection or contact to infected pigs or carcasses. Such cases of disease have an impact on the individual they affect. We have grouped the hazards that were identified in the hazard identification based on the following parameters: symptoms, duration, degrees of complications, hospitalization rate, and mortality. Three categories were used: mild, moderate or severe. The details of the grouping can be found in Appendix C and a summary is presented in Table 3.

Human infection with tuberculosis is considered severe. For avian tuberculosis this is only the case for vulnerable groups of the population, which consists of small children, immunosuppressed persons as well as people with pre-existing lung lesions (please see section 3.1.1. for a more thorough description). Infection with *Streptococcus suis* is seldom observed in humans but it might result in meningitis (Higgins & Gottschalk, 2006). The remaining diseases are considered to have a mild or moderate impact of the individual (Table 5).

Table 3

Qualitative assessment of impact of specific infection possibly related to pigs and pork on the individual patient, Denmark 2008

Pathogen	Assessment
<i>Streptococcus suis</i>	Mild to Severe
<i>Staphylococcus aureus</i>	Mild
<i>Erysipelothrix rhusiopathiae</i>	Mild
<i>Mycobacterium bovis</i>	Severe
<i>Mycobacterium avium</i>	Severe among vulnerable groups
<i>Campylobacter</i> spp.	Moderate
<i>Salmonella</i> spp.	Moderate
<i>Yersinia enterocolitica</i>	Moderate

See Appendix C for a detailed description of the assessment

5.2 Observed number of human cases in Denmark

In Denmark, a report of zoonotic diseases in animals and man is published annually and can be found at: <http://www.food.dtu.dk/Default.aspx?ID=9202#74145>. However, not all diseases are notifiable, and hence, for some of the non-notifiable our knowledge about their incidence is limited. The most common cause of food-borne disease in humans in Denmark is *Campylobacter* spp. and the primary source of campylobacteriosis is poultry and poultry products (Anon., 2006). The second most common cause is *Salmonella*. Here, the primary sources are eggs, poultry and pork of either national or imported origin (Anon., 2006). Currently, Denmark is going through a *Salmonella* epidemic due to a specific strain of *S. Typhimurium* called U292. By November 2008, the source was still unknown (<http://www.foedevarestyrelsen.dk/forside.htm> - accessed November 26, 2008).

The question of interest is the number of human cases ascribed to pork (outbreaks not included). These are estimated in Table 4. It is noted that *Yersinia enterocolitica* is ascribed to the highest number of human cases (215 cases) followed by *Salmonella enterica* (6.1% of 1,658 cases = 101 cases)

(Anon., 2006). *S. aureus* can act directly as an occupational hazard giving rise primarily to skin infections in humans. It can also be related to food poisoning, but here it is a result of the bacteria developing an enterotoxin during inadequate cooling of e.g. meat products (Sutherland & Varnam, 2002).

In 2006, three cases of bovine tuberculosis in elderly people were reported in Denmark. Infection was believed to consist of a reactivation of an infection acquired years ago when bovine tuberculosis was present in Denmark (Anon., 2006).

Human cases of avian tuberculosis are not notifiable making it difficult to know the exact incidence in Denmark. A survey was made based on specimens received at the Statens Serum Institut in 1995 and 1996. Based on these data, a total of 198 patients were found to be infected with *M. avian* complex (MAC) (Thomsen et al., 2002). If the assumption is made that the incidence has remained the same (and the patients in the 1995-96 study were newly infected and successfully treated), then around 100 cases or less of MAC can be expected per year in Denmark. The number of MAC is lower today than ten years ago because of better treatment possibilities of HIV patients which results in an improvement of their immune system (Stout & Hamilton, 2006). The cause of infection is unknown but is probably a result of environmental exposure (See section 3.1.1 for a further discussion).

Table 4

Incidence of human Danish cases of infection with selected zoonotic pathogens and assessed proportion that is ascribed to pork as well as judgement of ways of transmission, 2008

Pathogen	Incidence ^a	No. of cases	Proportion ascribed to pork	Comment on transmission	Source of information
<i>Streptococcus suis</i>	<0.02	<1 per year	100%	Occupational hazard	Statens Serum Institut, 2005
<i>Staphylococcus aureus</i>	Not notifiable ^b	Unknown	Unknown	Two routes: Occupational hazard and foodborne ^c	Statens Serum Institut, 2008, Sutherland & Varnam, 2002.
<i>Erysipelothrix rhusiopathiae</i>	Not notifiable ^b	Unknown	Unknown, probably very low ^d	Occupational hazard	Reboli & Farrar, 1989
<i>Mycobacterium bovis</i>	0.05	3 cases – all elderly people	Zero	Reactivation of latent infection acquired long ago	Anon., 2006
<i>Mycobacterium avium</i>	2 ^e	100 ^e	Unknown, probably close to zero	Primarily environmental exposure	Thomsen et al., 2002
<i>Campylobacter</i>	60	3,242	Minority of cases	Batch cooling after slaughter kills <i>Campylobacter</i>	Anon., 2006
<i>Salmonella</i> spp.	30.5	1,658	6.1%	Food-borne	Anon., 2006
<i>Yersinia</i>	4	215	100%	Food-borne	Anon., 2006

a: Incidence is measured as number of new cases during the year per 100,000 inhabitants

b: It is not possible to estimate the number of cases of a disease which is not notifiable

c: Enterotoxin might develop during inadequate cooling of heat-treated meat product

d: Contact to Danish Slaughterhouse Workers' Union (NNF) revealed that the prevalence is very low

e: Based on data from a two-year survey from 1995-1996 (Thomsen et al., 2002); lower today due to more effective treatments of HIV-infections

A contact to the Danish slaughterhouse workers' union (NNF), the Confederation of Danish Industry as well as the slaughterhouse Danish Crown revealed that the number of human cases of *Streptococcus* and *Erysipelothrix* among slaughterhouse workers is so low that these hazards are not considered a problem (M. Eliassen, personal communication).

The estimated probability of exposure is presented in Fig. 4 followed by the estimated probability of becoming ill due to consumption of Danish pork (Fig. 5). The figures display the overall risk irrespective of the type of meat inspection in place. The uncertainty around these estimates is displayed too. For example, regarding bovine tuberculosis, our estimate is that there is no risk and we are certain about. The reason is that we are free from this disease since 1980 and we have a surveillance program in place to document freedom. It is noted that there is a high degree of certainty for all prevalence estimates except for avian tuberculosis. Regarding exposure, we know the prevalence of *M. avium* in finisher pigs is very low, but we do not know exactly how low. Moreover, regarding consequences the prevailing opinion in the literature is that *M. avium* is not meat-borne, but we do not know for sure.

Campylobacter is primarily related to poultry and not to pork. Moreover, *Rhodococcus equi*, *Streptococcus* spp. and *Erysipelothrix rhusiopathiae* are considered occupational hazards that only occasionally result in human infection. Only *Staphylococcus aureus* might be food-borne and that is related to development of toxin as a result of inadequate cooling after heat-treatment. This makes *Salmonella* spp. and *Yersinia enterocolitica* the most important pathogens related to Danish pork. Meat inspection *per se* does not have any impact on *Salmonella* or *Yersinia* unless specifically considered. Therefore, a *Salmonella* surveillance-and-control program is in place in Denmark since 1995 (Alban et al., 2002).

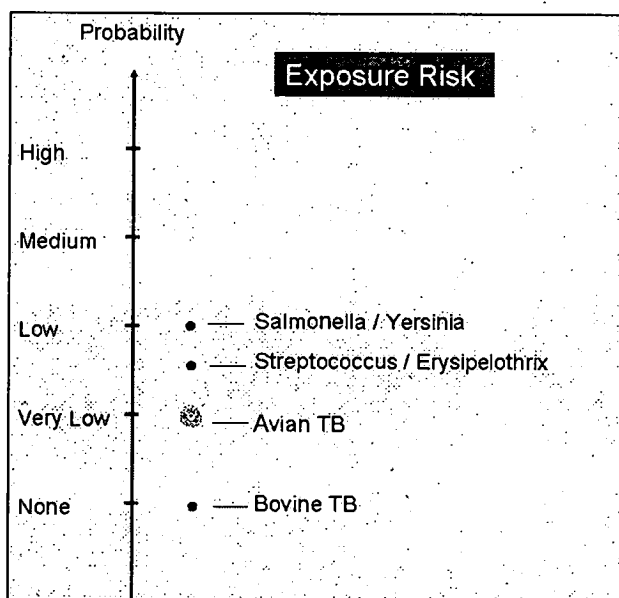


Figure 4

Exposure risk – Probability of exposure of consumers due to consumption of Danish pork, irrespective of type of meat inspection, Denmark 2008

Explanation of symbols used in Fig. 4 and Fig. 5:

- = High certainty linked to estimate of probability
- ◉ = Some uncertainty linked to estimate

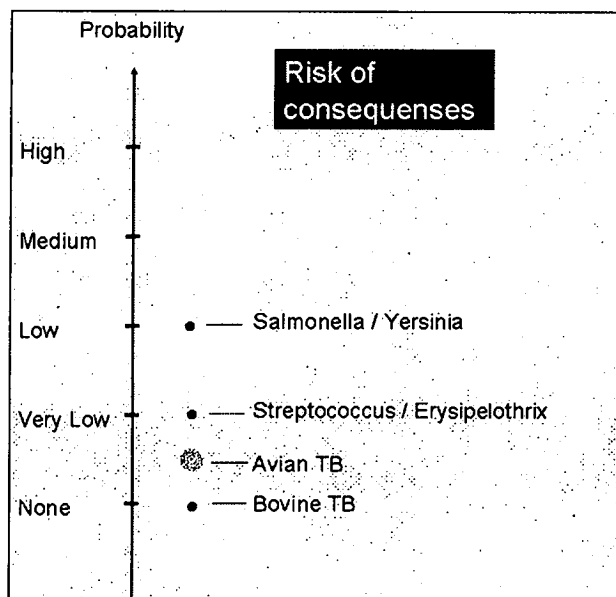


Figure 5

Risk of consequences – Probability of getting ill from consumption of Danish pork, irrespective of type of meat inspection, Denmark 2008

Summary of section 6: Bovine tuberculosis was eradicated in 1980. Hence, there is no risk of this infection related to Danish pork. Avian tuberculosis is not considered meat-borne, neither is *Rhodococcus equi*. Hence, these hazards are not of concern. The pathogens found in the heart are occupational hazards and they are not considered meat-borne. This is contrary to *Salmonella* spp. and *Yersinia enterocolitica* which cause disease in a non-negligible number of people. These infections are considered of medium severity in the individual infected. Hence, *Salmonella* spp. and *Yersinia enterocolitica* are the most important hazards related to Danish pork. A surveillance-and-control program for *Salmonella* is in place since 1995.

6. Effect of meat inspection

6.1 The regulatory framework

The regulatory framework for meat inspection is among others described in the Danish circular regarding performance of meat inspection (DVFA, 2007a). In here it has been specified in details which action to take in case of any macroscopically finding. This is graphically described in Fig. 6 and Fig. 7. Accordingly, if lymph nodes with granulomatous lesions are found in the head or the mesenteric area of a pig, local condemnation of the affected organ is required. The finding of lesions indicative of tuberculosis outside the head and the mesenteric area requires that the veterinarian sends the material for further laboratory examination to the Danish Veterinary Institute. This only happens infrequently; one to three cases are received per year including one or two pigs per case – and *Mycobacterium*

avium is not found each time (S.B Giese, personal communication). If *M. avium* is found in the latter cases, the carcass is condemned. As noted in Fig. 2, this occurs but not very often.

If healed endocarditis is found, local condemnation of the heart is required. In case additional lesions linked to endocarditis are present on the carcass, the entire carcass will be condemned. In case of trombozing endocarditis (ulcerative or verrucous) the judgment will be condemnation of the entire carcass too. According to in-house slaughterhouse statistics, around 89% of the cases of endocarditis result in condemnation of the entire carcass at present (Fig. 3). This strict judgment is a result of the habit to react on knowledge obtained: the presence of endocarditis possibly increases the exposure to several pathogens. Although when the heart is incised, the pathogens possibly present are not considered food-borne but occupational – and they have already exposed the slaughterhouse workers and meat inspectors

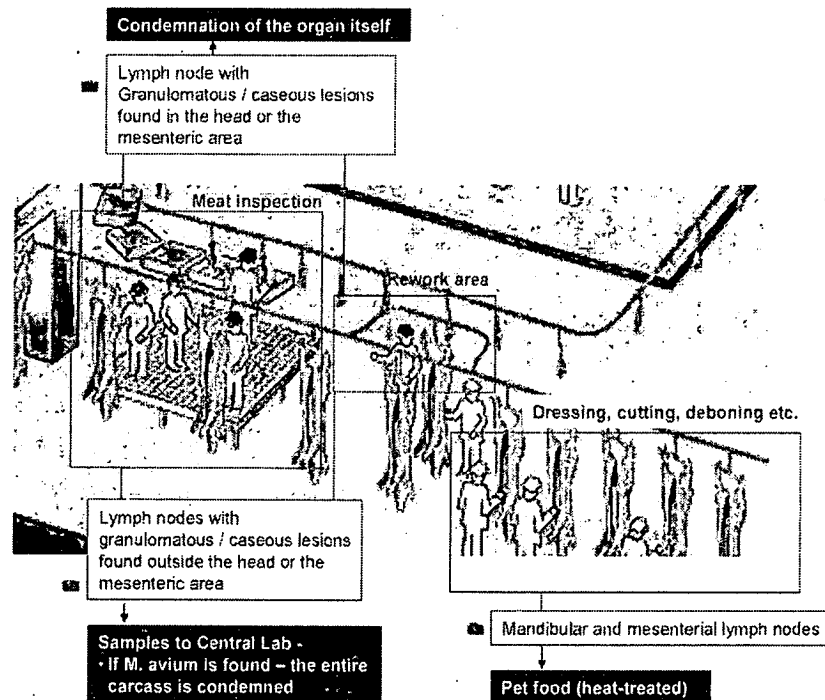


Figure 6

Graphical description of how traditional meat inspection is conducted with respect to the mandibular lymph nodes, Denmark 2008

Supply Chain Meat Inspection will only be conducted on finishers from integrated production systems where the finishers have been kept in-door since weaning. Moreover, exchange of food chain information prior to the slaughter of the pigs is required. This makes documentation and auditing of the pig production system vital. Moreover, performance standards are needed in order to measure the quality of the meat inspection. These element are not part of the risk assessment but are described elsewhere (Anon., 2008bc) and it is a part of the regulatory framework.

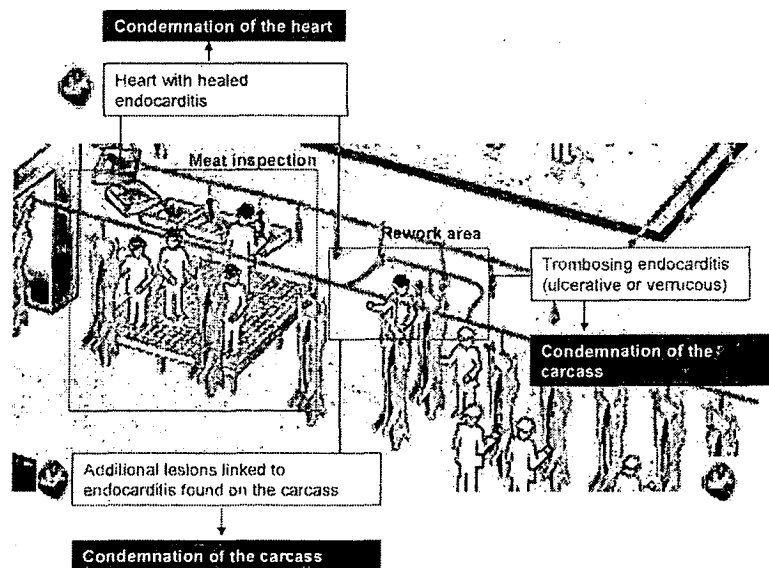


Figure 7

Graphical description of how traditional meat inspection is conducted regarding hearts, Denmark 2008

6.2 Comparison of traditional inspection with Supply Chain Meat Inspection

For any kind of meat inspection the difficult working conditions and the limited time available to inspect a carcass, will question the validity of the quality of the classification of lesions (Willeberg et al., 1984/85). This makes performance standards important. These have been developed specifically for Supply Chain Meat Inspection (Anon., 2008bc). By use of these, the quality of the meat inspection can be assessed.

The main question of interest for the present risk assessment is what effect the suggested changes will have on food safety. Focus will be on the difference in exposure between the two ways of conducting meat inspection: traditional versus risk-based (defined as not opening the heart and not cutting the mandibular lymph nodes routinely but only upon suspicion (Table 5). The effect on zoonosanitary status is dealt with in section 7.

The number of human cases ascribed to pork will most likely remain unchanged due to the introduction of Supply Chain Meat Inspection. If cross-contamination can be reduced as a result of less cutting into the carcass, the prevalence of *Salmonella* spp. and *Yersinia enterocolitica* might decrease. This conclusion is supported by the experience obtained through a large slaughterhouse study that was conducted in Denmark in 1993 (will be presented in the following) as well as by findings from the literature.

In Denmark, a comparative study of the frequency of lesions, detected by visual and traditional inspection of slaughter pigs was conducted from January to July 1993 at a Danish slaughterhouse authorised for export. The study included 183,383 slaughter pigs which were first subjected to an en-

tirely visual inspection and then to traditional meat inspection procedures (incision and palpation) by two different inspection teams (Mousing et al., 1997).

The results of the study showed that a system based entirely on visual inspection in general performed slightly poorer than traditional inspection because the non detection rates (ADNDR) was higher for all classes of lesions, including those that are detected visually in both systems, for example, chronic pleuritis. This inferior performance of the visual procedure was due to a greater monotony of the physical work involved.

It should here be noted that the present risk assessment does not evaluate an entirely visual inspection; but only omission of the routine opening of the heart and the mandibular lymph nodes. The figures presented in the following can therefore be interpreted as worst case scenario with regards to which and how many lesions will be overlooked.

Mousing et al. (1997) estimated that per 1,000 carcasses, an additional 2.5 abscessal lesions in the edible tissue containing *S. aureus*, 0.2 with arthritis due to *Erysipelothrix rhusiopathiae*, 0.1 with granulomatous lymphadenitis, 0.7 was contaminated with *Salmonella enterica* and 3.4 with *Yersinia enterocolitica* would remain undetected as a result of changing from traditional to an entire visual inspection. This should be balanced by the risk of cross-contamination due to infection with *Yersinia enterocolitica* (Mousing et al., 1997; Mousing et al., 1999).

Unfortunately, the effect of meat inspection on endocarditis was not evaluated in the study by Mousing et al. (1997). The authors mention that 5.5 chronic pericarditis cases might be overlooked per 1,000 carcasses – however they did not consider this meat as edible tissue. For acute pericarditis – which was considered belonging to edible tissue - around 0.16 cases would be overlooked (Mousing et al., 1997)

A valuable reason for the implementation of a visual system (without palpation, incision or manual handling of the carcass) is the potential for decreased cross-contamination of hazardous bacteria, in particular from the contaminated pharyngeal region and from the plucks (Mousing et al., 1997).

This is in line with Petersen et al. (2002) who state that traditional meat inspection will result in cross-contamination of food safety pathogens like *Salmonella* from the oral cavity and the head. This is a result of the techniques used which involve removal of the tongue with the tonsils attached, together with the trachea, lungs, liver and heart (the plucks), and possibly splitting the head while the meat inspector palpates the surface of the head and cuts into the lymph nodes. Therefore, Petersen et al. (2002) recommend that the slaughter technique where the head is not being split, the tongue is left in the oral cavity, and the head is only inspected visually, without palpation or incision.

This recommendation goes far beyond the changes suggested to the current meat inspection which only deals with omission of two specific routine incisions; into the heart and the mandibular lymph nodes.

6.2.1 The mandibular lymph node

The exposure risk for bovine tuberculosis is considered negligible for both kinds of meat inspection because Denmark is officially free from bovine tuberculosis since 1980 (Please see section 7.1).

According to Wisselink et al. (2006) meat inspection in general has a low sensitivity with respect to diagnosing infection with *Mycobacterium avium*. Wisselink et al. (2006) based this conclusion on an experimental study where only half of the artificially infected pigs developed lesions either in the mandibular lymph nodes or the mesenteric lymph node. However, the prevailing opinion is that *M. avium* is not meat-borne (see section 3.1.1. for a detailed discussion). As long as freedom from bovine tuberculosis can be documented, the question about imperfect sensitivity of both traditional and Supply Chain Meat Inspection plays no role. Moreover, mandibular lymph nodes from Danish finisher pigs are not consumed by humans but end up in pet food after adequate heat-treatment (G. Pedersen, personal

communication; S. Tinggaard, personal communication). Hence, there is no food safety relevance, neither an aesthetic issue.

A possible disadvantage related to Supply Chain Meat Inspection is that minor lesions in the lymph nodes not giving rise to an observable increase in size are not found during meat inspection. Apart from granulomatous lesions that could e.g. consist of abscesses and foreign bodies. Moreover neoplasm like melanoma in duroc pigs could be overlooked. However, the efficiency of incision of lymph nodes is limited. A number of mycobacterial infections in pigs caused by *M. avium* might not be detected by incision of lymph nodes because the lesions are not visible. Hird et al. (1983) e.g. isolated *M. avium* from 6.7% of 280 *Inn. mesenteriales*, with no visible lesions. Many of the younger meat inspectors in countries where bovine tuberculosis has been eradicated have never seen tuberculosis in slaughter animals. Some of these inspectors might not be familiar with the appearance of tuberculosis, and hereby, the disease might not be detected. However, we believe that when the lesions are large and observed in several lymph nodes, they will be found. In line, infection with *M. avium* might also be detected by visual inspection of the liver. In this context it is important that the meat inspector is able to distinguish mycobacterial lesions in pig livers from spots of other origin, especially "milk spots" caused by ascarid larvae (Alfredsen, 1992). In line, lymphadenopathy in the liver might be a differential diagnosis to *M. avium* in the liver (Jensen et al., 2006).

When the mandibular lymph nodes are not palpated and incised routinely, the risk of cross-contamination with pathogenic bacteria will be lowered (Nesbakken et al., 2003, Petersen et al., 2002). A study performed by Nesbakken et al. (2003) showed that it was possible to isolate *Yersinia Enterocolitica* from around 5-13 % of the mandibular lymph nodes investigated. In line, Pointon et al. (2000) showed that it was possible to isolate *Salmonella* spp. and *Yersinia Enterocolitica* in 2% of enlarged mandibular lymph nodes compared to 1.4% in normal sized mandibular lymph nodes.

Table 5

Exposure risk for the most relevant food safety hazards present in Danish finisher pigs from integrated production systems: A comparison of the effect of traditional versus Supply Chain Meat Inspection, 2008

Food safety hazard	Type of meat inspection	
	Traditional	Supply Chain Meat Inspection ^a
<i>Bovine Tuberculosis</i>	No risk ^b	No risk ^b
<i>Avian tuberculosis</i>	Very low risk ^c	Very low risk ^c
<i>Salmonella and Yersinia</i>	Risk of cross-contamination	Possibly reduced risk of cross-contamination
<i>Erysipelothrix rhusiopathiae</i> and <i>Streptococcus</i> spp	Risk of exposure and cross-contamination	Possibly reduced risk ^d of cross-contamination

- Lymph nodes and the hearts will only be opened upon suspicion. Moreover, a food chain information system is in place ensuring that all relevant information reach the slaughterhouse prior to slaughter of the pigs
- Denmark is officially free from bovine Tuberculosis since 1980 (Anon., 2007c)
- The mandibular lymph nodes are used for pet food after adequate heat-treatment
- If hearts are opened separately by slaughterhouse workers, then the risk of cross-contamination from the heart to the carcass will be lower than at present

6.2.2 The heart

According to our analysis, the hazards that are found in association with endocarditis are mainly occupational and not food-borne. In this case an omission of the routine opening will reduce the spreading of the organisms to the remaining part of the carcass. When the heart is not opened, blood coagula will be present as well as occasional findings of endocarditis. A cleaning of the heart is there-

fore required prior to the sale to the consumer. To reduce exposure of consumers to the occupational hazards that might be present in case of endocarditis, we suggest that the hearts are opened by slaughterhouse workers separately after meat inspection and prior to the hearts leaving the slaughterhouse. An opening of the hearts at this stage will reduce spreading of these organisms to other parts of the carcass. Moreover, it will allow the identification of abscesses in the myocardium as well as cases of pericarditis not found during meat inspection. Presence of any lesion in the heart should result in condemnation of the heart.

If the infection is generalised, other organs will be infected, too, and hence this will be found during visual meat inspection. The current meat inspection circular contains a specified list of actions required in case of different pathological findings (DFVA, 2007a). Accordingly, any carcass with abnormalities will undergo extended control. Hereby, it can be judged whether condemnation of the organs or possibly the entire carcass is required. According to our study 2 on hearts, 28% of the cases with endocarditis had other lesions which would have lead to an extended examination whereby the hearts would have been opened anyway. The proportion of carcasses with endocarditis which had other lesions too is probably higher than 28%. This is because the recording of other lesions was not believed to have functioned properly in study 2. This implies that at least 28% of the endocarditis cases will be found in Supply Chain Meat Inspection.

Based on the before-mentioned it is concluded that omission of the routine opening will not jeopardise food safety. This is in accordance with Leps & Fries (2008) and in line with the US meat inspection rules (Anon., 2007a).

It should here be noted that around 30% of the pig hearts are sold directly to Danish supermarkets, whereas more than 50% of the hearts are exported to export countries outside the EU e.g. Russia and USA. The remaining 20 % are sold to supermarkets within the EU (G. Pedersen, personal communication; S. Tinggaard, personal communication).

Summary of section 6: For any kind of meat inspection the difficult working conditions and the limited time available to inspect a carcass, will question the validity of the quality of the classification of lesions. Therefore, performance standards for meat inspection are needed in order to conduct an effective quality control. Moreover, training of personnel is required so they are prepared for the new way of meat inspection. A documentation-and-auditing programme for the herds supplying finishers is required to ensure the correctness of the food chain information; in particular, whether the pigs were kept in-door since weaning.

Omission of the routine incision into the mandibular lymph nodes does not seem to have an impact on food safety since the hazards possibly present are not meat-borne. Moreover, less handling will reduce the risk of cross-contamination with food safety hazards like *Salmonella* and *Yersinia*. The agents found in pig hearts are primarily occupational hazards and not meat-borne. To reduce exposure of the consumers to these hazards, it is suggested that the hearts are opened after meat inspection slaughterhouse workers but prior to sales by. Any heart with lesions should be condemned. This will reduce the spreading of these hazards from the heart to the carcass and further on to slaughterhouse personnel and consumers. The number of human cases ascribed to pork will most likely not change because of the introduction of Supply Chain Meat Inspection.

7. Impact on zoo-sanitary status

It is important for a large pig-producing and exporting country like Denmark to ensure that we are not jeopardizing animal health when we change our way of management; in this case the way meat inspection is conducted. We have therefore included zoo-sanitary hazards in the risk assessment. This is both for the sake of the Danish pig production and the export of breeding pigs and pork. Denmark has been declared officially free from a number of livestock diseases that might cause disease in pigs (Table 6). In the following, the impact of Supply Chain Meat Inspection compared to traditional inspection will be evaluated for Tuberculosis (both due to *M. bovis* and *M. avium*), Foot and mouth disease, Classical swine fever, Aujeszky's disease, Brucellosis (both due to *B. abortus* and *B. suis*) as well as *Trichinella*. It will be noted, that all these diseases (apart from *M. avium* and *B. suis*) are exotic in Denmark as a result of successful eradication followed by implementation of large-scale surveillance programmes (or they have never been seen in the country). Moreover, the diseases are notifiable in animals. Moreover, because the national population is naïve with respect to these diseases, clinical signs related to any of these diseases - except trichinellosis - will be pronounced. Therefore, diagnosis would probably first be made in live animals, either on farms or during the ante-mortem inspection at the slaughterhouse and only secondly at post-mortem.

7.1 Tuberculosis

Denmark is officially free from bovine tuberculosis since 1980 (Table 6). The Danish surveillance programme for demonstrating absence of bovine tuberculosis in cattle consists of a clinical examination in conjunction with meat inspections and tuberculin tests of selected animals. All slaughter animals are examined at the meat inspection for macroscopic lesions indicative of tuberculosis. Furthermore, bulls are tuberculin tested prior to the introduction into a bull station, and cattle are tuberculin tested prior to exportation (Anon., 2007c). Denmark only imports a limited number of cattle and pigs, and requirements for testing and quarantine are in place (Bronsvort et al., 2004; Bronsvort et al., 2008). Hence, if bovine tuberculosis should enter the country, there is a high probability that it will be found during quarantine. Bovine tuberculosis has been found in farmed deer previously. However, no free-living deer have ever been found tuberculosis-positive in Denmark (DVFA, 2008).

The pigs considered for supply chain meat inspection originate from integrated production systems with no contact to wildlife, limiting the probability of exposure to bovine tuberculosis, should this occur in wildlife. Outdoor-reared pigs will be subjected to traditional meat inspection. Breeding pigs are - as for cattle - tested prior to export to certain countries which require testing. The number of tuberculin tests taken vary considerably, and e.g. from April to September 2008, 467 samples were taken only by veterinarians working for the Danish Pig Production Company. Other similar tests are taken by the veterinary practitioners visiting farms from which breeding animals are leaving for export. A double test is used enabling the differentiation between *M. bovis* and *M. avium*. Neither *M. bovis* nor *M. avium* have been found for more than ten years (T. Kjeldsen, personal communication).

According to Danish law, all types of tuberculosis in animals are notifiable. However, the finding of avian tuberculosis in a bird or any other animal does not result in any actions taken by the Veterinary Services (P. Vestergaard, personal communication). Therefore, if a pig reacts positive to *M. avium*, it will not be exported but remain in Denmark without any further actions required (P. Vestergaard, personal communication; T. Kjeldsen, personal communication).

In Ireland, both avian and bovine tuberculosis are present. As a part of the control programme for bovine tuberculosis, cattle are tuberculin tested. A double test is made enabling a differentiation between *Mycobacterium bovis* and *Mycobacterium avium* (J. Cassidy, personal communication). Like in

Denmark, the finding of a reaction against the latter does not result in any action because the agent is not considered meat-borne.

This is in line with the USA, where regulations of the Meat and Poultry Inspection Programme of the USDA require local condemnation if lesions are only found in one primary site on the carcass. If lesions indicative of tuberculosis are found in more than one primary site, the carcass needs to undergo heat-treatment (76.7°C for 30 minutes). If no cooking facilities are available, the carcass is condemned (Thoen, 2006).

Only in The Netherlands is there a concern about the possible meat-borne route related to pig meat. This has led to the introduction of a surveillance programme for avian tuberculosis in Dutch finisher herds (Jelsma, 2008).

The international organisation for animal health, OIE, has recently adjusted its list of diseases which are of international concern. For a disease to be on the list, certain conditions should be met:

- 1) capacity to be spread internationally,
- 2) zoonotic impact,
- 3) significant morbidity or mortality in naïve populations, and
- 4) emerging disease.

Please see Appendix VIII in <http://www.oie.int/tahsc/eng/Reports/A TAHSC SEP2005 A.pdf> for a more detailed description of these criteria. According to Resolution No. XVIII adopted by the International Committee of the OIE during its 76th General Session, 25 – 30 May 2008, avian tuberculosis will be deleted from the list because:

"It is ubiquitous and has no significance for international spread. The morbidity and mortality are not significant in birds. Human infections may occur under exceptional circumstances, but natural infection in humans is rare".

The report from the working group can be downloaded from <http://www.oie.int/tahsc/eng/Reports/A SCCDBJAN2005.pdf> (please see Appendix XXVIII). The Terrestrial Animal Health Code Chapter 2.1.1 will be changed as suggested by the Code Commission in Appendix VI in Report of the Meeting of the OIE Terrestrial Animal Health Standards Commission, 17 - 28 January 2005.

7.2 Foot and Mouth Disease

Denmark is officially free country where vaccination is not practised. The last case of Foot and mouth disease (FMD) was observed in 1983. Combination of a limited import of breeding pigs and a volunteer testing and quarantine programme in place as well as no import of pigs for slaughter and a unique geographical location has made it possible for Denmark to stay free from this disease for decades. FMD is not present in Europe, and should it be found in a European country, several risk-mitigating strategies will be put in place (Anon., 2007c). FMD is associated with the development of vesicles in the mouth and on the feet, which will be observed during ante-mortem inspection. Hence, Supply Chain Meat Inspection will not lower the probability of identifying a case of FMD.

7.3 Classical Swine Fever

Denmark is free from Classical swine fever (CSF) – the last case was seen in 1933 (Table 6). Wild and domestic pigs are the only natural reservoirs. CSF is a notifiable disease in the European Union (EU) since 1983. In the 1970s, CSF was virtually endemic in the then six EU member states and routine

vaccination was a commonly practiced control measure. In contrast the newly entering states Denmark, Ireland and the UK were CSF-free (Bendixen, 1988). The different national policies to control CSF were replaced by the Community legislation in 1980 (according to Council directive 80/217/EEC). Between 1986 and 1990, a non-vaccination policy of CSF was adopted by all Member States (Terpstra et al., 2000). Although the disease has been eradicated from domestic pigs in western Europe, CSF remains endemic in some populations of wild boar, and farms in these areas are at risk of reintroduction (Fritzemeier et al., 2000). In Eastern Europe, the large numbers of backyard herds makes it difficult to control the disease and therefore leads to many outbreaks (<http://www.oie.int/wahid-prod/public.php>, visited 18th February 2008). The surveillance programme in place to demonstrate absence of CSF in Denmark includes serological samples from around 7,000 samples from nucleus herds, as well as 18,000 from sows and boars annually (Martin et al., 2007b; Anon., 2007c; P.T Christensen, personal communication). The pathological findings in post mortem examinations of both domestic pigs and wild boar are swollen, oedematous and haemorrhagic lymph nodes, petechial to ecchymotic bleedings in the skin, kidneys, urinary bladder, larynx, epiglottis and heart (Gruber et al., 1995). Moreover, an infectious disease like CSF would usually result in not just one but several infected animals which would increase suspicion of the disease being present. Most likely, a case of CSF will be diagnosed in the herd or during pre-slaughter inspection. Hence, omitting incisions into the heart and the mandibular lymph node will not lower the probability of identifying a case of CSF.

Table 6

Denmark's zoo-sanitary status^a for a number of diseases in pigs, 2008

Disease	Status	Last case seen in year
African swine fever		Never recorded
Aujeszky's disease	Officially free ^b since 1992	1991
Avian Tuberculosis		2008 ^e
Bovine Brucellosis (<i>B. abortus</i>)	Officially free ^b since 1979	1962
Brucellosis in pigs (<i>B. suis</i>)		Outdoor herd 1999 Wild hares 2002
Brucellosis in sheep and goats (<i>B. melitensis</i>)		Never recorded
Bovine Tuberculosis	Officially free ^b since 1980	1988
Classical swine fever		1933
Foot and mouth disease	Officially free ^c country where vaccination is not practised	1983
Swine vesicular disease		Never recorded
Transmissible gastroenteritis		Never recorded
Trichinellosis	Officially recognised by EU as area with negligible prevalence since 2007 ^d	1930

a: General source: Anon. (2007)

b: Status is based on a recognition by the European Union

c: Status is based on a recognition by OIE

d: Based on Alban et al. (2008)

e: One bird from a zoological garden found positive in 2008

7.4 Aujeszky's Disease

Denmark is free from Aujeszky's disease since 1992. Pigs are the natural host of Aujeszky's disease; other species are dead-end hosts. The disease is characterised among others by very high mortality among young piglets. In these animals severe neurological disorders are observed. Respiratory

signs are seen among older pigs and sows. The clinical course is very severe in naïve pig populations (Pejsak & Truszczyński, 2006). Because of its significance for pig production, Denmark has a surveillance programme in place which includes the samples taken for CSF, as well as additional samples taken yielding a total of more than 40,000 samples taken annually (Anon., 2007c). Based on this it is judged that the suggested change in meat inspection will have no impact on the ability to identify a case; should Aujeszky's disease enter Denmark, then it will be diagnosed in a herd and not at an abattoir.

7.5 Brucellosis

Denmark is free from *B. abortus* since 1979 (Table 6). A surveillance programme is in place to demonstrate absence of this agent. The programme includes testing of around 8,000 bulls per year (T. Grubbe, personal communication). Moreover, clinical surveillance of live cattle (abortions and swollen testicles) post-mortem inspection of slaughtered cattle is conducted.

Brucella melitensis has never been observed, and a surveillance programme is in place including annual blood testing of 5,000-7,000 sheep and goats (Anon., 2007c).

A testing programme is also conducted for *B. suis*. This includes testing of boars entering and leaving boar stations. So far no positive results have been found (T. Kjeldsen, personal comment). *Brucella suis* is occasionally found in hares in some restricted areas in Denmark; the most recent finding of an infected hare was in 2002 (Anon., 2008a). In 1994 and 1999, a total of two outdoor herds, located in the area where infected hares have been found previously, were found infected with *B. suis*. The signs in the herds were swollen testicles and abortions which are the classical signs related to brucellosis (MacMillan et al., 2006). The testicles of one of the boars found in 1994 were around four times the normal size (K.D. Winther, personal communication). This implies that omitting incisions into the mandibular lymph nodes and into the heart will have no impact on the ability to detect a case of brucellosis. Furthermore, only pigs from integrated production systems that have been reared in-door since weaning will be able to undergo Supply Chain Meat Inspection. All outdoor pigs will need to go through traditional meat inspection.

7.6 Trichinellosis

In 2007, Denmark was recognised by the EU as an area with negligible prevalence of *Trichinella* in pigs. The background for this status is that millions of Danish pigs have been tested annually for more than 70 years, and no positive samples have ever been found. This implies that Denmark intends to change the surveillance towards a risk-based surveillance where only subpopulations (outdoor pigs as well as sows and boars) of higher risk will be surveyed directly (Alban et al., 2008). *Trichinella* larvae cannot be observed macroscopically but requires laboratory diagnostics (Stewart and Hoyt, 2006). Hence, omitting incisions into the mandibular lymph nodes and into the heart will have no impact on the ability to detect a case of trichinellosis

Summary of section 7: There is no negative impact on the zoo-sanitary status because most of the pig diseases are more easily recognised in a live animal than on a carcass. The only exception is *Trichinella*, where laboratory testing is required. Denmark is officially recognised by the EU as a country with a negligible prevalence of *Trichinella* in pigs. Moreover, extensive surveillance programmes are in place for most of the infections of concern.

8. Impact on working environment

It is well known that performing meat inspection is an activity which is a physical strain. During a working day, the workers stand up for many hours inspecting the carcasses and organs. Moreover, the work is carried out at the line speed of the slaughter line and is characterized as a repetitive work task.

This one-sided, repeated work causes high risk for back and shoulder problems. Traditional meat inspection includes incision of the mandibular lymph nodes as well as an incision into the heart. These routine incisions add to the risk of back and shoulder problems. In particular, the incision of the mandibular lymph nodes requires that the meat inspectors on most of the slaughter plants bend forward in order to palpate and cut the lymph nodes in the head and throat area. This action results in a risk of work-related musculoskeletal disorders.

On some plants the meat inspection platforms have been changed so that the head is presented for inspection already separated from the rest of the carcass, which lowers the risk of injury in the back due to bending forward to cut the lymph nodes).

Additionally, the handling of knives might result in risk of damage by cutting. In 2007, 17 cases with reference to cutting damage were reported from the abattoirs to the Danish Veterinary and Food Administration (DVFA, 2007b).

Supply Chain Meat Inspection is estimated to reduce the strain of the physical activity in performing the meat inspection. This is supported by studies of meat inspection of finisher pigs in Sweden and The Netherlands (Hall, 2007; Jelsma, 2008). In general, these studies conclude that less time is used on performing the post mortem inspection along the slaughter line after introduction of Supply Chain Meat Inspection. Furthermore, these studies conclude that the staff – both company employee and veterinarians belonging to the official control – is more satisfied and pleased with their work mainly because of improvements of the environment.

This assessment is preliminary since we do not have sufficient data to evaluate the impact on working environment thoroughly.

Summary of section 8: The preliminary analysis indicated that Supply Chain Meat Inspection might have a positive effect on the working environment.

9. Risk estimation

In the following all elements described in the previous sections (release, exposure and consequences) are integrated to form a risk estimate regarding the effect on food safety related to the proposed changes to meat inspection.

The risk for the zoo-sanitary status was evaluated in section 7 – it is judged that the probability of diagnosing a pig with an exotic disease remains unchanged when the palpation and incision into the mandibular lymph nodes and the heart are omitted. Moreover, the serological surveillance programmes in place in Denmark ensure a high confidence of freedom from disease and act as effective tools to identify disease should it enter the country. The assessment of the impact on working environment is only preliminary because we do not have sufficient data to evaluate it thoroughly.

According to Danish slaughterhouse statistics, the prevalence of granulomatous lesions in lymph nodes is low (0.01%) in finisher pigs. The lesions occur primarily in the mandibular lymph node and the mesenteric lymph node, and they have various causes. The most common is infection with *R. equi*, and this organism is not considered meat-borne. Because Denmark is officially free from bovine tuber-

culosis since 1980, there is no risk of infection with bovine tuberculosis when consuming pork meat regardless of the type of meat inspection. *Mycobacterium avium* is occasionally observed in old hens from backyard herds or zoological gardens. In pigs, no high-quality data are available regarding prevalence of avian tuberculosis. Based on the results found in Study 1 and consultations with the official veterinary laboratory for *Mycobacterium* spp. in Denmark, it was concluded that *M. avium* occurs at a very, very low prevalence in pigs from integrated production systems. The predilection site for *M. avium* is the mandibular and mesenteric lymph nodes. These organs are used for pet food after adequate heat-treatment. Furthermore, the prevailing opinion in the literature is that this organism is not considered meat-borne. In conclusion, omission of the routine palpation and incision of the major mandibular lymph not increase the risk of *M. avium*. Moreover, omission of incision as a routine action will lower the probability of spreading of known food safety hazards like *Salmonella* and *Yersinia*. In conclusion, there is no increased risk for human health associated with omission of routine palpation, incision and inspection of the mandibular lymph nodes.

Table 7

Estimation of consumer risk associated with Supply Chain Meat Inspection of finishers from integrated production systems, reared in-door, compared to traditional inspection, Denmark, 2008 – the mandibular lymph node

Organ	Release Assessment	Exposure Assessment	Consequence assessment	Risk estimation
Mandibular lymph node	Granulomatous lymph nodes observed at a prevalence of 0.01-0.02%	Denmark officially free from bovine tuberculosis since 1980.	The number of cases* related to <i>Salmonella</i> spp and <i>Yersinia enterocolitica</i> will not increase but maybe decrease	No risk for consumers associated with omission of routine palpation, incision of the mandibular lymph nodes
	<i>Rhodococcus equi</i> main cause.	Lymph nodes not eaten but used for pet food only	No risk of bovine tuberculosis	
	Avian tuberculosis observed primarily in old backyard hens or in the Zoo (1-7 cases per year) and 0-3 times per year in pigs	Probably very low probability of exposure to avian tuberculosis and <i>R. equi</i>	Avian tuberculosis and <i>R. equi</i> not considered meat-borne	

*: Omission of routine incision into the mandibular lymph nodes will lower the risk of cross-contamination to the rest of the carcass

Regarding the hearts, endocarditis is the condition of relevance for this work because often pericarditis and epicarditis can be observed without incision. Abscesses might also be overlooked initially (see later). Parasitic conditions related to myocarditis will be observable in other organs too if present, however, they occur with a very low prevalence in Danish pigs from integrated production systems. According to the Danish slaughterhouse statistics, endocarditis in finisher pigs occurs with a prevalence of 0.01-0.02%.

According to the literature and the results of study 2, the organisms found in endocarditis are mainly occupational hazards like *Streptococcus* spp. and *Erysipelothrix rhusiopathiae*. Hence, omissions of routine incisions into the heart will lower the probability of spreading these occupational hazards to the carcass. Furthermore, less handling will result in less spreading of food safety organisms

like *Salmonella* spp. and *Yersinia enterocolitica* which are the two most important sources of infection related to Danish pig meat (Fig. 4 and Fig. 5). To reduce exposure of consumers to these occupational hazards, we suggest that the hearts should be opened by slaughterhouse workers separately after meat inspection and prior to the hearts leaving the slaughterhouse. An opening of the hearts at this stage will also allow the identification of abscesses in the myocardium as well as cases of pericarditis initially overlooked during meat inspection. Presence of any lesion in the heart should result in condemnation of the heart.

Table 8

Estimation of consumer risk associated with Supply Chain Meat Inspection of finishers from integrated production systems, reared in-door, compared to traditional inspection, Denmark, 2008 – the heart

Organ	Release Assessment	Exposure Assessment	Consequence Assessment	Risk estimation
Heart	Endocarditis observed at a prevalence of 0.01% <i>Streptococcus</i> spp. and <i>Erysipelothrix rhusiopathiae</i> main causes	Low probability of exposure to <i>Streptococcus</i> spp. and <i>Erysipelothrix rhusiopathiae</i> . Even lower probability if hearts with lesions are disposed of*	<i>Streptococcus</i> spp. and <i>Erysipelothrix rhusiopathiae</i> are not meat-borne but occupational hazards The number of cases related to <i>Salmonella</i> spp and <i>Yersinia enterocolitica</i> will not increase but maybe decrease	No risk for consumers associated with omission of routine incision into the heart

*: It is recommended that the hearts are opened prior to sales by a slaughterhouse worker, and any heart with lesions should be disposed of.

There seems to be no increased risk for human health associated with omission of routine palpation and incision into the mandibular lymph node or the heart. In line, the number of human cases is not expected to change with the introduction of Supply Chain Meat Inspection. This is conditioned on that if lesions are found, the carcass should be subjected to extended meat inspection.

This conclusion is valid for finisher pigs, reared in-door in herds that are part of an integrated production system and where exchange of food chain information is in place

This is in line with Hathaway and McKenzie (1991): As tuberculosis and other classic zoonoses have become rare in most developed countries, contamination of carcasses during slaughtering, dressing and meat inspection is the main public health hazard linked to meat.

We expect that around 90% of the finishers slaughtered in Denmark will qualify for Supply Chain Meat Inspection. A documentation-and-auditing programme for the herds supplying finishers is required to ensure the correctness of the food chain information; in particular, whether the pigs were kept in-door since weaning. Moreover, performance standards for the meat inspection are needed to conduct an effective quality control. Finally, training of personnel is required so they are prepared for this way of meat inspection. All these issues have been dealt with prior to the possible introduction of the Supply Chain Meat Inspection (Anon., 2008b). However, these issues will not be described here because they are not a part of a risk assessment.

Summary of section 9: there seems to be no increased risk for human health associated with omission of routine palpation and incision into the mandibular lymph node or the heart conditioned on if lesions are found, the carcass should be subjected to extended meat inspection. This is valid for finisher pigs, reared in-door since weaning, in herds that are part of an integrated production system and where exchange of food chain information is in place.

10. Conclusion

According to the risk assessment, the two suggested changes to the traditional meat inspection – the omission of the routine incision into the mandibular lymph nodes as well as the routine opening of the heart – seem to have limited impact on food safety. Nor is there a negative effect on the zoo-sanitary status. Finally, the preliminary assessment indicated that the modernisation will have a positive impact on the working environment. These conclusions are valid for finisher pigs reared in-door and originating from herds belonging to integrated production systems where exchange of food chain information is in place prior to slaughter. In case lesions are observed on the carcass, the carcass should undergo extended meat inspection. Hearts should be opened by slaughterhouse workers prior to sales to remove blood coagula from the hearts. Any heart with abnormal findings should be condemned.

We call this way of slaughter Supply Chain Meat Inspection – The Danish way.

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Appendix A: Sample size considerations

Initially, we decided to collect a sample size large enough to be able to estimate the prevalence of *M. avium* in finisher pigs and to look into whether there was a difference in the prevalence of microorganisms in pig hearts with and without endocarditis.

We subsequently used the data regarding prevalence of each of these conditions from the DMA slaughterhouse database. The prevalence of both lesions is about 0.01%. That implies that if 1 mio. pigs are slaughtered, then we would expect 100 cases of granulomatous lymphadenitis and endocarditis, respectively. This was a reasonable sample 100 lymph nodes with granulomatous lesions as well as 100 hearts with endocarditis and 100 normal hearts acting as controls.

Objective 1: Lymph nodes

However, for the lymph nodes we discovered problems in collecting the desired number of samples. This was because 1) granulomatous lesions are more common in the mesenteric lymph nodes than in the mandibular lymph node, hence, there were very few cases of granulomatous lymphadenitis in the mandibular lymph nodes seen, and 2) slaughterhouse workers routinely cut out observable changes in the mandibular lymph nodes before the carcass reaches the meat inspectors. We succeeded in collecting 43 samples from the mandibular lymph nodes. This limited sample size was negative for tuberculosis; however, it is far from large enough to conclude anything about the prevalence of *M. avium*. Therefore, we collected information about findings of tuberculosis in poultry and pigs from the official veterinary laboratories. These data supported the results of the small study: the prevalence of *M. avium* in finisher pigs in Denmark is very low. However, we are not able to estimate the prevalence closer than this.

Objective 2: Comparison of hearts with and without endocarditis

Also here, we had problems in collecting the desired number of samples; however, to a lesser degree (we got 88 hearts with endocarditis and 56 heart without endocarditis).

Pig hearts with endocarditis are considered unfit for human consumption, since it is believed that occupational hazards like *Erysipelothrix rhusiopathiae* or *Streptococcus* spp. might be present in large numbers and hereby expose the consumers. The zero-hypothesis was that there is no difference in the prevalence of zoonotic bacteria between hearts with and without macroscopic endocarditis. To estimate the needed sample size to evaluate the hypothesis the software programme EpiInfo version 3.4.3 November 2007 was used.

The following parameters were chosen:

Confidence level: 95%

Power: 80%

Ratio between case and control: 1:1

Exposure among controls: 10%

Exposure among cases: 26%

Resulting sample size (n) = 99 of each group => 198

During the study we came to the conclusion that it was of higher importance for us to get an idea about which pathogens are present in hearts with endocarditis than to compare between hearts with and without endocarditis (there were obvious difference in the prevalence of the pathogens found). And here we saw that the sample size obtained (88 hearts) was indeed providing us with that information.

Appendix B: Comments from external reviewers

Review of the "Assessment of risk due to proposed changes to carcass inspection of finisher pigs in Denmark"

Katharina Stärk, Professor, Veterinary Public Health, Royal Veterinary College, London, Great Britain

General comments

This risk assessment presents evidence related to possible effects of changes in organoleptic meat inspection of slaughter pigs in Denmark. The specific proposal is to move the following specific elements of meat inspection to visual inspection:

- a) The incision and palpation of the major mandibular lymph nodes
- b) The opening and incision of the heart

The outcomes of the assessments are food safety risks for individual consumers, but also national zoo-sanitary risk and occupational risk.

1. For communication purposes, it could have been useful to translate the risk outcome into number of additional cases of human infection/disease per year, but necessary information may not be available. ***We do not expect that the number of cases will change. We have highlighted this in section 6.2, Comparison of traditional inspection with Supply Chain Meat Inspection and in section 9, Risk estimation. Only if the meat inspectors and slaughterhouse workers can keep their hands in the pocket as much as possible and only touch the carcass when necessary, then there is definitely a lower probability of spreading Salmonella and Yersinia. This is explained in section 1.2, Identification of relevant modification to the meat inspection as well as in section 6.2, Comparison of traditional inspection with Supply Chain Meat Inspection.***

2. The impact on zoo-sanitary risk and ergonomic risk are considered at much lower level of detail than food safety risks. They are only discussed at the end as part of the risk estimation. For hazards discussed in sections 6.2.2-6.2.6, it is not clear why these additional hazards are introduced here. These pathogens do not lead to specific lesions that would be affected by the proposed changes and meat inspection in general and the specific elements considered in this assessment are not usually considered critical for the detection of these hazards. I propose to delete them and only mention additional effects in a more general way. ***We included zoo-sanitary hazards into the risk assessment because it is important for a large pig producing and exporting country like Denmark to ensure that we are not jeopardizing animal health when we change meat inspection. This is both for the sake of our own pig production and related to the export of breeding pigs and pork. You cannot be certain about side-effects related to a change in management unless you evaluate it carefully, which is what we have done. We have inserted a couple of sentences that explains this in the beginning of section 7, Impact on zoo-sanitary status.***

3. Similarly, for ergonomic risks, not enough data are presented to make this a formal element of the assessment in my opinion. ***The evaluation is only preliminary because we do not have sufficient data to make a thorough evaluation. This was already stated in section 1.4, Aim. We have made this clearer in the layman summaries and in section 8, Impact on working environment as well as in section 9, Risk estimation and section 10, Conclusion,***

4. In terms of risk management, the use of food chain information (FCI) as well as requirements for pigs to be produced in an integrated production system are mentioned from the beginning. However, the benefits

of these measures and how they would contribute to offset potential negative effects does not become clear. For example, the occurrence of pathogens is likely to be clustering within farms. Additional information on the possible clustering of the pathogens of concern would therefore be useful together with the discussion of the use of FCI in this context. ***In section 1.2 we have inserted a description of how we expect that the diseases pattern of finishers from integrated production systems that are kept indoor since weaning have less variation than pigs from other production systems. Moreover, in section 6.1, Regulatory framework, we describe that Supply Chain Meat Inspection will include a documentation-and-auditing programme of the finisher pig herds and that performance standards have been developed – but this is not a part of the risk assessment and hence not described here. We repeat this in section 9, Risk estimation. A reference to the programmes is given (Anon., 2008bc).***

5. It is not clear how many farms/pigs would fulfil the selection criteria regarding integrated production system and would therefore be processed in such a way. This appears to be an important dimension that would impact on the annual risk to consumers. ***Around 90% of the annual production of pigs would qualify for Supply Chain Meat Inspection. This we have mentioned in section 9, Risk estimation.***

6. The section on comparative risk in the NL who uses the same approach which was assessed by USA is useful. If the USA did also conduct a risk assessment, more specific details on that would be interesting. ***In section 1.3, Risk based meat inspection in other countries, we have elaborated on the description of the process that was carried out in the US with respect to modernisation of meat inspection.***

7. Two specific studies were conducted to provide additional data required for the assessment. However, very little information is provided regarding the sampling approach used. It would be important to ascertain that the samples were representative. ***In Appendix A we have described our intentions to collect 100 lymph nodes and hearts respectively. We have also described why we did not reach this number. This is now also mentioned in section 1.2, Data collection. We find that the combination of data (own-collected, official data from the veterinary services, as well as expert opinion) provide a better background for estimating the prevalence than 100 or even 500 lymph nodes could have provided when seen in isolation. This is already described in section 2.2.***

8. In study 2, it would be interesting to know how many of the carcasses would have been condemned if the inspection of the heart was visual only. ***We recorded presence of other lesions on 28% of the endocarditis cases. These lesions would have resulted in condemnation. We find that this figure probably underestimates the true proportion of endocarditis cases that has other lesions. This is explained in section 6.2.2, The heart.***

9. In general, I would have welcomed a bit more structure in the assessment, for example, at the end of each section you could have summarised the conclusions in terms of qualitative probability as well as uncertainty of the finding. The latter is currently completely missing and should be added. All steps can then be summarised in a final table as you have done in your Table 7. ***We have inserted a short summary at the end of each section. We have explained about the uncertainty in section 5.2, Observed number of human cases in Denmark. We have also inserted two new figures (Fig. 4 and Fig. 5) which in a graphical way displays the exposure risk (what are you exposed to) and the consequence risk (what do you get ill from) and herein explained about the uncertainty related to the prevalence estimates. The figures are also explained in the text in this section.***

10. A graphical risk pathway could have been provided as additional information and to provide structure. ***Please see Fig. 4 and Fig. 5 and the comments to issue number 9.***

Specific comments:

11. In Table 3, the use of the term "negligible risk" requires a risk management decision as to what is acceptable. This level should therefore be defined, e.g. 1 in 1 Mio. for Salmonella and Yersinia. In the same table, should it not say "reduced risk of cross-contamination"? The table is a little confusing as it is focusing on food safety risk (as stated in caption) but also includes occupational risks. For the latter, it is not clear what type of cross-contamination would be relevant. I would have expected direct exposure to be most relevant. ***We have exchanged the term "negligible risk" with "no risk" where we are talking about bovine TB – because as you mention it is the risk manager and not the risk assessor who decides what is negligible or not. Moreover, table 5 (former Table 3) has been revised.***

12. Figures 2 and 3: The data look a bit odd, as if there were identical values for most years. In Figure 2, there is no explanation why values in 1999 and 2007 are so different. ***You are right – it did look odd, and it was because too few decimals were used when creating the figures. That is now corrected in Fig. 2 and Fig. 3.***

13. Hazard characterisation: It is not clear whether *R. equi* infection might be food-borne. ***R. equi is not known to be food-borne. This is now specified in section 3.1.2. Two more references are inserted which shows that when R. equi causes infection it is most frequently in immunosuppressed patients like HIV-patients or transplantation patients***

14. P. 13: Are there any data on number of cases in meat inspectors due to heart incision/pathogens found there, e.g. Erysipeloid. Would these carcasses normally go into the food chain? ***A contact to the slaughterhouse workers' union (NNF), the Confederation of Danish Industry as well as the slaughterhouse Danish Crown revealed that human cases of Streptococcus and Erysipelothrix are occurring at such a low prevalence that it is not considered a problem (Mogens Eliassen, NNF, personal communication). This has been inserted into section 5.2, Observed number of human cases. A part of the carcasses would go into the food chain – as also demonstrated in Fig. 3.***

15. Are there any reported cases due to *S. suis* in slaughterhouse workers? I would expect slaughterhouses to have such data. ***Same answer as to question.14***

16. P. 16: The term "circular" is not very clear, do you mean cycle? ***No, a circular is a part of the regulatory framework. We have changed the title of section 5.1 to Regulatory framework and we have elaborated a bit on the sentence in this section to increase understanding.***

17. Section 6.1.(current section 5.1) Arguments are not reproducible for all pathogens, particularly not for "mild" categories. Information or other justification should be provided. ***You could elaborate a lot on this table, but the intention is merely to give an overview of the consequences of infection of the different hazards, so we decided to stop here.***

Evaluation of the report "Assessment of the risk for humans associated with specific changes in meat inspection of Danish finisher pigs, 2008"

Truls Nesbakken, Professor, Food Safety, Norwegian School of Veterinary Science, Oslo

General comments

The assessment of the risk for humans associated with specific changes in meat inspection of Danish finisher pigs is carried out in a scientific and thorough way. Based on the available documentation presented, the conclusions are reasonable.

1. I fully agree with the conclusions of Hathaway and McKenzie (1991): As tuberculosis and other classic zoonoses have become rare in most developed countries, contamination of carcasses during slaughtering, dressing and meat inspection is the main public health hazard linked to meat. **Reference cited and inserted in section 7, Risk estimation**, The specific changes in meat inspection described in the Danish risk assessment report, and in particular, the avoidance of incision of lymph nodes is a step in the right direction in a veterinary public health perspective.

2. In general, I do not think that it is right to conclude that "risk-based meat inspection" is the same as "visual meat inspection" (per definition), and used as a synonym, see for instance in Table 3, and page 17, headline: "Comparison of traditional inspection with risk-based inspection". "Comparison of traditional inspection with visual meat inspection" might be more optimal. This is also one of the discussions which we had during the completion of the Nordic Council of Ministers report "Risk-based meat inspection in a Nordic context" (Tema Nord, 2006), and may be it should have been discussed and clarified in the Danish risk assessment report as well. **You are correct – we should be more specific. We have changed the title in Table 3 (Table 5 in new version of report) to say that we are comparing traditional meat inspection with Supply Chain Meat Inspection. Moreover, in section 1.2 Identification of relevant modifications to the meat inspection we have defined Supply Chain Meat Inspection and listed the requirements to the herds.**

Some specific comments

3. Some more aspects connected to avoidance of incision of lymph nodes might be mentioned. One example is that some tumours will not be detected i.a. melanoma in duroc pigs (Anon. 1991). **We agree with you and have extended the discussion in section 6.2.1, The mandibular lymph node.** However, additional arguments and references show that there are some doubts connected to the efficiency of incision of lymph nodes and support the conclusions in the report:

4. A number of mycobacterial infections in pigs caused by *M. avium* might not be detected by incision of lymph nodes because the lesions are not visible. Hird et al. (1983) isolated *M. avium* from 6.7% of 280 *Inn. mesenteriales* with no visible lesions, **Inserted into section 6.2.1, The mandibular lymph node**

5. Due to the difficult work conditions and the limited time available, the validity of the quality of the classification of lesions has been questioned (Willeberg et al., 1984/85), **Inserted into section 6.2, Comparison of traditional inspection with Supply Chain Meat Inspection**

6. Many of the younger meat inspectors in the Nordic countries have never seen tuberculosis in slaughter animals or some of them might even not be familiar with its appearance, and the disease

might not be detected. ***We believe that when the lesions are large and observed in several lymph nodes, then they will be found. This is inserted into section 6.2.1.***

7. Infection with *M. avium* might also be detected by visual inspection of the liver. In this context it is important that the meat inspector is able to distinguish mycobacterial lesions in pig livers from spots of other origin, especially "milk spots" caused by ascarid larvae (Alfredsen, 1992). ***We agree with you - training of personnel is important. We have used the reference in section 6.2.1, The mandibular lymph node, and listed it in the reference list. Moreover, in section 9, Risk estimation, we have highlighted the need for training of personnel and explained that this is a part of the Supply Chain Meat Inspection.***

8. One comment in the end: Both the words "carcasses" and "carcases" are used in the report. ***This has been corrected so only one kind of spelling (carcasses) is being used throughout the report***

9. References

We would like to thank you for suggesting these scientific papers to us. We have used them all

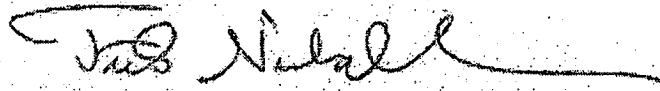
Alfredsen, S.A, 1992. Differentiation between parasitic interstitial hepatitis and mycobacterial lesions in pig livers. Bull. Scand. Soc. Parasitol. 2, 33-35. ***Used in section 6.2.1, The mandibular lymph node, and cited in the reference list***

Hathaway, S.C., McKenzie, A.I., 1991. Postmortem meat inspection programs; separating science and tradition. J. Food Protect. 54, 471-475. ***Reference used in section 9, Risk estimation, and cited in the reference list***

Hird, D.W., Lamb, C.A., Lewis, R.W., Utterback, W.W., 1983. Isolation of mycobacteria from California slaughter swine. In: Proceedings of the United States Animal Health Association, 87th Annual Meeting: 559-565. ***Reference used in section 6.2.1, The mandibular lymph node, and cited in reference list***

Nord, 1992. Kjøttkontroll i de nordiske land – forslag til harmonisering og modernisering av regelverk, Nordic Council of Ministers, Copenhagen, 122 pp. ***We believe that you are referring to a reference already cited in reference list under Tema Nord, 2006. You are also referring to it in your comment number 2.***

Willeberg, P., Gerbola, M.A., Kirkegaard Petersen, B., Andersen, B., 1984/1985. The Danish pig health scheme: Nation-wide computer-based abattoir surveillance and follow-up at the herd level. Prev. Vet. Med. 3, 79-91. ***Cited in section 5.2, Comparison of traditional inspection with Supply Chain Meat Inspection, and listed in reference list***



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External review of the report "Assessment of the risk for humans associated with specific changes in meat inspection of Danish finisher pigs"

I have been asked by Dr. Lis Alban to be one of three external experts to forward comments on the report presented. I have reviewed the report critically based upon my knowledge of meat inspection, epidemiology and risk assessments. My review has been undertaken without any discussions with dr. Nesbakken and dr. Stärk, the two other external experts.

The risk assessment is written within the approved tradition of OIE, a slightly different approach than the Codex Alimentarius approach. The work is a consequence of changed regulations in the EU, and builds upon a firm Nordic tradition of scientific views on the local adaptation of meat inspection with the infection status of pigs we have in the Nordic countries. Hopefully the report will also open for other countries to establish similar or other modifications of the meat inspection procedure for pigs.

I hope that my report will contribute to the important work of implementing a real risk-based meat inspection – not only in Denmark but also other countries.

I have some critical comments to the report, but fully support the conclusions presented.

Yours

Eystein Skjerve
Professor

Introductory comments

The specific comments cover the different parts of the reports, where the strengths and some weaknesses of the report are commented on. In spite of certain weaknesses, the report argues well and the conclusions are well supported.

Abstract

The abstract summarizes the report in an adequate way, and brings the reader into the questions addressed as well as summarizes well the conclusions of the report.

Introduction

The introduction comments on the term risk-based meat inspection, refers to the reports of importance and the legislative changes the last years. Of special importance is the documentation of the quality of the chain information in the Danish pig production chain. It is likely that Denmark has the pig production chain with the best documented production and disease status in the world, also including a professional interaction between the pig industry and the national authorities.

1. Based upon 4 criteria, the report presents the procedures questioned; the incision of mandibular lymph nodes and the opening of the heart. The report is a bit unclear on this point, and it is suggested that the report may present the reason for these two procedures to be questioned, as there is no direct relationship between the 4 criteria and the two (relevant) procedures. The form required of the risk assessment template may be one reason for this, as in principle the hazard identification should be the part where this is done. *The identification of which modification to change was revealed through discussions with meat inspectors working at the slaughterhouse as also states in section 1.2, Identification of relevant modifications to the meat inspection. Then we evaluated the chosen modifications (omission of incisions into lymph nodes and heart) against the four criteria – so there is no direct relationship prior to that.*

The arguments against the use of the two procedures are linked to the disease situation in Denmark and the possible contamination of the carcasses by the incisions made in the procedures. Of special importance is the fact that it is possible to reduce contamination from enteric as *Salmonella* or *Yersinia* by avoiding the mandibular incisions. The report also brings the most important references documenting that visual inspection procedures are found as efficient as incision-based procedures. The report gives a proper introduction to the experiences from other countries, especially the Netherlands and USA, with Sweden in line without having concluded on any change so far.

The introduction ends with presenting the aim of the report, in full line with the rest of the introduction. For the reader, this aim may seem self-evident after reading the rest of the introduction, but it is still relevant to present the aim in such a precise way.

Materials and methods

2. After describing the essentials about the risk assessment procedures used, before presenting the data used in the risk assessment. There is an abundance of data from the Danish system, and some are presented in the report. Figure 1 and 2 could have been presented a bit more clearly with more marks on the y-axis, and Figure 2 gives a strange impression with the 1999 and 2007 almost exactly the double of the intermediate years. *We have corrected Fig. 2 and Fig. 3. The odd appearance was a result of choosing too few decimals.*

As an input to the risk assessment, 25 mandibular lymph nodes and 76 abnormal/ 56 normal hearts were sampled. These data and their use are commented upon later.

Hazard identification

As in most microbiological risk assessment, the hazard identification seems a bit artificial, but the authors were strict to the procedures described, and this is more a reflection of the problems of using the risk assessment template. It does, however bring the basic information about tuberculosis in animals, also referring to the fact that Denmark is considered free of *M. bovis*, while the *M. avium* can occasionally be found in pigs. As the report states, there are no indications that *M. avium* lymph nodes represent any substantial health risk. Of more interest is the documentation that bacteria causing endocarditis in pigs are more likely an occupational hazard than a food borne hazard, underlining that it may be better not to incise the heart.

Release assessment

The main part of this chapter is based upon previous Danish data and data from the Netherlands, but the table brings the results from the current examination of the 25 lymph nodes as well as describes the bacteria found in the hearts with and without endocarditis. As the chapter stands, the data from the current dataset have a very small number of observations, and the main rationale behind the conclusions is linked to previous, published studies and not to the presented current data – although they are in line with the previous data.

Exposure assessment

The most interesting part here is the comparison between traditional meat inspection and the suggested revised procedure. As mentioned, a full visual procedure is not in question here, only removing two of the incision procedures. The main arguments are summarized in Table 3, where it is clearly documented that the revised procedure may be a better procedure for public health concerns. The lack of documented links between most agents in pigs and food borne infections are well documented in Table 4, where it correctly is stated that under the Danish scenario, the main public health concerns linked to pork are two enteric bacteria (*Salmonella* and *Yersinia*), which may be promoted by the incisions in the traditional procedures.

Consequence assessment

3. This is a bit long, and also brings in other zoonotic agents not present in Denmark and exotic swine diseases. It may be an idea to delete these from the report, or possibly mention them only in the introduction and not focus on these on the consequence assessment. It would be easier to read the chapter if the focus on possible agents linked to mandibular incisions and heart opening were focused. A strong side of the text on consequence assessment is the discussion about the impact on the working environment. *Denmark is a large exporter of breeding pigs and pork. Hereby, it becomes very important to stay free of exotic animal diseases. Any change you make might have unexpected drawbacks which can only be predicted if a careful analysis has been made – which is what we have done. But we do agree that the chapter was very long. We have divided the chapter into three chapters: Consequences (section 5), Zoo-sanitary impact (section 7), and Working environment (section 8). This will hopefully make the report more readable.*

Risk estimation

4. This chapter is the best part of the report, and brings a clear and concise message about the assessments presented. The arguments behind the conclusion are mainly qualitative (appropriate enough), and it remains a bit obscure how the new data brought into the report were used. The report could have been written without these data, with exactly the same conclusions. However, I fully support the views of this chapter. *We were of the opinion that it would be useful to collect own data in relation to the risk assessment, and we agree that the sample size stated in the version of the report that was sent for external review (25 lymph nodes and 76 hearts) was not going to impress anybody. Since then, more lymph nodes and hearts have been collected and analyzed. By November 28, 2008, we have 43 lymph nodes and 88 hearts with endocarditis, which is a bit better than the numbers we had the*

previous month. We are of the opinion that the best picture is when multiple sources of data are collected: own data, official laboratory data, expert opinion and published literature. If all these data point to the same direction, then we feel more confident about the conclusion. We have explained about this approach in section 2.2, Data collection

Conclusions

The conclusions are written clearly and directly to the point, and there is no doubt that the conclusions are rational.

Appendix A. Sample size considerations

5. The text on lymph nodes and the number of samples demonstrates that these data really could not mean much for the conclusion of the report. For the heart, the authors claim that a case-control approach would result in 99 samples in each group. This sample size approach is very crude and the real life is a bit more complex, as there are several categories of bacteria detected. Further, if the problem was the lack of heart samples, it would be easy to obtain more negative samples for culturing to improve the power of the study. Again, it seems as these data are not really important for the conclusions taken. It may be better to delete the appendix and rather bring the necessary text into the report itself – or delete the use of these data. *The appendix A on Sample size considerations has been rewritten. Please, also see comment to Risk estimation.*

Conclusions from the reviewer

I agree with the conclusions drawn and support the view that Denmark should allow a simplified procedure for certified herds of pigs, omitting mandibular incisions and heart opening.

6. However, the report could have brought forward the same message in a much shorter form, as the literature cited without doubt supports the conclusions. The risk assessment form chosen seems to obscure the question more than needed. *For people working in the area of meat inspection, a large part of the risk assessment seems obvious (and could be written in a shorter way). But for those who are not familiar with the area (politicians), or interested in food safety in general (like consumer protection groups) it is necessary to carefully analyze the impact of the suggested changes. In line, for a meat inspector who has been working with one regulatory framework for years, and is now being asked to change, it makes sense to provide him or her with a thorough analysis dealing with all concerns there might arise. Finally, an importing country might not be aware of the specific situation in Denmark which allows for a specific conclusion; again here a careful evaluation is needed.*

7. Having said this, I accept that the template of a risk assessment may have to be used in these evaluations, but this more shows that risk assessment may have severe limitations in this rather simple situation, where using such a template mainly leads to a report of many more words than necessary. *Yes, the report is long. Hopefully, the edited version with a better division into chapters and sections might assist in identifying the issues of importance to the individual reader. We have also chosen to summarize each chapter.*

8. A more relevant objection to the report is the use of the new data used in the report. The low number of mandibular lesions has of course no documentation effect compared to the overwhelming historical documentation of the absence of *M. bovis* in Denmark. Further, the sample size calculations for the heart data are rather crude. The authors may consider deleting these two datasets from the report, as they do not influence the conclusions, and only seem to be there to justify that some new empirical data have been presented. *Same comment as to issue number 4, Risk estimation*

Appendix C: Impact of disease on the individual

Table C1

Assessment of impact of specific diseases possibly related to pigs and pork on the individual human

Pathogen	Symptoms	Duration	Complications	Hospitalization	Mortality	Assessment ^a
<i>Streptococcus suis</i>	Fever, nausea and vomiting ^b		In severe cases meningitis, skin bleedings, toxic shock and coma ^b	Yes, in severe cases	20% ^a	Mild to Severe
<i>Staphylococcus aureus</i>	Vomiting, diarrhoea, headache ^c	1 day ^c <2 days ^e	No	No	Close to 0%	Mild
<i>Erysipelothrix rhusiopathiae</i>	Localized cutaneous infection or diffuse cutaneous disease			No	Close to 0%	Mild
<i>Mycobacterium bovis</i>	Fever, weight loss, fatigue. Lung-tuberculosis: coughing and expectorate	Months to years		Yes		Severe
<i>Mycobacterium avium</i>	Small children: glandular symptoms. People with pre-existing lung infection: pulmonary infection. HIV/AIDS patients: disseminated infection	Months to years		Yes, in vulnerable groups	High in untreated HIV/AIDS patients	Severe among vulnerable groups
<i>Campylobacter</i> spp.	Self-limiting gastroenteritis	2-7 days ^e 5-10 days ^c	Relapse with abdominal pain. Infrequently reactive arthritis ^c , and rarely Guillain-Barré syndrome (neurologic illness) ^{c,e,f}	5%	Close to 0% - 1 pr. 20.000 ^b	Moderate
<i>Salmonella</i> spp.	Gastroenteritis, diarrhoea, vomiting	Mild course: 2-5 days ^e . Up to several weeks ^c	Infrequently sepsis (few percent) ^c appendicitis, arthritis, meningitis, peritonitis ^e	Yes, when sepsis occur	0,1% ^c - 0,7% ^{fg} - depending upon <i>Salmonella</i> strain	Moderate
<i>Yersinia enterocolitica</i>	Enterocolitis, diarré, diarrhoea, arthralgia. Appendicitis-like syndrome in children ^e	14-22 days ^e 5-14 days ^e . However up to months ^{c,e,f}	Infrequently reactions in skin and connective tissue. Reactive arthritis 10-30% ^f . Sepsis rarely seen ^c	Sepsis is possible but often caused by blood transfusion	Sepsis: 7.5-50% ^f	Moderate

References to Table C1

- a) The assessment is based on the most common form of infection seen
- b) <http://www.ssi.dk/sw32119.asp>
- c) Anon, 1999. Vejledning om vurdering af patogene mikroorganismer i fødevarer. Fødevaredirektoratet. 80 pp.
- d) <http://www.ssi.dk/sw665.asp>
- e) Anon, 1996. Microorganisms in foods, 5. Microbiological specifications of food pathogens. ICMSF, Blackie Academic & Professional. London, England
- f) Anonym, 2002. Infections of the gastrointestinal tract, second edition. Lippincott, Williams & Wilkins.
- g) Helms, M., Vastrup, P., Gerner-Smidt, P., Mølbak, K., 2003. Overdødelighed i relation til antibiotikaresistent Salmonella Typhimurium. Ugeskrift for Læger. 165, 235-239.

Layman summary – in English

A modernisation of meat inspection will make it possible to deal with the hazards that are relevant today. A risk assessment of Danish finisher pigs shows that it is unnecessary to cut into the mandibular lymph nodes and the heart routinely when slaughtering finisher pigs. A precondition is that the pigs originate from integrated production systems, where the pigs are kept indoor since weaning. And that food chain information is made available to the slaughterhouse prior to slaughter.

The aim of meat inspection is to ensure that the meat we consume is savoury and safe. Around 100 years ago people became ill from bovine tuberculosis and brucellosis. Meat inspection was designed to identify and dispose of carcasses from animals infected with these bacteria. Meat inspection is – in other words – targeting the hazards that were important 100 years ago. Since, bovine tuberculosis and bovine brucellosis have been eradicated from Denmark. Nowadays, other hazards fill up the statistics for food borne disease. In particular, Salmonella and Campylobacter are resulting in a larger number of human cases.

The rules for meat inspection should be updated to take into account the hazards that are most important at a given point in time. This is the philosophy behind recent changes in the legislation of the European Community that have made it possible to update the meat inspection. There are three requirements, which should be fulfilled. Firstly, a risk assessment should be undertaken. And this should demonstrate that the suggested changes do not jeopardise food safety. Secondly, only finishers from integrated production systems, where pigs are kept indoors since weaning can undergo a modernised meat inspection. And thirdly, the pig herds should ensure that food chain information has been made available to the slaughterhouse prior to slaughter. This includes among other data on use of antibiotics.

Two questions are relevant in relation to slaughter of Danish finisher pigs. Firstly, what is the effect of cutting into the large mandibular lymph nodes? Secondly, what is the effect of opening the heart? Both are done routinely today. The idea is only to make these incisions on carcasses where pathological changes are observed. This might reduce the spreading of Salmonella and Yersinia bacteria for the benefit of the consumer.

A risk assessment was undertaken in collaboration between University of Copenhagen (the former Royal Veterinary and Agricultural University), the Danish Veterinary and Food Administration and Danish Meat Association (DMA). The aim was to assess the impact on the suggested changes on food safety. Furthermore, it was of interest to evaluate the impact on the ability to identify exotic animal diseases, like foot and mouth disease. Finally, it was the intention to get an idea of the impact of the working environment on the slaughterhouses.

Samples were collected from ten Danish slaughterhouses. Mandibular lymph nodes with granulomatous/caseous lesions (the lymph nodes looks like gritty cheese on the inside) were collected and it was investigated which bacteria had caused the altered look. In line, it was investigated which bacteria were present in hearts with infection on the inside. Moreover, information was collected from the DMA slaughterhouse database as well as from the literature and experts.

The results show that the prevalence of granulomatous/caseous lymph nodes is very low among Danish finisher pigs (0.01-0.02%). Several pathogens might lead to this appearance among others avian and bovine tuberculosis. And the fear of bovine tuberculosis is in fact the reason for cutting into this lymph node. Denmark is officially free from bovine tuberculosis since 1980. Moreover, an extensive surveillance program is in place. Therefore, there is no risk of bovine tuberculosis as a result of Danish pork.

No bacteria were found in 35% of the collected lymph nodes. In 63% a bacterium called *Rhodococcus equi* was found, and in one case a bacterium called *Nocardia* was found. Neither *Rhodococcus equi* nor *Nocardia* are food-borne.

Veterinarians from official Danish laboratories stated that between zero and three cases of avian tuberculosis in poultry are found annually. The cases consist primarily of old hens from backyard herds or from zoological gardens. Approximately the same number of pigs is investigated, and occasionally avian tuberculosis is found. Human cases of avian tuberculosis are seen, in particular among AIDS patients. According to the literature the source of human infection is found in the environment. Avian tuberculosis bacteria are e.g. found in water, sphagnum, and cigarettes. When pigs are slaughtered, the mandibular lymph nodes are removed and end up in pet food after adequate heat-treatment.

Conclusively, there is no risk for humans associated with the omission of the routine cutting of the mandibular lymph nodes. On the contrary, unnecessary palpation and cutting will increase the risk of spreading bacteria such as *Salmonella* and *Yersinia*.

If pig hearts are not opened routinely, cases of infection on the inside of hearts might be overlooked. According to the DMA slaughterhouse database this occurs only at seldom (0.01%). The collected data shows that such infections are primarily caused by *Streptococcus* bacteria (51%) or swine erysipelas bacteria (32%). The types of bacteria found are primarily occupational hazards since they are known for giving rise to infections in wounds in people working with live animals or carcasses. These bacteria are generally not food-borne.

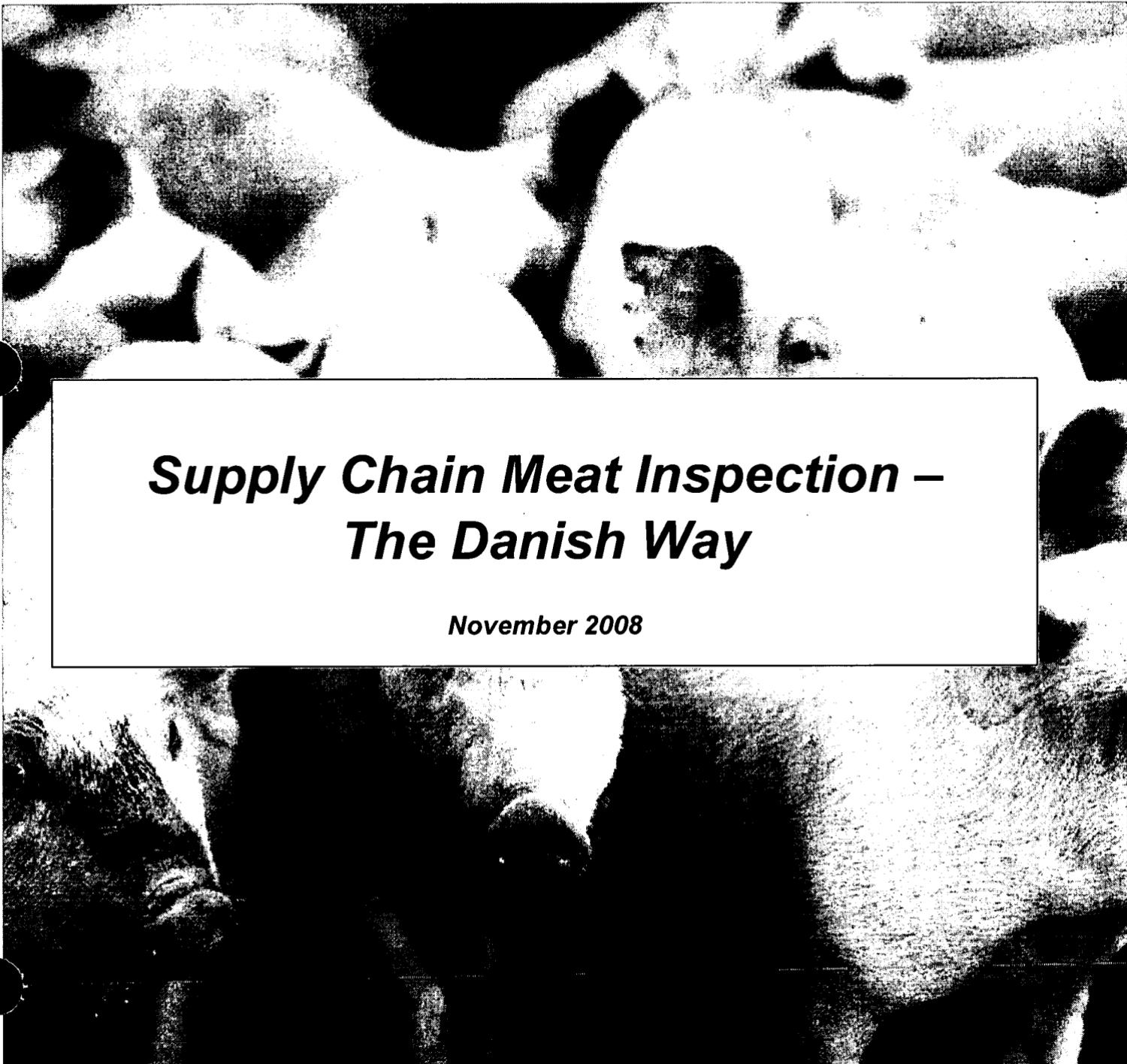
Other serious pathological changes were observed in 28% of the cases where infection on the inside of a pig heart was found. That led to an extensive control of the carcass and presumably to condemnation. Hearts are sold to supermarkets etc. They need to be opened to clean the heart from blood coagula prior to sales. If changes are seen when opening the heart, it will be disposed of. This can be conducted by slaughterhouse workers separately and after meat inspection. This will lower the spreading of bacteria to the rest of the carcass. The judgement is that there is no extra risk for the consumer, because the bacteria possibly present are not food-borne.

Exotic animal diseases are more easily observed in live animals than on carcasses. *Trichinella* is an exception and requires laboratory testing. In Denmark, extensive surveillance programs are in place. Hence, the ability to find these infections is not affected by the suggested changes to meat inspection.

Regarding the working environment, the preliminary assessment showed that fewer cases of cut damages are expected if the routine cutting of hearts and lymph nodes is omitted. Moreover, the strain of physical activity will probably be reduced, because the slaughterhouse workers do not have to bend over the carcass to palpate and cut routinely.

Conclusively, there is no risk associated with the omission of the routine cutting into the mandibular lymph nodes and the heart. There seems to be a positive effect on the working environment. And there is no impact on the ability to find exotic animal diseases. We call this way of slaughter "Supply Chain Meat Inspection – The Danish way" to emphasize that it is based on requirements to the pig herds.

The risk assessment can be found on the homepage of the Danish Veterinary and Food Administration on <http://www.foedevarestyrelsen.dk/forside.htm> and DMA <http://www.danishmeat.dk/Forside.aspx>



***Supply Chain Meat Inspection –
The Danish Way***

November 2008

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0. Summary

Within the framework of national and EU-legislation, it is possible to use alternative post mortem inspection procedures for finishers kept indoors since weaning.

Denmark intends to make use of this possibility and suggests that routine incisions of mandibular lymph nodes and hearts are replaced by a visual inspection.

This document describes a revised meat inspection system – named the “Supply Chain Meat Inspection – the Danish Way” based on two suggested changes during the post mortem inspection aiming at an equivalence approval of the system by Food Safety and Inspection Service, USA.

The below-mentioned prerequisites will be in place before applying the Supply Chain Meat Inspection prerequisites programs and conditions for delivering pigs for slaughter in order to ensure reduction of incidences of food borne pathogens in finishers. Section 2 describes these preconditions and includes

- the outcome of the risk assessment of the risk for humans related to omission of the routine incisions of heart and mandibular lymph nodes,
- animal health and zoosanitary status in Denmark combined with
- the Danish pig production system ensuring that pigs are borne and raised in Denmark and
- mandatory requirements for Food Chain Information including information on housing condition

Government inspection programs for the identification and removal of unhealthy animals and adulterated carcasses from the supply chain are dealt with in sections 3 and 5.

The accuracy of the performance of the post mortem inspection including visual inspection of lymph nodes and heart for removal of both food safety and non-food safety defects will be enforced through a governmental verification program as described in sections 3 and 5.

The Danish Veterinary and Food Administration will follow the process of changing the meat inspection very closely. If the evaluation of the Supply Chain Meat Inspection indicates major difficulties concerning compliance with the requirements of the Food Chain Information and in particular information on housing conditions, traditional meat inspection may be reintroduced. Depending on the nature of the difficulties in complying with the requirements this may also apply to other slaughterhouses than the slaughterhouse in question.

1. Introduction

The objective of the meat inspection is to control the hazards that constitute a risk for food safety. Moreover, it should be ensured that the inspection of finisher pigs conducted ante and post mortem is performed in a way that results in a high level of food safety. Prior to the introduction of any change to the way that meat inspection is conducted, it must be ensured that food safety and the zoosanitary standards are not affected negatively.

The suggested changes to the Danish Meat inspection system consists of omitting the routine incisions of the mandibular lymph nodes and hearts.

The Danish meat production system is covered by a thorough registration, marking and documentation. This makes it possible to trace the meat through the production chain which is in line with the mandatory requirements of the EU legislation regarding exchange of information from all parts of the food chain before animals are sent off for slaughter = food chain information¹.

¹ EC Regulation 852/2004, 853/2004 and 854/2004)

"The Supply Chain Meat Inspection – the Danish Way" combines the exchange of food chain information between the farmer and the slaughterhouse (verified by the competent authority) with the suggested changes in post mortem inspection procedures for finisher pigs from integrated production systems. Approximately 90 % (21 million pigs) of the pig production originate from integrated production systems, kept indoor since weaning.

2. Prerequisites for changing the meat inspection procedures

a. Risk assessment of the risk for humans related to omission of the routine incisions of heart and mandibular lymph nodes

To identify the changes that needed to be evaluated, an analysis of the entire meat chain was conducted. Any modification of the meat inspection will have an effect not only on food safety, but often also on other aspects like the working environment. Through discussions in Denmark it was revealed that it was questionable whether two specific routine procedures had any positive impact on food safety. The first dealt with palpation and incision of the mandibular lymph nodes and the second with the opening of the heart.

Alban et al. (2008) conducted a risk assessment on the above subject. From the work done it was concluded that the two suggested changes to the traditional meat inspection – omission of the routine incisions of the mandibular lymph nodes as well as the routine opening of the hearts – seemed to have limited impact on food safety. Nor is there a negative effect on the zoosanitary status. Finally, the modernisation is expected to have a positive impact on the working environment. These conclusions are valid for finisher pigs that originate from herds belonging to integrated production systems in which exchange of information is in place prior to slaughter. If pathological changes are observed during routine post mortem inspection, the carcass shall undergo extended meat inspection. The heart shall be opened by slaughterhouse workers before retail sale to remove the blood coagula. Any heart with abnormal findings should be condemned.

b. Production system of finishers in Denmark

The DANISH Standard

In Denmark the production of safe food is ensured within a fully integrated system. Each production stage, from breeding through the processing, contributes to the delivery of safe meat and meat products.

Since no chain is stronger than the weakest link, all types of risks: chemical, physical and biological must be managed and controlled at all stages. Fig. 1 gives an overview of the pig production

The DANISH Product Standard sets up the requirements for production of pigs for pig meat in Denmark, and the owner of the herd is responsible for complying with the requirements of the Standard. All pig herds in Denmark must meet the requirements of the Standard, which is accredited according to the international standard EN45011. An independent body carries out audits of the herds to check and ensure compliance with the requirements of the Standard.

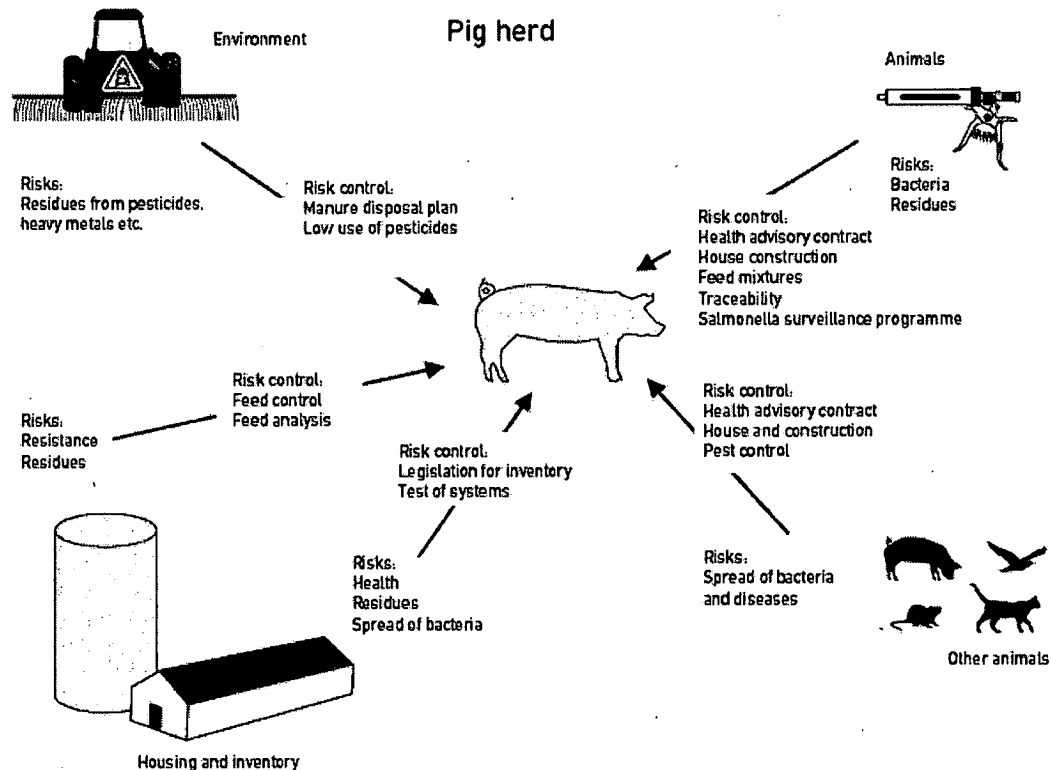


Fig. 1. Pig Production System in Denmark

The main focus of the Standard is on the key areas that affect animal welfare, food safety and traceability in the primary production of pigs. In specific:

- Pig identification and traceability
- Regulation of feed
- Herd health use of medicine
- Treatment of sick or injured pigs
- Housing and equipment
- Management and
- Delivery of pigs

The pig identification system and farm management practices must demonstrate that pigs produced are of Danish origin and that all pigs used in the production are of Danish origin.

The majority – 90% - of Danish pigs are housed in insulated buildings with mechanical ventilation and heating systems. After weaning, the pigs remain in the finishing unit until they reach a weight around 100 kg after which they are dispatched for slaughter. At that time they are about the age of 5 months. In Denmark a medium-sized herd produces 1,000 – 3,000 pigs per year.

As illustrated in fig. 1 a complex set of procedures and controls are in place in the primary production in order to ensure food safety and traceability of the production. Annex 1 contains a brief summary of the systems in place.

Traceability in Danish pig and pig meat production

In Denmark, all pig herds must be registered in the Central Husbandry Register (CHR) with a so-called CHR-No., which ensures a high level of animal identification and registration. The database is owned by the Ministry of Food Agriculture and Fisheries.

To ensure a high level of data quality of the CHR, various procedures of data validation are carried out. These include printouts from the database to the farmers with information about the registered data. The farmer is required to correct discrepancies. The CHR also contains automatic procedures for the following-up on missing, inconsistent or late notifications (The system is called SVIKO).

Food Safety is based on the healthy production and correct use of feedstuff for farm animals intended for human consumption. The Danish Plant Directorate, the Department of Feedstuff and Fertilizers is the responsible body according to national and EU-regulations.

CHR-numbers are used in connection with all contacts between the herd owner and the public system. The register provides a comprehensive view of all animal herds in Denmark. A herd can thus be localised swiftly together with information about all other herds in the area. This can be used in connection with serious disease outbreaks of e.g. Foot and Mouth Disease, during which the CHR-register makes it possible immediately to stop all movements of pigs in a limited area to avoid spreading of the infection.

Fig. 2 on the following page illustrates the route of identification from stable to table described briefly in the following.

When pigs are moved from the original herd (**M1**), i.e. the herd in which they were born, the main rule in Denmark is that they must be supplied with an ear tag approved by the Veterinary and Food Administration and embossed with: DK, a protected logotype plus CHR-number.

Batches of piglets are transported to the slaughterhouse according to a permanent agreement between seller and buyer (**M2**)

The slaughterhouses only receive pigs directly from the farmers (**M3**). The transport for slaughter is coordinated by the slaughterhouse, which also has a contract with each haulage company for the transport. During each trip, the haulage contractor must have information about the place of departure, the destination and the owner of the animals. Before the pigs are loaded at the producer, each pig is marked with a five digit number on each hind leg. This number ('the supplier's number') identifies the supplier to the abattoir.

Approximately 20% of the piglet trade takes place in pool arrangements in which the buyer receives piglets from different herds that can be identified by ear tags (**M4**). The piglets are sold before they are dispatched and therefore the receiver is always known, so is the health condition of the piglets.

As a part of the pig ring agreement, each batch of piglets must have a transport document with information about:

- CHR-numbers, names and addresses of supply and reception herds
- Registration number of the vehicle used for transport
- The number of animals being moved
- Date of movement

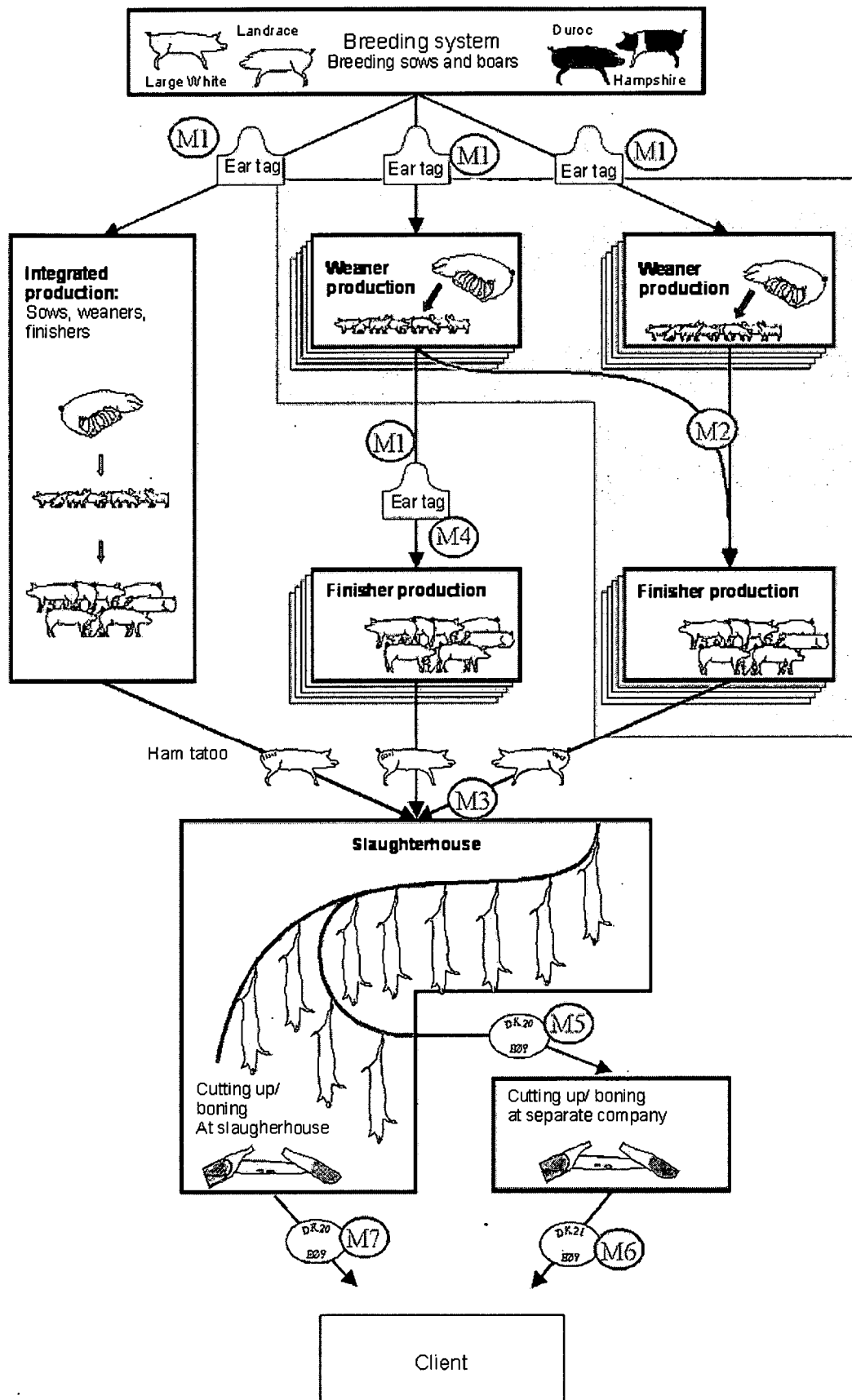


Fig. 2 Traceability stable to table

When the pigs have been slaughtered and the public meat inspection has approved the carcass for human consumption, all carcasses will be stamped with the authorisation number of the slaughterhouse in question (M5).

If the carcasses are cut at another plant, the cuts are marked with the authorisation number of the cutting plant (M6). If the meat products are processed at a separate plant, the products will be marked with the authorisation number of this plant. If slaughter, cutting and processing are carried out in the same plant, only one number is used (M7).

c. The Danish Salmonella Surveillance Programme

In cooperation with the Danish Veterinary and Food Administration the industry has launched an action plan to reduce and control Salmonella in pigs. The first plan was implemented in 1995, and it is constantly adjusted and improved – based on science and data. Right now a fourth plan is being revised.

The control programme for Salmonella applies to the entire food chain from stable to table. The programme comprises the surveillance of all Danish finishing herds that deliver more than 200 slaughter pigs per year, special slaughter of pigs from risk herds and the monitoring of fresh pork at the slaughterhouses. Furthermore, all breeding and multiplier herds and sow herds selling from risk farms are subject to controlled surveillance.

Surveillance on the farm

Surveillance of finisher farms includes sampling of meat juice from slaughter pigs. On a monthly basis, the finisher herds are allocated to one of three levels.

Herds assigned to levels at risks; i.e. levels 2 or 3 are subjected to sampling of faeces, and a reduction plan is recommended in highly infected herds.

Pigs from Salmonella-infected herds at level 3 are slaughtered under increased sanitary precautions. During the slaughter process itself, preventive measures are also taken; e.g. additional personnel on the slaughterline or sprinkling of the carcasses with hot water (82 °C). Besides this, Salmonella-infected pigs are transported separately to the slaughterhouse

Monitoring at the slaughterhouse

On each slaughter day, five fresh carcasses will be tested for the presence of Salmonella. If the prevalence of Salmonella in pork is above 2.2% in 4 out of 6 months, the slaughterhouse must improve its sanitary precautions immediately, and a written action plan must be provided to the competent authority within a month. The implementation of the plan must document a consistent Salmonella reduction within 6 months. If the plan is not met, the Danish Veterinary Authorities might demand new Salmonella mitigating initiatives.

Feed

As a part of the Salmonella surveillance programme all feedstuff companies must produce salmonella-free feedstuff. All ready-mixed feed from feeding mills must undergo heat-treatment. Furthermore, the Danish Plant Directorate tests feed samples from all feeding mills.

d. Food Chain information

Elements of the food chain information system and how is it covered

Exchange of information between the primary producer and the slaughterhouse concerning

- Animal health status including name and address of the herd owner,
- Salmonella status,
- Treatment with veterinary drugs,
- Name and address of the private veterinary practitioner in charge of the herd in question, and
- Relevant reports on previous ante- and post mortem inspections

is a mandatory requirement within the Regulation (EC) 853/2004 which lays down specific hygiene rules for food of animal origin.

It is the responsibility of the herd owner to provide relevant food chain information to the slaughterhouse before the animals are transported to the slaughterhouse. This enables the slaughterhouse to take appropriate measures concerning meat inspection and logistics.

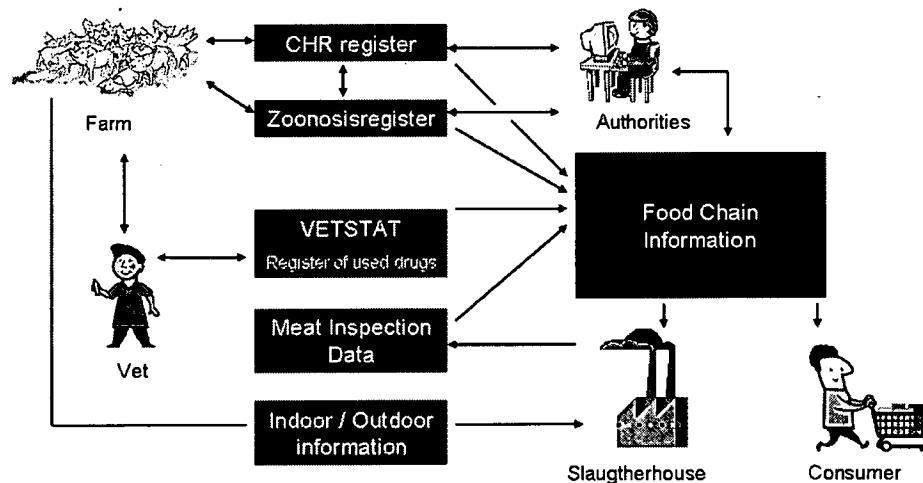


Fig. 3 Description of the connection between the collection of food chain information during animal production and at the slaughterhouse, Denmark, 2008).

In Denmark, electronic recording systems are used to collect data on the exchange of food chain information between the owner of the herd and the slaughterhouse, and therefore items of information have been registered and kept in data bases for years. An overview of the database is given in fig. 3 shown above.

The CHR (see section 2 c for further details about the system) covers information about animal health status and any restrictions on the herd. Another example is the central recording of the use of veterinary medication, the so-called VetStat (and as well as the Zoonosis Register, which contains information about the Salmonella status of the herd). The consumer will receive information through television, radio, or newspaper if meat sold on the market has to be recalled. Such recalls occur through the rapid alert system (http://ec.europa.eu/food/food/rapidalert/index_en.htm).

Only finishers kept indoor since weaning can undergo visual inspection, and the food chain information of the Supply Chain Meat Inspection will therefore be extended to also include information on housing conditions.

Obligations of the primary producer

For many years, contracts between the owner of the herd and the slaughterhouse have been in place (as a part of a Code of Practice). For instance, the owner of the herd is obliged to inform the slaughterhouse about changes of the health status.

Before sending the animals off for slaughter, the owner must register the animals at the slaughterhouse. This is done electronically. In the Supply Chain Meat inspection system the farmer must also inform the slaughterhouse about the pigs having access to indoor or outdoor areas.

As a part of the Code of Practice, the owner of the herd will be audited by the slaughterhouse once a year

Obligation of the slaughterhouse – enforcement and verification

Before accepting the animals for slaughter, the slaughterhouse must check the information about the herd. This is done when the owner of the herd signs in the slaughtering of the animals.

The control of the food chain information will focus on "deviations". In the case of any situation where the obligations laid down in the Code of Practice/agreement between the owner of the herd and the slaughterhouse are not met, the farmer must inform the slaughterhouse about this in advance. An example could be a broken needle or a suspected part of a needle in the animals delivered for slaughter. In such a case, the animal must be accompanied by a written document signed by the owner of the herd.

The system is audited by the slaughterhouse, which performs checks of a predefined part (minimum 1%) of the owners to secure that the required information is present and valid.

Before applying the Supply Meat Chain Inspection System, the slaughterhouse must ensure that their databases are updated with information from the herd owners on the housing condition of all herds from which pigs are delivered to the individual slaughterhouse in order to plan the inspection.

If finishers arrive at the slaughterhouse without information on housing conditions, the pigs will undergo traditional inspection.

Obligations of the competent authority – enforcement and verification

The official veterinarian checks the Food Chain Information to ensure that the slaughterhouse requests, receives, checks and acts upon it and complies with the regulations. The procedures are verified by audits performed by the official veterinarian.

In addition to the general Food Chain Information, it is mandatory for the slaughterhouses to receive information to the effect that the finishers have been held indoor since weaning if the animals are intended for supply chain inspection. As a part of the inspection of the Food Chain Information, the official veterinarian checks that the animals received for slaughter can undergo visual inspection only if the required information is present before the slaughter of the animals. If the information is not available or the animals have had access to outdoor areas since weaning, the animals must undergo traditional meat inspection. The procedures are verified by audits performed by the official veterinarian.

3. Meat inspection

a. Ante mortem inspection

The official veterinarian inspects all pigs arriving at the slaughterhouse before slaughter to ensure that no meat unfit for human consumption enters the food chain at this stage. This implies among others that animals that are dead on arrival at the slaughterhouse, dying or killed in the stables must be condemned as soon as possible and declared unfit for human consumption.

b. Post mortem inspection - in general

Routine inspections include: Visual inspection of the carcass and all organs, palpation of the lungs and incisions of the mandibular lymph nodes and opening of the hearts. An inspection decision is made which means that the carcass and organs are either approved or sent off for further inspection at the rework platform before final approval and/or condemnation.

The routine post mortem inspection is performed by the official auxiliaries working under the responsibility and supervision of the official veterinarian. The final decision to condemn a carcass must be made by the official veterinarian according to a circular letter on the performance of meat inspection.

The introduction of supply chain inspection will change the way the post mortem inspection is performed. Due to the results of the risk assessment on finishers born and raised in Denmark in integrated production systems and held indoor since weaning, the mandibular lymph nodes will not be cut and the hearts will not be opened as a part of the routine post mortem-inspection. This change means that the meat inspectors (official auxiliaries and official veterinarians) need to be trained for this change in their work. The change will mean that the inspectors will have no knife during the routine inspection and will have to focus more on the visual findings.

Before the pilot studies will be initiated (see section 8), the Danish Veterinary and Food Administration will prepare a written instruction for the inspectors that explains the change of inspection. The chief veterinarian on each slaughterhouse will follow the inspection closely to make sure that the instruction is changed according to any problem identified. It is expected that initially there will be a temporary increase in the number of carcasses and organs that will be sent for further inspection at the rework platform.

c. Verification of post mortem inspection – performance standards for meat inspection

In addition to the audits of the food chain information system, verification of the quality of the post mortem inspection will be performed.

In the following is a detailed description of the verification procedure on the performance of the official staff (veterinarians and auxiliaries):

Introduction

The traditional meat inspection is carried out on the slaughter line at the line speed of each slaughter house.

The meat inspection is carried out by official veterinarians and auxiliaries all employed by the Danish Veterinary and Food Administration. The auxiliaries work under the responsibility and the supervision of the official veterinarian.

On the line, the post mortem (PM) inspection is most commonly performed by auxiliaries. If no abnormalities are observed, the carcass and the organs are accepted as fit for human consumption. If abnormalities are found, the carcass and the organs will be sent to the rework platform, where the abnormalities are removed (by the slaughterhouse staff), and the pathology is evaluated more closely by auxiliaries or by an official veterinarian. This evaluation leads to a decision whether to accept or condemn the carcass and the organs.

According to EU regulations², the official veterinarian must check the work of the official auxiliaries regularly. The Danish Veterinary and Food Administration will ensure that this criterion is met by the use of performance standards.

The verification procedure on the quality of the PM-inspection

As of 1 January 2009, the performance standard for the meat inspection will be introduced for all pig slaughter houses, the standard being as follows (monitored daily in each slaughterhouse);

- Inspection tasks (palpation, incision and hygienic behavior):

Not more than 5% non-compliance.

The PM-inspection has to be performed in compliance with Regulation (EC) 854/2004. The verification is made on the inspection platform. The size of the random sample is determined by \sqrt{n} (n being the number of animals slaughtered per day in the slaughterhouse). See Annex 3 for sample size considerations.

The official veterinarian carries out the verification.

- Pathological findings:

Not more than 6% non-compliance

- 2% non-compliance on the carcass
- 2% non-compliance in plucks
- 2% non-compliance in other organs

In Regulation (EC) 854/2004, annex I, section II, chapter V, the pathological abnormalities that result in meat being declared unfit for (animal or human) consumption are listed. The standard is set at 6% non-compliance, i.e. the auxiliaries can miss only 6% of the pathological abnormalities in the random sample. The 6% is a cumulative standard (consisting of a 2% standard for the carcass, a 2% standard for the plucks and a 2% standard for the intestines). See annex 3 for sample size considerations.

- Registration of hygienic slaughter:

Not more than 2% non-compliance for registration of contamination and a 0% non-compliance for fecal contamination.

Fecal contamination is a CCP for which the slaughterhouse is responsible.

In addition, the standard for the carcass contamination is 2%, and for fecal contamination the standard is 0%.

For sample size considerations, see Annex 3.

² Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004, annex I, section III, chapter 1 point 3

Monitoring of performance

The draft form to be filled in when the official veterinarians monitor the performance of the meat inspection is listed in Annex 2.

How to use the performance standards

The guideline for the official veterinarians includes a description of actions that need to be taken to ensure that the standard is met. If the performance standard is not met, the guideline also describes that the official veterinarian must ensure that the performance of the meat inspectors is corrected, to make sure that the standard is observed.

The performance standards must be met, and if not, corrective action should be taken right-away. Corrective action means that errors are corrected immediately and the employee that is performing the post mortem-inspection is instructed to ensure that the standard is observed. It is the responsibility of the chief veterinarian of each slaughter plant to ensure that the performance standard is met.

4. Process control – hygienic slaughter

a. Own check procedures in general

All pig slaughterhouses are approved according to EU-legislation and own check procedures based on HACCP-principles are in place. Plants approved for export to the USA also fulfil the supplementary requirements as laid down in the US legislation (Pathogen Reduction; hazard analysis and critical control point system (HACCP); final Rule, Food Safety and Inspection Service, 1996). Internal audits – performed by the company staff is carried out at a predefined frequency. Furthermore, the own check programmes are audited by the competent authority, which in our case is the Danish Veterinary and Food Administration.

Figure 6 on the following page gives an overview of the risks which are accounted for and taken care of when operating in a slaughterhouse

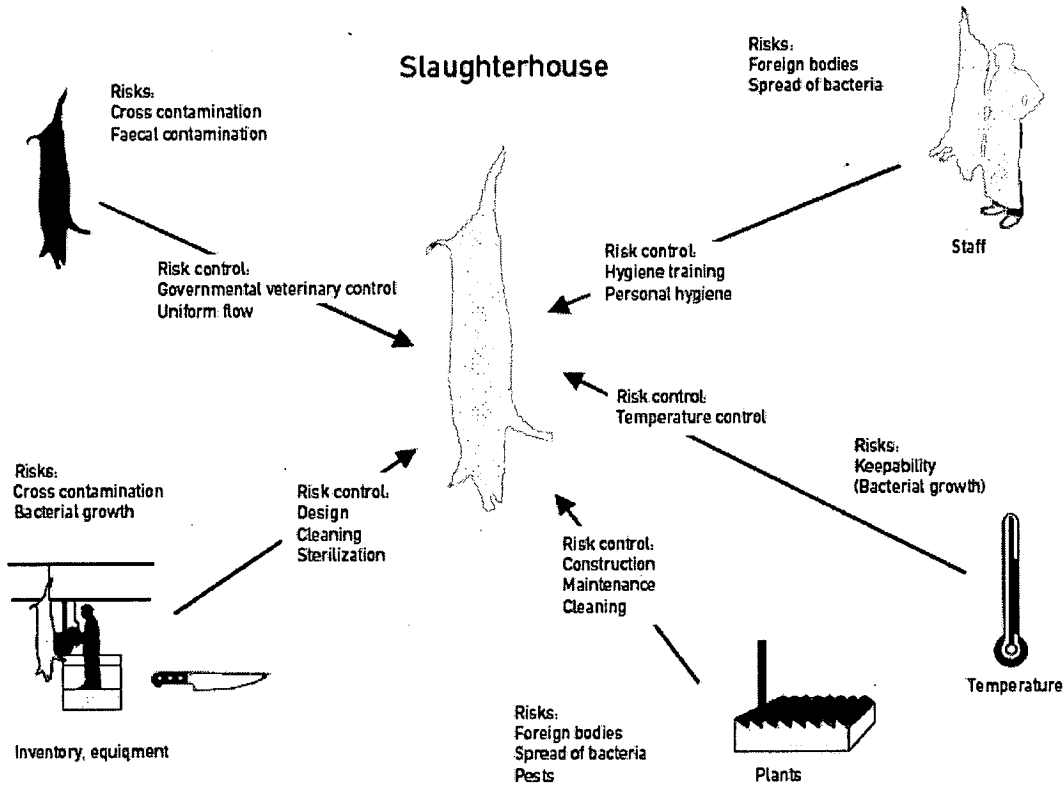


Fig. 6 - Handling of risks at the slaughterhouse

b. Faecal contamination

The own check programme in place also includes procedures for faecal contamination for which there is a zero tolerance.

c. Process control criteria – carcasses E. coli, Total Viable Count and Salmonella

As a part of the EU requirements and requirements for export of pig meat to the USA, procedures for the monitoring of E. coli, Total Viable Count and Salmonella have been in place since 1997/1998. Under the supply meat chain inspection system these will continue as previously.

5. Enforcement procedures – competent authorities

a. Procedures for audit – HACCP system and in general

The Danish Veterinary and Food Administration carries out audits of the HACCP systems at all EU approved slaughterhouses and slaughterhouses approved for export to the USA.

The Official Veterinarian carries out the official inspection tasks in the slaughterhouses in accordance with Regulation (EC) 854/2004. The inspection includes all relevant issues of the regulations including audits of good hygiene practices and HACCP-based procedures.

The requirements for performance standards of Salmonella on pig carcasses as laid down in US-regulation (Mega Reg.) are modified according to bilateral agreement between Denmark and USA. In Denmark the establishments take Salmonella samples, and the competent authority takes verification samples. The requirements for establishment sampling are laid down in Order no. 1282 of 6 November 2007, annex 7, Chapter 8.

Each establishment takes one sample on each slaughter day. In case of non-compliance, i.e. more than 6 positive samples for each 55 samples, the establishment must carry out corrective actions. Requirements for Authority verification sampling are laid down in the Danish Veterinary and Food Administration export inspection guidance.

The Authority takes one sample per week in each establishment. In case of non-compliance, i.e. more than 6 positive samples for each 55 samples the Authority must impose relevant sanctions on the establishment.

b. Verification program of the quality of the post mortem inspection

See Section 3 c.

6. Verification programs – competent authority

a. Procedures in general

Verification of food chain information including information about indoor/outdoor access is described in Section 2 d.

Verification on process control criteria; please see section 5.b

b. Procedures on performance standards

See section 3 b.

7. Verification procedures - establishment

a. Quality control of the performance at the rework platform

Verification of the performance of how defects are handled and corrected on the rework station by the slaughterhouse will be introduced under the Supply Meat Chain Inspection System. The overall aim is to improve the performance of the meat inspection and to continue the reduction and/or elimination of the defects that pass through traditional inspection.

The performance standard to meet the specification is set at compliance levels at 98% a day and 98% a week of the checked carcasses. Four times 40 carcasses are checked every day to ensure that the performance standards are met. For organs and plucks, the standard frequency is two times 40 carcasses.

In case of non-compliance (the standard is not met), additional instruction will be given to the staff, and the frequency will be increased. If more than 2% deviations occur on a day, additional checks will be performed on the following day.

If the performance standard is exceeded in more than two cases per week, the frequency of checks will be increased to five checks per day (5 x 40 carcasses) for a full week. For plucks and organs the frequency will be increased to three checks per day for a period of one week.

c. Opening of the hearts

The hearts will be opened, preferably separately from the carcass, to remove blood clots present. Findings of any abnormalities will result in the condemnation of the heart itself.

8. Implementation-plan

a. Precondition for implementation:

- The risk assessment has concluded that there is no additional risk for humans. The risk assessment has been accepted by the competent authorities in Denmark and abroad.
- Acceptance from Food Safety and Inspection Service, USA
- Own check procedures on the quality of the post mortem inspection = performance standard is in place
- Own check procedure for the opening of the hearts before the hearts are sold in retail to remove blood coagula and to condemn any hearts with abnormalities.
- Any necessary changes to the platforms, light etc. are in place.
- Adequate and sufficient instructions and training of employee - both competent authority and food business operators.

b. Plan – preliminary schedule

The Supply Chain Meat Inspection will be implemented initially at two selected medium-sized slaughterhouses – Danish Crown, Holstebro and Tican, Thisted.

In November and December 2008, a dialogue takes place between the competent authorities and the plants. during which the necessary adjustments will be prepared.

Depending on the acceptance of the suggested changes to the Danish Meat Inspection System by the end of 2008 and if practical issues run smoothly, the revised post mortem inspection can begin late January 2009.

c. Evaluation and verification

The performance on the two selected plants will be followed closely both by the competent authority and the plants themselves.

Besides evaluation of the performance standards for meat inspection, we will focus on the process criteria for E. coli, Total Viable Count and Salmonella. A decline in the prevalence of these contaminants might be associated with an improvement of the performance of the post mortem inspection of the new system.

d. Time schedule for implementation:

To follow the implementation of the new system closely and to adjust on an ongoing basis, it has been decided to implement the Supply Chain Meat Inspection stepwise. An introduction period of two months at the two selected plants is considered acceptable before the system can be introduced to other plants.

ANNEX 1

Monitoring of Risks in the Danish Pig Production – an overview

Chemical risks:

Residues

Chemical risks may result from the presence of residues in meat. Residues may originate from feed or medicine or in some cases from equipment and machinery or the production environment itself. EU legislation provides rules for the composition of feed. The Danish Plant Directorate ensures that feedstuff companies observe the rules governing feed mixes, and the surveillance results are published on a regular basis. In addition, the Danish industry has drawn up guidelines and undertakes comparative trials to ensure that pig producers receive feed of the best quality. Sick animals may only receive medication from a veterinarian or the farmer provided that the latter has a health advisory agreement with the veterinarian. Use of medication is only allowed following formal diagnosis by the veterinarian, and any prophylactic treatment is forbidden in Denmark. By instructing the farmer in correct use of the medicine, the veterinarian ensures that the farmer is aware of the withdrawal period. Use of hormones or other growth promoting substances is forbidden. Danish legislation also requires that buildings and equipment must not be a source of substances that is harmful to pigs. Strict environmental laws also prevent the possibility of contamination by pesticides or heavy metals. The farmer must also obtain official approval for his slurry disposal plan.

Monitoring of residues

The Danish industry has built up a food surveillance system to detect the presence of residues in all foods including meat. The following categories of residues are included in the surveillance programme

- Antibiotics and chemotherapeutics
- Hormones and growth promoting substances
- Pesticides
- Heavy metals

The surveillance programme is planned by the Danish Veterinary and Food Administration. The level of sampling and detection limits for each residue is in compliance with EU legislation (96/23/EEC).

The surveillance programme is based on both a statutory surveillance and the self-audit system. The Danish Veterinary and Food Administration is responsible for statutory surveillance, although the analytical work is carried out by the Government Serum Institute. The self-auditing work is carried out by the member companies of Danske Slagterier, who collect the samples and have them analysed in their own approved laboratories.

Antibiotics and chemotherapeutics

For the last 20 years, the Danish Veterinary and Food Administration has conducted random tests for residue concentrations of antibiotics and chemotherapeutics in meat in compliance with Danish legislation. The analyses are based on biological and chemical tests of kidney tissue in accordance with EU requirements. In the last ten years, the analyses have detected minimal presence of residues of antibiotics and chemotherapeutics in the range of zero to 0.03% of the samples analysed. In recent years between 18,000 and 20,000 samples per year have been analysed. A rise in the number of samples showing residues of Sulphadimidine in pigs in 1989 and 1990 lead to a ban on

the use of this substance in the pig production. If the analyses carried out reveal any presence of residues, the result will be reported to the Regional Control and Enforcement Units, who then assess whether legislation has been transgressed, in which case the producer will receive a fine. A veterinarian visits the herd, usually accompanied by the local veterinarian, and a report on the use of antibiotics is then prepared. On the basis of this report, the Regional Control and Enforcement Units then decide whether the case should be submitted to the police for criminal investigation. If the analysis reveals presence of a residue at a level below the permitted maximum level, the producer will be informed, and a report is produced as a part of the self-audit documentation. If presence is established above the permitted maximum level, the authorities are notified and a veterinarian from the Danish Meat Association will visit the herd to discuss improvements. A report is then sent to the producer and the slaughterhouse company, who then determines whether or not to add the producer to a special list, which entails additional testing of future deliveries.

Hormones

There is a ban in the EU on the use of hormones for growth-promoting purposes. In the last twenty years, Danish meat has also been analysed for the presence of residues of hormones on a random basis. The analyses for various hormones are conducted on samples of muscles, urine, blood and faeces. Residues of hormones have never been detected in Danish pork.

Pesticides and PCB

The use of chlorine-based pesticides and PCBs by farmers is not permitted, nor must any such products be held in areas where food or feedstuffs are being produced. The use of DDT, Dieldrin and Lindane was banned in the early 1980s. In the last 20 years, the Danish Veterinary and Food Administration has planned and conducted random tests for residue concentrations of pesticides and PCBs in food – both in animal and vegetable products. The random tests of pigs is performed on kidney fat and for a number of years only trace amounts of pesticides and PCBs have been detected. However, the maximum recommended limits have never been exceeded. Low levels of residues of these substances are still occasionally found because of their slow biodegradability.

Heavy metals

The random tests for residues of heavy metals in meat are undertaken by the Danish Veterinary and Food Administration. Samples of muscles, kidneys and liver are examined for residues of lead, cadmium and mercury and for trace elements of nickel, selenium and chromium.

For a number of years, only a single sample has revealed residues of heavy metals above the maximum recommended level. The low levels of mercury and selenium have been unchanged in the last ten years, while that of cadmium, lead, nickel and chromium have been decreasing.

Physical risks

All extraneous matters such as bone fragments, cartilage, remnants of equipment and labels are regarded as foreign bodies. Through strict enforcement of product specifications and comprehensive training of employees, the industry works to ensure that pig meat is free from bones, cartilage and other foreign bodies. In addition, all finished products are subject to detailed inspection. Where defects are found, these are rectified and the working processes are examined and steps taken to avoid any repeat occurrence.

Biological risks

Diseases

High health level in livestock is crucial to the production of safe food. Danish farmers seek to prevent transmission of diseases from the surrounding environment through pest and insect control and by safeguarding the farm buildings against intrusion by predatory animals. Good housing design and batch or multi-site production systems also ensure high health levels.

Bacteria

The Danish industry implements rigorous controls to prevent the spread of pathogenic zoonotic bacteria. Zoonoses are diseases, which can be transmitted from animals to humans. Food of animal origin is often the main source of contamination when humans are infected with zoonotic diseases. A number of bacteria can cause food borne diseases in humans, either as food poisoning or as food infection. Food poisoning is caused by pathogenic bacteria that produce a toxin in the food prior to its consumption. Food infections are characterised by a live bacterium, which itself induces disease. A changing production environment, preservation methods and eating habits all involve a risk of spreading novel bacteria types. In addition, improved analysis techniques make it possible to detect new types of bacteria. The industry continuously assesses new bacteria types to evaluate their possible health risks. Major research is also focused on the development of quicker methods for detection of specific bacteria as well as mapping and controlling salmonella. Salmonella and yersinia bacteria originate from the same source (the digestive tract) and can be controlled in a similar manner.

Feed

All feedstuff companies must produce salmonella-free feed. All ready-mixed feed from feeding mills must be heat-treated, and the Danish Plant Directorate tests feed samples from all feeding mills. Research has shown that there is a greater risk of Salmonella infection when heat-treated feed is used rather than home-mixed rations. Overall, home-mixed feed and fermented liquid feed have been found to offer better protection against salmonella contamination due to the effect of the feed on gastro-intestinal health.

Resistant bacteria

In Denmark, strategies have been implemented to prevent the development of resistant bacteria. This led to a ban on the use of the growth promoters avoparcin and virginiamycin and a voluntary ban on the use of all antibiotic growth promoters in the Danish pig production from January 2000. The Danish authorities monitor the development of resistant bacteria by regular analyses of random samples from animals, meat products and the human population (DANMAP).

ANNEX 2

Performance Standard of meat inspection

Date and time: _____ Slaughterline: _____

Sample size: _____ Official veterinary signature.: _____

Inspection tasks - maximum 5% non-compliance ³				
	OK	Not OK Describe non-compliance	Follow-up action	
Inspection of head				
Incision of the mandibular lymph nodes				
Inspection of the mouth, fauces and tongue				
Carcass inspection				
Inspection of both internal and external surfaces of the carcass?				
Intestine inspection				
Is the entire set of intestines inspected?				
Palpation of the mesenteric lymph nodes				
Inspection of the spleen?				
Inspection of gastric lymph nodes				
Pluck inspection				
Visual inspection of lungs, trachea and mediastinal lymph nodes?				
Palpation of the lungs and lymph nodes				
Inspection of the pericardium and incision of the heart				
Inspection of the liver and lymph nodes				
Inspection of the kidneys?				
Pathological decisions - maximum 6 % non-compliances²				
Inspection of head				
Is pathological lesion diagnosed correctly?				
Is pathological lesion registered correctly?				
Carcass inspection				

³ Palpation, incision and hygienic behaviour maximum 5% non-compliance

² Maximum 6% accumulated non-compliance (2% on the carcass, 2% on hearts, 2% in pluck)

Is pathological lesion diagnosed correctly?				
Is pathological lesion registered correctly?				
Inspection of intestines				
Is pathological lesion diagnosed correctly?				
Inspection of plucks				
Is pathological lesion diagnosed correctly?				
Is pathological lesion registered correctly?				
For registration of hygienic slaughter maximum 2% non-compliance³				
Hygiene (for all inspection locations)				
Is contamination registered correctly?				
Is fecal contamination registered correctly?				
After control/rework platform – auxiliary				
Is the slaughterhouse staff removing the right parts (incl.regional lymph nodes)?				
Presentation of removed parts for inspection?				
Registrations changed correctly?				
Inspection of the plucks in connection with the carcass?				
After control area/rework platform (OV):				
Is pathological lesion diagnosed correctly?				
Is registration correctly conducted?				
Retained plucks and intestines inspected before final inspection decision is made?				

³ 0% non-compliance for fecal contamination

Ministry of Food, Agriculture and Fisheries

Danish Veterinary and Food Administration

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ANNEX 3

SAMPLE SIZE EVALUATIONS

A. Prevalence estimation

Table 1

Sample size (n) based on the number of finisher pigs slaughtered in a day as well as precision of prevalence estimate divided according to expected prevalence (6% or 2%)

n	10	20	40	80	100	200	400	600	800	1,000	2,000	4,000	6,000	8,000	10,000	12,000
√n	3	4	6	9	10	14	20	24	28	32	45	63	77	89	100	110
6%	0.27	0.22	0.19	0.16	0.15	0.13	0.11	0.10	0.09	0.08	0.07	0.06	0.05	0.05	0.05	0.05
2%	0.16	0.13	0.11	0.09	0.09	0.07	0.06	0.06	0.05	0.05	0.04	0.04	0.03	0.03	0.03	0.03

The aim is to identify the prevalence by use of a sample. The precision of such a result depends on the sample size (n) ; the higher the sample size, the more precise is the resulting prevalence estimate. The precision also depends on the expected prevalence of the condition of interest; here set to 2% or 6% and the confidence level is 95%.

N= Number of pigs slaughtered during a slaughter day

n= Number of pigs in a sample determined as the square root of N – as suggested by The Netherlands

The precision, L, is estimated based on the following formula:

$$L = (4 \cdot pq/n)^{0.5}$$

This is valid for large populations, e.g. $N > 200$. For population sizes < 200 , the precision listed in Table 1 is underestimated (the result of the investigation of the sample is closer to the true prevalence than shown in the table)

Example: If 2,000 finisher pigs are slaughtered in a day, 45 carcasses should be included in the sample. If a prevalence of 6% is expected, then the precision is 4%; in other words the true prevalence is $\pm 4\%$ from the result of the sample (in 95 out of 100 times). If 3 out of the 45 investigated carcasses were positive, then the estimated prevalence of the condition in the population consisting of the 2,000 carcasses is $3/45 \pm 4\% = 7\% \pm 4\% = 95\% \text{ confidence interval: } 3\text{-}11\%$

B. Documentation of absence of a condition (faecal contamination)

Table 2

Sample size required to estimate maximum prevalence P_{\max} by use of sample n in population of size N . The entire sample is examined and found negative

n	10	20	40	80	100	200	400	600	800	1,000	2,000	4,000	6,000	8,000	10,000	12,000
\sqrt{n}	6	9	13	18	20	28	40	49	57	63	89	126	155	179	200	219
Diseased	3	4	7	11	13	19	27	34	40	45	64	92	113	131	147	161
P_{\max}	0.26	0.22	0.18	0.14	0.13	0.09	0.07	0.06	0.05	0.04	0.03	0.02	0.02	0.02	0.01	0.01

The aim is to document absence of a condition e.g. faecal contamination of a carcass. The larger the sample analysed and found negative, the more confident we are that the condition is not present or low-prevalent. We measure this as the maximum prevalence that could "hide" in the population, despite of the negative sample.

N = number of finishers slaughtered in a day

n = sample size = $2 \cdot N^{0.5}$ – as suggested by The Netherlands

The maximum prevalence that could "hide" in the population is determined by the following formula:

Max number of diseased = $(1 - (0.05)^{(1/n)})(N - (n - 1)/2)$

P_{\max} = Max number of diseased / N

Example: if 2,000 finisher pigs are slaughtered in a day, 89 should be examined. If all these are found negative, then we are 95% confident that true prevalence of the condition of interest is less than 3%.

Reference for formulas used in Section A and B:

Martin, S.W., Meek, A.H., Willeberg, P., 1987. Veterin

ary Epidemiology – Principles and Methods. Iowa State University. Ames, Iowa. 22-47.

Ministry of Food, Agriculture and Fisheries

Danish Veterinary and Food Administration



Supply Chain Meat Inspection – The Danish Way

An overview including references and links to Regulations etc

	Subject	INSPECTION SYSTEMS		References and links related to the specific sections
		Traditional meat inspection	Supply chain meat inspection	
Prerequisites	Animal health and zoosanitary status	Denmark is officially free from TB		1). Alban et al., 2008; Assessment of the risk for humans associated with specific changes in meat inspection of Danish finisher pigs, 2008 – Version for external review (<i>enclosed</i>)
	Origin of the pigs	Born and raised in Denmark		2). The DANISH Standard- December 2007 (<i>enclosed pdf-file</i>) –further information: http://www.dansksvineproduktion.dk/Services/DANISH_Produktstandard/Bilag_Produktstandard.html
	Delivery of pigs for slaughter	All pigs + sows and boars	Only finishers from integrated production systems and kept indoor since weaning	3). Danish Quality Assurance (<i>enclosed pdf-file</i>)
	Food Chain Information			4). The Central Husbandry Register (CHR) (http://www.glr-chr.dk/pls/glrchr/chrmenu\$menu) 5). The central recording of the use of veterinary medication called VetStat (http://www.vet.dtu.dk/Default.aspx?ID=9205)
Preconditions – for delivery and slaughtering pigs	(Required information have for years been registered and kept in databases (VETSTAT, CHR, Zoonosis Register) and exchanged between slaughterhouse and primary producer as part of a Code of Practice From 1 January 2008 mandatory for pigs within the EU	General information on <ul style="list-style-type: none"> Animal health status, incl. name and address of the owner of the herd Salmonella status treatment on veterinary drugs any relevant reports from previous ante- and post mortem inspection name and address of the private veterinarian 	General information on <ul style="list-style-type: none"> Animal health status, incl. name and address of the owner of the herd Salmonella status treatment on veterinary drugs any relevant reports from previous ante- and post mortem inspection name and address of the private veterinarian information on indoor/outdoor access 	6). Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2004R0853:20071114:EN:PDF 7). Danish Veterinary and Food Administration, Guideline on Food Chain Information, December 2007 - Danish https://www.retsinformation.dk/Forms/R0710.aspx?id=114350
	The Danish Salmonella surveillance and control programme	Main elements in the surveillance and control programme <ul style="list-style-type: none"> Feed Breeder and multiplier herds Finisher herds Sow herds Fresh meat 		8). Link to the Danish Salmonella Surveillance programme http://www.danskeslagterier.dk/smcms/Danish_English/Information/DANISH_Information/Danish_Information/Salmonella_surveillance/Index.htm?ID=9783#Salmonella%20surveillance%20programme%20III%20-%20background%20and%20purpose 9). Alban et. al., 2002; The new classification system for slaughter-pig herds in the Danish Salmonella surveillance and control programme (<i>pdf-fil enclosed</i>) 10). Sørensen et al., 2007; Estimation of <i>Salmonella</i> prevalence on individual-level based upon pooled swab samples from swine carcasses (<i>pdf fil enclosed</i>)

	Subject	Traditional meat inspection	Supply chain meat inspection	References and links related to the specific sections
Meat inspection according to Regulation 854/2004 on official control on products of animal origin	Ante-mortem inspection	All pigs are inspected by the Official Veterinarian	All pigs are inspected by the Official Veterinarian	11). Circular letter of 26 July on Meat inspection http://www.foedevarestyrelsen.dk/NR/rdonlyres/7543EB75-2A29-47C3-8842-9F9E8152C9DF/0/KKcirk97242007.pdf
	Post-mortem inspection	Routine inspection includes: Visual, palpation and incisions of lymph nodes and opening of hearts. Inspection leads to either approval or further inspection before final approval and/or condemnation	Routine inspection includes: Visual inspection and palpation. No incisions of lymph nodes and opening of hearts. Inspection leads to either approval or further inspection before final approval and/or condemnation	12). Annex 7 – Order No. 1282 of 6 November 2007 on export of food for third countries (export Order https://www.retsinformation.dk/Forms/R0710.aspx?id=32086 - Bil7
Process control – hygienic slaughter	Fecal contamination	Zero tolerance - CCP	Zero tolerance – CCP	13). Annex 7 and in specific chapter 8 +9 in Export Order No 1282 of 6 November 2007 https://www.retsinformation.dk/Forms/R0710.aspx?id=32086
	Process control criteria – carcass testing	E. coli + Total viable count according to EU and US-requirement modified under equivalence agreement between US and DK Enforcement procedures and statistical calculating methods are used	E. coli + Total viable count according to EU and US- requirement modified under equivalence agreement between US and DK Enforcement procedures and statistical calculating methods are used	14). Danish Veterinary and Food Administration Export Inspection Guideline, 2008 export inspection guidance

Enforcement programs - government	Audit procedures	Audit of the HACCP system including audit of the Food Chain Information	Audit of the HACCP system including audit of the Food Chain Information including information on indoor/outdoor access	15) Guidance for the control of FCI (Danish): https://www.retsinformation.dk/Forms/R0710.aspx?id=114350
	Salmonella testing	FSIS requirements are adopted and followed due to equivalence agreement On going sampling program – set of 55 Performance standard an enforcement procedures are followed Sample verification testing is performed by official veterinarian	FSIS requirements are adopted and followed due to equivalence agreement On going sampling program – set of 55 Performance standard an enforcement procedures are followed Sample verification testing is performed by official veterinarian	16). Export Order No of 6 November 2007, in specific annex 7, chapter 8 https://www.retsinformation.dk/Forms/R0710.aspx?id=32086
	<i>Standardized government verification program of the quality of the post mortem inspection – performance standard</i>	<i>Introduced from January 1 2009</i> <i>Ensuring the performance for inspection tasks as well as pathological findings by the official meat inspection</i>	<i>Introduced from January 1 2009</i> <i>Ensuring the performance for inspection tasks as well as pathological findings by the official meat inspection</i>	17). See Section 3 b in the document Supply Chain Meat Inspection – The Danish Way -
Verification programs - government	Procedures in general	Verification of <ul style="list-style-type: none"> Food Chain Information process control criteria 	Verification of <ul style="list-style-type: none"> Food Chain Information, including information on indoor/outdoor access process control criteria 	18). See Prerequisites in this document

	Procedures on performance standard	Verification and evaluation of the performance of handling and correction of all defects on the rework station	Verification and evaluation of the performance of handling and correction of all defects on the rework station	19). See <i>Section 3 b</i> in the document Supply Chain Meat Inspection – The Danish Way - November 2008
Enforcement and verification program - establishment	Verification of the performance at the rework platform	Will be introduced in the beginning of 2009 and stepwise at all pig slaughterhouses		20). Own check procedure in the pipeline – see section 7 in the document Supply Chain Meat Inspection – The Danish Way - November 2008
Implementing plan	<ul style="list-style-type: none"> - Precondition - Preliminary Schedule - Evaluation and verification 	<p><i>Precondition:</i></p> <ul style="list-style-type: none"> - Risk assessment terminated – concluding no risk for human in omission of the routine incisions of lymph nodes and hearts, and - Accepted by National competent authority and FSIS, USA - Enforcement and verification programs in place including practical arrangements <p><i>Preliminary Schedule:</i></p> <ul style="list-style-type: none"> - Implementing stepwise – starting with two selected slaughterhouses – January 2009 ? - Stepwise at other slaughterhouses <p><i>Evaluation:</i></p> <ul style="list-style-type: none"> - Close follow up on the performance in the two selected slaughterhouses 		21) See <i>Section 8</i> in the document Supply Chain Meat Inspection – The Danish Way - November 2008

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The new classification system for slaughter-pig herds in the Danish Salmonella surveillance-and-control program

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Abstract

The Danish surveillance-and-control program for Salmonella in slaughter pigs was introduced in 1995. The key element of the program is a quick and correct identification of herds with high seroprevalence. After 5 years, the classification scheme was evaluated—and a revision was made. Data from two Salmonella screenings including a total of 1902 slaughter pig herds were used. For each herd, information was available on Salmonella status based on both microbiology and serology. Based on analyses of these data, suitable changes in the scheme were identified and their effect estimated by use of data from the Danish Salmonella Database including all herds in 2000. The classification scheme has been adjusted on the following points. (1) The sampling has been simplified into 60, 75, or 100 samples per herd per year depending on herd size. This means more-precise estimates for the seroprevalence among smaller herds. (2) Herds with an annual kill ≤ 200 finishers will not form part of the surveillance; this leaves 1.6% of the slaughter pigs outside the surveillance scheme. (3) The cut-off for individual meat-juice samples has been reduced from OD% 40 to OD% 20—doubling the number of positive samples. (4) The results of the previous 3 months' serological samples will be weighed 0.6:0.2:0.2 (the immediate month counting three times as much as the previous months), and the weighed average is called the "serological Salmonella index" for slaughter pig herds. A herd with an increasing seroprevalence will be assigned to a higher Salmonella level more-quickly under the new scheme. (5) A herd will be assigned monthly to one of three levels. The limit between Levels 1 and 2 has been set to \geq index 40, and the limit between Levels 2 and 3 to \geq index 70. If the Danish swine producers are interested, a Level 0 may be introduced (consisting of seronegative herds as an indication of a negligible Salmonella prevalence). The classification scheme was introduced in August 2001. © 2002 Elsevier Science B.V. All rights reserved.

Keywords: Pig; *Salmonella enterica*; Control program; Sample size; Detection level; Herd classification

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1. Introduction

1.1. The previous classification scheme in the Danish surveillance-and-control program for *Salmonella* in slaughter pigs

During the early 1990s, *S. Typhimurium*, phage type 12 (DT12) was the most-prevalent *Salmonella* serotype in Danish pig herds. At the same time, the identical strain was increasingly isolated from Danes suffering from Salmonellosis (Baggesen and Wegener, 1994; Hald and Wegener, 1999). In spring 1993, an infection with *S. Infantis* was traced from certain pig herds through abattoirs to consumers where it caused a human epidemic (Wegener and Baggesen, 1996). This episode initiated the establishment of a nation-wide *Salmonella enterica* surveillance-and-control program in Danish pig herds (Bager and Wegener, 1995; Mousing et al., 1997).

The primary aim of the control program was to reduce the prevalence of *Salmonella*—in both pig herds and pork. The classification scheme was based on a serological survey, where meat-juice samples (collected at the abattoirs) were examined for *Salmonella* antibodies; a mix-ELISA containing the O-antigen factors 1, 4, 5, 6, 7 and 12 was used (Nielsen et al., 1995). Calibrated optical densities were obtained by regression analyses of positive and negative reference sera and expressed as OD% (Nielsen et al., 1998). A cut-off of 40 OD% initially was selected for the control program (Mousing et al., 1997). Individual samples were coded positive if the OD% was >40 and negative if the OD% was ≤ 40 . The number of samples examined in each herd depended on the herd size (Table 1). Herds with an annual kill <100 pigs were excluded; they were considered insignificant, because pigs from such herds only constituted around 1% of the total number of pigs slaughtered at the time. Also, relatively more animals would need to be sampled to estimate the prevalence in these herds with an acceptable precision.

Table 1

The classification scheme^a for slaughter pig herds in the previous Danish *Salmonella* surveillance-and-control program

Estimated annual kill (<i>N</i>)	% Pigs to be examined (% of <i>N</i>)	Within-herd intervention prevalence (%)	
		Level 2 ^b	Level 3
1–100 ^c	0.0	—	—
101–200	25.0	$>50^d$	>50
201–500	9.9	>25 –50	>50
501–1000	7.2	>23 –50	>50
1001–2000	4.3	>20 –50	>50
2001–3000	3.3	>17 –50	>50
3001–5000	3.3	>17 –50	>50
>5000	3.5	>10 –33	>33

^a Slightly modified after Mousing et al. (1997).

^b Mandatory advisory service and sanitary slaughter.

^c These herds were not included in the surveillance.

^d If a herd had $>50\%$ positive samples, the herd was assigned Level 3 directly, Level 2 was not used for herds of this size.

All serological results were transferred to a central database (the Zoonosis Register, ZOOR). Once a month, all herds were assigned to an official *Salmonella* level (1, 2 or 3) according to the results from the preceding 3 months. Level 1 included herds with a low acceptable prevalence of *Salmonella*, Level 2 included herds with a moderate still-acceptable prevalence of *Salmonella*, and Level 3 included herds with a high unacceptable prevalence (Table 1). Herds in Levels 2 and 3 received mandatory advisory visits where the extent and the serotype of the *Salmonella* infection was established by bacteriological examination of pen fecal samples from all stables/sections (bacteriological follow-up). Means to reduce the *Salmonella* prevalence in these herds had to be initiated, e.g. changes in management procedures. Additionally, special precautions had to be taken at the abattoirs when pigs from Level 3 herds were slaughtered (Mousing et al., 1997). To cover these expenses, a penalty fee of 3–9% of the slaughter value was imposed.

The control program was based on the assumption that there was an association between serological reaction and bacteriological *Salmonella* prevalence. This association has been described (e.g. Nielsen et al., 1995; Stege et al., 1997; Christensen et al., 1999; Sørensen et al., 2000). The general conclusion of these studies was that the serological test was effective mainly at herd-level—and especially well suited to detect high-prevalence herds. A central question is how best to describe the association between serology and bacteriology, because the serological results from a herd may be interpreted differently, according to:

- (a) which cut-off OD% is applied when evaluating the individual test;
- (b) which herd-prevalence limits are applied; and
- (c) how the previous monthly serological results are weighted.

1.2. Revision of the classification scheme

In 1993, the approximate number of human cases of Salmonellosis—caused by consumption of pork—was 1100 per year. In 2000, this number was reduced to 166 human cases per year (Anon., 2001). The marked decrease of human cases indicated that the surveillance-and-control program was working efficiently. But after 5 years with the current classification scheme, it was appropriate to evaluate (and possibly, to adjust) the sampling strategy to ensure the most-efficient reduction of the *Salmonella* prevalence. A group was appointed in June 2000, consisting of members representing the Danish Veterinary Laboratory, the Danish Veterinary and Food Administration, and the Danish Bacon and Meat Council. The aim was to evaluate the present classification scheme and suggest appropriate changes. Subsequently, these changes would be implemented in the surveillance-and-control program. It was decided that any proposals to improve the classification scheme should comply with the following demands: (1) the classification scheme should identify herds with increasing seroprevalence quickly and correctly; (2) all cut-offs applied (individually as well as herd level) should ensure a high association between serology and bacteriology; and (3) the model for the adjusted classification scheme should be simple. To meet these demands, the following questions needed to be examined:

1. Which sample size is appropriate for different herd sizes?
2. What is the effect of leaving the smallest herds out of the surveillance?
3. Which individual cut-off OD% for the serological test is most appropriate?
4. How should the results from the previous 3 months be weighted?
5. How many Salmonella herd levels should be used and what should be the inclusion criteria for each level?

2. Materials and methods

Two datasets were used for the analyses. The first dataset had an over-representation of slaughter pig herds from Levels 2 or 3. It consisted of 1902 slaughter pig herds that participated either in a Danish screening for Salmonella DT104 carried out in 1998 (Anon., 1998) or in a general screening for Salmonella in 1999 (Sørensen et al., 2000). For each herd, 10 slaughter pigs were examined for the presence of Salmonella in the caecal contents. Additionally, information was obtained about the herd's previous-3-months serological results (data from ZOOR).

The second dataset consisted of all Danish slaughter pig herds that delivered finishers for slaughter between 1 June and 31 August 2000. For each herd, information was obtained from the Danish Salmonella database on results of serological testing (OD% of individual meat-juice samples), as well as number of slaughter pigs delivered through the last 13 weeks. These data were used to estimate the effect of the proposed changes in a new classification scheme.

The statistical software program SAS was used: PROC GENMOD, PROC CORR, and PROC FREQ (SAS, 1989a,b).

When a population (in this case, a herd) is examined by a sample and all individuals are negative, one may conclude that if infection is present in the population, the prevalence (P) is below a certain level (P_{\max}) at a given confidence level. P_{\max} could be referred to as the "detection-limit" and depends on the sample size relative to the herd size (population size). To calculate the maximum number of infected animals possibly present in a population—where all individuals in the sample was negative—we used the following equation (slightly modified from Martin et al., 1987):

$$D = [1 - a^{1/n}][N - \frac{1}{2}(n - 1)]$$

in which we assumed that Se and Sp = 1 as used by Mousing et al. (1997), and that: N , population size; a , error term (here, 0.05, for a 95% confidence level); n , sample size; D , maximum number of infected animals in the population if the sample was all-negative.

P_{\max} then can be calculated as

$$P_{\max} = \frac{D}{N} \times 100$$

In the calculations above, it was assumed that the ELISA test for meat juice was perfect (i.e. sensitivity (Se) = 1.00 and specificity (Sp) = 1.00). Nielsen et al. (1995) found that 45 out of 46 experimentally infected pigs produced increased optical densities (OD) in the serum. Additionally, Nielsen et al. (1998) found that the relative Se and Sp of the test when used on

meat juice was 85 and 99%, respectively. However, when used in the field where pigs might be in all stages of infection, the sensitivity might be lower. We do not know the exact sensitivity of the test when applied in a real-life situation, but we assumed that it varies according to the infection level in the herd and can be as low as 50%. We have no reason to doubt that the specificity is close 100%.

The individual-test characteristics (Se and Sp) may be taken into account while calculating the probability of observing zero reactors in the samples by use of the program FreeCalc in Survey Toolbox (Cameron and Baldock, 1998). The calculations were made for within-herd prevalence = 5%, Se = 50 or 85%, and Sp = 98%.

3. Results and discussion

3.1. Which sample size is appropriate for different herd sizes?

The herd-size is defined as the annual kill, which is estimated at any relevant point in time, based on the number of finishers delivered for slaughter during the past 13 weeks. The herd-size determines the number of individuals that are sampled. According to the previous classification scheme, the within-herd *Salmonella* prevalence was determined with much more certainty in large herds than in small (Table 1). This was accepted because it was believed that the smallest herds contributed only a small part of the total *Salmonella* presence. However, that meant that larger herds were examined with disproportionately thoroughness—while for smaller herds, the prevalence estimates could be unreliable.

The Danish swine producers have shown interest in introducing a Level 0, for herds with all-negative samples over a time period as an indication of minimal within-herd *Salmonella* prevalence. Such Level 0 herds presumably would have an advantage in exporting animals or meat.

Therefore, we decided to determine the number of samples needed in each herd-size category to ensure a within-herd prevalence $\leq 5\%$. The detection level P_{\max} was calculated for all the herd-size categories, both for the previous and the new sample sizes (Table 2). In these calculations, the test Se and Sp both are assumed to be 100%, because these characteristics were used by Mousing et al. (1997).

When assuming a (probably more-realistic) test Se of 50 or 85% and Sp 98%, the probability of observing zero reactors in the samples—assuming a true within-herd prevalence $>5\%$ —was negligible ($\leq 6.6\%$ for Se = 50%, and ≤ 2.1 for Se = 85%) for all herd sizes (Table 3). Hence, for all herd sizes, an all-negative sample (from the new sample sizes; Table 3) would be sufficient to declare the herd-prevalence $\leq 5\%$ at the 95% confidence level.

The dataset representing all herds delivering finishers during the time period 1 June through 31 August 2000 was used to calculate how many samples would be taken in the new scheme. Compared to the previous scheme, there would be an increase in the number of samples taken in the small herds, an almost-equal number of samples taken in the medium-sized herds and a reduction in the number of samples taken in the large herds. In total, we predict that approximately 13% fewer samples would be taken (Table 2).

Table 2

Sample size and detection limits for *Salmonella* herd seroprevalences at different herd sizes using the previous and the new sampling schemes, respectively, including prediction of total number of samples to be taken yearly from Danish slaughter pig herds

Estimated annual kill (<i>N</i>)	Previous program		New program		Distribution of Danish herds 1 June to 31 August 2000			
	Number of pigs examined (<i>n</i>)	Detection limits ^a for <i>Salmonella</i> (%)	% Pigs to be examined (% of <i>N</i>)	Number of pigs examined (<i>n</i>)	Detection limits ^a for <i>Salmonella</i> (%)	Number of Danish herds in each stratum	Predicted number of samples per year using	
							Previous scheme ^b	New scheme (<i>n</i> = 60, 75, 100)
1–100	0	–	0	0	–	6799	0	0
101–200 ^c	25–50	10.2–9.9	(0) ^c	(60)	(3.5–4.2)	1277	47888	(63850) ^c
201–500	20–50	13.2–5.5	30–12	60	4.2–4.6	1892	65651	113520
501–1000	36–72	7.7–3.9	12–6	60	4.6–4.7	1682	91098	100920
1001–2000	43–86	6.6–3.3	6–3	60	4.8	2440	157380	146400
2001–3000	66–99	4.3–3.0	3.7–2.5	75	3.9	1431	118058	107325
3001–5000	99–165	3.0–1.8	2.5–1.5	75	3.9	1368	180576	102600
>5000						772	162120	77200
Ex: 5001	175	1.7	2	100	2.9			
Ex: 6000	210	1.4						

^a Maximum prevalence (P_{\max}) in a herd with an all-negative sample.

^b The number of samples which to be taken was calculated as the percentage of pigs to be examined per herd times number of herds in each strata—calculated for the midpoints of the herd-size classes.

^c Herds with an annual kill ≤ 200 pigs are not surveilled in the new program.

Table 3

Predicted probabilities of observing zero reactors (at different sample sizes) at within-herd *Salmonella* prevalence >5% using the assumed individual-test sensitivity and specificity ($Sp = 98\%$) on the meat-juice samples from Danish slaughter pigs in the Danish mix-ELISA

Herd size (midpoint of annual kill)	Sample size in new program	Probability of observing 0 reactors, if true prevalence >5%	
		Se = 50%	Se = 85%
350	60	0.060	0.017
750	60	0.064	0.020
1500	60	0.066	0.021
2500	75	0.034	0.008
4000	75	0.034	0.008
>5000	100		
Ex: 6000		0.011	0.002

3.2. What is the effect of leaving the smallest herds out of the surveillance?

In the previous control program, herds with an annual kill of ≤ 100 finishers were not included, because too many animals would need to be sampled to estimate the herd-prevalence with sufficient precision. In herds with 101–200 finishers produced per year, 25% of the finishers were sampled; this ensured a detection limit for *Salmonella* corresponding to within-herd prevalences >10%. However, it was the intention to introduce a Level 0 for herds with seroprevalence <5%. Hence, an even-larger proportion of the finishers would need to be sampled, and this would be unrealistic economically. Furthermore, the number of smallest herds in Denmark is constantly decreasing (Anon., 2000). Therefore, we also wished to exclude herds with ≤ 200 finishers per year from the survey. This would be acceptable if animals outside the program only constituted a negligible source of *Salmonella*.

The dataset representing all herds delivering finishers during the time period 1 June through 31 August 2000 was used to estimate the effect. As it is seen in Table 4, around 124,000 animals were already left out due to the limit of 100 finishers per year. If this limit were increased to 200, around 193,000 animals more would be left out (corresponding to 1% of the total number of finishers produced in Denmark per year and 7% of the Danish herds). An increasing percentage of the herds delivering few finishers each year consists of sow herds, which primarily produce piglets or growers for sale at either 7 or 30 kg. These herds will be followed indirectly through the finisher herds to which they sell their piglets. Unfortunately, it was not possible to estimate how large a fraction of such piglets would be followed this way (data quality was too poor in the official herd database). Other studies showed that the *Salmonella* prevalence in the smallest herds was low (Dahl, 1997; Mousing et al., 1997). Hence, it was concluded that human health was not jeopardized when leaving out herds producing ≤ 200 slaughter pigs per year from the surveillance.

3.3. Which individual cut-off value for the serological test is appropriate?

In the previous program, the individual cut-off for a positive meat-juice sample was OD% 40. This was a “convenient cut-off” and ensured that no more herds were assigned

Table 4

Estimated number of herds and finishers that are left out of the control program, when only herds with an annual kill^a of >200 finishers are surveilled (based on data from all Danish herds delivering pigs to slaughter during June–August 2000)

Unit	Herds with an annual kill of				Total herds or animals	
	0–100 ^b		101–200			
	Number	%	Number	%	Number	%
Herds	6799 ^c	38.5	1277	7.2	17661	100
Finisher pigs	124108	0.6	192900	1.0	20250800	100

^a The annual kill was estimated from the deliveries of finisher pigs in 13 weeks.

^b These herds already were excluded from the previous program.

^c Half of these herds (3083) did not deliver any pigs for slaughter during those 13 weeks.

into Level 3 than the system was able to handle (cooling and storage facilities for carcasses were needed while the bacteriological examination was performed, as was heat treatment of all contaminated meat). However, several studies showed a better agreement between serology and bacteriology at cut-off OD% 11 (Nielsen et al., 1995; Stege et al., 1997). Therefore, we examined the consequences of reducing the individual cut-off.

The association between serology and the proportion of positive caecal-contents samples was examined using logistic regression with the proportion of positive caecal-contents samples as the outcome. The herd's serological result for each of the 3 previous months was used as explanatory variables. Because the serological results were interpreted for four different cut-offs (11, 20, 30, and 40 OD%), four models were run and compared (Table 5).

The best association was the model with the lowest deviance; this was found when using individual cut-off OD% 11; and, the higher the cut-off, the poorer the association. This was repeated for a sub-sample of data consisting of herds with >10% positive meat-juice-samples (3 months weighted average). Again, the best association was found when using the lowest cut-off OD%. However, for both analyses, the actual difference in effect between the four cut-offs was limited.

We suggest that for a herd to be assigned Level 0, all of its samples must be seronegative. Here, presence of false-positives would constitute a problem, and the lower the cut-off OD%, the higher the likelihood of false-positive reactions. Therefore, we decided to apply individual cut-off OD% 20.

Table 5

Comparison of four cut-off OD% describing the association between serology and bacteriology for Salmonella by use of logistic-regression analysis of data from 1902 Danish slaughter pig herds collected in 1998–1999

Cut-off OD%	Month 1			Month 2			Month 3			Deviance	d.f.
	<i>b</i>	S.E.	<i>P</i>	<i>b</i>	S.E.	<i>P</i>	<i>b</i>	S.E.	<i>P</i>		
11	2.25	0.30	<0.001	0.72	0.33	0.030	1.06	0.29	<0.001	2721	1898
20	2.25	0.32	<0.001	0.71	0.35	0.046	1.46	0.31	<0.001	2739	1898
30	2.55	0.34	<0.001	0.52	0.36	0.156	1.73	0.32	<0.01	2778	1898
40	2.44	0.34	<0.001	0.99	0.38	0.009	1.75	0.35	<0.001	2841	1898

To estimate the effect of this cut-off on the number of positive samples, the dataset covering for 1 June to 30 August 2000 was used again. With the individual cut-off OD% of 40, 4.0% of the samples taken were judged “positive”—while with the OD% 20 cut-off, almost twice as many (7.7%) were judged “positive”.

3.4. How should the results from the previous 3 months be weighted?

In the previous program, the serological results of the previous 3 months are averaged. However, a weighting might improve the association between serology and bacteriology, as is known from the Danish PRRS-surveillance and the Salmonella surveillance in the breeding and multiplier herds.

To investigate this, the parameter estimates from the four models described in Table 5 suggested which relative weights to apply to each of the 3 months. The parameter estimates varied slightly depending on the cut-off. For cut-off OD% 20, a relative weighing of 3:1:1 (absolute: 0.6:0.2:0.2) was the chosen.

The combination of applying individual cut-off OD% 20 and the weighing was called the *serological Salmonella index* for slaughter pig herds. In the following, we present two examples of calculating the index. In each herd, 10 finishers were sampled monthly for 3 months (*italic values indicate positive samples*).

Herd assigned to Level 3

January	23, 35, 0, 1, 70, 45, <i>100</i> , 20, 30, 6	⇒ six positives ≈ 60%
February	25, 60, 89, 56, 10, 7, 5, 64, 85, 90	⇒ seven positives ≈ 70%
March	76, 45, 23, 5, 9, 90, 79, 45, 31, 89	⇒ eight positives ≈ 80%

Weighted average = $0.2 \times 60 + 0.2 \times 70 + 0.6 \times 80$; index = 74.

Herd assigned to Level 1

January	46, 24, 27, 1, 1, 5, 9, 39, 15, 14	⇒ four positives ≈ 40%
February	22, 1, 1, 11, 8, 1, 1, 1, 18, 32	⇒ two positives ≈ 20%
March	1, 1, 1, 1, 1, 1, 1, 15, 11, 19	⇒ zero positives ≈ 0%

Weighted average = $0.2 \times 40 + 0.2 \times 20 + 0.6 \times 0$; index = 12.

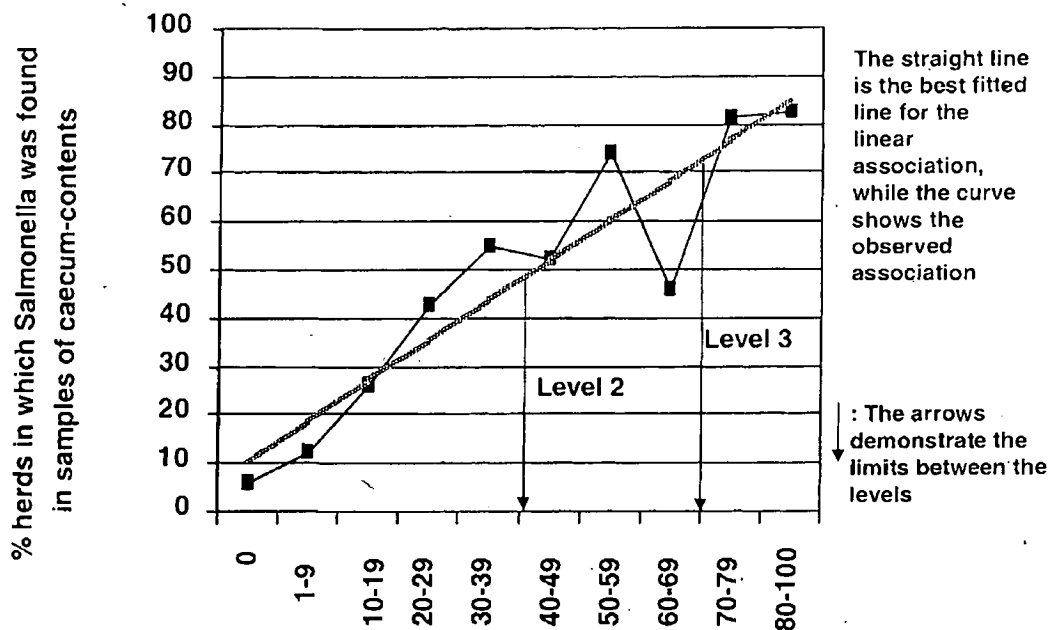
The weighting implies that the serological result of the previous month means three times as much as those of the 2 months before. Therefore, when the herd seroprevalence increases, the herd may be assigned a higher level one month earlier (or in extreme cases, even 2 months earlier) than in the previous system. Likewise, as Salmonella-reducing procedures are implemented in such a herd, the herd would leave the higher level sooner than in the current system. We believe this will be incentive for farmers to introduce better control more-quickly than today. Additionally, the likelihood of finding Salmonella during the mandatory bacteriological follow-up would probably increase.

Furthermore, we believe there would be more-timely overlap between the possible shedding of bacteria and the special measures taken at the slaughterhouse. This would reduce the possible Salmonella contamination of the meat.

3.5. How many levels should be included and what should the cut-off point be for each level?

In the previous program, three official *Salmonella* levels were used (Levels 1, 2 and 3, resembling low, moderate and high *Salmonella* prevalence) (Table 1). However, the assignment of *Salmonella* level depended not only on the within-herd *Salmonella* prevalence but also on the herd size (Mousing et al., 1997). As a result, smaller herds were “allowed” a relatively higher *Salmonella* prevalence than larger herds before being assigned Level 3. Furthermore, as a consequence, changes in herd-size could result in changes in *Salmonella* level in a rather peculiar manner. In example, a herd delivering 5000 finishers per year had 49% seropositive pigs, hence, was classified Level 2; subsequently, production expanded to 5001 finishers, and the herd was now assigned Level 3 automatically (Table 1). Therefore, we decided that the present limits for being assigned Levels 1, 2 or 3 needed evaluation. Additionally, it was of interest to introduce a Level 0.

The dataset representing the 1902 selected herds was chosen to investigate this. For each herd, the serological *Salmonella* index was calculated. Next, the association between the index and the likelihood of finding *Salmonella* in the 10 samples of caecum content was estimated (Fig. 1). The figure shows that among herds that were seronegative during the entire 3-month period, no *Salmonella* was found in the caecum samples in 94.4% of the herds. The figure also shows that there was an almost-linear association ($r^2 = 85\%$) between the index and the proportion of herds in which *Salmonella* was found in the caecal-contents.



The serological salmonella index for slaughter pig at individual cut-off OD% 20

Fig. 1. Observed association between serological *Salmonella* index (a weighted average of the previous 3 months serological results) and bacteriology among 1902 Danish finisher herds ($r^2 = 85\%$).

The level model should not be considered static—but rather a changing measure, used as an adaptable tool in the over-all attempt to reduce the *Salmonella* prevalence over time. Considering that the number of herds assigned the highest *Salmonella* level should not exceed the capacity of the abattoirs to slaughter possibly *Salmonella*-contaminated carcasses safely, we decided using index ≥ 40 and ≥ 70 as limits between Levels 1 and 2, and Levels 2 and 3, respectively (Fig. 1).

3.5.1. Level 0

Having only seronegative tests over ≥ 3 months is an indication of negligible *Salmonella* prevalence, because the within-herd seroprevalence is $< 5\%$ —when all samples taken over 1 year are negative. *Salmonella* bacteria only could be isolated from samples of caecal contents in 5.6% of these herds (Fig. 1).

3.5.2. Level 1

This level include herds with “acceptable, low” *Salmonella* prevalence, which we define as herds with a serological *Salmonella* index ranging from 1 to < 40 . In the dataset we studied, *Salmonella* bacteria could be isolated from samples of caecal contents from 5.6 to 50% of these herds (Fig. 1).

3.5.3. Level 2

Herds with “moderate” *Salmonella* prevalence we defined as herds with an index ranging from 40 to < 70 . *Salmonella* bacteria could be isolated from samples of caecal contents from 50 to 74% of these herds (Fig. 1).

3.5.4. Level 3

Herds with unacceptable high *Salmonella* prevalence we defined as herds with index ≥ 70 . *Salmonella* bacteria could be isolated from samples of caecum content in $> 74\%$ of these herds in the dataset we studied (Fig. 1).

3.5.5. Distribution of herds into levels

Table 6 shows the distributions of herds in levels for the new and the previous scheme. Official data were used to describe the effect of the previous assignment on the distribution of the Danish herds into levels. These data include a total of 14,109 herds, which is more than the data describing the suggested assignment, because it only was possible to calculate the serological *Salmonella* index for herds which delivered finishers for slaughter in both June, July, and August 2000. Hence, a comparison can be made only based on percentages.

In the previous program, 3.1% of the herds were in Level 2 and 1.2% in Level 3. Hence, bacteriological follow-up were carried out in 4.3% of the herds (because bacteriologic follow-up is carried out in all Level-2 and -3 herds). When index ≥ 40 and index ≥ 70 are used as limits for Levels 2 and 3, respectively, 3.3% of the herds will be assigned to Level 2 and 1.6% to Level 3—and more herds will be assigned to a bacteriological follow-up in the new system than in the previous system. Furthermore, because the index includes a weighting of the previous 3 months' serological results, even-more herds might be assigned temporarily to a higher level than at present. On the other hand, the increase in sample size used to assess the seroprevalence among the smaller herd sizes will reduce the accidental

Table 6

Distribution into four Salmonella levels of 11,166 Danish slaughter pig herds (which delivered finishers between 1 June and 30 August 2000) based upon the new and the previous assignment scheme

	Level 0, negligible prevalence of Salmonella	Level 1, low prevalence of Salmonella	Level 2, moderate prevalence of Salmonella	Level 3, unacceptable high prevalence of Salmonella
Distribution of herds into Salmonella levels according to <i>new</i> assignment—based on a serological index (a 3-month weighted average prevalence and individual cut-off OD% 20)				
Serological index (%)	0	1 to <40	40 to <70	≥70
% of herds	60.6	34.5	3.3 ≈ 380 herds	1.6 ≈ 173 herds
Distribution of herds into Salmonella levels according to the <i>previous</i> assignment ^a —based on the average 3-month prevalence, interpreted at individual cut-off OD% 40				
Prevalence (%)	0	Large herd: <10% Small/medium herd: <17–25%	Large herd: 10–33% Small/medium herd: 17/25–50%	Large herd: >33% Small/medium herd: >50%
% of herds	60.6 ^b	35.2	3.1 ≈ 433 herds	1.2 ≈ 163 herds

^a These data consisted of all slaughter pig herds in Denmark, but the data describing the new assignment only included herds for which it was possible to calculate the index, i.e. they delivered finishers in both June, July, and August 2000.

^b Level 0 did not exist in the previous program.

assignment to Levels 2 or 3 due to imprecise estimates in these herds. Because data corresponding to the suggested sampling were not available, it was not possible to estimate the precise effect on the actual number of herds being assigned to bacteriological follow-up over 1 year. Finally, note that 60.6% of the herds were seronegative. However, these herds might not all be assigned to Level 0, because the inclusion would depend on the exact criterion (i.e. the minimum number of seronegative).

4. Conclusions

The classification scheme for slaughter pig herds in The Danish surveillance-and-control program for *Salmonella* has on August 2001 been adjusted on the following points:

- The sampling has been simplified into 60, 75 or 100 samples per year, depending on the herd size. This means more-precise estimates for the seroprevalence among the smaller herds.
- Herds with an annual kill ≤ 200 slaughter pigs are not a part of the surveillance; 1.6% of the slaughter pigs are not surveilled.
- The cut-off for evaluating individual meat-juice samples has been reduced from OD% 40 to OD% 20—doubling the number of positive samples.
- The previous 3 months' serological samples are weighted 0.2:0.2:0.6, and the weighed average is called the "serological *Salmonella* index" for slaughter pig herds. A herd with an increasing seroprevalence will be assigned to a higher *Salmonella* level more-quickly.
- A herd is assigned to one of three levels monthly. Additionally, the producers might introduce a Level 0 for tested-seronegative herds (assumed to have negligible *Salmonella* prevalence; $P < 5\%$). The limit between Levels 1 and 2 will be set to index ≥ 40 , and the limit between Levels 2 and 3 will be index ≥ 70 .

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Estimation of *Salmonella* prevalence on individual-level based upon pooled swab samples from swine carcasses

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Abstract

Pooling of samples might be an effective means to increase cost-effectiveness in routine surveillance. The present study assessed the effect on the sensitivity of detection of *Salmonella* when pooling swab samples from swine carcasses compared to individual analyses. A total of 18,984 samples from nine Danish swine abattoirs were collected during 1 year, covering 2017 slaughter days. At each abattoir, swab samples were taken on a daily basis from 10 carcasses randomly selected. From each carcass, an area of 3 cm × 100 cm was swabbed. Five of these samples were analysed individually and the other five were analysed as one pooled sample. Standard culture methods were used.

A logistic regression model was built, where the response was whether a sample was *Salmonella* positive or not. The explanatory factors were abattoir, type of sampling (individual or pooled sample), and season of year 2000 (four quarters). The odds ratio (OR) of the effect of type of sampling in the logistic model accounting for abattoir and season was interpreted as the conversion factor between pooled and individual sample prevalence.

The results of the individually analysed samples showed a low prevalence of *Salmonella* (1.4%). When *Salmonella* was isolated, mostly only one positive sample was found among the five individually analysed samples per slaughter day. On a few days >1 positive samples were found (9 out of 2017 days ~0.4%). The pooled sample prevalence was 4.1%. Because the individual prevalence was low, the pooled sample prevalence would have been around five times higher than the individual-level prevalence—if there had been no loss of sensitivity. However, we found that due to loss of sensitivity the pooled prevalence was only three times higher (OR = 2.7; CI 2.0–3.7). Therefore, a conversion factor of 3 instead of 5 should be applied to calculate the individual prevalence from a pooled prevalence. This approach has been used in the national surveillance of Danish pork since 2001. The estimated conversion factor and accept of pooling samples do not necessarily apply to a population with a higher prevalence or to other types of samples (e.g. faeces or lymph nodes) or diagnostic procedures.

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Keywords: *Salmonella*; Sensitivity; Carcass swabs; Sample pooling; Swine

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1. Introduction

In 1998, the Danish pig industry agreed to introduce aims to reduce the prevalence of *Salmonella* in Danish pork. To document a statistical reduction in a low prevalence, a high number of comparable samples are required. The national surveillance of *Salmonella* in pork – which had been in place since 1993 – ensured collection of a high annual number (around 27,000) of samples. However, the surveillance was based upon samples of carcasses and different cuts, and the results were not comparable between abattoirs. A more standardised sampling technique, conducted in an internationally approved way was sought after.

The Danish Bacon and Meat Council – in collaboration with the Danish veterinary authorities – went for the US standard way of sampling swine carcasses after cooling because this was widely recognised and in use among countries exporting to the US. This included swabbing selected areas of one carcass, one a daily basis, at an abattoir (FSIS, 1996). In Denmark, it was of interest to extend this to include swab sampling of more carcasses from every abattoir daily, in the FSIS-prescribed manner, to ensure a high number of samples annually.

The existing data indicated that the prevalence of *Salmonella* on swine carcasses was low. During the period 1996–1999, the Danish *Salmonella* surveillance had shown a prevalence of 0.9–1.2% in pork, measured as a total for carcasses, bone-in cuts and bone-less cuts (Nielsen et al., 2001).

With a low individual prevalence, pooling of samples might be an effective means to increase cost-effectiveness, because it is most likely that a positive pool, consisting of five individual samples, only contains one single positive sample (Cowling et al., 1999). Furthermore, an inquiry to the laboratories involved revealed, that pooling would imply a reduction to 23–35% of the cost compared to analysing five samples individually. The cost is not reduced to merely 1/5 of the cost of analyzing five individual samples. The reason is primarily the pre-enrichment, where 250 ml pre-enrichment broth is used to the pooled sample compared to 50 ml to one individual sample. The pooled sample also takes up more space during incubation.

To get pooling approved as a part of routine surveillance of pork by the Danish veterinary

authorities, we undertook the present study with the aims to:

1. Document how often more than one positive sample is present in a pool of 5.
2. Estimate any loss of sensitivity related to pooling instead of analysing samples individually, and in case of loss of sensitivity, to calculate a factor converting a pooled sample prevalence to individual carcass prevalence.

2. Materials and methods

2.1. Description of study

The study was conducted from 1 January to 31 December, 2000. Sampling during one full year ensured that seasonal variation was covered. Based upon results from the ongoing surveillance in pork, four abattoirs representing higher (abattoirs D, F, G and H) and five abattoirs representing lower prevalence of *Salmonella* (abattoirs A, B, C, E and I) in pork were identified and included in the study. The limit between higher and lower prevalence was set at 1.5% *Salmonella* in the current national surveillance of meat cuts.

The total number of finishers slaughtered at the abattoirs varied from around 1600 to around 12,500 per day. Every day, 10 carcasses were selected for sampling at each participating abattoir. The selection was carried out by the use of a computer-based PLC (programmable logical controller) in accordance with US regulations. This should ensure that the selected carcasses were representative of the slaughter and the day. The selected carcasses were located on a separate line. The side of carcass swabbing was determined on some of the abattoirs by tossing a die, on others according to the slaughter number, even or uneven.

The study was designed as a cross-sectional study, where samples from one abattoir were evaluated independently and in pools of five, day by day.

2.2. Sample size consideration

One requirement for the new surveillance was that it should be able to document a prevalence, p , of 1% with a precision, L , of 0.5%. This would require 1521

samples ($n = 196^2 \times pq/L^2$). If 5 samples were analysed at an abattoir per slaughter day, around 1320 samples were collected annually, and the precision, L , would be 0.55%. This made comparison over time for one abattoir possible—and comparisons between abattoirs acceptable.

Furthermore, the veterinary authorities wanted to maintain the intensity of the surveillance. This demand would also be met by sampling five carcasses per day.

2.3. Sampling and culture technique

Carcasses were sampled after 12 h of chilling. The swabbing was performed with a gauze tampon size 10 cm × 10 cm. Before swabbing, the gauze tampon was moistened with 10 ml of buffered peptone water. Three areas each covering 10 cm × 10 cm yielding a total of 300 cm² were swabbed; the hind leg near the tail, the chest near the sternum, and the cheek. The three areas were swabbed with the same gauze tampon, which after swabbing was placed in a plastic bag intended for the analysis.

Preliminary studies revealed that it was important, to place the five gauze tampons, that should form part of the pooled sample, together in the same plastic bag immediately after swabbing. This plastic bag should be large enough for the following pre-enrichment that included adding 250 ml of buffered peptone water. If not, the *Salmonella* pooled prevalence was artificially low, perhaps because the bacteria would adhere to the walls of five small plastic bags. For the individual samples, pre-enrichment was performed directly in the original small plastic bag by adding 50 ml of buffered peptone water, hence, presumably adhesion to the wall did not result in lower sensitivity.

After pre-enrichment, analyses were carried out by the abattoirs' officially approved laboratories either according to NMKL no. 71 (Anonymous, 1991) by the Danish Veterinary and Food Administration's modifications or by the use of EiaFoss (Krusell and Skovgaard, 1993). Any positive findings were confirmed according to the NMKL. The NMKL is a traditional bacterial culturing method. After pre-enrichment at 37 °C for about 18 h, 0.1 ml of pre-enriched sample is transferred to a selective enrichment broth and this is incubated at

42 °C for 24 h. Then, an aliquot from the selective enrichment broth is inoculated on two selective agar plates and incubated at 37 °C for about 24 h. Presumptive *Salmonellae* are subcultured on a suitable plate and are biochemically and serologically verified.

The EiaFoss is an ELISA-test. After pre-enrichment for 19–24 h at 41.0 °C, there is another pre-enrichment for 3 h at 42.0 °C. Subsequently, the sample is boiled for 15 min, chilled until the temperature is below 35 °C, and then the EiaFoss analyses is performed on the sample. Positive samples must be confirmed by traditional culture.

The two analytical methods are approved as equivalent by the Danish veterinary authorities.

2.4. Statistics

The expected number of *Salmonella* positive samples in a pool of five, given independence between samples, was calculated by use of a binomial distribution. Here, the prevalence, p , was the individual prevalence of *Salmonella* positive carcass samples found in the present study. The software programme Excel was used for this purpose.

The estimation of the conversion factor was based on a logistic regression. A logistic regression model was built where the response was whether a sample was *Salmonella* positive or not. The explanatory factors were abattoir, type of sampling (individual or pooled sample), and season (four quarters of year 2000). In short, the model explained the prevalence of *Salmonella* from these three factors. Every abattoir got its own prevalence level, and likewise for the four seasons and the two types of sampling. The procedure GENMOD in SAS was used (SAS, 1996). To account for over-dispersion due to day-to-day variation in the *Salmonella* prevalence at an abattoir, a repeated statement was included with compound symmetry as the correlation structure (SAS, 1996).

The odds ratio (OR) of the effect of type of sampling in a logistic regression model accounting for abattoir and season was interpreted as the conversion factor between pooled and individual sample prevalence. If there had been no loss of sensitivity, the OR for the prevalence relationship would be around 5, given the prevalence was low.

3. Results

3.1. Prevalence of *Salmonella*

During the study, a total of 18,984 carcass swab samples were taken on 2017 slaughter days. Among these 10,099 were analysed as individual samples, and the remaining 8885 samples were analysed in pools of five yielding 1777 pools. Due to monetary constraints, no pooled samples were taken on one abattoir (abattoir B). Likewise, on abattoir A samples were only collected during the first 4 months of 2000. On the other abattoirs a few samples were missing; on 10 slaughter days, <10 samples were taken implying that 1–4 samples were missing. Moreover, on two slaughter days, more than 10 samples were taken.

The results of the individually analysed samples showed that 138 samples out of 10,099 were *Salmonella* positive yielding a prevalence of 1.4% (Table 1). These 138 positive samples were found on 126 slaughter days (6.2% positive slaughter days).

The results of the 1777 pooled samples revealed 72 positive pools (4.1%). If there had been no loss of sensitivity, then the expected prevalence would have been $5 \times 1.4\% = 7.0\%$. In conclusion, pooling of five samples into one resulted in loss of sensitivity.

Table 1 presents the distribution of the number of positive samples out of the 5 samples collected daily from an abattoir among the 10,099 samples, which were analysed individually. It is noted that on most days no positive samples were found. If positive samples were found, usually only one out of the five samples taken daily was *Salmonella* positive. Exceptionally, two, three, or four positive samples were found. On no days all five samples were positive.

Table 1 also presents the expected number of days the respective number of positive samples given independence between samples. It is noted that there is

a fair agreement between the observed and expected number of positive samples; however, not for the finding of three and four positive samples.

3.2. Estimation of conversion factor

Table 2 presents the individual and pooled prevalence of *Salmonella* by abattoir and season. It is noted that there was a considerable variation between the nine abattoirs; the individual prevalence varied from 0.2% to 2.6% and the pooled prevalence varied from 2.5% to 6.6%. There was some seasonal effect on the pooled prevalence (varied from 3.1% to 5.9%) and limited effect on the individual prevalence of *Salmonella* (varied from 1.2% to 1.6%).

All data from abattoir B were deleted from the logistic regression analysis, because no data on pooled samples were available. Hence, data from 8 abattoirs were included in this part of the analysis. The variable season was removed because of non-significance ($p = 0.40$) and no confounding effect on the two other explanatory variables.

The observed prevalence relationship between the two kinds of sampling varied from 1.4 to 5.0 between the eight abattoirs (Table 2). At abattoir F the observed prevalence ratio of 1.7 was so low that it could not be distinguished statistically from 1.0 (five was expected). However, there was no other strong justification for leaving out data from this abattoir. Hereby, the logistic regression analysis provided the following estimate for the prevalence relationship between the pooled/individual sample prevalence:

conversion factor : 2.7

(95% confidence interval = 2.1 – 3.6)

According to the final logistic regression model, type of sampling (pooled/individual) was strongly

Table 1

Distribution of observed (%) and expected number of *Salmonella* positive samples out of five analysed per day per abattoir in a Danish study performed on nine abattoirs including a total of 10,099 swine carcasses sampled on 2017 slaughter days, 2000

	No. of days (%) swab samples were found <i>Salmonella</i> positive out of five per day					
	0 positive	1 positive	2 positives	3 positives	4 positives	5 positives
Observed	1891 (93.8)	117 (5.8)	7 (0.3)	1 (0.05)	1 (0.05)	0 (0.00)
Expected	1883	130	4	0	0	0

The expected number was calculated by use of a binomial distribution with an individual prevalence of 1.4% and based on the assumption of independence between samples.

Table 2

Prevalence of *Salmonella* for individual and pooled swab samples of pork carcasses based on data from nine Danish abattoirs including a total of 18,984^a samples, 2000

Variable and levels	Individual samples ^b		Pooled samples ^b		Crude prevalence relationship ^c
	Positive/total	% positive	Positive/total	% positive	
Abattoir					
A	3/405	0.7	3/81	3.7	5.3
B	2/1155	0.2			
C	18/1263	1.4	9/242	3.7	2.6
D	32/1221	2.6	16/244	6.6	2.5
E	13/1242	1.1	12/246	4.9	4.5
F	18/1179	1.5	6/236	2.5	1.7
G	21/1185	1.8	10/239	4.2	2.3
H	22/1230	1.8	10/245	4.1	2.3
I	9/1219	0.7	6/244	2.5	3.6
Season in 2000					
January–March	33/2710	1.2	15/486	3.1	2.6
April–June	34/2404	1.4	25/421	5.9	4.2
July–September	31/2516	1.2	18/436	4.1	3.4
October–December	40/2469	1.6	14/434	3.2	2.0
All abattoirs	138/10,099	1.4	72/1777	4.1	2.9
Excluding F	118/7765	1.5	66/1541	4.3	2.9

^a Among the 18,984 samples, 8885 were analysed in pools of 5, yielding 1777 pools.

^b Prevalence of *Salmonella*.

^c The crude prevalence relationship was obtained by dividing the prevalence of *Salmonella* in the pooled samples by the prevalence in the individual samples.

significant ($p < 0.0001$). Likewise, abattoir was significant ($p = 0.02$). There was only a limited over-dispersion, because the correlation between samples taken within a day was only 0.05. The interaction between abattoir and the conversion factor was non-significant ($p = 0.751$). If data from abattoir F were excluded from the logistic regression analysis, an estimate of 2.9 (95% CI: 2.2–3.9) was obtained instead of 2.7.

4. Discussion

Estimating the individual prevalence from pool prevalence only makes sense if most commonly only one positive sample is found in a positive pool (Cowling et al., 1999). This will occur in a population with a low prevalence of the agent of interest.

If the aim is to identify, e.g. presence of *Salmonella* (yes/no), then pooling also makes sense when prevalence is moderate to high. An example of the latter is found in the Danish surveillance of pig herds

with moderate to higher levels of *Salmonella*, where pooling of four pen faecal samples is routinely used (Enøe et al., 2003).

In the present study, we found an individual prevalence of 1.4% *Salmonella* positive swab samples. In general, only one positive sample was found out of the five taken on the same day and analysed individually. At one abattoir, three positive samples were found on 1 day, and here, nothing could explain the high number of positive samples. At another abattoir, four positive samples were found on 1 day. Here, the defective condition of a packing in a bung dropper was the cause, and this error was found and corrected during the same slaughter day. This, presumably, explained the high number of positive samples found on that day. In total, on 7% of the slaughter days where *Salmonella* was found, more than one sample out of five was positive. This, we judged, was acceptable for the use of pooling of carcass swabs.

Due to economic constraints, the amount of *Salmonella* present in positive samples was left

un-quantified, because the aim of the study was to compare two different methods: analysis of individual samples versus pooled samples. If there only was a limited loss of sensitivity associated with pooling compared to analysing samples individually, then pooling was judged acceptable. A conversion factor would then be included in the national surveillance to compensate for the relative loss of sensitivity due to pooling.

The quantitative prevalence of *Salmonella* in Danish pig carcass swab samples is low in general (Olsen et al., 2001). Furthermore, in 1993, an internal study of the number of *Salmonellae* in swab samples of carcasses was conducted. That study found, that a carcass swab with a total load of only 20 *Salmonella* bacteria would turn out positive. This result was found by use of MPN-analysis (unpublished results). Therefore, we assume that the observed loss of sensitivity is mainly due to dilution of the original positive sample into levels below the detection limit.

One abattoir did not collect samples for the analysis of the pooled prevalence, and another abattoir only collected samples for four instead of 12 months. Both reductions were due to financial limitations. Still, the total number of samples was very high, 18,984.

At abattoir F, the observed prevalence ratio of 1.7 was so low that it could not be distinguished statistically from 1.0 (five was expected). If data from abattoir F were excluded from the final estimation of the conversion factor, the conversion factor would have been 2.9. Hence, there was limited effect of leaving out data from abattoir F. In conclusion, the results are robust.

The observed loss of sensitivity found in the present study is in line with Enøe et al. (2003), who also observed a loss of sensitivity when pooling four pen-faecal samples into one. Price et al. (1972) found no loss of sensitivity when pooling pre-enrichment broth cultures into a single enrichment broth. Their study, however, included dry food materials. It is unknown how such a method would have influenced the sensitivity of pooled carcass swab samples.

There was some variation in the *Salmonella* prevalence between the abattoirs. This was expected because the abattoirs were selected based on this parameter. The average *Salmonella* prevalence among the four abattoirs initially selected because of a higher prevalence (abattoirs D, F, G and H) was 1.9%,

whereas it was 0.8% for the remaining five lower-prevalence abattoirs. The selection of abattoirs representing higher and lower levels of *Salmonella*, respectively, was chosen, because the study aimed at covering all abattoirs in Denmark.

It should be noted that the individual conversion factor is higher for the abattoirs representing lower prevalences of *Salmonella* compared to abattoirs representing higher levels of *Salmonella* (Table 2). An individual conversion factor for each abattoir could have been considered. This would reflect variations in, e.g. test handling, sample handling, *Salmonella* prevalence, and risk of cross contamination between abattoirs. However, the management at an abattoir is very dynamic and related to the present personnel. Moreover, the *Salmonella* prevalence varies over time. Therefore, it was decided to estimate one common conversion factor for all abattoirs. The estimated conversion factor and accept of pooling samples do not necessarily apply to a population with a higher prevalence or to other types of samples (e.g. faeces or lymph nodes) or diagnostic procedures.

In Denmark, a peak in the incidence of human salmonellosis is usually seen during summer (Anonymous, 2004). However, we found no seasonal variation in the *Salmonella* prevalence of pork in our study. According to the national surveillance of Danish pork from 2001 to 2003 no clear seasonal variation has been observed (Anonymous, 2004). The seasonal variation in human cases of salmonellosis is, therefore, probably related to changes in cooking behaviour in summer and to the fact that other food source apart from pork, which contribute to human salmonellosis.

We chose to include five carcasses daily instead of the one required by FSIS (FSIS, 1996). This ensured that any increase or decrease in *Salmonella* prevalence could be identified at an early stage at an individual abattoir. If only one sample had been taken daily, the precision would have been insufficient (seen over 1 year: 1.2% compared to 0.55%) to identify changes in the prevalence at these abattoirs which all had a low *Salmonella* prevalence ($\leq 2.6\%$ according to Table 2). The difference in cost between an individual and a pooled sample of five is around € 3.5 more for the pooled sample (2006 figures). That means that for a relatively small amount of money we get much more information on *Salmonella* upon which to take action.

Analysis of pooled samples and use of a conversion factor is now a routine in the national surveillance of Danish pork (Anonymous, 2004). A conversion factor of 3 is used—as a result of rounding of 2.7.

To ensure that the sample reflects the prevalence at an abattoir, the five carcasses selected for sampling should be evenly distributed over the slaughter day. If more slaughter lines are present, the samples should represent all lines. Likewise, if more shifts are carried out (e.g. morning compared to evening) this should be reflected in the sampling (Anonymous, 2005a).

In May 2002, the system was extended into a formal control programme, where each abattoir is evaluated monthly with respect to its *Salmonella* prevalence, based upon data from the previous 12 months (moving average). The abattoir is noted if the individual *Salmonella* prevalence is $\geq 2.2\%$. If an abattoir is noted four times during a 6-month period, it is obliged to initiate an intensified *Salmonella* control programme (Sørensen and Møgelmoose, 2005).

By 1 January 2006, the European Union introduced microbiological criteria for *Salmonella* in pork (Anonymous, 2005b). According to this order, abattoirs have to sample five carcasses weekly. The carcasses can be sampled on the same day, and pooling of the five samples is allowed. If pooling is used, the result is presented as a pooled prevalence.

The new zoonosis directive recently issued by the European Union (Anonymous, 2003) will be implemented in the years to come. In this context, surveillance programmes for *Salmonella* and possibly other zoonoses will be developed and implemented in many EU countries. The results of the present study might be of help to these countries. A future surveillance should be adapted to meet local requirements, e.g. with respect to how common *Salmonella* is in the national pig population and what has already been done to mitigate the risk of exposure to humans.

5. Conclusion and implications

The individual prevalence of *Salmonella* in carcass swab samples of Danish pork was low, 1.4%. Moreover, only occasionally more than one sample out of five in a pool was positive. Because of this, pooling of carcass swab samples was accepted by the Danish veterinary authorities. Pooling resulted in a

loss of sensitivity. If there had been no loss of sensitivity the pooled prevalence was expected to be five times higher than the individual prevalence. However, according to our data there was only a factor of 3 in difference. Therefore, a conversion factor of 3 instead of 5 should be applied to calculate the individual prevalence from the pooled prevalence. The estimated conversion factor and accept of pooling samples do not necessarily apply to a population with a higher prevalence or to other types of samples (e.g. faeces or lymph nodes) or diagnostic procedures.

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We would like to thank the laboratory technicians at the participating laboratories for their commitment and willingness to collect and analyse the samples.

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UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
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DENMARK EQUIVALENCE DETERMINATION FOR

**An alternative post-mortem inspection
procedure (visual inspection instead of
palpation of mesenteric lymph nodes) for
slaughtered pigs**

Priya Kadam

01/09/2012



**UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
OFFICE OF INTERNATIONAL AFFAIRS
INTERNATIONAL EQUIVALENCE STAFF
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**Denmark
EQUIVALENCE DETERMINATION
FOR Individual Sanitary Measure**

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FILE CHECKLIST—INDIVIDUAL SANITARY MEASURE

Alternative post-mortem inspection: Visual inspection instead of palpation of mesenteric lymph nodes for slaughtered pigs.

CERTIFICATION STATEMENT

The contents of this file have been reviewed in accordance with the Equivalence Management Controls established by the Office of International Affairs as certified by the Project Leader assigned to the file and reviewed by the Director, International Equivalence Staff, and Office of International Affairs.

COUNTRY AND EQUIVALENCE REQUEST

Denmark has requested an alternative post-mortem inspection system. Denmark as a part of the 'Supply Chain Meat Inspection- the Danish Way' proposes to conduct visual inspection of mesenteric lymph nodes instead of palpation of slaughtered pigs.

STATUS OF FILE (checked areas are complete)

- ☒ Correspondence to the country and correspondence from the country
- ☒ Original documents provided by the country and their translations
- ☒ Meeting records of all document reviews
- ☒ Summaries of all meetings and teleconferences with country representatives
- ☒ Signed decision memorandum

CERTIFIED BY:

P. C. Kadam
PROJECT LEADER

DATE 01/09/2012

REVIEWED AND CONCURRED BY:

[Signature]
DIRECTOR, INTL. EQUIVALENCE STAFF

DATE 1.20.2012

**DECISION MEMORANDUM—
INDIVIDUAL SANITARY MEASURE
Denmark**

Daniel Oestmann, Shannon McMurtrey and Priya Kadam

EQUIVALENCE REQUEST:

Denmark has submitted a request for an equivalence determination for an alternative post-mortem inspection i.e. visual inspection instead of palpation of mesenteric lymph nodes of slaughtered market hogs.

BACKGROUND:

On December 16, 2008 in FSIS-Denmark bilateral meeting a team of FSIS experts had met and reviewed Denmark's Supply Chain Inspection system, reference materials supporting this inspection system, and presentations by Danish officials. The Supply Chain Inspection system allows inspection of market hogs raised under an integrated quality control program coupled with an on-site verification at slaughter establishments for checking accuracy of visually inspected carcasses and organs to ensure that passed carcasses and parts are wholesome and not adulterated.

In a letter dated December 24th 2008 FSIS had approved Denmark's use of an alternative post-mortem inspection procedure for market hogs as a part of the Supply Chain Meat Inspection. This proposed alteration was to conduct a visual inspection instead of incising mandibular lymph nodes.

In the current submission of April 23, 2010 Denmark is proposing an additional alteration in the post-mortem inspection procedure i.e. visual inspection instead of palpation of mesenteric lymph nodes of slaughtered market hogs.

FSIS FOOD SAFETY MEASURE:

The purpose of post-mortem inspection of livestock is to protect the public health by ensuring that carcasses and parts that enter commerce are wholesome and not adulterated. To achieve this goal, in swine slaughter establishments operating under traditional inspection or in those establishments operating under the HACCP-Based Inspection Models Project (HIMP), FSIS inspectors perform ante-mortem and post-mortem inspection procedures to detect diseases, abnormalities, and contamination of livestock carcasses and parts.

In establishments operating under HIMP, FSIS requires that the establishment implement ante-mortem and post-mortem sorting procedures and present to FSIS only normal and healthy-appearing animals and carcasses and parts that are wholesome and free of defects. HIMP also requires additional FSIS verification procedures to ensure that the establishment produces only safe, wholesome products.

OBJECTIVE OF THE FOOD SAFETY MEASURE:

FSIS inspectors conduct ante-mortem inspection of live swine and post-mortem inspection of carcasses and parts on a carcass by carcass basis. In market age swine, FSIS performs inspection under either the traditional inspection system or under the HIMP inspection system. In both cases, inspection procedures are intended to identify and remove unwholesome and adulterated carcasses and parts from the food supply.

EQUIVALENCE CRITERIA:

The criteria used for making an equivalence determination for an alternative post-mortem inspection procedure for market-age hogs are equivalent to the U.S. inspection procedure for market age hogs are set forth below:

1. The government inspection service administers an inspection program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass.
2. The government inspection system requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market hog carcasses presented for inspection.
3. The incidence of diseases in market hogs, such as TB, is no higher than the incidence in the United States.
4. The market swine must be born and raised in the country.
5. The government inspection service must implement a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects).

EQUIVALENCE EVALUATION:

The government inspection service administers an inspection program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass.

This criterion is met. As per Denmark's Supply Chain Inspection system, Denmark uses a combination of pre-slaughter data collection and post-mortem inspection to ensure the identification and removal of diseased carcasses and parts from the food supply. Pre-slaughter data must be presented to the slaughter establishment prior to slaughter of the swine. The Official Veterinarian at the slaughter establishment will verify that this information is supplied to the slaughter establishment. Without this information, swine will not undergo slaughter. This system allows for full traceability of swine and provides the health information of all swine prior to slaughter. Ante-mortem inspection occurs in the same way as conducted by FSIS. The proposed alteration to post-mortem inspection

is related to the visual inspection instead of palpation of the mesenteric lymph nodes of slaughtered market hogs. Denmark has conducted, and submitted to FSIS, a risk assessment¹ which focused on the areas of swine carcass inspection that will be altered under their "Supply-Chain Inspection" proposal. This risk assessment was conducted on the visual inspection of stomach and intestines instead of palpation of the intestinal lymph nodes of slaughtered market hogs.

The outcome of this risk assessment was that the changes proposed:

1. Did not increase risk related to exotic, contagious livestock diseases because these diseases manifest themselves as either clinical symptoms in the living animal or in lesions in organs other than the intestinal lymph nodes
2. Will not have any substantial influence on the herd health assessment and welfare made by the owner, the veterinarian or the authorities
3. Ensures a high degree of certainty that finisher pigs under the Supply Chain Meat Inspection really come from integrated herds
4. Palpation of the intestinal lymph nodes does not essentially contribute to the judgement on whether a carcass is infected with *Salmonella*, *Campylobacter* and *Yersinia*, because occasionally these pathogens cause changes in the gastro-intestinal tract or the intestinal lymph nodes

Therefore, there is only a negligible risk involved in inspecting the stomach and the intestines instead of inspecting and palpating the intestinal lymph nodes. This assessment covers only finisher pigs from indoor herds. Thus this alternate post-mortem inspection is effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain.

The government inspection system requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market hog carcasses presented for inspection.

This criterion is met. Denmark has adopted a sanitary measure that is same as the FSIS requirement. No equivalence determination is needed. Denmark requires establishments to conduct generic *E. coli* testing. In addition, Danish authorities conduct *Salmonella* performance standard testing per the FSIS requirements.

The incidence of diseases in market hogs, such as Tuberculosis (TB), is no higher than the incidence in the United States.

This criterion is met. Denmark has been recognized as free of *Mycobacterium bovis* (bovine tuberculosis) since 1980. A large-scale surveillance program in cattle in Denmark is in place ensuring a constant documentation of the free status.

The market hogs must be born and raised in the country.

¹ Is palpation of the intestinal lymph nodes a necessary part of meat inspection of finisher pigs? By Lis Alban, Birthe Steenberg, Jesper Valentin Petersen and Susanne Jensen. Danish Agricultural & Food Council, Axeltorv 3, DK-1609 Copenhagen V, Denmark. Translated into English July 2, 2010

This criterion is met. In order to qualify for this program, the producer must demonstrate that the market hogs are of Danish origin. Only swine that have been raised indoors since weaning and are raised under controlled circumstances are eligible for this inspection procedure. There is complete segregation of the swine from other species while on the farm, during transport to the slaughter establishment, during lairage and slaughter.

The government inspection service must implement a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects).

This criterion is met. In 2008 Danish Veterinary and Food Administration (DVFA) had submitted performance standards for verifying inspection for the removal of both food safety and non-food safety defects. These standards were introduced for all market hogs slaughterhouses on January 1, 2009. The standards include: 1) not more than 5% non-compliances for inspection tasks (palpation, incision and hygienic behavior), 2) not more than 6% cumulative non-compliances for pathological findings (2% for the carcass, 2% for the plucks and 2% for other organs), and 3) for hygienic slaughter not more than 2% non-compliances for contamination in general and 0% fecal contamination. The quality of the meat inspection is conducted by the official veterinarian by checking 100 carcasses including organs per line per shift after post mortem inspection. If non-compliances exceed the performance standards then additional instructions are given to the staff and the frequency of checks is increased.

This year the DVFA revisited the standards and made changes.

Main changes in the new performance standards:

- The standard is covering the overall performance monitoring of the whole meat organization, however the daily check of the official auxiliaries is not part of this standard
- Greater focus on evaluation and corrective actions
- Key performance indicators to compare between slaughterhouses
- New sample frequencies according to the principles in DS/ISO 2859-1
- New procedures for supervision

Number of samples:

- Number of samples is statistically calculated and depends on number of pigs slaughtered at a particular slaughterhouse. One sample consists of 'one animal' i.e. ante-mortem, post-mortem (carcasses, plucks, intestines, etc) inspection and inspection on the rework platform.
- At a minimum 5 procedures for each sample. Supervisor makes an inspection of the procedures (palpation, incision, behavior), and supervisor makes an ordinary inspection of carcasses which have already been through post-mortem control to make sure the right decisions are made by the inspectors.
- If food safety is compromised there will be an immediately correction. Furthermore there will be a monthly evaluation. At the monthly evaluation a 3% differentiation is accepted with out changing sample size. If more than 3% the

frequency will go up. Focus will be on follow up to make sure the right corrective actions are made.

Other verification procedures:

- Inspection for absence of visible fecal contamination. The absence of visible fecal contamination is monitored on a daily basis. The inspection is done after post-mortem inspection but before the carcasses enter the chilling room.
- Supervision of the individual employees. The supervision takes place every third year and used as a tool for development of the individual staff member.
- The official veterinarian checks the work of official auxiliaries on a daily basis.

Denmark has observed that these performance standards have been a viable tool to supervise and assess the quality of the meat inspection at each slaughterhouse.

RECOMMENDATION:

FSIS has determined that Denmark's request for an equivalence determination for an alternative post-mortem inspection i.e. visual inspection instead of palpation of mesenteric lymph nodes of slaughtered market hogs meets the established criteria. Therefore, Denmark's equivalence request should be granted.

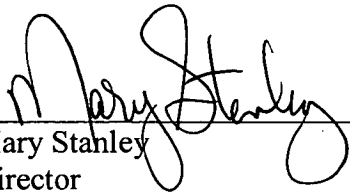
APPROVAL:



Andreas Keller
Director
International Equivalence Staff
Office of International Affairs, FSIS

1.10.12

Date



Mary Stanley
Director
International Policy Division
Office of Policy and Program Development, FSIS

11 January 2012

Date

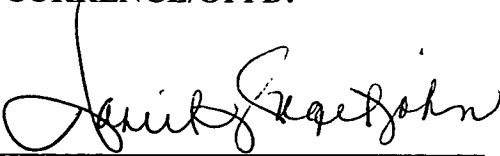
CONCURRENCE/OIA:



Ronald K. Jones
Assistant Administrator
Office of International Affairs, FSIS

1-18-12
Date

CONCURRENCE/OPPD:



Daniel Engeljohn
Assistant Administrator
Office of Policy and Program Development, FSIS

1/31/12
Date

**EQUIVALENCE REVIEW
INDIVIDUAL SANITARY MEASURE
MEETING RECORD
Denmark**

Alternative post-mortem inspection (visual inspection instead of palpation of mesenteric lymph nodes)

02/23/ 2011

EQUIVALENCE REQUEST:

Denmark in the letter dated April 23, 2010 requested equivalence determination for an alternative post-mortem inspection i.e. visual inspection instead of palpation of mesenteric lymph nodes of slaughtered market hogs.

PARTICIPANTS:

Daniel Oestmann and Shannon McMurtrey (OPPD/IPD), and Priya Kadam (OIA/IES).

BACKGROUND:

On December 16, 2008 in FSIS-Denmark bilateral meeting a team of FSIS experts had met and reviewed Denmark's Supply Chain Inspection system, reference materials supporting this inspection system, and presentations by Danish officials. The Supply Chain Inspection system allows inspection of market hogs raised under an integrated quality control program coupled with an on-site verification at slaughter establishments for checking accuracy of visually inspected carcasses and organs to ensure that passed carcasses and parts are wholesome and not adulterated.

In a letter dated December 24th 2008 FSIS had approved Denmark's use of an alternative post-mortem inspection procedure for market hogs as a part of the Supply Chain Meat Inspection. This proposed alteration was to conduct a visual inspection instead of incising mandibular lymph nodes.

In the current submission of April 23, 2010 Denmark is proposing an additional alteration in the post-mortem inspection procedure i.e. visual inspection instead of palpation of mesenteric lymph nodes of slaughtered market hogs.

FSIS FOOD SAFETY MEASURE:

The purpose of post-mortem inspection of livestock is to protect the public health by ensuring that carcasses and parts that enter commerce are wholesome and not adulterated. To achieve this goal, in swine slaughter establishments operating under traditional inspection or in those establishments operating under the HACCP-Based Inspection Models Project

(HIMP), FSIS inspectors perform ante-mortem and post-mortem inspection procedures to detect diseases, abnormalities, and contamination of livestock carcasses and parts.

In establishments operating under HIMP, FSIS requires that the establishment implement ante-mortem and post-mortem sorting procedures and present to FSIS only normal and healthy-appearing animals and carcasses and parts that are wholesome and free of defects. HIMP also requires additional FSIS verification procedures to ensure that the establishment produces only safe, wholesome products.

OBJECTIVE OF FOOD SAFETY MEASURE:

FSIS inspectors conduct ante-mortem inspection of live swine and post-mortem inspection of carcasses and parts on a carcass by carcass basis. In market age swine, FSIS performs inspection under either the traditional inspection system or under the HIMP inspection system. In both cases, inspection procedures are intended to identify and remove unwholesome and adulterated carcasses and parts from the food supply.

DOCUMENTS REVIEWED:

- 1) Annex to Supply Chain Meat Inspection – The Danish way; How to ensure continuous freedom from bovine tuberculosis in finisher pigs when changing meat inspection?
- 2) Evaluation of the report "Palpation of the intestinal lymph nodes a necessary part of meat inspection of finisher market hogs?"
- 3) Is palpation of the intestinal lymph nodes a necessary part of meat inspection of finisher pigs? By Lis Alban, Birthe Steenberg, Jesper Valentin Petersen and Susanne Jensen. Danish Agricultural & Food Council, Axelstorv 3, DK-1609 Copenhagen V, Denmark. Translated into English July 2, 2010
- 4) Performance Standards for Meat Inspection in Denmark received on November 11, 2011.

EQUIVALENCE CRITERIA:

The criteria used for making an equivalence determination for an alternative post-mortem inspection procedure for market-age hogs are equivalent to the U.S. inspection procedure for market age hogs are set forth below:

1. The government inspection service administers an inspection program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass.
2. The government inspection system requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market hog carcasses presented for inspection.

3. The incidence of diseases in market hogs, such as TB, is no higher than the incidence in the United States.
4. The market swine must be born and raised in the country.
5. The government inspection service must implement a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects).

EQUIVALENCE EVALUATION:

The government inspection service administers an inspection program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass.

This criterion is met. As per Denmark's Supply Chain Inspection system, Denmark uses a combination of pre-slaughter data collection and post-mortem inspection to ensure the identification and removal of diseased carcasses and parts from the food supply. Pre-slaughter data must be presented to the slaughter establishment prior to slaughter of the swine. The Official Veterinarian at the slaughter establishment will verify that this information is supplied to the slaughter establishment. Without this information, swine will not undergo slaughter. This system allows for full traceability of swine and provides the health information of all swine prior to slaughter. Ante-mortem inspection occurs in the same way as conducted by FSIS. The proposed alteration to post-mortem inspection is related to the visual inspection instead of palpation of the mesenteric lymph nodes of slaughtered market hogs.

Denmark has conducted, and submitted to FSIS, a risk assessment¹ which focused on the areas of swine carcass inspection that will be altered under their "Supply-Chain Inspection" proposal. This risk assessment was conducted on the visual inspection of stomach and intestines instead of palpation of the intestinal lymph nodes of slaughtered market hogs.

The outcome of this risk assessment was that the changes proposed:

1. Did not increase risk related to exotic, contagious livestock diseases because these diseases manifest themselves as either clinical symptoms in the living animal or in lesions in organs other than the intestinal lymph nodes
2. Will not have any substantial influence on the herd health assessment and welfare made by the owner, the veterinarian or the authorities
3. Ensures a high degree of certainty that finisher pigs under the Supply Chain Meat Inspection really come from integrated herds.

¹ Is palpation of the intestinal lymph nodes a necessary part of meat inspection of finisher pigs? By Lis Alban, Birthe Steenberg, Jesper Valentin Petersen and Susanne Jensen. Danish Agricultural & Food Council, Axelstorv 3, DK-1609 Copenhagen V, Denmark. Translated into English July 2, 2010

4. Palpation of the intestinal lymph nodes does not essentially contribute to the judgement on whether a carcass is infected with *Salmonella*, *Campylobacter* and *Yersinia*, because occasionally these pathogens cause changes in the gastro-intestinal tract or the intestinal lymph nodes.

Therefore, there is only a negligible risk involved in inspecting the stomach and the intestines instead of inspecting and palpating the intestinal lymph nodes. This assessment covers only finisher pigs from indoor herds. Thus this alternate post-mortem inspection is effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain.

The government inspection system requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market hog carcasses presented for inspection.

This criterion is met. Denmark has adopted a sanitary measure that is same as the FSIS requirement. No equivalence determination is needed. Denmark requires establishments to conduct generic *E. coli* testing. In addition, Danish authorities conduct *Salmonella* performance standard testing per the FSIS requirements.

The incidence of diseases in market hogs, such as Tuberculosis (TB), is no higher than the incidence in the United States.

This criterion is met. Denmark has been recognized as free of *Mycobacterium bovis* (bovine tuberculosis) since 1980. A large-scale surveillance program in cattle in Denmark is in place ensuring a constant documentation of the free status.

The market hogs must be born and raised in the country.

This criterion is met. In order to qualify for this program, the producer must demonstrate that the market hogs are of Danish origin. Only swine that have been raised indoors since weaning and are raised under controlled circumstances are eligible for this inspection procedure. There is complete segregation of the swine from other species while on the farm, during transport to the slaughter establishment, during lairage and slaughter.

The government inspection service must implement a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects).

This criterion is met. In 2008 Danish Veterinary and Food Administration (DVFA) had submitted performance standards for verifying inspection for the

removal of both food safety and non-food safety defects. These standards were introduced for all market hogs slaughterhouses on January 1, 2009. The standards include: 1) not more than 5% non-compliances for inspection tasks (palpation, incision and hygienic behavior), 2) not more than 6% cumulative non-compliances for pathological findings (2% for the carcass, 2% for the plucks and 2% for other organs), and 3) for hygienic slaughter not more than 2% non-compliances for contamination in general and 0% fecal contamination. The quality of the meat inspection is conducted by the official veterinarian by checking 100 carcasses including organs per line per shift after post mortem inspection. If non-compliances exceed the performance standards then additional instructions are given to the staff and the frequency of checks is increased.

This year the DVFA revisited the standards and made changes.

Main changes in the new performance standards:

- The standard is covering the overall performance monitoring of the whole meat organization, however the daily check of the official auxiliaries is not part of this standard
- Greater focus on evaluation and corrective actions
- Key performance indicators to compare between slaughterhouses
- New sample frequencies according to the principles in DS/ISO 2859-1
- New procedures for supervision

Number of samples:

- Number of samples is statistically calculated and depends on number of pigs slaughtered at a particular slaughterhouse. One sample consists of 'one animal' i.e. ante-mortem, post-mortem (carcasses, plucks, intestines, etc) inspection and inspection on the rework platform.
- At a minimum 5 procedures for each sample. Supervisor makes an inspection of the procedures (palpation, incision, behavior), and supervisor makes an ordinary inspection of carcasses which have already been through post-mortem control to make sure the right decisions are made by the inspectors.
- If food safety is compromised there will be an immediately correction. Furthermore there will be a monthly evaluation. At the monthly evaluation a 3% differentiation is accepted with out changing sample size. If more than 3% the frequency will go up. Focus will be on follow up to make sure the right corrective actions are made.

Other verification procedures:

- Inspection for absence of visible fecal contamination. The absence of visible fecal contamination is monitored on a daily basis. The inspection is done after post-mortem inspection but before the carcasses enter the chilling room.
- Supervision of the individual employees. The supervision takes place every third year and used as a tool for development of the individual staff member.

- The official veterinarian checks the work of official auxiliaries on a daily basis.

Denmark has observed that these performance standards have been a viable tool to supervise and assess the quality of the meat inspection at each slaughterhouse.

FINDING:

FSIS has determined that Denmark's request for an equivalence determination for an alternative post-mortem inspection i.e. visual inspection instead of palpation of mesenteric lymph nodes of slaughtered market hogs meets the established criteria. Therefore, Denmark's equivalence request should be granted.

Kadam, Priya - FSIS

From: Oestmann, Daniel - FSIS
Sent: Tuesday, November 29, 2011 4:55 PM
To: McMurtrey, Shannon - FSIS; Kadam, Priya - FSIS
Subject: RE: Visual inspection for mesenteric lymph node - Denmark

Hi Shannon;

Priya reminded me this morning that IPD needs to give feedback on the Denmark request for equivalence for an inspection change.

The main change is further documentation on the 5th equivalency requirement.

I'm assuming that the numbers and sample frequencies are verified during an audit. Is that correct Priya? This is detailed enough for verification. I do not see any policy issues.

For a check list I have

Equivalency Request for visual inspection

Risk assessment

09-11-2011 Performance Standards for Meat Inspection in Denmark

Decision Memorandum from Denmark Final.

This request is similar to equivalence inspection previously determined for veal in the Supply Chain Inspection Danish Way.



Performance
standards November.



Denmark decision
memo for visu...

Things to be aware of in the future:

1. In the future equivalence should be determined on a "systems" basis rather than a step-by-step basis. This was discussed early and it was determined that in the future that would be the goal but this equivalency determination was all ready in progress.
2. This equivalence determination is limited to integrated operations for market hogs only.
3. This procedure cannot be applied to US inspection as the US does not have the same TB status as Denmark and a system is not in effect that separates integrated market hog product from other pork products.

Do we need to conference with Priya if there are issues?

Hope I have included everything,

Daniel J. Oestmann, DVM, PhD

USDA, FSIS, OPPD - International Policy Division

Veterinary Medical Officer, EIAO

Phone: 402-344-5000

FAX: 402-344-5007

daniel.oestmann@fsis.usda.gov

FSIS provides information concerning export requirements on its website, which you can access by clicking [here](#).

You can also submit export related questions through [askFSIS](#).

From: Kadam, Priya - FSIS
Sent: Monday, November 21, 2011 3:45 PM
To: Oestmann, Daniel - FSIS; McMurtrey, Shannon - FSIS
Subject: Visual inspection for mesenteric lymph node - Denmark

Hello:

As per our request, Denmark sent us the updated performance standards. I have summarized the 2008 and the new standards in the decision memo. Please review the revised decision memo.

<< File: Denmark decision memo for visual inspection of mesenteric lymph node 11-09-2011.docx >> << File: Performance Standards November 2011.pdf >>

*Thanks,
Priya*

**Priya Kadam Ph.D. | Senior Microbiologist | Office of International Affairs | International Equivalence Staff
Food Safety and Inspection Service | U.S. Department of Agriculture
Room 3843 South Bldg. | 1400 Independence Avenue, S.W. | Washington, D.C. 20250-3700
Tel: 202.690.1353**

Kadam, Priya

From: Oestmann, Daniel
Sent: Wednesday, February 23, 2011 10:00 AM
To: Kadam, Priya; Gillespie, Kevin
Subject: RE: Supply chain inspection-Danish Way

Good Morning Priya;

As we discussed yesterday I concur that the Denmark proposal to change their post-mortem inspection procedure from palpation to visual inspection of mesenteric lymph nodes meets the 5 equivalence criteria used to evaluate a change in procedure. We discussed the "intestinal lymph node" is the same as mesenteric lymph node. Also as discussed, on page 4 under "The outcome of this risk assessment was that the changes proposed" #5 can be deleted as it is addressed in item #4. With those minor changes I think the Equivalence Review, Individual Sanitary Measure Meeting Record can move forward.

Thank you for your help and patience.

Daniel J. Oestmann, DVM, PhD
Veterinary Medical Officer, PHV, ELAO
International Policy Division
USDA, FSIS, OPPD
Phone: 402-344-5000
FAX: 402-344-5007
daniel.oestmann@fsis.usda.gov

Kadam, Priya

Subject: Supply chain inspection-Danish Way
Location: Call-in number 1-866-904-9608 participant 7601400 3rd floor (Rm 3843 S. bldg)
Start: Tue 2/15/2011 11:00 AM
End: Tue 2/15/2011 12:00 PM
Show Time As: Tentative
Recurrence: (none)
Meeting Status: Not yet responded
Organizer: Kadam, Priya
Required Attendees: Stanley, Mary; McMurtrey, Shannon; Keller, Andreas; Seeböhm, Scott; Oestmann, Daniel; Gillespie, Kevin

Hello:

In a letter date 12/18/2008 (attached) FSIS had granted Denmark equivalence to use the supply chain inspection for the alternate PM inspection procedure (visual inspection of mandibular lymph nodes instead of palpation). At that time the listed criteria were used to make the determination.

In a letter dated 04/23/2010 (attached) Denmark requested an additional equivalence determination as part of the supply chain inspection, and that's also an alternate post-mortem inspection procedure i.e. visual inspection of stomach and intestines instead of palpation of the intestinal lymph nodes of slaughtered market hogs. They also submitted risk assessment as supporting documents.

So what is Supply Chain-Danish Way: It was submitted in 2008 (attachment). It is the meat inspection of finisher pigs, housed under controlled conditions. In addition, mandatory requirement within the EU that food chain information from all parts of the food chain should be exchanged prior to sending animals for slaughter. This includes primary producer, the slaughterhouse and the competent authority. This in addition to the alternative PM inspection procedure (visual inspection of mandibular lymph nodes instead of palpation) constitutes Supply Chain Inspection system-Danish way.

Denmark has been granted supply chain inspection should we be evaluating any new modifications that Denmark submits.



FSIS letter 23 April
2010.doc



OIA_Sharpe_MX31
00N@fsis.usda.g...



OIA_Sharpe_MX31
00N@fsis.usda.g...

Kadam, Priya

From: Stanley, Mary
Sent: Tuesday, January 18, 2011 8:37 PM
To: Kadam, Priya; Oestmann, Daniel
Cc: McMurtrey, Shannon; McKee, Laura; Seebohm, Scott; Lauro, Alexander
Subject: Equivalence determination-Visual Inspection

Priya

Yes-I think we should review the criteria previously applied. While our inspection procedures may not have changed, we are looking at several alternative inspection systems that are driving change so we should always re-evaluate. However, I cannot make this decision in a vacuum.

A couple of questions:

1. You refer to an attached letter but I did not receive an attachment.
2. Has Denmark previously submitted a request or were these criteria applied to the equivalence determination submitted by the Netherlands?

Dan

From a policy viewpoint, I would like for you to take the lead to review the criteria that Priya provided below which were previously used to assess a request to replace palpation with visual inspection. I suggest that the team includes appropriate staff from PDD (I have included Laura or Scott for the assignment—perhaps you can share the material you have been provided). Alex is available to assist with this step in the determination. This will serve a dual purpose—to incorporate their expertise as well as to expand their knowledge to alternative approaches to the way FSIS approaches inspection. As summarized by the National Food Institute, there are benefits to food safety as the risk of cross contamination associated with palpation of the intestines will be reduced.

To expedite the process, we can certainly meet to discuss these criteria. Please schedule as appropriate.

Mary H. Stanley
International Policy Division
Office of Policy and Program Development
Food Safety and Inspection Service

Phone: 202.720.0287
Cell: 202.257.3505
FAX: 202.720.4929

From: Kadam, Priya
Sent: Tuesday, January 18, 2011 1:36 PM
To: Stanley, Mary; Oestmann, Daniel; McMurtrey, Shannon
Cc: Keller, Andreas; Smith, David
Subject:

Hello Mary:

Dan Oestmann and I have been working on Denmark's equivalence determination submission for an alternative post-mortem inspection procedure i.e. visual inspection of stomach and intestines instead of palpation of the intestinal lymph nodes of slaughtered market hogs (attached letter dated April, 2010). Following, are the criteria that we are planning to use for the evaluation. Denmark had a similar submission in December 2008, and at that time David Smith and Bob Ragland had developed these criteria. It has been 2 years, and so we are wondering if we need to revisit them or can we continue using the same.

Criteria:

The criteria used for making an equivalence determination for an alternative post-mortem inspection procedure for market-age hogs is equivalent to the U.S. inspection procedure for market age hogs are set forth below:

1. The government inspection service administers an inspection program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass.
2. The government inspection system requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market hog carcasses presented for inspection.
3. The incidence of diseases in market hogs, such as TB, is no higher than the incidence in the United States.
4. The market swine must be born and raised in the country.
5. The government inspection service must implement a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects).

*Thanks,
Priya*

**Priya Kadam Ph.D. | Office of International Affairs | International Equivalence Staff |
Food Safety and Inspection Service | U.S. Department of Agriculture
Room 3843 South Bldg. | 1400 Independence Avenue, S.W. | Washington, D.C. 20250-3700
Tel: 202.690.1353 | BB: 202.258.3058**

Kadam, Priya

From: Steen Steensen [steste@um.dk]
Sent: Monday, January 31, 2011 2:04 PM
To: Kadam, Priya
Subject: RE: Request for confirmation of equivalence of next step in supply chain meat inspection in Denmark.

Hello again,

I have already received a reply from Copenhagen – that no new submissions for alternate inspections are under preparation. With the present request our meat inspection system is reaching our maximum ambitions within the general EU system incl. the inspection system for The Netherlands already approved by the United States – as far as I am informed.

Our submission is therefore expected to be limited to the current one and it is very unlikely that new requests for altering meat inspection systems will be submitted within the next couple of years.

Best regards
Steen

From: Kadam, Priya [mailto:Priya.Kadam@fsis.usda.gov]
Sent: 31 January 2011 13:22
To: Steen Steensen
Cc: Keller, Andreas
Subject: RE: Request for confirmation of equivalence of next step in supply chain meat inspection in Denmark.

Hello Mr. Steensen:

I got your message and we are reviewing the Supply chain inspection-Danish Way--- request for alternate PM inspection. One question do you have several submissions for alternate PM inspections that you are considering to submit in future or is it limited to the current submission.

*Thanks,
Priya*

Priya Kadam Ph.D.
USDA/FSIS/OIA/IES
Tel: 202.690.1353 | BB: 202.258.3058

From: Steen Steensen [mailto:steste@um.dk]
Sent: Monday, January 31, 2011 1:14 PM
To: Kadam, Priya
Subject: Request for confirmation of equivalence of next step in supply chain meat inspection in Denmark.

Dear Dr. Kadam,

As far as I recall our latest telephone conversation your final risk assessment of our request would be ending around this time. Our authorities are very anxious to learn your final assessments so we are looking forward to your communications. – Thanking you in anticipation.

Best regards

Steen Steensen

STEEN STEENSEN / STESTE@UM.DK
MINISTER COUNSELLOR, FOOD & AGRICULTURE
DIRECT (202) 797 5341

ROYAL DANISH EMBASSY, WASHINGTON DC
3200 WHITEHAVEN STREET / WASHINGTON, DC 20008
PHONE +1 (202) 234 4300 / WWW.AMBWASHINGTON.UM.DK



Please consider the environment before printing this message

Kadam, Priya

Subject: Supply chain inspection-Danish Way
Location: Call-in number 1-866-904-9608 participant 7601400 3rd floor (Rm 3843 S. bldg)
Start: Tue 2/15/2011 11:00 AM
End: Tue 2/15/2011 12:00 PM
Recurrence: (none)
Meeting Status: Meeting organizer
Organizer: Kadam, Priya
Required Attendees: Stanley, Mary; McMurtrey, Shannon; Keller, Andreas; Seebohm, Scott; Oestmann, Daniel; Gillespie, Kevin

Hello:

In a letter date 12/18/2008 (attached) FSIS had granted Denmark equivalence to use the supply chain inspection for the alternate PM inspection procedure (visual inspection of mandibular lymph nodes instead of palpation). At that time the listed criteria were used to make the determination.

In a letter dated 04/23/2010 (attached) Denmark requested an additional equivalence determination as part of the supply chain inspection, and that's also an alternate post-mortem inspection procedure i.e. visual inspection of stomach and intestines instead of palpation of the intestinal lymph nodes of slaughtered market hogs. They also submitted risk assessment as supporting documents.

So what is Supply Chain-Danish Way: It was submitted in 2008 (attachment). It is the meat inspection of finisher pigs, housed under controlled conditions. In addition, mandatory requirement within the EU that food chain information from all parts of the food chain should be exchanged prior to sending animals for slaughter. This includes primary producer, the slaughterhouse and the competent authority. This in addition to the alternative PM inspection procedure (visual inspection of mandibular lymph nodes instead of palpation) constitutes Supply Chain Inspection system-Danish way.

Denmark has been granted supply chain inspection should we be evaluating any new modifications that Denmark submits.



FSIS letter 23 April
2010.doc



OIA_Sharpe_MX31
00N@fsis.usda.g...



OIA_Sharpe_MX31
00N@fsis.usda.g...

Kadam, Priya

From: Troy.T.Bigelow@aphis.usda.gov
Sent: Tuesday, August 24, 2010 2:38 PM
To: Oestmann, Daniel
Cc: Alecia.L.Naugle@aphis.usda.gov; John.A.Korslund@aphis.usda.gov; Kadam, Priya
Subject: RE: Request from FSIS: inspection procedure in finished hogs

Good Afternoon Daniel

Thank you for asking APHIS about TB in swine.

Unfortunately, we do not track the incidence of TB (M avium) in the National herd. M. avium is still commonly observed in isolated situations. We are only aware of this observation because of the efforts FSIS puts into doing postmortem inspections. During these inspections, inspectors do on occasion find TB like lesions in the mesenteric and mandibular lymph nodes. These findings are commonly recorded in FSIS' eADRS database. APHIS officials review this data to observe trends in the National herd. Our policy is to rule out the possibility of finding M. bovis, if there are lesions in multiple places (more likely thoracic cavity) to send in samples for analysis.

APHIS veterinary services laboratories receives on average less than 20 samples per year for TB analysis.

I could safely say M. bovis has not been observed in US swine in a long time.. (I do not know when observed last) but M avium is still a concern and can be economically devastating to those isolated producers who have a problem controlling M avium. M avium is usually spread by birds.

Unfortunately, since we do not have M bovis in swine (usually M. avium) I do not have the data you are requesting.

I hope this helps

Troy

Troy T. Bigelow, DVM
Swine Disease Staff Officer
USDA APHIS VS NCAHP ASEP
Federal Building, Room 891
210 Walnut Street
Des Moines, Iowa 50309
Office Phone 515-284-4121
Cell Phone (515) 333-2221

"Oestmann, Daniel" <Daniel.Oestmann@fsis.usda.gov>

08/24/2010 12:26 PM

To <John.A.Korslund@aphis.usda.gov>, <Troy.T.Bigelow@aphis.usda.gov>
cc <Alecia.L.Naugle@aphis.usda.gov>, "Kadam, Priya" <Priya.Kadam@fsis.usda.gov>
Subject RE: Request from FSIS: inspection procedure in finished hogs

Good Morning;

Denmark is instituting a change in their post-mortem inspection of finish hogs. They will no longer observe and palpate the mandibular and mesenteric lymph nodes.

They maintain that palpation of the LN is unnecessary because:

Their risk assessments determined that observation is sufficient in finish hogs

Denmark is TB free and
Finish hogs have negligible exposure,
They maintain a sampling program (not sure of the details of that program at this point).

FSIS is looking to determine if this procedure is still equivalent to US PM inspection. Dir. 6100.2 and our training materials direct inspectors and PHV's to observe and palpate the mesenteric and tracheobronchial lymph nodes of swine viscera, although this is not a regulatory requirement.

Does APHIS have data on TB number and results of sample submissions or incidence of TB in finish hogs from states that are classified as Accredited – Free? Seems that number would give us a starting point to determine if TB free states have a similar TB incidence of submission with (US) and without palpation (Denmark).

Thanks for the help and Thank you Dr. Naugle for pointing me in the right direction.

Dan O.

Daniel J. Oestmann, DVM, PhD
Veterinary Medical Officer, PHV, EIAO
International Policy Division
USDA, FSIS, OPPD
Phone: 402-344-5000
FAX: 402-344-5007
daniel.oestmann@fsis.usda.gov

From: Alecia.L.Naugle@aphis.usda.gov [<mailto:Alecia.L.Naugle@aphis.usda.gov>]
Sent: Monday, August 23, 2010 8:58 AM
To: John.A.Korslund@aphis.usda.gov; Troy.T.Bigelow@aphis.usda.gov
Cc: Daniel.Oestmann@usda.gov; Oliver.Williams@aphis.usda.gov; David.G.Pyburn@aphis.usda.gov; Debra.C.Cox@aphis.usda.gov
Subject: Request from FSIS: inspection procedure in finished hogs

Hi, Guys!

I just spoke with Dr. Dan Oestmann from FSIS. Apparently, Denmark is proposing to change their PM inspection procedures to eliminate palpation of mesenteric lymph nodes in finished pigs. Dan is working on a project to determine equivalency with US inspection. I gave Dan your names and phone numbers since I believe that you will be better able to assist him and perhaps provide some data he can use in his evaluation.

Please let me know if I can be of further assistance,

Alecia

Alecia Larew Naugle, DVM, PhD
National TB Program
National Center for Animal Health Programs
USDA, APHIS, VS
4700 River Road Unit 43, Riverdale, MD 20737
Phone 301-734-7569
Email: Alecia.L.Naugle@aphis.usda.gov

Kadam, Priya

From: Oestmann, Daniel
Sent: Tuesday, August 24, 2010 1:26 PM
To: John.A.Korslund@aphis.usda.gov; Troy.T.Bigelow@aphis.usda.gov
Cc: Alecia.L.Nauble@aphis.usda.gov; Kadam, Priya
Subject: RE: Request from FSIS: inspection procedure in finished hogs

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Thanks for the help and Thank you Dr. Nauble for pointing me in the right direction.

Dan O.

Daniel J. Oestmann, DVM, PhD
Veterinary Medical Officer, PHV, EIAO
International Policy Division
USDA, FSIS, OPPD
Phone: 402-344-5000
FAX: 402-344-5007
daniel.oestmann@fsis.usda.gov

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Please let me know if I can be of further assistance,

Kadam, Priya

From: Oestmann, Daniel
Sent: Wednesday, August 25, 2010 10:10 AM
To: Kadam, Priya
Subject: Denmark equivalence

Good Morning Priya;

The US PM inspection focus of observation / palpation of LM is in on M. bovis . But APHIS has no reports of that in hogs in a long time. Occasionally M avium is seen but that isn't a human health. Given this information how do we proceed? Draft a decision memo? I haven't' been with IPD long enough to have seen one of those.

Let me know what we should do now.
Thanks,

Daniel J. Oestmann, DVM, PhD
Veterinary Medical Officer, PHV, EIAO
International Policy Division
USDA, FSIS, OPPD
Phone: 402-344-5000
FAX: 402-344-5007
daniel.oestmann@fsis.usda.gov

Kadam, Priya

From: Oestmann, Daniel
Sent: Wednesday, August 18, 2010 4:57 PM
To: Kadam, Priya
Subject: RE: Visual inspection of mesenteric lymph nodes of hogs -Denmark

Follow Up Flag: Follow up
Due By: Friday, September 03, 2010 10:00 AM
Flag Status: Flagged

Good Afternoon Priya;

I've reviewed the FSIS Dir. 6100.2 and my PHV training materials on post-mortem inspection of swine. Under the specific circumstances described in the Denmark docs (market hog from confinement operations), I can't find a regulatory requirement to palpate mesenteric LN. The plants I've been in do grasp the cecum and lift it to turn the viscera over.

The main reason to palpate the LN is because they are a primary sight for TB. In swine the most common TB is M. avian, which isn't a big humane pathogen and not reportable. I've never seen it but my OFO vet friends say they see it once in awhile. M bovis is reportable, cattle being the main source. There are 4 states (CA, NM, MN, MI) that are not accredited TB free states. There may be others so I've inquired from APHIS for a update.

The basic rule is 1 site/lesion, the organs are condemned, 2 lesions it gets trimmed and sent for pet food, 3 lesions all parts are condemned.

Don't know if we can make the same assumptions Denmark did because the US is not TB free.

Please let me know if there will be a call tomorrow.

Thanks,

Daniel J. Oestmann, DVM, PhD
Veterinary Medical Officer, PHV, EIAO
International Policy Division
USDA, FSIS, OPPD
Phone: 402-344-5000
FAX: 402-344-5007
daniel.oestmann@fsis.usda.gov

From: Kadam, Priya
Sent: Thursday, August 12, 2010 3:22 PM
To: Oestmann, Daniel
Subject: RE: Visual inspection of mesenteric lymph nodes of hogs -Denmark

Oh no Dan. Please enjoy your weekend.

How about an initial teleconference next Thursday; after you have reviewed the documents.
We had gone through a similar exercise with New Zealand, and I am attaching meeting minutes from that discussion.

think it might help to know domestically, if we inspect mesenteric lymph nodes of slaughtered pigs, why we inspect, and now we inspect.

Thanks,

Priya

Priya Kadam Ph.D.
USDA/FSIS/OIA/IES
Tel: 202.690.1353 | BB: 202.258.3058

From: Oestmann, Daniel
Sent: Thursday, August 12, 2010 4:11 PM
To: Kadam, Priya
Subject: RE: Visual inspection of mesenteric lymph nodes of hogs -Denmark

Sorry Priya;
Some of the issues with poultry export keep demanding all our time.

I looked up the directive instructions for post mortem inspection. It is ok on the "what" to do but kind of short on the "why" do we do it. I'll search for information there. There was a meat and poultry inspection manual referenced but it must be an old document that OFO doesn't use any more. Didn't even get a goggle hit.
Both of us being new to equivalence I have Alex Lauro Mary said I could lean on. But he's pretty busy too. Aren't we all. I guess the approach I'd look for is if they don't have the same "why" as we do then there is no reason for them to do the same "what" we do. I'll read the attachments this weekend and see if I can figure that out and try to send something by Tue.

I really hope you meant next Thursday and not today. If you meant today I apologize sincerely.

Dan O.

Daniel J. Oestmann, DVM, PhD
Veterinary Medical Officer, PHV, EIAO
International Policy Division
USDA, FSIS, OPPD
Phone: 402-344-5000
FAX: 402-344-5007
daniel.oestmann@fsis.usda.gov

From: Kadam, Priya
Sent: Tuesday, August 10, 2010 1:46 PM
To: Oestmann, Daniel
Subject: Visual inspection of mesenteric lymph nodes of hogs -Denmark

Hello Dan:

It was nice talking to you this morning. As per our discussion attached are the supporting documents.
Can we have a follow-up call next Thursday? As Mary mentioned I am also waiting for a team member from OPPD/RIMD.

Thanks,
Priya

Priya Kadam Ph.D. | Office of International Affairs | International Equivalence Staff |
Food Safety and Inspection Service | U.S. Department of Agriculture
Room 3843 South Bldg. | 1400 Independence Avenue, S.W. | Washington, D.C. 20250-3700
Tel: 202.690.1353 | BB: 202.258.3058

Kadam, Priya - FSIS

From: Kadam, Priya - FSIS
Sent: Friday, January 06, 2012 11:10 AM
To: McMurtrey, Shannon - FSIS; Keller, Andreas - FSIS
Cc: Oestmann, Daniel - FSIS
Subject: FW: Happy New Year - Re. Performance standards - Denmark.
Attachments: Denmark decision memo for visual inspection of mesenteric lymph node 11-09-2011.docx

Importance: High

Hello Shannon:

This is the third reminder since Nov. 9, 2011 from Mr. Steensen. Please review the decision memo at your earliest. I am attaching the electronic copy.

If it's going to take longer then we might want to inform Mr. Steensen the reasons for the delay.

*Thank You,
Priya*

**Priya Kadam Ph.D.
Senior Microbiologist
USDA/FSIS/OIA/IES
Tel: 202.690.1353**

From: Steen Steensen [<mailto:steste@um.dk>]
Sent: Friday, January 06, 2012 10:58 AM
To: Kadam, Priya - FSIS
Subject: Happy New Year - Re. Performance standards - Denmark.

Dear Ms. Kadam,

I hope you have had some nice holidays and wish you a Happy New Year. – I would appreciate if you could drop me a line on the status of evaluation of our request.

Best regards

Steen

Kadam, Priya - FSIS

From: Steen Steensen [steste@um.dk]
Sent: Tuesday, November 22, 2011 11:17 AM
To: Kadam, Priya - FSIS
Subject: RE: Letter for Dr. Priya Kadam - Performance standards - Denmark

Dear Ms. Kadam,

Since we are now approaching Thanksgiving I want to thank you for your cooperation this year. We hope that the final review of our performance standards is well under way and are looking forward to hearing from you.

Wishing you a Happy Thanksgiving

Best regards
Steen

From: Kadam, Priya - FSIS [<mailto:Priya.Kadam@fsis.usda.gov>]
Sent: 09 November 2011 11:39
To: Steen Steensen
Subject: RE: Letter for Dr. Priya Kadam - Performance standards - Denmark

Dear Mr. Steensen:

Thank you for the information. We will review it in a timely manner.

*Thanks,
Priya*

Priya Kadam Ph.D.
Senior Microbiologist
USDA/FSIS/OIA/IES
Tel: 202.690.1353

From: Steen Steensen [<mailto:steste@um.dk>]
Sent: Wednesday, November 09, 2011 11:37 AM
To: Kadam, Priya - FSIS
Cc: Ida Heimann Larsen; Carl Johan Ulrik Rantzau; Charlotte Vest
Subject: Letter for Dr. Priya Kadam - Performance standards - Denmark

J.nr. 77.usa.1

Dear Dr. Kadam,

It is my pleasure to finally send you a letter from Deputy Director General, Ms. Annelise Fenger, Danish Veterinary and Food Administration with the additional information of our updated performance standards in the meat control – as requested.

We hope that the information is sufficient for finalising your evaluation and will be looking forward to your comments.

Thanking for your cooperation,

With best regards

Steen Steensen

Kadam, Priya - FSIS

From: Steen Steensen [steste@um.dk]
Sent: Wednesday, November 09, 2011 11:37 AM
To: Kadam, Priya - FSIS
Cc: Ida Heimann Larsen; Carl Johan Ulrik Rantzau; Charlotte Vest
Subject: Letter for Dr. Priya Kadam - Performance standards - Denmark
Attachments: Performance Standards November 2011.pdf

J.nr. 77.usa.1

Dear Dr. Kadam,

It is my pleasure to finally send you a letter from Deputy Director General, Ms. Annelise Fenger, Danish Veterinary and Food Administration with the additional information of our updated performance standards in the meat control – as requested.

We hope that the information is sufficient for finalising your evaluation and will be looking forward to your comments.

Thanking for your cooperation,

With best regards

Steen Steensen

Dr. Priya Kadam
Office of International Affairs
FSIS,USDA

Food and Feed Safety Division

09.11.2011

Dear Dr. Priya Kadam,

Performance Standards for Meat Inspection in Denmark

With reference to our previous correspondence, Mr. Steen Steensen from the Royal Danish Embassy informed us about your request for additional information on our updated performance standards.

The traditional meat inspection in Denmark is carried out by official veterinarians and auxiliaries all employed by the Danish Veterinary and Food Administration.

According to the EU regulation all Member States shall ensure that they have sufficient official staff to carry out the official controls required and a risk-based approach shall be followed to assess the number of official staff that need to be present on the slaughter line in any given slaughterhouse. The number of official staff involved shall be decided by the competent authority and shall be such that all the requirements of the regulation are met. Furthermore the official veterinarian must regularly check the work of official auxiliaries.

The Danish Veterinary and Food Administration ensure that these requirements are met by the use of different verification procedures.

This year we made an overall evaluation of the performance standards we sent to you in 2008. The experience is that the standard has been a viable tool to supervise and assess the quality of the meat inspection at each slaughterhouse. We decided, however, to make some changes to improve our procedures.

The main changes in our new performance standard are:

- The standard is covering the overall performance monitoring of the whole meat organization, however the daily check of the official auxiliaries is not part of this standard.
- Greater focus on evaluation and corrective actions.
- Key performance indicators to compare between slaughterhouses.
- New sample frequencies according to the principles in DS/ISO 2859-1
- New procedures for supervision.

The new Performance Standard for meat inspection

This standard is an overall performance monitoring of the whole meat inspection organization and performance to make sure all requirements are met and the tasks are performed in the most appropriate way to ensure food safety.

The number of samples is statistically calculated and depends on how many pigs are slaughtered at that particular slaughterhouse.

One sample consists of "one animal", that is Ante Mortem inspection, Post Mortem inspection (carcasses, plucks, intestines etc.) and inspection on the rework platform. That is, at minimum 5 procedures for each sample.

Furthermore the sample consists of two parts:

1. Supervisor makes an inspection of the procedures (palpation, incision, behavior)
2. Supervisor makes an ordinary inspection of carcasses, which have already been through post-mortem control to make sure the right decisions are made by the inspectors.

This means there will be supervision of inspection tasks and of the result of the inspection (pathological findings, contamination etc.).

If food safety is compromised there will be an immediately correction.

Furthermore there will be a monthly evaluation. At the monthly evaluation a 3 % differentiation is accepted without changing sample size. If less than 97 % the frequency will go up. Focus will be on follow up to make sure the right corrective actions are made.

Other verification procedures

- Inspection for absence of visible fecal contamination.

The absence of visible fecal contamination is monitored on a daily basis. The inspection is done after post-mortem inspection but before the carcasses enter the chilling room.

- Supervision of the individual employees

The supervision takes place every third year and is used as a tool for development of the individual staff member.

- Check of the work of official auxiliaries.

The official veterinarian checks the work of official auxiliaries on a daily basis.

In all types of verification there will be an immediately reaction if something is compromising food safety.

The Danish Veterinary and Food Administration hope this answers your questions.

Yours faithfully


Annette Fenger
Deputy Director General

Kadam, Priya

From: Annette Lychau Petersen (FVST) [ALPE@fvst.dk]
Sent: Monday, May 23, 2011 10:04 AM
To: Kadam, Priya
Cc: Steen Steensen (Washington)
Subject: Performance Standards for Meat Inspection in Denmark
Attachments: Performance Standards for Meat Inspection in Denmark.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Dear Dr. Priya Kadam,
Steen Steensen from The Royal Embassy in Washington informed us about your request for additional information on our experience with the Performance Standards for Meat Inspection in Denmark. The Danish Veterinary and Food Administration hope this answers your questions.

Best regards

Annette Lychau Petersen
Senior Veterinary Officer

Division for Microbiological Food Safety, Hygiene and Zoonoses Control

Tlf +45 7227 6845
Email: alpe@fvst.dk

Ministry of Food, Agriculture and Fisheries

Danish Veterinary and Food Administration
Mørkhøj Bygade 19
DK-2860 Søborg
Tlf. 72276500, Fax 72276501, e-mail fvst@fvst.dk , www.fvst.dk

Dr. Priya Kadam
Office of International Affairs
FSIS, USDA

DIVISION FOR MICROBIOLOGICAL
FOOD SAFETY, HYGIENE
AND ZOOSES CONTROL

23.05.2011

Dear Dr. Priya Kadam,

Performance Standards for Meat Inspection in Denmark

With reference to our letter of April 23, 2010 concerning omission of the routine palpation of the mesenteric lymph nodes of slaughter pigs in Denmark ("Supply Chain Meat Inspection – the Danish Way") and information sent in November 2008 about Performance Standards for Meat Inspection in Denmark, Steen Steensen from The Royal Danish Embassy in Washington informed us about your request for additional information on our experience with the performance standards.

According to The Danish Circular on meat inspection the official veterinarian has to make daily checks on both the decisions taken during meat inspection and the method used. These checks must include all staff and must be documented. The Danish Veterinary and Food Administration ensure that this criterion is met by the use of performance standards.

The performance standard for meat inspection was introduced for all slaughter houses for pigs January 1, 2009. The standard was evaluated later that year and a revised addition was implemented autumn 2009.

Beside the performance standard a supervision of the performance of the individual staff member during post-mortem inspection takes place every third year. This is used as a tool for development of the individual staff member.

The results of the performance standard have continuously been evaluated locally on every slaughterhouse. The experience is that the standard is a viable tool to supervise and assess meat inspection and secure food safety.

The performance standard and results from all the slaughterhouses will be further evaluated in 2011. To be able to compare between slaughterhouses the intention is to create a model, where Key Performance Indicators and inter calibration is part of the standard.

The Danish Veterinary and Food Administration hope this answers your questions.

Yours faithfully


Annelise Fenger
Deputy Director

Kadam, Priya - FSIS

From: Kadam, Priya - FSIS
Sent: Monday, January 09, 2012 12:05 PM
To: 'Steen Steensen'
Cc: Oestmann, Daniel - FSIS
Subject: RE: Happy New Year - Re. Performance standards - Denmark.

Dear Mr. Steensen:

Wish you a happy new year too.
I should be ready with a response very soon.
I am working on it. Thanks for your patience.

*Thank You,
Priya*

Priya Kadam Ph.D.
Senior Microbiologist
USDA/FSIS/OIA/IES
Tel: 202.690.1353

From: Steen Steensen [<mailto:steste@um.dk>]
Sent: Friday, January 06, 2012 10:58 AM
To: Kadam, Priya - FSIS
Subject: Happy New Year - Re. Performance standards - Denmark.

Dear Ms. Kadam,

I hope you have had some nice holidays and wish you a Happy New Year. – I would appreciate if you could drop me a line on the status of evaluation of our request.

Best regards

Steen

Kadam, Priya

From: Steen Steensen [steste@um.dk]
Sent: Wednesday, February 23, 2011 4:31 PM
To: Kadam, Priya
Subject: RE: Request for confirmation of equivalence of next step in supply chain meat inspection in Denmark.

Hello Dr. Kadam,

Thanks for your mail. – In order for me to respond correctly to your questions I will forward your mail to The Danish Veterinary and Food Administration. – I will revert to you a.s.a.p.

Best regards
Steen

From: Kadam, Priya [mailto:Priya.Kadam@fsis.usda.gov]
Sent: 23 February 2011 16:25
To: Steen Steensen
Cc: Keller, Andreas
Subject: RE: Request for confirmation of equivalence of next step in supply chain meat inspection in Denmark.

Hello Mr. Steensen:

The Danish Veterinary and Food Administration was going to establish a performance standard for meat inspection for all market hogs slaughterhouses. The performance standard was going to be monitored daily by the official veterinarian. The official veterinarian in turn was going to verify that the official auxiliaries are properly conducting their inspection activities. This was going to be effective January 1, 2009.

Can you please let us know if this was implemented, and an overview of performance standards for meat inspection for all market hogs slaughterhouses?

*Thanks,
Priya*

Priya Kadam Ph.D.
USDA/FSIS/OIA/IES
Tel: 202.690.1353 | BB: 202.258.3058

From: Steen Steensen [mailto:steste@um.dk]
Sent: Monday, January 31, 2011 2:04 PM
To: Kadam, Priya
Subject: RE: Request for confirmation of equivalence of next step in supply chain meat inspection in Denmark.

Hello again,

I have already received a reply from Copenhagen – that no new submissions for alternate inspections are under preparation. With the present request our meat inspection system is reaching our maximum ambitions within the general EU system incl. the inspection system for The Netherlands already approved by the United States – as far as I am informed.

Our submission is therefore expected to be limited to the current one and it is very unlikely that new requests for altering meat inspection systems will be submitted within the next couple of years.

Best regards
Steen

From: Kadam, Priya [mailto:Priya.Kadam@fsis.usda.gov]
Sent: 31 January 2011 13:22
To: Steen Steensen
Cc: Keller, Andreas
Subject: RE: Request for confirmation of equivalence of next step in supply chain meat inspection in Denmark.

Hello Mr. Steensen:

I got your message and we are reviewing the Supply chain inspection-Danish Way--- request for alternate PM inspection. One question do you have several submissions for alternate PM inspections that you are considering to submit in future or is it limited to the current submission.

*Thanks,
Priya*

Priya Kadam Ph.D.
USDA/FSIS/OIA/IES
Tel: 202.690.1353 | BB: 202.258.3058

From: Steen Steensen [mailto:steste@um.dk]
Sent: Monday, January 31, 2011 1:14 PM
To: Kadam, Priya
Subject: Request for confirmation of equivalence of next step in supply chain meat inspection in Denmark.

Dear Dr. Kadam,

As far as I recall our latest telephone conversation your final risk assessment of our request would be ending around this time. Our authorities are very anxious to learn your final assessments so we are looking forward to your communications. – Thanking you in anticipation.

Best regards

Steen Steensen

STEEN STEENSEN / STESTE@UM.DK
MINISTER COUNSELLOR, FOOD & AGRICULTURE
DIRECT (202) 797 5341

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Please consider the environment before printing this message

Kadam, Priya

From: Steen Steensen [steste@um.dk]
Sent: Monday, January 31, 2011 2:04 PM
To: Kadam, Priya
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Steen

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Sent: 31 January 2011 13:22
To: Steen Steensen
Cc: Keller, Andreas
Subject: RE: Request for confirmation of equivalence of next step in supply chain meat inspection in Denmark.

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Priya*

Priya Kadam Ph.D.
USDA/FSIS/OIA/IES
Tel: 202.690.1353 | BB: 202.258.3058

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Sent: Monday, January 31, 2011 1:14 PM
To: Kadam, Priya
Subject: Request for confirmation of equivalence of next step in supply chain meat inspection in Denmark.

Dear Dr. Kadam,

As far as I recall our latest telephone conversation your final risk assessment of our request would be ending around this time. Our authorities are very anxious to learn your final assessments so we are looking forward to your communications. – Thanking you in anticipation.

Best regards

Steen Steensen

STEEN STEENSEN / STESTE@UM.DK
MINISTER COUNSELLOR, FOOD & AGRICULTURE
DIRECT (202) 797 5341

ROYAL DANISH EMBASSY, WASHINGTON DC
3200 WHITEHAVEN STREET / WASHINGTON, DC 20008
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Please consider the environment before printing this message

Kadam, Priya

From: Anders Klöcker [andklo@um.dk]
Sent: Tuesday, July 06, 2010 10:37 AM
To: Kadam, Priya
Cc: Keller, Andreas; Charlotte Vilstrup (FVST); Washington
Subject: RE: Request for Confirmation of Equivalence of Next Step in Supply Chain Meat Inspection in Denmark
Attachments: Risikovurdering, krøslymfeknuder, kødkontrol, engelsk.doc; oversat vurderingsbrev fra DTUjuli2010.doc

Follow Up Flag: Follow up
Flag Status: Flagged

Hello Ms. Kadam,

Attached please find a translated version of the risk assessment and related correspondence from the Danish Technical University.

We look forward to a response at your earliest convenience.

Should you have any questions please forward these directly to:

Ms. Charlotte Vilstrup
E-mail: chvi@fvst.dk
Direct Tel. +45 33 95 62 75

Thanks,

Anders

ANDERS M. KLOCKER / ANDKLO@UM.DK
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From: Kadam, Priya [mailto:Priya.Kadam@fsis.usda.gov]
Sent: 21 June 2010 16:57
To: Anders Klöcker
Cc: Keller, Andreas
Subject: RE: Request for Confirmation of Equivalence of Next Step in Supply Chain Meat Inspection in Denmark

Hello Mr. Klöcker:

I reviewed the letter dated April 23, 2010, and the attachment titled, 'How to ensure continuous freedom from bovine tuberculosis in finisher pigs when changing meat inspection?'

As per the letter, a risk assessment was conducted on the effect of not palpating the mesenteric lymph nodes routinely. Can you please submit all the relevant documents supporting that there is no risk for food safety in the routine post-mortem inspection of the mesenteric lymph nodes of slaughtered pigs when it is changed to visual inspection only.

I will be more than happy to answer all your questions.

*Thanks,
Priya*

**Priya Kadam Ph.D. | Office of International Affairs | International Equivalence Staff |
Food Safety and Inspection Service | U.S. Department of Agriculture
Room 3843 South Bldg. | 1400 Independence Avenue, S.W. | Washington, D.C. 20250-3700
Tel: 202.690.1353 | BB: 202.258.3058**

From: Walker, Harry
Sent: Monday, June 21, 2010 1:40 PM
To: 'Anders Klöcker'
Cc: Kadam, Priya
Subject: RE: Request for Confirmation of Equivalence of Next Step in Supply Chain Meat Inspection in Denmark

Hi Anders,

Please address your questions to Dr. Priya Kadam. She is now the lead for Denmark.

Thank you,

Harry Lee Walker, DVM
Senior Equivalence Officer
IES, OIA, FSIS, USDA
Rm 4864 South Bldg, Mailstop 3729
1400 Independence Ave, SW
Washington, DC 20250-3700
Phone (202) 720-6288, Fax (202) 720-7378
Blackberry (202) 431-7428
harry.walker@fsis.usda.gov

From: Anders Klöcker [mailto:andklo@um.dk]
Sent: Monday, June 21, 2010 1:14 PM
To: Walker, Harry
Subject: RE: Request for Confirmation of Equivalence of Next Step in Supply Chain Meat Inspection in Denmark

Harry,

Hope everything is well with you.

Could inform me about status of this file?

Best regards,

Anders

ANDERS M. KLOCKER / ANDKLO@UM.DK
MINISTER COUNSELLOR / FOOD, AGRICULTURE AND FISHERIES
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From: Walker, Harry [mailto:Harry.Walker@fsis.usda.gov]

Sent: 20 May 2010 10:59

To: Anders Klöcker

Subject: RE: Request for Confirmation of Equivalence of Next Step in Supply Chain Meat Inspection in Denmark

Your last email gave me a really good laugh.

How about this one – when I went to Puerto Rico (part of the US but not a state) the car odometer was in miles and consequently I was traveling at miles per hour but the road signs were in kilometers (go figure) so I had to travel in kilometers per hour. I had great difficulty knowing how fast I was driving.

Harry Lee Walker, DVM

International Equivalency Staff

Office of International Affairs, FSIS, USDA

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harry.walker@fsis.usda.gov

From: Anders Klöcker [mailto:andklo@um.dk]

Sent: Thursday, May 20, 2010 10:32 AM

To: Walker, Harry

Subject: RE: Request for Confirmation of Equivalence of Next Step in Supply Chain Meat Inspection in Denmark

I sure can. As mentioned, I had the same challenge when arriving to the US. Not only did I have to get used to Fahrenheit, miles, pounds, feet and inches. I also had to get used to the fact that – compared to my part of the world – addresses were written quite awkwardly. Number of street before and not after name of street. Zip code after state – as opposed to Denmark, where they are put before the name of the city.

Anders

From: Walker, Harry [mailto:Harry.Walker@fsis.usda.gov]

Sent: 20 May 2010 10:29

To: Anders Klöcker

Subject: RE: Request for Confirmation of Equivalence of Next Step in Supply Chain Meat Inspection in Denmark

Thank you Anders. Sometimes I do not understand other country's addresses. Hope you can appreciate this.

Talk to you later.

Harry Lee Walker, DVM
International Equivalency Staff
Office of International Affairs, FSIS, USDA
Rm 4864 South Bldg, Mailstop 3729
1400 Independence Ave, SW
Washington, DC 20250-3700
Phone (202) 720-6288, Fax (202) 720-7378
Blackberry (202) 431-7428
harry.walker@fsis.usda.gov

From: Anders Klöcker [mailto:andklo@um.dk]
Sent: Thursday, May 20, 2010 10:27 AM
To: Walker, Harry
Subject: FW: Request for Confirmation of Equivalence of Next Step in Supply Chain Meat Inspection in Denmark

Harry,

All contact details are included in the already forwarded letter (see the bottom of the letter).

To avoid misunderstandings (personally I had to get used to the alternative format of US addresses) the address should be presented this way:

Danish Veterinary and Food Administration
Mørkhøj Bygade 19
DK-2860 Søborg

Best regards,

Anders

From: Anders Klöcker
Sent: 23 April 2010 10:17
To: 'andreas.keller@fsis.usda.gov'
Cc: 'harry.walker@fsis.usda.gov'; Washington; Caroline Kirk
Subject: Request for Confirmation of Equivalence of Next Step in Supply Chain Meat Inspection in Denmark

Dear Dr. Keller,

Attached please find a letter and enclosure from the Deputy Director of the Danish Veterinary and Food Administration (DVFA), Ms. Annelise Fenger.

Please don't hesitate to contact me in case of any questions.

On behalf of DVFA, I look forward to a response at your earliest convenience.

Best regards,

Anders

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Ministry of Food, Agriculture and Fisheries

Danish Veterinary and Food Administration



United States Department of Agriculture
Food Safety Inspection Service
Office of International Affairs
Dr. Andreas Keller, Director Equivalence

DIVISION FOR MICROBIOLOGICAL
FOOD SAFETY, HYGIENE
AND ZOOSES CONTROL

23 April, 2010

Dear Dr. Keller

Following the approval by FSIS dated December 24th 2008 of our revised meat inspection system for slaughter pigs ("Supply Chain Meat Inspection- the Danish Way") we have changed the traditional meat inspection to supply chain inspection on most of the larger slaughter plants for pigs.

As you know, the change meant that the routine inspection of the hearts and the sub-mandibular lymph nodes was changed to a visual inspection.

This changed system was demonstrated at one of the slaughter houses audited during the FSIS audit in 2009.

Supply chain meat inspection is possible only if the food chain information from the farm is available prior to slaughter and given that they include the information that the pigs have been kept in-door since weaning.

An independent risk assessment has recently been made on omission also of the routine palpation of the mesenteric lymph nodes of slaughter pigs in Denmark.

The risk assessment has been evaluated by the Danish Food Institute. Their conclusion is that there is no risk for food safety if the routine PM-inspection of the mesenteric lymph nodes of slaughter pigs is changed to a visual inspection only. Therefore, our intention is to implement this new procedure as soon as possible.

According to our understanding, this next step in our risk based inspection procedure is a logical continuation of the project that the Food Safety Inspection Service approved by the above mentioned letter. We kindly ask you to confirm this.

The Danish Veterinary and Food Administration value the good and fruitful cooperation with the Food Safety Inspection Service.

Yours faithfully

Annelise Fenger
Deputy Director

Charlotte Vilstrup
Danish Veterinary and Food Administration
4th Division

Translation of letter dated 30th of November 2009

Evaluation of the report "Palpation of the intestinal lymph nodes a necessary part of meat inspection of finisher pigs?"

DTU Food, National Food Institute, has been asked to evaluate the conclusions of the presented documentation of the report "Palpation of the intestinal lymph nodes a necessary part of meat inspection of finisher pigs?" by the authors Lis Alban, Birthe Steenberg, Jesper Valentin Petersen and Susanne Jensen, from the Danish Agricultural and Food Council, 24th of September 2009.

The National Food Institute finds the report sufficient in its discussion of the relevant issues and the presented documentation.

The National Food Institute agrees to the conclusion. The National Food Institute finds it well documented that there is no risk of food borne illness for the consumer by changing the procedure from palpation to visual inspection. The National Food Institute is of the opinion that the changing of the procedure in reality will be a benefit for food safety as the risk of cross contamination associated with palpation of the intestines will be reduced.

Yours faithfully

Jens Kirk Andersen

How to ensure continuous freedom from bovine tuberculosis in finisher pigs when changing meat inspection?

Denmark is officially free from bovine tuberculosis. A risk assessment of Danish finisher pigs shows that there is no added value related to the cutting into neither the mandibular lymph nodes nor the mesenterial lymph nodes during meat inspection. A precondition is that the pigs originate from integrated production systems, where the pigs are kept in-door.

The aim of meat inspection is to ensure that the meat we consume is savoury and safe. Meat inspection was designed 100 years ago when people in Denmark became ill among others from bovine tuberculosis (TB). Since, bovine TB has been eradicated from Denmark. Nowadays, other hazards fill up the statistics. In particular, Salmonella and Campylobacter are resulting in a larger number of human cases. The rules for meat inspection should be updated to take into account the hazards that are most important at a given point in time. This is the philosophy behind changes in 2006 to the legislation of the European Community that made it possible for the competent authority to decide that finisher pigs under certain conditions can undergo a modernised meat inspection.

There are three requirements, which should be fulfilled. First, a risk assessment should be undertaken and demonstrate that the suggested changes do not jeopardise food safety. Next, any change can only be made for finishers from integrated production systems, where pigs are kept in-door since weaning. Last, it is required that food chain information should be exchanged between the herd owner and the slaughterhouse prior to slaughter.

Our proposal is only to cut into the mandibular lymph nodes and mesenterial lymph nodes on carcasses where pathological changes are observed, because omission of the routine cutting might reduce the spreading of Salmonella and Yersinia bacteria for the benefit of the consumer.

One risk assessment was undertaken in collaboration between University of Copenhagen (the former Royal Veterinary and Agricultural University), the Danish Veterinary and Food Administration and Danish Meat Association (DMA). The aim was among others to assess the impact of not routinely palpating and cutting the mandibular lymph nodes on food safety. The next risk assessment (conducted by the industry alone and submitted to the Danish Veterinary and Food administration for acceptance) aimed at looking on the effect of not palpating the mesenterial lymph nodes routinely.

The result of both risk assessment showed that risk of bovine TB is the hazard of interest. A cow or a pig infected with bovine TB will have mandibular or mesenterial lymph nodes with a look like gritty cheese on the inside (called granulomatous lesions), however other bacteria might also cause this altered look. According to the Danish slaughterhouse database the prevalence of granulomatous lymph nodes is very low among Danish finisher pigs (0.01-0.02%).

Samples were collected from ten Danish slaughterhouses. No TB bacteria were found in any of the samples. Bovine TB was found in farmed deer in Denmark previously, but never in Danish free-living deer. In fact, Denmark is recognised by the EU as being officially free from bovine TB since 1980.

To ensure continuous freedom from bovine TB an extensive surveillance program is in place. The surveillance program consists of:

- Examination of cattle during meat inspection

- Testing of bulls before they enter a semen collection centre
- Testing of cattle before export
- Testing of pigs exported to certain countries that require testing for TB

Denmark only imports a limited number of cattle and pigs, and requirements for testing and quarantine are in place. Hence, if bovine TB should enter the country, there is a high probability that it will be found during quarantine.

Moreover, we will continue to cut into the mandibular and mesenterial lymph nodes of sows and boars as well finishers from herds that do not fulfil the criteria for being subjected to Supply Chain Meat Inspection. These groups of pigs are expected to be at higher risk than in-door reared finishers which only live for five months without any contact to other animals than their pen mates.

Conclusively, the surveillance program in place continuously documents freedom from bovine TB. Hence, there is no risk of bovine TB associated with the omission of the routine cutting of the mandibular lymph nodes or the mesenterial lymph nodes. On the contrary, unnecessary palpation and cutting will increase the risk of spreading bacteria such as Salmonella and Yersinia.

Moreover, the mandibular and mesenterial lymph nodes are considered inedible tissue. It is being used as pet food after adequate heat treatment. Moreover, according to the current regulation such findings will only result in local condemnation. Contrary, findings of TB in lungs, kidney or the liver are an indication of generalised avian TB in which case total condemnation is required. We will continue to inspect the lungs, the liver, and the kidneys. Hence, our ability to find avian TB will remain unchanged.

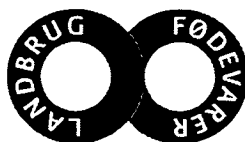
As a part of a quality control, the risk assessment on mandibular lymph nodes underwent a peer-review process where comments from three independent professors from Great Britain and Norway were incorporated. The risk assessment can be found on the homepage of the Danish Veterinary and Food Administration on <http://www.foedevarestyrelsen.dk/forside.htm> and DMA <http://www.danishmeat.dk/Forside.aspx>. Moreover, the risk assessment about the mesenterial lymph nodes was sent from the Danish Veterinary and Food Administration to the Danish Food Institute for an independent evaluation. According to the Food Institute, the food safety risk would not alter if the mesenterial lymph nodes were no longer palpated routinely.

Finally, it has been decided to discourage Danish farmers from using untreated peat as litter material to reduce the exposure of pigs to avian TB. Untreated peat is considered the main source of avian TB. This has been done by including it into the Danish Standard which is a certification system with auditing visits every third year.

Is palpation of the intestinal lymph nodes a necessary part of meat inspection of finisher pigs?

By Lis Alban, Birthe Steenberg, Jesper Valentin Petersen and Susanne Jensen

Danish Agricultural & Food Council, Axeltorv 3, DK-1609 Copenhagen V, Denmark.



September 24, 2009

- Translated into English July 2, 2010

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Preface

The basic principles behind the present meat inspection are more than a hundred years old. Since then, the disease picture has changed in Denmark. Previously, the challenge was to handle animals with serious infections as tuberculosis and brucellosis. The traditional meat inspection was here a worthy tool. However, the main challenges for Danish pork are currently *Salmonella* Spp. and *Yersinia enterocolitica* – and here, traditional meat inspection is not the answer. It is therefore appropriate to evaluate all elements of meat inspection to ensure that the best methods are applied. According to the current meat inspection circular, a number of specific intestinal lymph nodes must be palpated for each carcass. But why? What kind of lesions might be found in these intestinal swine lymph nodes? And are those lesions caused by a zoonotic agent? – Or in other words: Can humans be infected from eating meat from a finisher pig in which a lesion in the intestinal lymph node passed control? That is the focus of the following risk assessment.

Summary

According to present rules, meat inspection requires that a number of specific intestinal lymph nodes are inspected and palpated in every slaughtered swine. But why? - And is this in fact necessary? Could a visual inspection of the stomach and intestines be sufficient? To find an answer to this question, a qualitative risk assessment in finisher pig from indoor herds was undertaken. The method follows international guidelines on risk assessment and is based on existing data and literature as well as expert opinion from professionals.

The assessment shows that the far majority of swine disorders which brings pathological changes to the stomach, intestines and intestinal lymph nodes result in lesions which are found by inspection of the stomach and intestines alone. The far most prevalent lesions are caused by hazards which are not zoonotic, and hence, are not transferred to humans. Exceptions from this are *Salmonella*, *Campylobacter* and *Yersinia* which – despite of a relative high frequency in live pigs – only occasionally causes changes in the gastro-intestinal tract or the intestinal lymph nodes. Therefore, palpation of the intestinal lymph nodes does not essentially contribute to the judgement on whether a carcass is suitable for human consumption or not. Likewise, the handling of intestines today is performed in such a professionally-secure way that exposure is limited regarding employees.

Thereby, tuberculosis is the one disease with relevance to food safety which manifests itself in the intestinal lymph nodes only. Since 1980, Denmark is officially recognised as being free of bovine tuberculosis, which is a hazard that can pass to humans. Avian tuberculosis is rarely seen within Danish finisher pigs and when it occurs it is primarily detected as changes in the mandibular lymph nodes and/or the intestinal lymph nodes. In these cases, the action taken is local condemnation, whereas lesions outside of the intestinal lymph nodes results in total condemnation. On rare occasions, avian tuberculosis might pass on to humans, but according to the literature this is not considered to be caused by pork. Immuno-compromised humans infected with avian tuberculosis might fall very ill, if not medically treated.

The mesenterium including intestinal lymph nodes are today used for production of animal feed. In the future, the raw material might as well be used for production of spray-dried protein as an element in the manufacturing industry. During production, heat treatment takes place at high temperatures (90-110° C) and for a long time (more than four hours). This effectively secures the elimination of bacteria.

There is no increased risk related to introduction of exotic, contagious livestock diseases when refraining from palpation of the intestinal lymph nodes. This is so, because these diseases are detectable by obvious clinical symptoms in the live animal or in lesions in other organs than the intestinal lymph nodes.

Omitting palpation has only a negligible significance with respect to animal health or welfare, since the lesions which are relevant for these purposes almost in total are observed in connection with meat inspection – also in situations where the intestinal lymph nodes are not inspected or palpated. You might miss some disease cases, primarily those which presents themselves as no macroscopic lesions besides from a swollen lymph node. This is estimated to be of negligible significance to the farmer's or the authority's surveillance on animal health or welfare.

All in all, there is only a negligible risk involved in inspecting the stomach and the intestines instead of inspecting and palpating the intestinal lymph nodes. This assessment covers only finisher pigs from indoor herds.

1. Background

1.1 Introduction

There is a need for an update on the rules on meat inspection to make them match the elements of infections which are causing human disease today. This is the viewpoint underlying the changes in 2006 to the European legislation on food, which make it possible to change existing routines in practical meat inspection. Three demands are to be met:

1. A risk assessment must be undertaken. This must prove that the proposed changes do not impact food safety negatively
2. Only finisher pigs from indoor herds may be slaughtered differently from what is described in the traditional meat inspection
3. The owner of a pig herd must give in food chain information to the abattoir prior to slaughter, e.g. information about medical treatments

In 2008, a risk assessment was undertaken assessing the effect of omitting the routine incision into the mandibular lymph and the opening of the heart of finisher pigs. Both incisions have been conducted on a routine basis on every carcass. The risk assessment showed that food safety is not jeopardized when these routine incisions are not conducted. Neither is the risk of introducing exotic contagious diseases in domestic animals (Alban et al., 2008). This risk assessment is available in English on the internet

(<http://www.lf.dk/Aktuelt/Publikationer/~media/lf/Aktuelt/Publikationer/Svinekod/palpererapport.ashx>).

The risk assessment is also described in a short article by Alban et al. (2009).

During the spring of 2009, the new procedures of meat inspection were tested in two abattoirs – Danish Crown in the cities of Esbjerg and Sæby. The experience from these pilot experiments will be implemented in the new form of meat inspection in a number of Danish abattoirs from September 1, 2009. An interim evaluation shows that a change to a visual control of hearts and lymph nodes is possible (Anon., 2009b). And according to section 20 in the revised Danish circular on meat control of August 28, 2009, the mandibular lymph nodes, the heart and the epicardium are just to be inspected. The heart and the epicardium, though, must be further examined when lesions indicating generalised infection are present on the carcass (Anon., 2009a).

This new form of meat inspection is called Supply Chain Meat Inspection – The Danish Way to stress the farm-to-table view in which information about the herd is an element in the decision making regarding which kind of meat inspection an animal must go through.

According to present rules on meat inspection every carcass must have the intestinal lymph nodes palpated (Anon., 2004). But is this necessary? Or is a visual inspection of stomach and intestines sufficient? Before answering to this, it is necessary to study the basis of judging the carcasses.

1.2 Judging the carcasses

In connection with meat inspection a set of ratings are used (Table 1). Unconditioned approval (UA) is used when the entire carcass and every organ are approved for human consumption. The rate total rejection (TR) is used for carcasses where a general condition is present which makes the meat unsuited for human consumption. In case of local lesions without significance to the rest of the carcass or other organs the rate local rejection is

used (LR), whereby parts of the meat or specific organs are discarded whereas the remaining carcass is approved. The rating also includes approval of a carcass for de-boning or manufacturing. In 2008, 0.4 % of the carcasses were totally rejected while 68 % were unconditionally approved (Table 1). In a very few cases (0.02 %) the carcass was approved for de-boning. Approximately the same distribution of rating was seen in 2006 and 2007 (Appendix A).

Table 1

List of various possible ratings of finisher pig carcasses as well as the distribution of findings in 2008 according to the Danish abattoir database

Rating	Description	Prevalence
Unconditioned approval - UA	The entire carcass and all organs are approved. The meat is suited for human consumption no matter the way of preparation.	68.0%
Total rejection - TR	The entire carcass and every organ are discarded. Adequate for carcasses which are not suitable for human consumption because of a general condition or local lesions, suffering or contamination which is not to be eliminated or which has an impact on the general condition.	0.4%
Local rejection - LR	Discarding of parts of the carcass, some organs or parts of organs in connection with cleaning the regional lymph nodes. This always includes the regional lymph nodes. The rating is used on local lesions or disorders without an impact on the general condition. Locally rejected material without signs of disease may be approved for manufacturing of feed if certain conditions are met.	31.6%
Approval for de-boning - AD	All bones, joints and visible pathological changes are discarded. Used in case of diseases in which the skeletal musculature and organs are approved suitable for human consumption. In cases where further changes are found during de-boning those lesions must be included in the total rating.	No data
Approval for manufacturing - AM	Meat from pigs with a limited spread of changes in muscles in form of PSE (pale, soft, exudative) or DFD (dark, firm, dry) may be used for manufacturing of meat products after de-boning. Parts with a high grade of changes are locally rejected and unchanged parts are approved.	0.02%

Source: Jensen et al. (2006), Anon., (2009b) and the Danish abattoir database

1.3 Purpose

The purpose of the present work is to assess whether there is a risk when omitting palpation of the intestinal lymph nodes and instead inspecting the stomach and intestines visually during meat inspection. This assessment covers only finisher pigs from herds raised in integrated production systems that are kept in-door since weaning.

Risk is here seen as a negative effect on food safety or an increased probability of introduction of exotic livestock diseases. The impact on animal health and welfare shall also be mentioned briefly.

In order to throw light on this, a qualitative risk assessment on finisher pigs from indoor farms has been undertaken.

2. Material and method

The risk assessment is based on existing data, literature and expert opinion from professionals and follows international guidelines. Thus the following five steps are examined:

1. Hazard identification
2. Release assessment
3. Assessment of exposure
4. Assessment of consequences
5. Risk estimation

As a part of hazard identification, the present meat inspection concerning palpation of intestinal lymph nodes is described and hazards relevant to the risk assessment are identified (1). Next, it is assessed how often each hazard is found in live finisher pigs from indoor herds (2). This is followed by an assessment on how often the specific hazards occur in pork or pork products, which are consumed by humans or animals (3). Then, the consequences of this are examined (4). Eventually, all information is gathered for an assessment on the final risk (5).

3. Hazard identification

3.1 *In general*

3.1.1 *Intestinal lymph nodes and their function*

Intestinal lymph nodes can be seen as protective organs for the organism since they function as filters of the floating lymph. Hereby, they play a significant role in the reaction against infections and other harmful actions to the body. Every group of lymph nodes receives lymph from certain areas of the organism. Pathological lesions in an area which is drained by a group of lymph nodes will be reflected in changes to these lymph nodes.

Presence of an agent will usually cause instant changes in the tissue of the drain area. For instance as abscess creation or reactive hyperplasia, or in case of tuberculosis or actinomycosis: different granulomatous or pyo-granulomatous infections of the lymph nodes. Malignant tumour growth often creates metastatic changes in the corresponding lymph nodes while bleedings – for instance as a result of fractures or contusions – easily are detected by blood infiltrations in the lymph node even though the underlying processes are not directly visible. Here lies the significance of the lymph nodes in the assessment of the carcass. It is therefore of importance that the inspector knows the normal look of the lymph nodes and their ways of reaction to different pathological conditions as well as their position and drain area. The inspector actually has to assess whether the carcass with its organs can be approved for human consumption and - if so - under which conditions (Table 1).

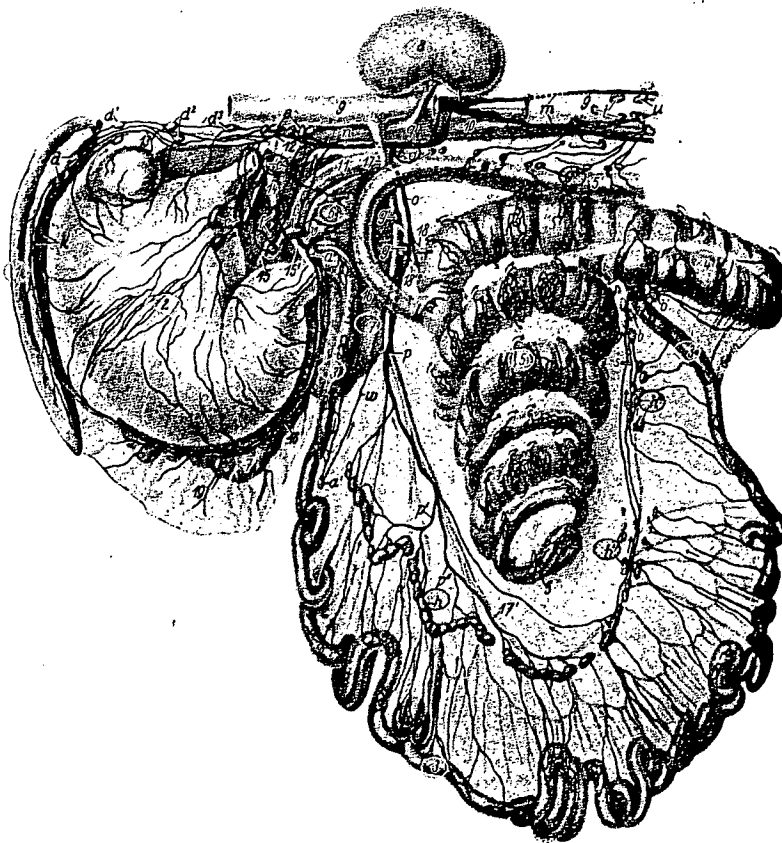
3.1.2 *Organ lymph nodes and meat lymph nodes*

In meat inspection there is a marked difference between organ lymph nodes and meat lymph nodes. Meat lymph nodes receive lymph solely from musculature (and corresponding connective tissue and fat tissue), bones, joints and skin. If the skin in the region is intact and infections of skin or soar can be excluded, reactions in the meat lymph nodes can be interpreted as a manifestation of a general spread of an infectious agent. This indicates that a general infection with blood-borne spread of an agent has occurred. The condition of the meat lymph nodes is therefore of utmost importance for the decision regarding whether an infection is local or general

and thereby for assessment of the destination of the meat from the carcass. All things being equal, a general condition will be assessed more severe than a local condition (Table 1).

In contrast to this, changes to the organ lymph nodes do not necessarily suggest a general pathological condition. Changes to organ lymph nodes might be a reaction to a local intrusion by an agent in the organ from which the lymph node receives lymph. One example of organ lymph nodes is the lymph nodes of the alimentary tract (Jepsen, 1968).

According to present rules on meat inspection the lymph nodes Lnn. gastrici and Lnn. mesenterici craniales et caudales must be examined and palpated in pigs (Anon., 2004). According to teachers at the Danish Slaughterhouse School in Roskilde this is not the group of lymph nodes that is inspected and palpated. Instead the intestinal lymph nodes (Lnn. jejunaes) are palpated. This is so because these lymph nodes are easy to observe while Lnn. mesenterici craniales et caudales are not easily found. This risk assessment concerns both intestinal lymph nodes and the lymph nodes mentioned in the regulation. Figure 1 shows the gastro intestinal tract with the corresponding tissue and the mentioned lymph nodes.



Figur 1

① Milt, ② Mavesæk, ③ Tyndtarm, ④ Blindtarm, ⑤ Tyktarm, ⑥ Bugspytkirtel, ⑦ Lever, ⑧ Venstre nyre, Tarmlymfeknuder ⑨ Nll. gastrici ⑩ Nll. mesenterici caudalis ⑪ Nll. mesenterici cranialis ⑫ Nll. jejunaes. Kilde til billede: Nickel et al. (1984)

It must be assessed which pathological conditions might be neglected as a result of omitting the routine palpation of the intestinal lymph nodes. The intestinal lymph nodes are organ lymph nodes with stomach and intestines as their drain area. Therefore, we will look into the different diseases which affect the stomach and the intestines of swine. Thereafter, we will assess – disease by disease - whether there is a risk of neglecting the specific lesion if the intestinal lymph nodes when inspecting the stomach and the intestines visually. Eventually, it must be assessed 3) whether these pathological conditions are significant to either food safety or the introduction and spread of contagious exotic livestock diseases.

3.2 Pathological conditions in the stomach, intestines and intestinal lymph nodes in swine

3.2.1 Diseases in live pigs

Pigs can suffer from a variety of diseases. Some of them are not present in Denmark either because the disease was never observed or it was eradicated. With the intensification of the livestock production systems, the variation in the pathological picture has simultaneously decreased. Moreover, the diseases are usually dominant in certain age group. On basis of a list of disorders made by the Danish Veterinary Union it is possible to get an overview of disorders in Danish finisher pigs (Table 2). The diseases are divided into three groups: septicaemia, diarrhoea and respiratory disorders. Animals suffering from septicaemia are identified on the background of clinical symptoms either by the producer, the driver or during the *ante mortem* inspection in the abattoir. This group of animals is hereby not slaughtered. Similarly, animals with respiratory disorders have clinical symptoms in other organs than the gastro-intestinal tract. Thus, of these three groups, only diarrhoea is relevant to this risk assessment.

Table 2

List of disorders observed among weaners and finisher pigs divided according to their relevance for the inspection of intestinal lymph nodes

Disease group	Disorder (agent)	Relevance to intestinal lymph nodes
Septicemia	Arthritis (<i>Mycoplasma</i> , <i>Streptococcus suis</i>)	With an agent involved in these disorders the clinical symptoms are primarily seen in other organs than the gastro-intestinal tract
	Cerebrospinal meningitis (<i>Streptococcus suis</i>)	
	Gläser's disease (<i>Hæmophilus parasuis</i>)	
	Sequelae to tail bite infection	
Diarrhea	Diarrhea (<i>E. Coli</i>)	All agents in this group affect the gastro-intestinal tract
	Spirochaetal diarrhea (<i>Brachyspira pilosicoli</i>)	
	Proliferative enteropathy (<i>Lawsonia intracellularis</i>)	
	Dysentery (<i>Brachyspira hyodysenteriae</i>)	
Respiratory disease	Atrophic rhinitis (<i>Bordetella bronchiseptica</i> , <i>Pasteurella</i>)	With an agent involved in these disorders the clinical symptoms are primarily seen in other organs than the gastro-intestinal tract
	Pneumonia (<i>Mycoplasma hyopneumoniae</i> APP, <i>Pasteurella</i> , <i>Streptococcus</i> spp.)	
	Pertussis (<i>Bordetella bronchiseptica</i>)	
	Gläser's disease (<i>Hæmophilus parasuis</i>)	

Source: Holm (2009) and <http://www.infosvin.dk>

The relative distribution of these disorders is shown in Figure 2. In here, the animal daily doses of antimicrobials (ADD) reported to VETSTAT for treatment for a variety of disorders in all Danish finisher pigs in 2008 in presented (Appendix B contains specification in Danish for the data drawn from VETSTAT database). The far most

prevalent disorder group is gastro-intestinal diseases followed by respiratory disorders followed by arthritis. Finally, urogenital tract disorders, metabolic disorders and udder diseases occur but on a much lower level.

A number of food-borne agents are found in pigs e.g. *Salmonella* spp., *Yersinia enterocolitica* and *Campylobacter*. These agents do not necessarily cause clinical disease in pigs. Contrary, human-pathogen vetotoxin-producing *E. coli* (VTEC) is primarily related to cattle.

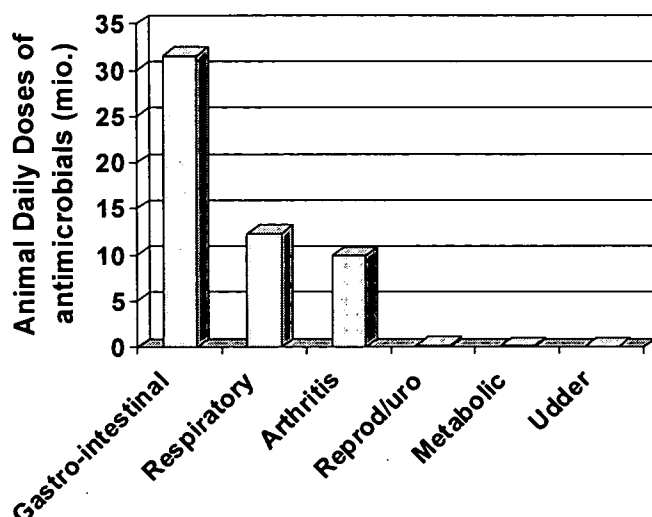


Figure 2. Animal daily doses of antimicrobials (ADD) reported to the VETSTAT database for treatment for a variety of disorders in all Danish finisher pigs during 2008

3.2.2 Pathological manifestations in the carcass

Pathological manifestations observed in the gastro-intestinal tract in finisher pigs includes: Idiopathic conditions, acute infections in the stomach, acute intestinal infection, chronic intestinal infection as well as parasitic gastro-intestinal infection. Furthermore, general conditions as emaciation, anaemia and tuberculosis might result in manifestation observed in the gastro-intestinal tract.

As described in section 3.2.1 *Salmonella*, *Yersinia* and *Campylobacter* are often present in the intestines of pigs. That does not necessarily cause lesions which are observable during meat inspection. These bacteria are human pathogenic.

Tuberculosis might manifest itself solely in the intestinal lymph nodes, and bovine and human tuberculosis are human pathogenic. There is, therefore, generally speaking a risk of neglecting tuberculosis when the intestinal lymph nodes are not examined. This condition is therefore more thoroughly described in this section. More details regarding pathology, cause, agent, assessment and significance are described in Appendix C in Danish.

Tuberculosis is observed in finisher pigs as granulomatous lesions in the intestinal lymph nodes and is caused by contamination by different sorts of *Mycobacterium* species. The most relevant are *Mycobacterium bovis*, *M. humanum* and *M. avium* subspecies *avium*. The two first mentioned types are pathogenic to humans, whereas *M. avium* is considered less pathogenic in that it primarily causes disorders in immuno-compromised patients

such as caused by HIV/AIDS and that do not receive proper treatment. For more than 30 years Denmark has been officially declared free from bovine tuberculosis and a surveillance program is in place. Human tuberculosis occurs primarily among immigrants and it spreads especially from person to person. Avian tuberculosis occurs – rarely – in finisher pigs.

Yet, in the summer of 2009 an outbreak of avian tuberculosis in a swine herd was observed. From June until this moment (September 2009) changes in the intestinal lymph nodes due to tuberculosis were found in 50 to 75 % of the carcasses. Furthermore, changes were found in liver and in lung in some finisher pigs at every delivery from the herd. Because of the widely spread in the herd (and for other reasons) the herd was subjected to official supervision in June 2009 on suspicion of bovine tuberculosis. The supervision was cancelled on September 1st when a laboratory analysis indicated that the disease was caused by avian tuberculosis. The outbreak was probably caused by the use of non-heat treated sphagnum as bedding in the farrowing stable (Bente Johansen, personal message in June 2009; C. Brasch-Andersen, personal message in June 2009).

The health management at the SPF-Denmark company (SPF-SuS) has an approval program that includes peat to avoid contamination by pathogens such as avian tuberculosis. The industry could discuss a requirement that peat used as bedding in swine herds must be approved by the SPF-SuS. Such control could be part of the auditing program conducted as a part of the Danish Standard Scheme for all Danish pigs herd. *Author's comments after finalisation of Danish report in September 2009: this was been implemented in 2010.*

Tuberculosis in swine is practically always a matter of feed infection. The primary complex is either found in the pharynx and in the lymph nodes of the head (mandibular lymph nodes) or in the small intestine and in the intestinal lymph nodes. Just as seen in the recent outbreak, the majority of the cases of infection by *M. avium* cause only local tuberculosis lesions in the mentioned lymph nodes without a general spread. In a few cases, general tuberculosis is developed with lesions in lung and liver. Affected lymph nodes are usually enlarged.

In the present circular about meat inspection an extended examination for tuberculosis in swine is only mandatory when processes have been observed in other places than the mandibular lymph nodes or in the intestinal lymph nodes (Anon., 2009a). On presence of lesions of general tuberculosis, the carcass is rejected. According to the conclusion from a recently conducted risk assessment, there is no increase in risk to food safety when the routine cutting of the mandibular lymph nodes is refrained from (Alban et al, 2008). This is due to the fact that:

- bovine tuberculosis (which is a serious zoonosis) has been eradicated in Denmark (official free-status since 1980) and a surveillance program is in place,
- the occurrence of avian tuberculosis is rare among finisher pigs and occurs mainly because of the use of non-heat treated peat or presence of poultry and swine on the same premises,
- the mentioned lymph nodes are used for animal feed after sufficient heat treatment,
- Mycobacteria are environmentally-adapted bacteria which are found in for instance water, cigarettes and cheese. Humans are usually not falling ill when exposed to *M. avium*, and
- it is the prevailing opinion in the literature that the consumption of pork is not related to the risk of developing avian tuberculosis (Bauer, 1999).

The contagious form of tuberculosis which is likely to be found in cattle in countries with bovine tuberculosis is not known in swine. In practice, swine are always infected by other species; by infected cattle, poultry or humans (Jepsen, 1968).

3.3 Exotic contagious livestock diseases

One of the purposes of meat inspection is to identify exotic contagious livestock diseases. For swine, this includes classical and African swine fever, swine vesicular disease, foot and mouth diseases, Teschen disease and Aujeszky's disease. Other diseases caused by virus – such as circo-virus related diseases – are to be judged in meat inspection according to the general principles regarding acute or chronic inflammation processes. This means, that feverish animals are rejected no matter the underlying cause of fever. Acute or chronic inflammations are assessed with respect to degree of spread: general or local. This as well as other complications present form part of the assessment in which it is decided whether local or total condemnation is the relevant decision.

Denmark is free from a high number of the listed exotic contagious livestock diseases – among these classical and African swine fever, foot and mouth disease, *Trichinella* (domestic pigs) and bovine tuberculosis. A thoroughly investigation into these diseases has been carried out in a previous risk assessment (Alban, 2008). This risk assessment stated that a variety of surveillance programs are in place with the purpose of 1) locate infected animals as soon as possible after introduction in Denmark and 2) to continuously document the Danish status as being free from these diseases.

It has been assessed that the ability to identify all these diseases is not affected if the stomach and the intestines are visually inspected instead of a palpation of the intestinal lymph nodes. This is so because:

- 1) Should one of these unwanted infections enter the country it will occur primarily in other species than swine (*Mycobacterium bovis* and *Brucella abortus*: cattle)
- 2) The infection will not be recognised by palpation (*Trichinella* spp),
- 3) The infection usually results in lesions in other organs than in the intestinal lymph nodes (Classical or African swine fever is seen as multiple bleedings for instance in the spleen, and foot and Mouth as vesicles in the oral cavity and on the coronary band of the hooves. Aujeszky's disease has neurological symptoms in piglets and weaners, and *B. suis* manifests itself by swollen genitals and abortions),
- 4) The infection has never occurred in Denmark (African swine fever, *B. melitensis*, swine vesicular disease, transmissible gastroenteritis)

3.4 Disease pathways

If a slaughter animal carries an infection, which is neglected in connection with slaughtering there is a risk that the carcass contains the infection. After slaughtering the meat is prepared in different degrees. This is done at the abattoir (cutting-up), in a manufacturing industry (e.g. sausage production) or in the consumer's home (usually involves heat treatment). In some cases, by-products are used in for manufacturing of mixed products for human consumption. Certain infectious material can survive these different ways of preparing the meat; and some will grow while others will be reduced or eliminated. Waste from slaughtering of approved slaughter animals is used for manufacturing of animal feed. In this way, pets might be exposed to infectious material unless the industry takes appropriate care of it. Besides from infectious material, other remnants might be neglected in the meat inspection such as heavy metals, antimicrobials and colouring agents.

3.5 Identification of relevant hazards

The function of the intestinal lymph nodes in connection with meat inspection is primarily to make the inspector aware of possible pathological conditions in the stomach, intestine and lymph nodes. In some cases, conditions in the stomach, intestine and intestinal lymph nodes might be neglected if the intestinal lymph nodes are not palpated on a routine basis. The hazard identification indicates that this especially includes infections relevant to

animal health (*E. coli*, *Brachyspira hyodysenteriae*, *Brachyspira pilosicoli* and *Lawsonia intracellularis*). A few infections are relevant to food safety (*Salmonella* spp., *Yersinia enterocolitica*, *Campylobacter* spp.). There is no certainty in the literature with regards to whether avian tuberculosis is a hazard regarding pork. The prevailing opinion is that there is no risk (Bauer, 1999).

The hazard identification shows, that if the stomach and the intestines are visually inspected instead of palpating the intestinal lymph nodes, a few cases of pathological conditions in stomach, intestines and intestinal lymph nodes might be neglected. A number of these conditions are caused by pathogens, among which the majority do not have a zoonotic potential but solely result in animal diseases. A few of the pathogens have a zoonotic potential and it is those that are relevant. *Salmonella*, *Campylobacter* and *Yersinia* are human-pathogenic hazards. These agents might be prevalent in the gut of pigs. Tuberculosis might be present in gastro-intestinal tract solely, and some types of tuberculosis are zoonotic. There might be a risk of not finding all cases of tuberculosis, if the intestinal lymph nodes are not inspected. Some of the pathological conditions that are not caused by pathogens e.g. anaemia, emaciation and dietary disorders are primarily of aesthetic importance. It is assessed that there is no risk related to exotic contagious livestock diseases from omission of routine palpation of the intestinal lymph nodes.

4. Release assessment

Pathological manifestations are routinely reported to the Danish abattoir database. Between 1996 and 2008 several codes were used to describe lesions in the gastro-intestinal tract: Emaciation, acute and chronic intestinal infection, hernia, acute and chronic peritonitis, and lesions indicative of tuberculosis (which also covers other causes of lymph node lesions than those caused by *Mycobacterium* Spp.).

Table 3

The distribution of various lesions found during meat inspection of the gastro-intestinal tract of Danish finisher pigs as well as prevalence of total rejection*, 2006-2008, Denmark. Brackets indicate percentage of slaughtered pigs

Lesion	Code	2006		2007		2008	
		Number of Registrations	Total Rejection	Number of registrations	Total rejection	Number of registrations	Total rejection
Acute intestinal infection	30	2,643 (0.01)	2,403 (0.01)	2,808 (0.01)	2,560 (0.01)	3,634 (0.02)	3,335 (0.02)
Chronic intestinal Infection	31	26,268 (0.13)	5,529 (0.03)	24,907 (0.13)	5,961 (0.03)	26,713 (0.14)	6,519 (0.04)
Acute peritonitis	40	2,794 (0.01)	2,693 (0.01)	2,932 (0.02)	2,808 (0.01)	3,350 (0.02)	3,206 (0.02)
Chronic peritonitis	41	142,436 (0.71)	2,680 (0.01)	140,582 (0.72)	2,653 (0.01)	133,385 (0.72)	2,982 (0.02)
Hernia	42	238,161 (1.19)	1,733 (0.01)	191,128 (0.98)	1,493 (0.01)	171,750 (0.92)	1,342 (0.01)
Emaciation	74	10,009 (0.05)	9,631 (0.05)	9,310 (0.05)	8,883 (0.05)	9,323 (0.05)	8,905 (0.05)
Tuberculous changes	78	1,888 (0.01)	35 (0.0002)	2,977 (0.02)	58 (0.0003)	2,553 (0.01)	24 (0.0001)

*: The assessment depends not only on the lesion mentioned in the table but also on other lesions observed concurrently on the carcass and organs.

The most frequent lesion is umbilical hernia, which is often seen in connection with local, chronic peritonitis (Table 3). A variety of causes lies behind hernia, among these are genetic and navel infection which has developed into an umbilical hernia. This lesion rarely results in total rejection. Chronic intestinal infection which is mostly caused by *L. intracellularis*, is number three in frequency (0.13-0.14 %) and between 21 and 24 % of these carcasses were totally rejected. Regarding acute intestinal infection, most carcasses were totally rejected (91-92 %). Emaciation rarely occurs (0.05 %) but in these cases total condemnation is always certain. Finally, carcasses with lesions indicative of tuberculosis are only seldomly rejected probably because they are restricted to the mandibular lymph nodes and the mesenteric lymph nodes. The final decision to with regards to local or total condemnation is also based on other findings on the carcass and in organs - as described in Table 1.

Table 4 presents the most frequently reported causes for condemnation sorted accordance to frequency of local condemnation. Chronic pleuritis is observed in nearly 25 % of all finisher pigs. This lesion hereby makes up far most of all local condemnations (73 %). All other causes for local condemnation are low prevalent and occur each in less than 2 % of the finisher pigs. When looking at total condemnation, osteomyelitis, bite and infection in tail and pyemia make up 79 % of all causes of total rejection. This is in accordance with the causes for condemnation stated in Table 1: such findings express a general condition.

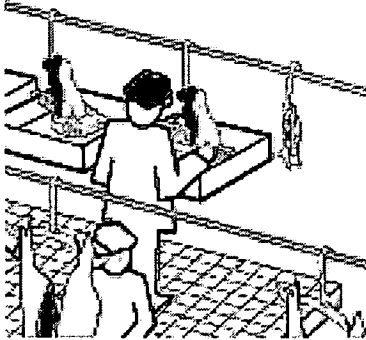
Table 4

Distribution of causes of condemnation in 18 million finisher pigs slaughtered in Denmark in 2008

Code of remark / lesion	Registrations of finisher pigs			
	Local condemnation		Total condemnation	
	Percentage	Number	Percentage	Number
23 Chronic pleuritis	23.28	4,325,885	0.01	2,429
71 Scar / contusion	2.08	385,601	< 0.01	623
63 Abscess in leg	1.73	320,927	0.04	6,708
18 Abscess in throat / breast	1.64	304,063	0.04	7,897
69 Tail bite infection	1.10	203,881	0.11	20,545
42 Hernia	0.92	170,408	0.01	1,342
41 Chronic peritonitis	0.70	130,403	0.02	2,982
68 Abscess in hind part of carcass	0.68	126,547	0.06	10,554
43 Abscess in peritoneum	0.61	113,531	0.02	2,820
73 Eczema/scabies	0.58	106,908	< 0.01	433
17 Abscess in the head	0.53	98,749	< 0.01	439
66 Chronic bone fracture	0.52	97,107	< 0.01	498
21 Chronic pneumonia	0.51	95,252	0.01	2,078
62 Chronic joint infection	0.34	62,691	0.02	3,171
11 Chronic pericarditis	0.27	50,822	< 0.01	304
56 Retained testicle	0.27	50,348	< 0.01	12
65 Acute bone fracture	0.26	49,130	< 0.01	162
64 Osteomyelitis	0.23	43,592	0.14	26,162
31 Chronic intestinal infection	0.11	20,194	0.04	6,519
34 Torsion of the spleen	0.10	17,934	< 0.01	1,362
14 Pyemia	0.05	8,665	0.08	14,056
In total	32.03	5,952,784	0.42	77,460

Palpation of the intestinal lymph nodes involves an increased risk of spread of zoonotic bacteria such as *Salmonella* spp., *Y. enterocolitica* og *Campylobacter* spp. In opposition to this, a visual inspection of stomach and intestines involves no increased risk of spreading. This allows of an inspection of stomach and intestines with plucks as shown in Figure 3.

Figure 3. Inspection with plucks hanging below the intestines



When visually inspecting the stomach and intestines instead of a palpation of the intestinal lymph nodes you may - as previously mentioned - neglect some cases of finisher pigs infected with *Salmonella* spp., *Yersinia* og *Campylobacter*. The result of these agents are usually none or just weak lesions. Furthermore, *Yersinia* and *Campylobacter* are widely spread among living swine. This means that the occurrence in intestinal matter is already today substantial. This exposure is dealt with in the gut scraping unit in the abattoir which in

itself constitutes a hygiene zone (O. Pontoppidan, personal message, July 2009). A surveillance programme for *Salmonella* spp. is furthermore in place in Denmark. This includes for instance separate slaughtering of finisher pigs from the herds considered to be at highest risk of *Salmonella* and that intestines from such animals are discarded (Alban et al., 2002; Anon., 2005).

As the production system has become more intensified, the variation in the pathological picture of finisher pigs has reduced. Respiratory disorders and diarrhoea occur frequently in finisher pigs from indoor herd. The majority of lesions that are related to diarrhoea are observed directly in the intestines and do not depend on an inspection or palpation of the intestinal lymph nodes. Human pathogenic agents such as *Salmonella*, *Yersinia* and *Campylobacter* occur frequently in the intestines in finisher pigs without necessarily resulting in observable lesions in neither the intestines nor the lymph nodes. Examination of the intestinal lymph nodes is therefore not considered an action which prevents the occurrence of these bacteria. These agents are already today dealt with in another way. Tuberculosis is therefore the only disorder which is relevant for the present risk assessment. Denmark has since 1980 officially been free from bovine tuberculosis and a surveillance program is in place. Avian tuberculosis occurs rarely in finisher pigs and when it does the primarily findings are lesions in the mandibular lymph nodes and/or the intestinal lymph nodes. The judgement in these cases is local condemnation. Swine are totally rejected in case of tuberculous lesions in other organs than the mandibular lymph nodes and the intestinal lymph nodes, e.g. in lungs and liver, since this indicates a general infection. Lung and liver are still to be inspected in meat inspection of all Danish swine.

5. Assessment of exposure

In the following it is examined if and how mesenterial tissue and intestinal lymph nodes can reach a consumer or an animal. Likewise, the probability that pathogenic bacteria are found in these products after manufacturing is assessed. Mesenterial tissue and intestinal lymph nodes are covered by the definition of category 3 material and is additionally defined in the EU regulation regarding food safety concerning by-products made from meat (Anon., 2002a). There are specific requirements regarding category 3 material with regards to collection, trans-

port, storage and not least manufacturing. Manufacturing requires besides from a grinding a combination of time, temperature and pressure which among other things ensure the elimination of living microorganisms. A heating of animal by-products – after grinding – reaching a core temperature of >100°C for a minimum of 125 minutes is an example of a heating method which effectively kills all pathogens.

5.1 Production of fat used for feed

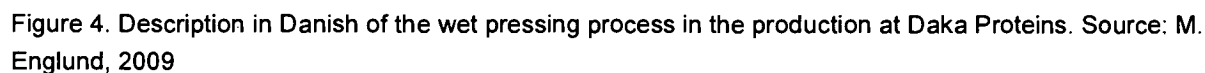
Today, Daka Proteins in the city of Løsning receives all by-products from the slaughtering of Danish finisher pigs approved for human consumption. This includes for instance mesenterial tissue including the intestinal lymph nodes. Daka manufactures the by-product into fat for feed as well as meat and bone meal. These processes are described in the following. The information comes from Daka Proteins (M. Englund, personal message 2009).

The mesenterial tissue is mixed with the rest of the slaughter offal and is transported to Daka where the by-products are grinded to a particle size of maximum 70 mm. Then, metal is detected and removed. A mincer subsequently chops the material into a particle size of maximum 19 mm. The product is then heated up until 85 °C to 90 °C. The heated fluids are separated as much as possible.

The liquid phase is heated up until 105 °C and is then divided into three parts: fat, lime water and dry matter. The lime water is concentrated and is lead back to the dry matter to the pressing cake. The fat is cleaned and sterilized by heating up until 110 °C for one hour. The final product consists of pure swine fat used as feed for swine.

The pressing cake is dried at 110 °C for approximately four hours. The meat meal (a product with high protein content) is then sifted out and the pieces of bone are grinded into a low protein product. Meat/bone meal is part of feed for pets. Through tests it is documented that the heating ensures the elimination of all agents. According to the company, *Salmonella* spp. is occasionally found in the final product as a result of re-contamination. Positive batches are discarded and then re-manufactured (heat treatment). The equipment is disinfected. The company continuously maps why and where *Salmonella* occurs in order to prevent future incidences. The company has incorporated a own-control program that includes a systematic sample taking for chemical and microbiological analyses.

It is assessed that the described heat treatment ensures that the product is free of microbiological hazards.



As described in section 5.1 the mesenterial tissue with the corresponding lymph nodes are today used in the production of feed for animals. As from the summer of 2009 it was proposed to use parts of the edible by-products in the manufacturing of spray-dried protein which then is supposed to enter the food production as an additive or as feed for animals. These by-products will be minced and heated up until 90 °C at the abattoir. The hot mass is loaded on road tankers and taken to a factory in Denmark which then takes over the manufacturing. During transport the temperature is kept at minimum 80 °C. Fat and protein are separated as described for Daka in the city of Løsning. Then the protein part is spray-dried (Andersen 2009).

5.3 Handling of stomachs and intestines

Own-control programs are in place with respect to manufacturing of both stomachs and the small intestines. Stomachs and intestines are scraped and emptied, and mucus is removed. This is done in the gut scraping unit in the abattoir. This step in the process can be done manually as well as by machine. The fresh intestines and stomachs are then cooled down by ice to a temperature of maximum 3 °C before transport from the abattoir to the manufacturing company. The low temperature impedes the growth of *Salmonella* if present.

The icy stomachs are speed-frozen either in cartons or they are plate-frozen and marketed as frozen. It appears from the product specifications (data sheet) that the stomachs are to be heat-treated prior to consumption. Stomachs are primarily sold to countries outside EU although a part is sold to other EU-countries.

The scraped, emptied and icy intestines are bleached at the manufacturing company. The intestines are sorted by size and iced before being preserved with salt. They are then put in a net and stored on ice. Sometimes the intestines are transported abroad for the sorting of size and then returned to Denmark for salting. Salting is a sort of preservation which reduces the food safety risk associated with a large number of pathogens. Intestines are sold to countries outside EU, within the EU as well as on the national market.

Mesenterial tissue including lymph nodes is today used as feed for animals. In the future, this raw material might also be used in the manufacturing of spray-dried protein and thereby used as an ingredient in the manufacturing industry. Heat treatment in the production of animal feed as well as spray-dried protein takes place at high temperatures (90°C to 110 °C) for more than four hours. This effectively ensures the killing of bacteria present and eliminates any risk to the consumers. Stomachs and intestines are cleaned and iced and should be heat-treated prior to consumption. Both products are sold for human consumption.

6. Assessment of consequences

6.1 Differentiation into zoonotic and non-zoonotic pathogens

By tradition, meat inspection has not distinguished between zoonotic and non-zoonotic pathogens. Meat inspection at the abattoir has been practised with the purpose of diagnosing pathological conditions which is believed to make the meat unsuitable for human consumption. As the inspector is making a decision he is not primarily focused on the risk to consumers when observing pathological changes. In other words: whether a disease can be transferred to humans when consuming the meat. In fact, the inspector cannot with certainty define the specific agent (Jepsen, 1968). Hence, in the classical meat inspection it is of no significance whether an agent is human pathogenic or not. The basic principles have been that acute, general conditions or general systemic disease determine a total condemnation of the carcass.

Today's knowledge is more comprehensive than yesterday's when it comes to pathogens observed with the different diseases in swine. Furthermore, indoor production of finisher pigs results in a more uniform set of pathological conditions. This is due to the fact that only a very low number of herds have different animal species in the same stable. Production has become more intensified and vaccines are used on a wider scale. This entails less variation in the pathological changes in finisher pigs than previously seen. Likewise, there is a greater knowledge about the zoonotic potential of the pathogens today compared to previously. Some pathogens can be transferred to humans through contact, others through meat, while a large group does not transfer disease to humans at all.

This knowledge will be accounted for in future meat control. For instance, a survey on endocarditis in swine showed that this is primarily an infection with *Streptococcus suis* and *Erysipelothrix rhusiopathiae*. The first of these bacteria is known to cause only a few numbers of infections in humans and is primarily considered an occupational risk. The latter bacteria is known to cause soar infections in humans working with animals or carcasses and considered an occupational risk whereas infections through consumption are not known. This knowledge is now applied in Denmark to the assessment of carcasses with endocarditis: If no other lesions on the carcass are present indicating a general disease (such as septicaemia or pyemia) the carcass will be approved while the heart will be locally discarded since the pathogens are not transferred in meat (Anon., 2009a).

Table 5 shows various pathogens which occur in finisher pigs divided according to zoonotic potential. It shows that *Salmonella* spp., *Y. Enterocolitica*, *Campylobacter* spp. make up the group of agents with zoonotic potential observed in Danish finisher pigs. This is also reflected in the statistics on humans. It ought to be mentioned, though, that *Campylobacter* spp. in pork poses a limited risk to humans. This is because the use of blast chilling – executed on carcasses after slaughtering – drastically reduces the prevalence of *Campylobacter* in pork (Alban et al., 2008).

Table 5

Various pathogens in finisher pigs divided according to zoonotic potential and by findings in Denmark, 2009

Zoonotic potential	Found in Danish finisher pigs	Not found in Danish finisher pigs
Yes	<i>Salmonella</i> spp., <i>Y. Enterocolitica</i> , <i>Campylobacter</i> spp.,	Bovine tuberculosis, <i>Trichinella spiralis</i> , <i>Brucella abortus</i> , <i>B. suis</i> *, <i>B. melitensis</i>
No	<i>L. intracellularis</i> , <i>Oesophagostomum dentatum</i> and <i>O. quadrispinulatum</i> , <i>Hyostrongylus rubidus</i> , <i>Brachyspira hyodysenteriae</i> and <i>B. pilosicoli</i>	Foot and mouth disease, African and classical swine fever, Aujeszky's disease, Swine vesicular disease, Transmissible gastroenteritis
Limited	<i>E. rhusiopathiae</i> (occupational risk), <i>S. suis</i> (occupational risk), Avian tuberculosis (not considered to spread through swine meat but is found in the environment)	

*: *B. suis* has been observed on few occasions in certain areas of Denmark among swine from outdoor herds.

Source: Alban et al. (2008)

By tradition, meat inspection has not distinguished between zoonotic and non-zoonotic pathogens. Meat inspection at the abattoir has been practised with the purpose of diagnosing pathological changes which results in a judgement that the meat as unsuitable for human consumption. Likewise, there is greater knowledge about the zoonotic potential of the different pathogens today compared to previously. Some pathogens can be transferred to humans through contact, others through meat, while a large group does not result in disease in humans at all. This knowledge will be incorporated in future meat inspection.

6.2 Consequences of infection by avian tuberculosis

The following is based on a description in Alban et al. (2008). In this it is shown how *Mycobacterium avium* can infect birds and animals such as swine and cattle. It is only potentially pathogenic to humans. The clinical cases of infection with *M. avium* can be divided into three main groups: 1) lung infections in patients with an already existing lung infection, 2) glandular infection of the throat in children who are otherwise well 3) multiple lung infection in patients with a seriously reduced immune system such as in AIDS patients. This third group was especially significant during the 1980s and the 1990s because of the HIV epidemic. Today, treatment of this group of patients has improved so that the infection can be treated.

Avian tuberculosis can be transferred to humans. Immuno-compromised humans might be very ill if not treated correctly.

6.3 Consequences to animal health and welfare

The Danish authorities conduct control regarding use of medication and animal welfare. The control visits is based on a risk assessment. This means that on basis of a series of risk parameters, individual herds and veterinarians are visited.

The Danish Veterinary and Food Administration has identified a variety of lesions in the registration obtained during meat inspection. Herds with a high proportion of animals with a certain diagnosis/lesions (or a combination of these and other risk parameters) can thereby be identified for welfare control. The relevant lesions are stated in Table 6.

Data on meat inspection provide the veterinarian and herd owner with a means of detecting disorders which maybe otherwise were not observed before slaughtering. Likewise, it is possible to keep an eye on the prevalence of problems in the herd already recognized. The calculations can be made up from production control or by making up one's own calculations out of the raw figures collected from the so-called landmandsportalen (farmers portal). This method is used by veterinarians but takes a good deal of prearrangement until the calculations and handling of the many data is in place. Experience from counselling proves a great difference in how much the registration on disorders in meat inspection is actually implemented in daily routines in the herds. In some herds, these data are not used at all while in other herds attention is continuously kept on the prevalence of for instance chronic pleuritis in finisher pigs.

Table 6

Provisional draft on relevant lesion possibly found during meat inspection of pigs regarding animal health and welfare, according to the Danish Veterinary and Food Administration, 2009

Code	Description	Code	Description
221	Acute epicarditis	501	Fresh bone fracture
222	Chronic epicarditis	502	Old bone fracture
230	Endocarditis	542	Dysplasia of hip or joint
251	Atrophic rhinitis	580 / 581 / 588 / 582	Abscess in hind part tail-related
585 / 569	Abscess, head	601	Tail bite/ tail infection
570 / 571 / 576	Abscess, throat / chest	602	Scar / Contusion
668	Injection lesion	132 / 131	Emaciation
289	Chronic pleuritis	113	Rejected on slaughtering – if reason given
320 / 321	Acute intestinal infection	114	Dead in stable – if reason given
325	Chronic intestinal infection Intes-	111	Dead on arrival – if reason given
331	Intestinal protrusion	902	Been beaten / Bite wounds
361 / 362 / 363	Hernia	455	Pregnant
615	Shoulder contusion	570	Scare, throat (abscess, throat)
402	Acute inflammation of kidneys	510	Enlarged claws (stable)
412	Chronic inflammation of kidneys	No code*	Tail length, defect biclavs, degenerative arthritis
421	Cystitis	625-629	Contusions in other places
431	Acute endometritis	336	Gastric ulcer
432	Chronic endometritis	614	Ulcer in ear
485	Semi boar	385	Ascaris suum in liver
531	Acute joint infection	568	Ascaris suum in intestines
532	Chronic joint infection	634	Scab
584	Abscess leg/toe	385	Liver spots

*: There is no code in the existing system

The farmer can also order an extended health control (USK). This is profitable when a herd has problems with respiratory diseases or gastric ulcer or with reproductive problems in sows. With a USK a great number of organs from slaughter animals are examined in connection with the slaughtering. Hereby, an overview of the problem is created as well as a possibility of a quantitative assessment (<http://www.vet.dtu.dk/Dyrslaegen/USK.aspx>). A change in the meat inspection with respect to omitting the routine palpation of the intestinal lymph nodes has no relevance to this possibility.

Whether meat inspection findings are used by authorities (for welfare reasons) or the veterinarian and owner of herd (for animal health) the registration at the abattoir much be carried out with great carefulness. Data of a bad quality is off course less useful if of any use at all.

7. Risk estimation

In the hazard identification it was assessed that the risk of introduction and spreading of exotic contagious livestock diseases is not increased if the intestinal lymph nodes are not palpated routinely. *Salmonella*, *Yersinia*, *Campylobacter*, and avian tuberculosis are considered a possible hazard to food safety. Table 5 gathers the assessment on the specific elements (release, exposure and consequences).

When it comes to *Salmonella*, *Yersinia* and *Campylobacter* these human pathogens occur in the intestinal tract in finisher pigs without necessarily giving rise to clinical disease nor pathological manifestations. Thus, an inspection of and a palpation of intestinal lymph nodes is not a sufficient way to handle these three pathogens. Therefore, for many years these agents have been dealt with by focusing on hygiene and an own-check program in the abattoirs. Furthermore, in Denmark *Salmonella* is controlled through a national surveillance program.

According to the risk assessment, avian tuberculosis is the only relevant hazard. It follows from Table 5 that the occurrence of avian tuberculosis is very low in finisher pigs. This is not considered a risk since mesenteric tissue and the associated lymph nodes are solely used as animal feed after a sufficient heat-treatment. If a consumer is exposed to avian tuberculosis in pork, the consequences are limited since avian tuberculosis is not regarded as meat-borne – according to the prevailing opinion in the present literature. However, in cases of tuberculous changes in other organs than mandibular lymph nodes and intestinal lymph nodes, a total rejection is the judgement – since this is an indication of a general infection. Lung and liver is still to be inspected in the meat control of all swine. In that way there is in all together no risk involved in omitting routine palpation of intestinal lymph nodes.

Table 5 Totalling specific elements of risk assessment in risk estimation

Risk to	Agent	Release	Exposure	Consequences	Risk estimation
Food safety	Avian TB	Very low	Negligible	Low	Negligible

In the USA, a visual inspection and a routinely palpation of intestinal lymph nodes is mandatory (Anon., 2007). In Australia, on the other hand, only a visual inspection of these lymph nodes is mandatory (Anon., 2002). The latter is equivalent to the routine meat control in New Zealand (Anon., 2000). Note that bovine tuberculosis occurs in both the USA and in New Zealand.

8. Conclusion

All in all, there is no increased risk related to omitting the routine palpation of intestinal lymph nodes. The existing procedures on palpation of intestinal lymph nodes can therefore be changed on three conditions:

1. The finisher pigs originate from Danish indoor herds.
2. The herd applies with the requirements for so-called integrated herds in which the animals have been kept in-door since weaning and has been raised under controlled circumstances.
3. Food chain information has been exchanged between producer and abattoir before slaughter.

With such animals, a visual inspection of stomach and the intestines is sufficient for an assessment of the carcass and organs.

It is assessed that this change in procedure might cause a slightly higher frequency of *Salmonella* spp. in the gut scraping unit. This is handled within the present own-check program.

There is no increased risk related to exotic, contagious livestock diseases. That is due to the fact that these diseases manifest themselves as either clinical symptoms in the living animal or in lesions in organs other than the intestinal lymph nodes.

The proposed change in meat inspection will not have any substantial influence on the assessment on health and welfare in a herd made by the owner, the veterinarian or the authorities.

The present delivering system ensures a high degree of certainty that finisher pigs under the supply Chain Meat Inspection really come from integrated herds. Finisher pigs from ecologically herds or outdoor production are slaughtered and undergo tradition meat inspection in the abattoir in the city of Herning. Furthermore, in connection with every delivery, the animal's origin is checked with the abattoir's database. And, at every delivery the farmer must indicate in writing whether the animals are raised indoor or outdoor.

Acknowledgements

Morten Englund (DAKA), Anne-Mette Olsen og Jaap Boes (Landbrug & Fødevarer), Annette Lychau Petersen og Anders Holm (Danish Veterinary Association), Ole Pontoppidan (Danish Meat Research Institute), Helle Stege, Grethe Hybschmann og Henrik Elvang Jensen (University of Copenhagen), Jens Kirk Andersen (Danish Technical University), Camilla Brasch-Andersen (Danish Veterinary and Food Administration), and Bente Johansen (LVK) are acknowledged for their contribution to the risk assessment.

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Appendix A – Meat inspection judgement

Distribution of ratings executed as part of meat inspection of finisher pigs, Denmark 2006-2008

Rating*	Year and category	Number	%
	2008		
	Total number of animals delivered	18,582,290	100.00
Primarily animals with LR + all with TR	Number of animals with remarks	5,952,786	32.03
TR	Of this, animals rejected in total	77,460	0.42
	Remarks in total	7,070,738	38.05
	Remarks on animals rejected	174,257	0.94
UA		12,629,504	67.97
AM	080 Degeneration of muscles	2,883	
	Of this, animals rejected in total	574	
	2007		
	Total number of animals delivered	19,502,941	100.00
Primarily animals with LR + all with TR	Number of animals with remarks	6,295,939	32.28
TR	Of this, animals rejected in total	82,883	0.42
	Remarks in total	7,467,659	38.29
	Remarks on animals rejected	184,768	0.95
UA		13,207,002	67.72
AM	080 Degeneration of muscles	2,862	
	Of this, discarded animals in total	701	
	2006		
	Total number of animals delivered	19,984,506	100.00
Primarily animals with LR + all with TR	Number of animals with remarks	6,795,927	34.01
TR	Of this, animals rejected in total	79,874	0.4
	Remarks in total	8,055,607	40.31
	Remarks on animals rejected	184,416	0.92
UA		13,188,579	65.99
AM	080 Degeneration of muscles	3,168	
	Of this, animals rejected in total	650	

*: LR: local rejection, TR: total rejection, UA: unconditioned approval, AM: approved for manufacturing



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

Dr. Jan Mousing
Chief Veterinary Officer
Danish Veterinary and Food Administration
Mørkhøj Bygade 19
DK-2860 Søborg

Dear Dr. Mousing,

I am writing to inform you of the equivalence determination made by this office with regard to your request for the use of an alternative post-mortem inspection procedure for market hogs. In the submission, Denmark requested an equivalence determination for:

- Supply Chain Inspection – The Danish Way

As part of the equivalence determination process, the Food Safety and Inspection Service (FSIS) establishes criteria for determining whether an alternative sanitary measure will ensure the same level of public health protection as the FSIS requirement. Accordingly, FSIS has established the following criteria for making equivalence determinations for an alternative post-mortem inspection procedure for market hogs:

- The government inspection service administers an inspection program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass.
- The government inspection system requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market hog carcasses presented for inspection.
- The incidence of diseases in market hogs, such as Tuberculosis (TB), is no higher than the incidence in the United States.
- The market hogs must be born and raised in the country.
- The government inspection service must implement a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects).

Based on the information submitted by the government of Denmark, FSIS has determined that this alternative post-mortem inspection procedure for market hogs meets the established criteria. Therefore, FSIS is granting the government of Denmark approval to use the supply chain inspection for the purposes of post-mortem inspection of meat products exported to the United States.

0.56
6.72

If you have any questions, please contact me at telephone number 202-720-3781, facsimile number 202-690-4040, or by e-mail at internationalequivalence@fsis.usda.gov.

Sincerely,

A handwritten signature in cursive script that reads "Sally White JD". The letters are fluid and connected, with a large, stylized "S" and "W".

Sally White
Director
International Equivalence Staff
Office of International Affairs

CC:

Steve Huete, Agricultural Attaché, American Embassy, The Hague
Anders Kløcker, Minister Counselor, Royal Danish Embassy
Bernard Van Goethem, Director, Directorate E, European Commission, Brussels
Wolf Maier, Counselor, Food Safety and Consumer Affairs, EC
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Country File

FSIS:OIA:IES:DSMITH:720-3395:DK SCI:12/18/08

EQUIVALENCE CRITERIA AND EVALUATION:

Criteria used to determine whether an alternative post-mortem inspection procedure for market age hogs is equivalent to the U.S. inspection procedure for market age hogs are set forth below:

1. The government inspection service administers an inspection program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass.
2. The government inspection system requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market hog carcasses presented for inspection.
3. The incidence of diseases in market hogs, such as TB, is no higher than the incidence in the United States.
4. The market swine must be born and raised in the country.
5. The government inspection service must implement a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects).

Application of Equivalence Criteria for an Alternative Post-Mortem Inspection Procedure for Market Age Hogs.

The government inspection service administers an inspection program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass.

This criterion is met. Denmark uses a combination of pre-slaughter data collection and post-mortem inspection to ensure the identification and removal of diseased carcasses and parts from the food supply. Pre-slaughter data must be presented to the slaughter establishment prior to slaughter of the swine. The Official Veterinarian at the slaughter establishment will verify that this information is supplied to the slaughter establishment. Without this information, swine will not undergo slaughter under the proposed program. This system allows for full traceability of swine and provides the health information of all swine prior to slaughter. Ante-mortem inspection occurs in the same way as conducted by FSIS. The proposed alteration to post-mortem inspection is related to the omission of mandibular lymph node incision.

Denmark has conducted, and submitted to FSIS, a peer reviewed risk assessment which focused on the areas of swine carcass inspection that will be altered under their "Supply-Chain Inspection" proposal. This risk assessment was conducted on the omission of incising the mandibular lymph nodes as well as the omission of incising the hearts. The heart incision aspect is not pertinent to this review because FSIS does not perform this task. The outcome of this risk assessment was that the changes proposed could potentially

improve food safety by reducing cross contamination of microorganisms such as *Salmonella*.

The government inspection system requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market hog carcasses presented for inspection.

Denmark has adopted a sanitary measure that is *same as* the FSIS requirement. No equivalence determination is needed. Denmark requires establishments to conduct generic *E. coli* testing. In addition, Danish authorities conduct *Salmonella* performance standard testing per the FSIS requirements.

The incidence of diseases in market hogs, such as Tuberculosis (TB), is no higher than the incidence in the United States.

This criterion is met. Denmark has been recognized as free of *Mycobacterium bovis* since 1980. A large-scale surveillance program in cattle in Denmark is in place ensuring a constant documentation of the free status.

The market hogs must be born and raised in the country.

This criterion is met. In order to qualify for this program, the producer must demonstrate that the market hogs are of Danish origin. Only swine that have been raised indoors are eligible for this inspection procedure, and there is complete segregation of the swine from other species while on the farm, during transport to the slaughter establishment, during lairage and slaughter.

The government inspection service must implement a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects).

This criterion is met. Effective January 1, 2009, the Danish Veterinary and Food Administration will establish a performance standard for meat inspection for all pig slaughterhouses. The performance standard is monitored daily by the Official Veterinarian. The Official Veterinarian verifies that the Official Auxiliaries are properly conducting their inspection activities.

RECOMMENDATION:

FSIS has determined that the alternate post-mortem procedure for market age hogs submitted by Denmark is equivalent to the FSIS post-mortem procedure for market age hogs. Therefore, Denmark's equivalence request should be granted.

DECISION CONFIRMATION AND APPROVAL:

 12/20/08

Sally White, Director
International Equivalence Staff
Office of International Affairs, FSIS

CONCURRENCE:

 12-23-08

Ronald Jones
Acting Assistant Administrator
Office of International Affairs

Assessment of risk for humans associated with Supply Chain Meat Inspection – The Danish Way



December 2008

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Preface

In 2007, the Danish Parliament decided that a modernisation of meat inspection should be initiated. As a part of the modernisation three institutions – The Danish Veterinary and Food Administration (DVFA), Department of Veterinary Pathobiology, Faculty of Life Science, University of Copenhagen (KU-Life) and Danish Meat Association (DMA) – in collaboration undertook a project regarding meat inspection of finisher pigs, housed under controlled conditions. The intention of the project was to identify how meat inspection could be modernised without jeopardising human health.

The objective of meat inspection is to focus on the hazards that constitute a risk for food safety. Moreover it should be ensured that the control of finisher pigs conducted ante- and post mortem is performed in a way that results in a high level of food safety.

When changing the meat inspection it must be ensured, that not just food safety but also the zoo-sanitary standards are not affected negatively.

The Danish pig meat production system is covered by a thorough registration, marking and documentation which makes a tracing of the meat through the production chain possible. This is in line with the mandatory requirement within the European Union that so-called food chain information from all parts of the food chain should be exchanged prior to sending animals for slaughter. This includes the primary producer, the slaughterhouse and the competent authority.

We suggest that two specific inspection procedures will be omitted from the routine meat inspection: the opening and incisions of the heart and the incisions and palpation of major mandibular lymph nodes. A carcass with visually observable pathological findings will still have its hearts and mandibular lymph nodes palpated and incised.

We combine this approach with the food chain information which is being exchanged between the herd and the slaughterhouse and we call the entire approach Supply Chain Meat Inspection – The Danish way. This modernisation of meat inspection will only apply to finisher pigs from integrated production systems.

Prior to initiating such a change, we undertook a risk assessment to identify if there was a risk for humans or for the zoo-sanitary status. We followed international guidelines for how to conduct risk assessments. To ensure the quality of the risk assessment, we asked three independent, internationally recognised as experts in food safety to act as external reviewers. Their reviews – and our response to the issues raised – have been included in an appendix to the risk assessment. The experts were:

- 1) Katharina Stärk, Professor, Veterinary Public Health, the Royal Veterinary College, London,
- 2) Truls Nesbakken, Professor, Food Safety, the Norwegian School of Veterinary Science, Oslo,
- 3) Eystein Skjerve, Professor, Epidemiology of Food-borne Diseases, the Norwegian School of Veterinary Science, Oslo.

The risk assessment is public and can be obtained either upon request or directly on the home page of our institutions www.danishmeat.dk and www.fvst.dk. The risk assessment acts as decision support for the Danish Meat Association. Just as importantly, it constitutes a documentation of why the changes suggested are safe for both humans and animal health. This is of importance for both our trading partners as well as the Danish consumers.

The authors

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Abstract

Recent changes in the legislation of the European Union enable the introduction of modifications of the traditional meat inspection of finisher pigs and calves from integrated production systems. Denmark intends to make use of this possibility, initially for finisher pigs and later on for calves. Based on an analysis of the pig-pork chain, two issues came up: what is the food safety value of the routine palpation and incision into the major mandibular lymph nodes as well as the routine opening of the heart? To address the impact on food safety when omitting these incisions, a risk assessment was conducted following international guidelines. To generate input data, two studies were conducted on ten Danish slaughterhouses. Study 1 included the collection of 43 lymph nodes with granulomatous lesions. Study 2 comprised the collection of 88 hearts with macroscopic changes indicating presence of endocarditis. Microbiological and pathological examinations were conducted. Moreover, relevant data from slaughterhouse and laboratory statistics as well as information from the literature and expert opinion were included in the risk assessment.

If lymph nodes are not opened routinely, lymph nodes with lesions might pass the meat inspection unnoticed. Among the different lesions possibly observed in lymph nodes, granulomatous lesions are the most important with respect to food safety, because these might be a result of infection with bovine tuberculosis. A very low prevalence of granulomatous lesions in lymph nodes is observed in Denmark (0.01-0.02%) and only a part of these lesions are found in the mandibular lymph nodes. Study 1 showed that all lymph nodes examined were negative for *Mycobacterium* spp. *Rhodococcus equi* was most commonly found (63%). In one case (2%) *Nocardia farcinica* was found, and the remaining 35% of the samples were culture-negative. Avian tuberculosis is occasionally found in backyard poultry, zoological gardens and pigs. There is no risk that consumers should acquire bovine tuberculosis from eating Danish pork because Denmark is officially free from this disease since 1980. There is a low risk of exposure to avium tuberculosis from pork, because of the low prevalence and because the mandibular lymph nodes are entirely used as pet food after adequate heat-treatment. Moreover, the prevailing opinion in the literature is that avian tuberculosis is not pork-borne. There is a very low exposure risk of *Rhodococcus equi* but this organism is not considered pork-borne either. It should be noted, that routine palpation and opening of lymph nodes in the head area might result in spreading of food safety hazards like *Salmonella* and *Yersinia*.

If hearts are not opened routinely, a case of endocarditis might pass the meat inspection unnoticed. A very low prevalence of endocarditis is generally observed in Danish finisher pigs (0.01%). Study 2 showed that endocarditis was primarily associated with *Streptococcus* spp. (51%), secondly by *Erysipelothrix rhusiopathiae* (32%), *Lactobacillus* (5%) and *Arcanobacterium pyogenes* (1%). The remaining samples were either awaiting identification (6%) or culture-negative (6%). The agents found in the hearts are primarily occupational hazards and not meat-borne. This implies that you do not get ill from consuming meat contaminated with these micro-organisms. To reduce exposure of the consumers to these occupational hazards, we suggest that the hearts are opened after meat inspection by slaughterhouse workers and prior to sales. This will reduce the spreading of these hazards from the heart to the carcass and further on to slaughterhouse personnel and consumers.

In conclusion, it was found that omitting the incisions into the mandibular lymph nodes as well as omitting the routine opening of the heart do not seem to be associated with an increased risk for human health. Likewise, the suggested changes seem to have a positive effect on the working environment, and there is no negative effect on the zoo-sanitary status.

Keywords: Pigs, Meat inspection; Risk-based; Food safety; Granulomatous lesions; *Mycobacterium* spp; Endocarditis; *Streptococcus* spp.; Supply Chain; Traceability

Denmark -

**DECISION MEMORANDUM—
INDIVIDUAL SANITARY MEASURE
Denmark**

Daniel Oestmann, Shannon McMurtrey and Priya Kadam

EQUIVALENCE REQUEST:

Denmark has submitted a request for an equivalence determination for an alternative post-mortem inspection i.e. visual inspection instead of palpation of mesenteric lymph nodes of slaughtered market hogs.

BACKGROUND:

On December 16, 2008 in FSIS-Denmark bilateral meeting a team of FSIS experts had met and reviewed Denmark's Supply Chain Inspection system, reference materials supporting this inspection system, and presentations by Danish officials. The Supply Chain Inspection system allows inspection of market hogs raised under an integrated quality control program coupled with an on-site verification at slaughter establishments for checking accuracy of visually inspected carcasses and organs to ensure that passed carcasses and parts are wholesome and not adulterated.

In a letter dated December 24th 2008 FSIS had approved Denmark's use of an alternative post-mortem inspection procedure for market hogs as a part of the Supply Chain Meat Inspection. This proposed alteration was to conduct a visual inspection instead of incising mandibular lymph nodes.

In the current submission of April 23, 2010 Denmark is proposing an additional alteration in the post-mortem inspection procedure i.e. visual inspection instead of palpation of mesenteric lymph nodes of slaughtered market hogs.

FSIS FOOD SAFETY MEASURE:

The purpose of post-mortem inspection of livestock is to protect the public health by ensuring that carcasses and parts that enter commerce are wholesome and not adulterated. To achieve this goal, in swine slaughter establishments operating under traditional inspection or in those establishments operating under the HACCP-Based Inspection Models Project (HIMP), FSIS inspectors perform ante-mortem and post-mortem inspection procedures to detect diseases, abnormalities, and contamination of livestock carcasses and parts.

In establishments operating under HIMP, FSIS requires that the establishment implement ante-mortem and post-mortem sorting procedures and present to FSIS only normal and healthy-appearing animals and carcasses and parts that are wholesome and free of defects. HIMP also requires additional FSIS verification procedures to ensure that the establishment produces only safe, wholesome products.

?
I have signed
The PM
included —
But am unclear
whether this
is the
reason that
you want
to move
forward
If so - suggest
that more info
be provided
from
the
HIMP
sign.

FILE CHECKLIST—INDIVIDUAL SANITARY MEASURE

Alternative post-mortem inspection: Visual inspection instead of palpation of mesenteric lymph nodes for slaughtered pigs.

CERTIFICATION STATEMENT

The contents of this file have been reviewed in accordance with the Equivalence Management Controls established by the Office of International Affairs as certified by the Project Leader assigned to the file and reviewed by the Director, International Equivalence Staff, and Office of International Affairs.

COUNTRY AND EQUIVALENCE REQUEST

Denmark has requested an alternative post-mortem inspection system. Denmark as a part of the 'Supply Chain Meat Inspection- the Danish Way' proposes to conduct visual inspection of mesenteric lymph nodes instead of palpation of slaughtered pigs.

STATUS OF FILE (checked areas are complete)

- ☒ Correspondence to the country and correspondence from the country
- ☒ Original documents provided by the country and their translations
- ☒ Meeting records of all document reviews
- ☒ Summaries of all meetings and teleconferences with country representatives
- ☒ Signed decision memorandum

CERTIFIED BY:

P. C. Kadam
PROJECT LEADER

DATE 6/8/2011

REVIEWED AND CONCURRED BY:

Kellu
DIRECTOR, INTL. EQUIVALENCE STAFF

DATE 6.16.11

**DECISION MEMORANDUM—
INDIVIDUAL SANITARY MEASURE
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Daniel Oestmann, Shannon McMurtrey and Priya Kadam

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OBJECTIVE OF THE FOOD SAFETY MEASURE:

FSIS inspectors conduct ante-mortem inspection of live swine and post-mortem inspection of carcasses and parts on a carcass by carcass basis. In market age swine, FSIS performs inspection under either the traditional inspection system or under the HIMP inspection system. In both cases, inspection procedures are intended to identify and remove unwholesome and adulterated carcasses and parts from the food supply.

EQUIVALENCE CRITERIA:

The criteria used for making an equivalence determination for an alternative post-mortem inspection procedure for market-age hogs are equivalent to the U.S. inspection procedure for market age hogs are set forth below:

1. The government inspection service administers an inspection program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass.
2. The government inspection system requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market hog carcasses presented for inspection.
3. The incidence of diseases in market hogs, such as TB, is no higher than the incidence in the United States.
4. The market swine must be born and raised in the country.
5. The government inspection service must implement a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects).

EQUIVALENCE EVALUATION:

The government inspection service administers an inspection program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass.

This criterion is met. As per Denmark's Supply Chain Inspection system, Denmark uses a combination of pre-slaughter data collection and post-mortem inspection to ensure the identification and removal of diseased carcasses and parts from the food supply. Pre-slaughter data must be presented to the slaughter establishment prior to slaughter of the swine. The Official Veterinarian at the slaughter establishment will verify that this information is supplied to the slaughter establishment. Without this information, swine will not undergo slaughter. This system allows for full traceability of swine and provides the health information of all swine prior to slaughter. Ante-mortem inspection occurs in the same way as conducted by FSIS. The proposed alteration to post-mortem inspection

is related to the visual inspection instead of palpation of the mesenteric lymph nodes of slaughtered market hogs.

Denmark has conducted, and submitted to FSIS, a risk assessment¹ which focused on the areas of swine carcass inspection that will be altered under their "Supply-Chain Inspection" proposal. This risk assessment was conducted on the visual inspection of stomach and intestines instead of palpation of the intestinal lymph nodes of slaughtered market hogs.

The outcome of this risk assessment was that the changes proposed:

1. Did not increase risk related to exotic, contagious livestock diseases because these diseases manifest themselves as either clinical symptoms in the living animal or in lesions in organs other than the intestinal lymph nodes
2. Will not have any substantial influence on the herd health assessment and welfare made by the owner, the veterinarian or the authorities
3. Ensures a high degree of certainty that finisher pigs under the Supply Chain Meat Inspection really come from integrated herds.
4. *Salmonella*, *Campylobacter* and *Yersinia* which – despite of a relative high frequency in live pigs – only occasionally causes changes in the gastro-intestinal tract or the intestinal lymph nodes. Therefore, palpation of the intestinal lymph nodes does not essentially contribute to the judgement on whether a carcass is suitable for human consumption or not.

The government inspection system requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market hog carcasses presented for inspection.

This criterion is met. Denmark has adopted a sanitary measure that is same as the FSIS requirement. No equivalence determination is needed. Denmark requires establishments to conduct generic *E. coli* testing. In addition, Danish authorities conduct *Salmonella* performance standard testing per the FSIS requirements.

The incidence of diseases in market hogs, such as Tuberculosis (TB), is no higher than the incidence in the United States.

This criterion is met. Denmark has been recognized as free of *Mycobacterium bovis* (bovine tuberculosis) since 1980. A large-scale surveillance program in cattle in Denmark is in place ensuring a constant documentation of the free status.

The market hogs must be born and raised in the country.

This criterion is met. In order to qualify for this program, the producer must demonstrate that the market hogs are of Danish origin. Only swine that have been raised indoors since

¹ Is palpation of the intestinal lymph nodes a necessary part of meat inspection of finisher pigs? By Lis Alban, Birthe Steenberg, Jesper Valentin Petersen and Susanne Jensen. Danish Agricultural & Food Council, Axeltorv 3, DK-1609 Copenhagen V, Denmark. Translated into English July 2, 2010

weaning and are raised under controlled circumstances are eligible for this inspection procedure. There is complete segregation of the swine from other species while on the farm, during transport to the slaughter establishment, during lairage and slaughter.

The government inspection service must implement a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects).

This criterion is met. According to the Danish Circular on meat inspection the official veterinarian has to make daily checks on both the decisions taken during meat inspection and the method used. These checks include all staff, and are documented. The Danish Veterinary and Food Administration ensure that this requirement is met by the use of performance standards which were introduced for all market hogs slaughterhouses on January 1, 2009. In addition, to the performance standard a supervision of the performance of the individual staff member during post-mortem inspection takes place every third year. This is used as a tool for development of the individual staff member.

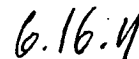
RECOMMENDATION:

FSIS has determined that Denmark's request for an equivalence determination for an alternative post-mortem inspection i.e. visual inspection instead of palpation of mesenteric lymph nodes of slaughtered market hogs meets the established criteria. Therefore, Denmark's equivalence request should be granted.

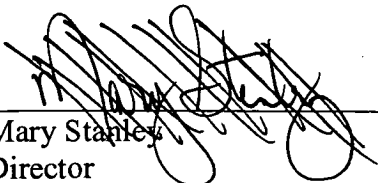
APPROVAL:



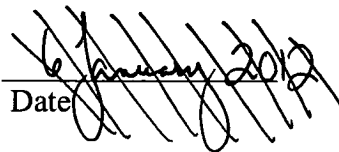
Andreas Keller
Director
International Equivalence Staff
Office of International Affairs, FSIS



Date



Mary Stanley
Director
International Policy Division
Office of Policy and Program Development, FSIS



Date

CONCURRENCE/OIA:

Ronald K. Jones
Assistant Administrator
Office of International Affairs, FSIS

Date

CONCURRENCE/OPPD:

Daniel Engeljohn
Assistant Administrator
Office of Policy and Program Development, FSIS

Date

Corrigendum to Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption

(Official Journal of the European Union L 139 of 30 April 2004)

Regulation (EC) No 854/2004 should read as follows:

**REGULATION (EC) No 854/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 29 April 2004
laying down specific rules for the organisation of official controls on products of animal origin
intended for human consumption**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(b) thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the opinion of the European Economic and Social Committee ⁽²⁾,

Having consulted the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁽³⁾,

Whereas:

- (1) Regulation (EC) No 852/2004 of the European Parliament and of the Council ⁽⁴⁾ lays down general hygiene rules applying to all foodstuffs and Regulation (EC) No 853/2004 of the European Parliament and of the Council ⁽⁵⁾ lays down specific hygiene rules for products of animal origin.
- (2) Specific rules for official controls on products of animal origin are necessary to take account of specific aspects associated with such products.
- (3) The scope of the specific control rules should mirror the scope of the specific hygiene rules for food business operators laid down in Regulation (EC) No 853/2004. However, Member States should also carry out appropriate official controls to enforce national rules established in accordance

with Article 1(4) of that Regulation. They may do so by extending the principles of this Regulation to such national rules.

- (4) Official controls on products of animal origin should cover all aspects that are important for protecting public health and, where appropriate, animal health and animal welfare. They should be based on the most recent relevant information available and it should therefore be possible to adapt them as relevant new information becomes available.
- (5) Community legislation on food safety should have a sound scientific basis. To that end, the European Food Safety Authority should be consulted whenever necessary.
- (6) The nature and intensity of the official controls should be based on an assessment of public health risks, animal health and welfare, where appropriate, the type and throughput of the processes carried out and the food business operator concerned.
- (7) It is appropriate to provide for the adaptation of certain specific control rules, through the transparent procedure provided for in Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004, to provide flexibility in order to accommodate the specific needs of establishments which use traditional methods, have a low throughput or are located in regions that are subject to special geographical constraints. The procedure should also allow pilot projects to take place in order to try out new approaches to hygiene controls on meat. However, such flexibility should not compromise food hygiene objectives.
- (8) Official controls on the production of meat are necessary to verify that food business operators comply with hygiene rules and respect criteria and targets laid down in Community legislation. These official controls should comprise audits of food business operators' activities and inspections, including checks on food business operators' own controls.

⁽¹⁾ OJ C 262 E, 29.10.2002, p. 449.

⁽²⁾ OJ C 95, 23.4.2003, p. 22.

⁽³⁾ Opinion of the European Parliament of 5 June 2003 (not yet published in the Official Journal), Council Common Position of 27 October 2003 (OJ C 48 E, 24.2.2004, p. 82), Position of the European Parliament of 30 March 2004 (not yet published in the Official Journal) and Council Decision of 16 April 2004.

⁽⁴⁾ Page 3 of this Official Journal.

⁽⁵⁾ Page 22 of this Official Journal.

- (9) In view of their specific expertise, it is appropriate for official veterinarians to carry out audits and inspections of slaughterhouses, game handling establishments and certain cutting plants. Member States should have discretion to decide which are the most appropriate staff for audits and inspections of other types of establishments.
- (10) Official controls on the production of live bivalve molluscs and on fishery products are necessary to check for compliance with the criteria and targets laid down in Community legislation. Official controls on the production of live bivalve molluscs should in particular target relaying and production areas for bivalve molluscs and the end product.
- (11) Official controls on the production of raw milk are necessary to check for compliance with criteria and targets laid down in Community legislation. Such official controls should in particular target milk production holdings and raw milk upon collection.
- (12) The requirements of this Regulation should not apply until all parts of the new legislation on food hygiene have entered into force. It is also appropriate to provide for at least 18 months to elapse between entry into force and the application of the new rules, to allow competent authorities and the industries affected time to adapt.
- (13) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ⁽¹⁾,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

1. This Regulation lays down specific rules for the organisation of official controls on products of animal origin.
2. It shall apply only in respect of activities and persons to which Regulation (EC) No 853/2004 applies.
3. The performance of official controls pursuant to this Regulation shall be without prejudice to food business operators' primary legal responsibility for ensuring food safety, as laid down in Regulation (EC) No 178/2002 of the European Parliament and of

the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety ⁽²⁾, and any civil or criminal liability arising from the breach of their obligations.

Article 2

Definitions

1. For the purposes of this Regulation, the following definitions shall apply:

- (a) 'official control' means any form of control that the competent authority performs for the verification of compliance with food law, including animal health and animal welfare rules;
- (b) 'verification' means checking, by examination and the provision of objective evidence, whether specified requirements have been fulfilled;
- (c) 'competent authority' means the central authority of a Member State competent to carry out veterinary checks or any authority to which it has delegated that competence;
- (d) 'audit' means a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives;
- (e) 'inspection' means the examination of establishments, of animals and food, and the processing thereof, of food businesses, and their management and production systems, including documents, finished product testing and feeding practices, and of the origin and destination of production inputs and outputs, in order to verify compliance with the legal requirements in all cases;
- (f) 'official veterinarian' means a veterinarian qualified, in accordance with this Regulation, to act in such a capacity and appointed by the competent authority;
- (g) 'approved veterinarian' means a veterinarian designated by the competent authority to carry out specific official controls on holdings on its behalf;
- (h) 'official auxiliary' means a person qualified, in accordance with this Regulation, to act in such a capacity, appointed by the competent authority and working under the authority and responsibility of an official veterinarian;

and

⁽¹⁾ OJ L 184, 17.7.1999, p. 23.

⁽²⁾ OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

(i) 'health mark' means a mark indicating that, when it was applied, official controls had been carried out in accordance with this Regulation.

2. The definitions laid down in the following Regulations shall also apply as appropriate:

(a) Regulation (EC) No 178/2002;

(b) the definitions of 'animal by-products', 'TSEs' (transmissible spongiform encephalopathies) and 'specified risk material' laid down in Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption⁽¹⁾;

(c) Regulation (EC) No 852/2004, except for the definition of 'competent authority';

and

(d) Regulation (EC) No 853/2004.

CHAPTER II

OFFICIAL CONTROLS IN RELATION TO COMMUNITY ESTABLISHMENTS

Article 3

Approval of establishments

1. (a) When Community legislation requires the approval of establishments, the competent authority shall make an on-site visit. It shall approve an establishment for the activities concerned only if the food business operator has demonstrated that it meets the relevant requirements of Regulations (EC) No 852/2004 and (EC) No 853/2004 and other relevant requirements of food law.
- (b) The competent authority may grant conditional approval if it appears from the on-site visit that the establishment meets all the infrastructure and equipment requirements. It shall grant full approval only if it appears from a new on-site visit carried out within three months of the granting of conditional approval that the establishment meets the other requirements referred to in (a). If clear progress has been made but the establishment still does not meet all of these requirements, the competent authority may prolong conditional approval. However, conditional approval shall not exceed a total of six months.

⁽¹⁾ OJ L 273, 10.10.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 813/2003 (OJ L 117, 13.5.2003, p. 22).

2. In the case of factory and freezer vessels flying the flag of Member States, the maximum periods of three and six months applying to the conditional approval of other establishments may be extended, if necessary. However, conditional approval shall not exceed a total of 12 months. Inspections of such vessels shall take place as specified in Annex III.

3. The competent authority shall give each approved establishment, including those with conditional approval, an approval number, to which codes may be added to indicate the types of products of animal origin manufactured. For wholesale markets, secondary numbers indicating units or groups of units selling or manufacturing products of animal origin may be added to the approval number.

4. (a) The competent authority shall keep the approval of establishments under review when carrying out official controls in accordance with Articles 4 to 8.

(b) If the competent authority identifies serious deficiencies or has to stop production at an establishment repeatedly and the food business operator is not able to provide adequate guarantees regarding future production, the competent authority shall initiate procedures to withdraw the establishment's approval. However, the competent authority may suspend an establishment's approval if the food business operator can guarantee that it will resolve deficiencies within a reasonable time.

(c) In the case of wholesale markets, the competent authority may withdraw or suspend approval in respect of certain units or groups of units.

5. Paragraphs 1, 2 and 3 shall apply both:

(a) to establishments that begin placing products of animal origin on the market on or after the date of application of this Regulation;

and

(b) to establishments already placing products of animal origin on the market but in respect of which there was previously no requirement for approval. In the latter case, the competent authority's on-site visit required under paragraph 1 shall take place as soon as possible.

Paragraph 4 shall also apply to approved establishments that placed products of animal origin on the market in accordance with Community legislation immediately prior to the application of this Regulation.

6. Member States shall maintain up-to-date lists of approved establishments, with their respective approval numbers and other relevant information, and make them available to other Member States and to the public in a manner that may be specified in accordance with the procedure referred to in Article 19(2).

Article 4

General principles for official controls in respect of all products of animal origin falling within the scope of this Regulation

1. Member States shall ensure that food business operators offer all assistance needed to ensure that official controls carried out by the competent authority can be performed effectively

They shall in particular:

- give access to all buildings, premises, installations or other infrastructures;
- make available any documentation and record required under the present regulation or considered necessary by the competent authority for judging the situation.

2. The competent authority shall carry out official controls to verify food business operators' compliance with the requirements of:

(a) Regulation (EC) No 852/2004;

(b) Regulation (EC) No 853/2004;

and

(c) Regulation (EC) No 1774/2002.

3. The official controls referred to in paragraph 1 shall include:

(a) audits of good hygiene practices and hazard analysis and critical control point (HACCP)-based procedures;

(b) the official controls specified in Articles 5 to 8;

and

(c) any particular auditing tasks specified in the Annexes.

4. Audits of good hygiene practices shall verify that food business operators apply procedures continuously and properly concerning at least:

(a) checks on food-chain information;

(b) the design and maintenance of premises and equipment;

(c) pre-operational, operational and post-operational hygiene;

(d) personal hygiene;

(e) training in hygiene and in work procedures;

(f) pest control;

(g) water quality;

(h) temperature control;

and

(i) controls on food entering and leaving the establishment and any accompanying documentation.

5. Audits of HACCP-based procedures shall verify that food business operators apply such procedures continuously and properly, having particular regard to ensuring that the procedures provide the guarantees specified in Section II of Annex II to Regulation (EC) No 853/2004. They shall, in particular, determine whether the procedures guarantee, to the extent possible, that products of animal origin:

(a) comply with microbiological criteria laid down under Community legislation;

(b) comply with Community legislation on residues, contaminants and prohibited substances;

and

(c) do not contain physical hazards, such as foreign bodies.

When, in accordance with Article 5 of Regulation (EC) No 852/2004, a food business operator uses procedures set out in guides to the application of HACCP principles rather than establishing its own specific procedures, the audit shall cover the correct use of these guides.

6. Verification of compliance with the requirements of Regulation (EC) No 853/2004 concerning the application of identification marks shall take place in all establishments approved in accordance with that Regulation, in addition to verification of compliance with other traceability requirements.

7. In the case of slaughterhouses, game handling establishments and cutting plants placing fresh meat on the market, an official veterinarian shall carry out the auditing tasks referred to in paragraphs 3 and 4.

8. When carrying out auditing tasks, the competent authority shall take special care:

(a) to determine whether staff and staff activities in the establishment at all stages of the production process comply with the relevant requirements of the Regulations referred to in paragraph 1(a) and (b). To support the audit, the competent authority may carry out performance tests, in order to ascertain that staff performance meets specified parameters;

(b) to verify the food business operator's relevant records;

- (c) to take samples for laboratory analysis whenever necessary;
- and

- (d) to document elements taken into account and the findings of the audit.

9. The nature and intensity of auditing tasks in respect of individual establishments shall depend upon the assessed risk. To this end, the competent authority shall regularly assess:

- (a) public and, where appropriate, animal health risks;
- (b) in the case of slaughterhouses, animal welfare aspects;
- (c) the type and throughput of the processes carried out;
- and
- (d) the food business operator's past record as regards compliance with food law.

Article 5

Fresh meat

Member States shall ensure that official controls with respect to fresh meat take place in accordance with Annex I.

1. The official veterinarian shall carry out inspection tasks in slaughterhouses, game handling establishments and cutting plants placing fresh meat on the market in accordance with the general requirements of Section I, Chapter II, of Annex I, and with the specific requirements of Section IV, in particular as regards:

- (a) food chain information;
- (b) *ante-mortem* inspection;
- (c) animal welfare;
- (d) post-mortem inspection;
- (e) specified risk material and other animal by-products;
- and
- (f) laboratory testing.

2. The health marking of carcasses of domestic ungulates, farmed game mammals other than lagomorphs, and large wild game, as well as half-carcasses, quarters and cuts produced by cutting half-carcasses into three wholesale cuts, shall be carried

out in slaughterhouses and game-handling establishments in accordance with Section I, Chapter III, of Annex I. Health marks shall be applied by, or under the responsibility of, the official veterinarian when official controls have not identified any deficiencies that would make the meat unfit for human consumption.

3. After carrying out the controls mentioned in points 1 and 2, the official veterinarian shall take appropriate measures as set out in Annex I, Section II, in particular as regards:

- (a) the communication of inspection results;
- (b) decisions concerning food chain information;
- (c) decisions concerning live animals;
- (d) decisions concerning animal welfare;

and

- (e) decisions concerning meat.

4. Official auxiliaries may assist the official veterinarian with official controls carried out in accordance with Sections I and II of Annex I as specified in Section III, Chapter I. In that case, they shall work as part of an independent team.

5. (a) Member States shall ensure that they have sufficient official staff to carry out the official controls required under Annex I with the frequency specified in Section III, Chapter II.

- (b) A risk-based approach shall be followed to assess the number of official staff that need to be present on the slaughter line in any given slaughterhouse. The number of official staff involved shall be decided by the competent authority and shall be such that all the requirements of this Regulation can be met.

6. (a) Member States may allow slaughterhouse staff to assist with official controls by carrying out certain specific tasks, under the supervision of the official veterinarian, in relation to the production of meat from poultry and lagomorphs in accordance with Annex I, Section III, Chapter III, part A. If they do so, they shall ensure that staff carrying out such tasks:

- (i) are qualified and undergo training in accordance with those provisions;

- (ii) act independently from production staff;

and

- (iii) report any deficiency to the official veterinarian.

- (b) Member States may also allow slaughterhouse staff to carry out specific sampling and testing tasks in accordance with Annex I, Section III, Chapter III, Part B.
7. Member States shall ensure that official veterinarians and official auxiliaries are qualified and undergo training in accordance with Annex I, Section III, Chapter IV.

Article 6

Live bivalve molluscs

Member States shall ensure that the production and placing on the market of live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods undergo official controls as described in Annex II.

Article 7

Fishery products

Member States shall ensure that official controls with respect to fishery products take place in accordance with Annex III.

Article 8

Raw milk and dairy products

Member States shall ensure that official controls with respect to raw milk and dairy products take place in accordance with Annex IV.

Article 9

Action in the case of non-compliance

1. When the competent authority identifies non-compliance with the Regulations referred to in Article 4(2)(a) and (b), it shall take action to ensure that the food business operator remedies the situation. When deciding which action to take, the competent authority shall take account of the nature of the non-compliance and the food business operator's past record with regard to non-compliance.
2. Such action shall include, where appropriate, the following measures:
 - (a) the imposition of sanitation procedures or any other corrective action deemed necessary to ensure the safety of products of animal origin or compliance with the relevant legal requirements;
 - (b) the restriction or prohibition of the placing on the market, import or export of products of animal origin;
 - (c) monitoring or, if necessary, ordering the recall, withdrawal and/or destruction of products of animal origin;

- (d) authorisation to use products of animal origin for purposes other than those for which they were originally intended;
- (e) the suspension of operations or closure of all or part of the food business concerned for an appropriate period of time;
- (f) the suspension or withdrawal of the establishment's approval;
- (g) in the case of consignments from third countries, seizure followed by destruction or re-dispatch;
- (h) any other measure that the competent authority deems appropriate.

3. The competent authority shall provide the food business operator concerned, or a representative, with:

- (a) written notification of its decision concerning the action to be taken in accordance with paragraph 1, together with the reasons for the decision;

and

- (b) information on rights of appeal against such decisions and of the applicable procedure and time limits.

Where appropriate, the competent authority shall also notify the competent authority of the Member State of dispatch of its decision.

CHAPTER III

PROCEDURES CONCERNING IMPORTS

Article 10

General principles and conditions

To ensure the uniform application of the principles and conditions laid down in Article 11 of Regulation (EC) No 178/2002 the procedures laid down in this chapter shall apply.

Article 11

Lists of third countries and parts of third countries from which imports of specified products of animal origin are permitted

1. Products of animal origin shall be imported only from a third country or a part of third country that appears on a list drawn up and updated in accordance with the procedure referred to in Article 19(2).

2. A third country shall appear on such lists only if a Community control in that country has taken place and demonstrates that the competent authority provides appropriate guarantees as specified in paragraph 4. However, a third country may appear on such lists without a Community control having taken place there if:

(a) the risk determined in accordance with Article 18(18) does not warrant it;

and

(b) it is determined, when deciding to add a particular third country to a list in accordance with paragraph 1, that other information indicates that the competent authority provides the necessary guarantees.

3. Lists drawn up in accordance with this Article may be combined with other lists drawn up for public and animal health purposes.

4. When lists are drawn up or updated, particular account shall be taken of the following criteria:

(a) the legislation of the third country on:

(i) products of animal origin,

(ii) the use of veterinary medicinal products, including rules on their prohibition or authorisation, their distribution, their placing on the market and the rules covering administration and inspection;

and

(iii) the preparation and use of feedingstuffs, including the procedures for using additives and the preparation and use of medicated feedingstuffs, as well as the hygiene quality of the raw materials used for preparing feedingstuffs and of the final product;

(b) the organisation of the third countries' competent authorities, their powers and independence, the supervision to which they are subject and the authority that they have effectively to enforce the applicable legislation;

(c) the training of staff in the performance of official controls;

(d) the resources, including diagnostic facilities available to competent authorities;

(e) the existence and operation of documented control procedures and control systems based on priorities;

(f) where applicable, the situation regarding animal health and procedures for notifying the Commission and relevant international bodies of outbreaks of animal diseases;

(g) the extent and operation of official controls on imports of animals and products of animal origin;

(h) the assurances which the third country can give regarding compliance with, or equivalence to, Community requirements;

(i) the hygiene conditions of production, manufacture, handling, storage and dispatch actually applied to products of animal origin destined for the Community;

(j) any experience of marketing of the product from the third country and the results of any import controls carried out;

(k) the results of Community controls carried out in the third country, in particular the results of the assessment of the competent authorities, and the action that competent authorities have taken in the light of any recommendations addressed to them following a Community control;

(l) the existence, implementation and communication of an approved zoonoses control programme;

and

(m) the existence, implementation and communication of an approved residue control programme.

5. The Commission shall arrange for up-to-date versions of all lists drawn up or updated in accordance with this Article to be available to the public.

Article 12

List of establishments from which imports of specified products of animal origin are permitted

1. Products of animal origin may be imported into the Community only if they have been dispatched from, and obtained or prepared in, establishments that appear on lists drawn up and updated in accordance with this Article, except:

(a) when, on a case-by-case basis, it is decided, in accordance with the procedure referred to in Article 19(2), that the guarantees that a specified third country provides in respect of imports of specified products of animal origin are such that the procedure provided for in this Article is unnecessary to ensure compliance with the requirements of paragraph 2;

and

(b) in the cases specified in Annex V.

In addition, fresh meat, minced meat, meat preparations, meat products and mechanically separated meat (MSM) may be imported into the Community only if they have been manufactured from meat obtained in slaughterhouses and cutting plants appearing on lists drawn up and updated in accordance with this Article or in approved Community establishments.

2. An establishment may be placed on such a list only if the competent authority of the third country of origin guarantees that:

- (a) that establishment, together with any establishments handling raw material of animal origin used in the manufacture of the products of animal origin concerned, complies with relevant Community requirements, in particular those of Regulation (EC) No 853/2004, or with requirements that were determined to be equivalent to such requirements when deciding to add that third country to the relevant list in accordance with Article 11;
- (b) an official inspection service in that third country supervises the establishments and makes available to the Commission, where necessary, all relevant information on establishments furnishing raw materials;

and

- (c) it has real powers to stop the establishments from exporting to the Community in the event that the establishments fail to meet the requirements referred to under (a).

3. The competent authorities of third countries appearing on lists drawn up and updated in accordance with Article 11 shall guarantee that lists of the establishments referred to in paragraph 1 are drawn up, kept up-to-date and communicated to the Commission.

- 4. (a) The Commission shall provide the contact points that Member States have designated for this purpose with regular notifications concerning new or updated lists that it has received from the competent authorities of third countries concerned in accordance with paragraph 3.

- (b) If no Member State objects to the new or updated list within 20 working days of the Commission's notification, imports shall be authorised from establishments appearing on the list 10 working days after the day on which the Commission makes it available to the public.

- (c) The Commission shall, whenever at least one Member State makes written comments, or whenever it considers that the modification of a list is necessary in the light of relevant information such as Community inspection reports or a notification under the rapid alert system, inform all Member States and include the point on agenda of the next meeting of the relevant section of the Standing Committee on the Food Chain and Animal Health for decision, where appropriate, in accordance with the procedure referred to in Article 19(2).

5. The Commission shall arrange for up-to-date versions of all lists to be available to the public.

Article 13

Live bivalve molluscs, echinoderms, tunicates and marine gastropods

1. Notwithstanding Article 12(1)(b), live bivalve molluscs, echinoderms, tunicates and marine gastropods shall come from production areas in third countries that appear on lists drawn up and updated in accordance with Article 12.

2. The requirement of paragraph 1 shall not apply to pectinidae harvested outside classified production areas. However, official controls with respect to pectinidae shall take place in accordance with Annex II, Chapter III.

- 3. (a) Before the lists referred to in paragraph 1 are drawn up, particular account shall be taken of the guarantees that the competent authority of the third country can give concerning compliance with the requirements of this Regulation on the classification and control of production zones.

- (b) An on-the-spot Community inspection visit shall take place before such lists are drawn up unless:

- (i) the risk determined in accordance with Article 18(18) does not warrant it;

and

- (ii) it is determined, when deciding to add a particular production area to a list in accordance with paragraph 1, that other information indicates that the competent authority provides the necessary guarantees.

4. The Commission shall arrange for up-to-date versions of all lists drawn up or updated in accordance with this Article to be available to the public.

Article 14

Documents

1. A document meeting the requirements set out in Annex VI shall accompany consignments of products of animal origin when they are imported into the Community.

2. The document shall certify that the products satisfy:

- (a) the requirements laid down for such products according to Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004 or provisions that are equivalent to those requirements;

and

- (b) any special import conditions established in accordance with Article 18(19).

3. Documents may include details required in accordance with other Community legislation on public and animal health matters.

4. Exemptions from paragraph 1 may be granted in accordance with the procedure referred to in Article 19(2) when it is possible to obtain the guarantees referred to in paragraph 2 of this Article in another manner.

Article 15

Special provisions for fishery products

1. The procedures laid down in this Chapter do not apply to fresh fishery products landed in the Community directly from a fishing vessel flying the flag of a third country.

Official controls with respect to such fishery products shall take place in accordance with Annex III.

2. (a) Fishery products imported from a factory or freezer vessel flying the flag of a third country shall come from vessels that appear on a list drawn up and updated in accordance with the procedure set out in Article 12(4).

(b) However, by way of exemption from Article 12(2)(b), a vessel may also be included on such lists:

(i) on the basis of a joint communication from the competent authority of the third country the flag of which the vessel is flying and from the competent authority of another third country to which the former competent authority has delegated responsibility for the inspection of the vessel concerned, on condition that:

— that third country appears on the list of third countries, drawn up in accordance with Article 11, from which imports of fisheries products are permitted,

— all fishery products from the vessel concerned that are destined for placing on the market in the Community are landed directly in that third country,

— the competent authority of that third country has inspected the vessel and has declared that it complies with Community requirements,

and

— the competent authority of that third country has declared that it will regularly inspect the vessel to ensure that it continues to comply with Community requirements;

or

(ii) on the basis of a joint communication from the competent authority of the third country the flag of

which the vessel is flying and from the competent authority of a Member State, to which the former competent authority has delegated responsibility for the inspection of the vessel concerned, on condition that:

— all fishery products from the vessel concerned that are destined for placing on the market in the Community are landed directly in that Member State,

— the competent authority of that Member State has inspected the vessel and has declared that it complies with Community requirements,

and

— the competent authority of that Member State has declared that it will regularly inspect the vessel to ensure that it continues to comply with Community requirements.

(c) The Commission shall arrange for up-to-date versions of all lists drawn up or updated in accordance with this Article to be available to the public.

3. When fishery products are imported directly from a fishing or freezer vessel, a document signed by the captain may replace the document required under Article 14.

4. Detailed rules for the implementation of this Article may be laid down in accordance with the procedure referred to in Article 19(2).

CHAPTER IV

FINAL PROVISIONS

Article 16

Implementing measures and transitional measures

Implementing measures and transitional arrangements may be laid down in accordance with the procedure referred to in Article 19(2).

Article 17

Amendment and adaptation of the Annexes

1. Annexes I, II, III, IV, V and VI may be amended or supplemented to take account of scientific and technical progress in accordance with the procedure referred to in Article 19(2).

2. Exemptions from Annexes I, II, III, IV, V and VI may be granted in accordance with the procedure referred to in Article 19(2), provided that they do not affect the achievement of the objectives of this Regulation.

3. Member States may, without compromising achievement of the objectives of this Regulation, adopt, in accordance with paragraphs 4 to 7, national measures adapting the requirements laid down in Annex I.

4. The national measures referred to in paragraph 3 shall:

(a) have the aim of:

- (i) enabling the continued use of traditional methods at any of the stages of production, processing or distribution of food;
- (ii) accommodating the needs of food businesses with a low throughput or that are situated in regions that are subject to special geographic constraints;

or

- (iii) permitting pilot projects to take place in order to try out new approaches to hygiene controls on meat;

(b) concern in particular the following elements of Annex I:

- (i) food chain information;
- (ii) the presence of the competent authority in establishments.

5. Any Member State wishing to adopt national measures as referred to in paragraph 3 shall notify the Commission and other Member States. Each notification shall:

- (a) provide a detailed description of the requirements that that Member State considers need to be adapted and the nature of the adaptation sought;
- (b) describe the establishments concerned;
- (c) explain the reasons for the adaptation, including, where relevant, by providing a summary of the hazard analysis carried out and any measures to be taken to ensure that the adaptation will not compromise the objectives of this Regulation;

and

(d) give any other relevant information.

6. The other Member States shall have three months from the receipt of a notification referred to in paragraph 5 to send written comments to the Commission. The Commission may, and when it receives written comments from one or more Member States shall, consult Member States within the committee referred to in Article 19(1). The Commission may decide, in accordance with the procedure referred to in Article 19(2), whether the envisaged measures may be implemented subject, if necessary, to appropriate amendments. Where appropriate, the Commission may propose general measures in accordance with paragraphs 1 or 2 of this Article.

7. A Member State may adopt national measures adapting the requirements of Annex I only:

- (a) in compliance with a decision adopted in accordance with paragraph 6;
- (b) if, one month after the expiry of the period referred to in paragraph 6, the Commission has not informed Member States that it has received written comments or that it intends to propose the adoption of a decision in accordance with paragraph 6.

8. When a Member State adopts national measures implementing a pilot project to try out new approaches to hygiene controls on meat in accordance with paragraphs 3 to 7, the Member State shall communicate the results to the Commission as soon as they are available. The Commission shall then consider proposing general measures in accordance with paragraph 1.

Article 18

Specific decisions

Without prejudice to the generality of Article 16 and Article 17(1), implementing measures may be laid down, or amendments to Annexes I, II, III, IV, V or VI adopted, in accordance with the procedure referred to in Article 19(2), to specify:

- 1. tests to assess the performance of food business operators and their staff;
- 2. the method of communicating inspection results;
- 3. criteria to determine when, on the basis of a risk analysis, the official veterinarian need not be present in slaughterhouses and game handling establishments throughout ante-mortem and post-mortem inspection;
- 4. rules concerning the content of tests for official veterinarians and official auxiliaries;
- 5. microbiological criteria for process control in relation to hygiene in establishments;
- 6. alternative procedures, serological or other laboratory tests that provide guarantees at least equivalent to specific post-mortem inspection procedures described in Annex I, Section IV, and may therefore replace them, if the competent authority so decides;
- 7. circumstances in which certain of the specific post-mortem inspection procedures described in Annex I, Section IV, are not necessary, having regard to the holding, region or country of origin and to the principles of risk analysis;
- 8. rules for laboratory testing;

9. the cold treatment to be applied to meat in relation to cysticercosis and trichinosis;
10. conditions under which holdings and regions can be certified as officially free of cysticercus or trichinae;
11. methods to be applied when examining for the conditions referred to in Annex I, Section IV, Chapter IX;
12. for fattening pigs, criteria for controlled housing conditions and integrated production systems;
13. criteria for the classification of production and relaying areas for live bivalve molluscs in cooperation with the relevant Community Reference Laboratory, including:
 - (a) limit values and analysis methods for marine biotoxins,
 - (b) virus testing procedures and virological standards,

and

 - (c) sampling plans and the methods and analytical tolerances to be applied to check compliance with the criteria;
14. organoleptic criteria for the evaluation of the freshness of fishery products;
15. analytical limits, methods of analysis and sampling plans for the official controls on fishery products required under Annex III, including with regard to parasites and environmental contaminants;
16. the method by which the Commission will make lists of third countries and establishments in third countries available to the public pursuant to Articles 11, 12, 13 and 15;
17. models for documents and criteria for the use of electronic documents;
18. criteria for determining the risk that particular products of animal origin imported into the Community present;
19. special import conditions for particular products of animal origin, taking account of the associated risks, information that relevant third countries have provided and, where necessary, the results of Community controls carried out in such third countries. These special import conditions may be

established for a single product of animal origin or for group of products. They may apply to a single third country, to regions of a third country, or to a group of third countries;

and

20. the conditions governing imports of products of animal origin from a third country or a region of a third country pursuant to the implementation of an equivalence agreement, or to a satisfactory audit, recognising that measures applied in that third country or region offer guarantees equivalent to those applied in the Community, if the third country supplies objective proof in this respect.

Article 19

Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Article 58 of Regulation (EC) No 178/2002.
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its Rules of Procedure.

Article 20

Consultation of the European Food Safety Authority

The Commission shall consult the European Food Safety Authority on matters falling within the scope of this Regulation whenever necessary and, in particular:

1. before proposing to modify the specific requirements concerning post-mortem inspection procedures laid down in Section IV of Annex I;
 2. before proposing to modify the rules of Annex I, Section IV, Chapter IX, on meat from animals in which post-mortem inspection has revealed lesions indicating infection with brucellosis or tuberculosis;
- and
3. before proposing implementing measures on the matters referred to in Article 18(5) to (15).

Article 21

Report to the European Parliament and to the Council

1. The Commission shall, not later than 20 May 2009, submit a report to the European Parliament and the Council reviewing the experience gained from the application of this Regulation.

2. The Commission shall, if appropriate, accompany the report with relevant proposals.

(b) Regulation (EC) No 853/2004

Article 22

Entry into force

This Regulation shall enter into force on the 20th day after that of its publication in the *Official Journal of the European Union*.

It shall apply 18 months after the date on which all of the following acts have entered into force:

(a) Regulation (EC) No 852/2004;

and

(c) Directive 2004/41/EC of the European Parliament and of the Council of 29 April 2004 repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption ⁽¹⁾.

However, it shall apply no earlier than 1 January 2006.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 29 April 2004.

For the European Parliament
The President
P. COX

For the Council
The President
M. McDOWELL

⁽¹⁾ OJ L 157, 30.4.2004, p. 33.

ANNEX I

FRESH MEAT

SECTION I: TASKS OF THE OFFICIAL VETERINARIAN

CHAPTER I: AUDITING TASKS

1. In addition to the general requirements of Article 4(4) concerning audits of good hygiene practices, the official veterinarian is to verify continuous compliance with food business operators' own procedures concerning any collection, transport, storage, handling, processing and use or disposal of animal by-products, including specified risk material, for which the food business operator is responsible.
2. In addition to the general requirements of Article 4(5) concerning audits of HACCP-based principles, the official veterinarian is to check that the operators' procedures guarantee, to the extent possible, that meat:
 - (a) does not contain patho-physiological abnormalities or changes;
 - (b) does not bear faecal or other contamination;
 - and
 - (c) does not contain specified risk material, except as provided for under Community legislation, and has been produced in accordance with Community legislation on TSEs.

CHAPTER II: INSPECTION TASKS

When carrying out inspection tasks in accordance with this Chapter, the official veterinarian is to take account of the results of the auditing tasks carried out in accordance with Article 4 and Chapter I of this Annex. Where appropriate he or she is to target inspection tasks accordingly.

A. Food chain information

1. The official veterinarian is to check and analyse relevant information from the records of the holding of provenance of animals intended for slaughter and to take account of the documented results of this check and analysis when carrying out ante- and post-mortem inspection.
2. When carrying out inspection tasks, the official veterinarian is to take account of official certificates accompanying animals, and any declarations made by veterinarians carrying out controls at the level of primary production, including official veterinarians and approved veterinarians.
3. When food business operators in the food chain take additional measures to guarantee food safety by implementing integrated systems, private control systems, independent third party certification or by other means, and when these measures are documented and animals covered by these schemes clearly identifiable, the official veterinarian may take this into account when carrying out inspection tasks and reviewing the HACCP-based procedures.

B. Ante-mortem inspection

1. Subject to paragraphs 4 and 5:
 - (a) the official veterinarian is to carry out an ante-mortem inspection of all animals before slaughter;
 - (b) that inspection must take place within 24 hours of arrival at the slaughterhouse and less than 24 hours before slaughter.

In addition, the official veterinarian may require inspection at any other time.

2. Ante-mortem inspection must in particular determine whether, as regards the particular animal inspected, there is any sign:
 - (a) that welfare has been compromised;
 - or
 - (b) of any condition which might adversely affect human or animal health, paying particular attention to the detection of zoonotic diseases and diseases on List A or, where appropriate, List B of the Office International des Epizooties (World organisation for animal health, OIE).
3. In addition to routine ante-mortem inspection, the official veterinarian is to carry out a clinical inspection of all animals that the food business operator or an official auxiliary may have put aside.
4. In the case of emergency slaughter outside the slaughterhouse and of hunted wild game, the official veterinarian at the slaughterhouse or game handling establishment is to examine the declaration accompanying the body of the animal issued by the veterinarian or the trained person in accordance with Regulation (EC) No 853/2004.
5. Where provided for in Section III, Chapter II, or in Section IV, ante-mortem inspection may be carried out at the holding of provenance. In such cases, the official veterinarian at the slaughterhouse need carry out ante-mortem inspection only when and to the extent specified.

C. Animal welfare

The official veterinarian is to verify compliance with relevant Community and national rules on animal welfare, such as rules concerning the protection of animals at the time of slaughter and during transport.

D. Post-mortem inspection

1. Carcases and accompanying offal are to be subjected without delay after slaughter to post-mortem inspection. All external surfaces are to be viewed. Minimal handling of the carcase and offal or special technical facilities may be required for that purpose. Particular attention is to be paid to the detection of zoonotic diseases and diseases on OIE List A and, where appropriate, OIE List B. The speed of the slaughter line and the number of inspection staff present are to be such as to allow for proper inspection.
2. Additional examinations are to take place, such as palpation and incision of parts of the carcase and offal and laboratory tests, whenever considered necessary:
 - (a) to reach a definitive diagnosis;
 - or
 - (b) to detect the presence of:
 - (i) an animal disease,
 - (ii) residues or contaminants in excess of the levels laid down under Community legislation,
 - (iii) non-compliance with microbiological criteria,
 - or
 - (iv) other factors that might require the meat to be declared unfit for human consumption or restrictions to be placed on its use,

particularly in the case of animals having undergone emergency slaughter.
3. The official veterinarian is to require carcases of domestic solipeds, bovine animals over six months old, and domestic swine over four weeks old to be submitted for post-mortem inspection split lengthways into half carcases down the spinal column. If the inspection so necessitates, the official veterinarian may also require any head or any carcase to be split lengthways. However, to take account of particular eating habits, technological developments or specific sanitary situations, the competent authority may authorise the submission for inspection of carcases of domestic solipeds, bovine animals over six months old, and domestic swine over four weeks old, not split in half.

4. During the inspection, precautions must be taken to ensure that contamination of the meat by actions such as palpation, cutting or incision is kept to a minimum.
5. In the event of an emergency slaughter, the carcase shall be subjected to post-mortem examination as soon as possible in accordance with paragraphs 1 to 4 before it is released for human consumption.

E. Specified risk material and other animal by-products

In accordance with specific Community rules on specified risk material and other animal by-products, the official veterinarian is to check the removal, separation and, where appropriate, marking of such products. The official veterinarian is to ensure that the food business operator takes all necessary measures to avoid contaminating meat with specified risk material during slaughter (including stunning) and removal of specified risk material.

F. Laboratory testing

1. The official veterinarian is to ensure that sampling takes place and that samples are appropriately identified and handled and sent to the appropriate laboratory within the framework of:
 - (a) the monitoring and control of zoonoses and zoonotic agents;
 - (b) specific laboratory testing for the diagnosis of TSEs in accordance with Regulation (EC) No 999/2001 of the European Parliament and of the Council ⁽¹⁾;
 - (c) the detection of unauthorised substances or products and the control of regulated substances, in particular within the framework of the National Residue Plans referred to in Council Directive 96/23/EC ⁽²⁾;and
 - (d) the detection of OIE List A and, where appropriate, OIE List B diseases.
2. The official veterinarian is also to ensure that any other necessary laboratory testing takes place.

CHAPTER III: HEALTH MARKING

1. The official veterinarian is to supervise health marking and the marks used.
2. The official veterinarian is to ensure, in particular, that:
 - (a) the health mark is applied only to animals (domestic ungulates, farmed game mammals other than lagomorphs, and large wild game) having undergone ante-mortem and post-mortem inspection in accordance with this Regulation and when there are no grounds for declaring the meat unfit for human consumption. However, the health mark may be applied before the results of any examination for trichinosis is available, if the official veterinarian is satisfied that meat from the animal concerned will be placed on the market only if the results are satisfactory;and
 - (b) health-marking takes place on the external surface of the carcase, by stamping the mark in ink or hot branding, and in such a manner that, if carcases are cut into half carcases or quarters, or half carcases are cut into three pieces, each piece bears a health mark.
3. The health mark must be an oval mark at least 6,5 cm wide by 4,5 cm high bearing the following information in perfectly legible characters:
 - (a) the mark must indicate name of the country in which the establishment is located, which may be written out in full in capitals or shown as a two-letter code in accordance with the relevant ISO standard.

In the case of Member States, however, these codes are AT, BE, DE, DK, ES, FI, FR, GR, IE, IT, LU, NL, PT, SE and UK;

⁽¹⁾ OJ L 147, 31.5.2001, p. 1. Regulation as last amended by Commission Regulation (EC) No 2245/2003 (OJ L 333, 20.12.2003, p. 28).

⁽²⁾ OJ L 125, 23.5.1996, p. 10. Directive as amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

- (b) the mark must indicate the approval number of the slaughterhouse;
 - and
 - (c) when applied in a slaughterhouse within the Community, the mark must include the abbreviation CE, EC, EF, EG, EK or EY.
4. Letters must be at least 0,8 cm high and figures at least 1 cm high. The dimensions and characters of the mark may be reduced for health marking of lamb, kids and piglets.
 5. The colours used for health marking must be authorised in accordance with Community rules on the use of colouring substances in foodstuffs.
 6. The health mark may also include an indication of the official veterinarian who carried out the health inspection of the meat. Competent authorities and food business operators may continue to use equipment that they ordered before entry into force of this Regulation until it is exhausted or requires replacement.
 7. Meat from animals having undergone emergency slaughter outside the slaughterhouse must bear a special health mark, which cannot be confused either with the health mark provided for in this Chapter or with the identification mark provided for in Annex II, Section I, to Regulation (EC) No 853/2004.
 8. Meat from unskinned wild game cannot bear a health mark unless, after skinning in a game handling establishment, it has undergone post-mortem inspection and been declared fit for human consumption.
 9. This Chapter is to apply without prejudice to animal health rules on health marking.

SECTION II: ACTION FOLLOWING CONTROLS

CHAPTER I: COMMUNICATION OF INSPECTION RESULTS

1. The official veterinarian is to record and to evaluate the results of inspection activities.
2.
 - (a) If inspections reveal the presence of any disease or condition that might affect public or animal health, or compromise animal welfare, the official veterinarian is to inform the food business operator.
 - (b) When the problem identified arose during primary production, the official veterinarian is to inform the veterinarian attending the holding of provenance, the food business operator responsible for the holding of provenance (provided that such information would not prejudice subsequent legal proceedings) and, where appropriate, the competent authority responsible for supervising the holding of provenance or the hunting area.
 - (c) If the animals concerned were raised in another Member State or in a third country, the official veterinarian is to inform to the competent authority of the Member State where the establishment is located. That competent authority is to take appropriate measures in accordance with applicable Community legislation.
3. The results of inspections and tests are to be included in relevant databases.
4. When the official veterinarian, while carrying out ante-mortem or post-mortem inspection or any other inspection activity, suspects the presence of an infectious agent mentioned on OIE List A or, where appropriate, OIE List B, the official veterinarian must immediately notify the competent authority and both must take all necessary measures and precautions to prevent the possible spread of the infectious agent in accordance with applicable Community legislation.

CHAPTER II: DECISIONS CONCERNING FOOD CHAIN INFORMATION

1. The official veterinarian is to verify that animals are not slaughtered unless the slaughterhouse operator has been provided with and checked relevant food chain information.
2. However, the official veterinarian may allow animals to undergo slaughter in the slaughterhouse even if the relevant food chain information is not available. In this case, all relevant food chain information must be supplied before the carcase is approved for human consumption. Pending a final judgement, such carcasses and related offal must be stored separately from other meat.

3. Notwithstanding paragraph 2, when relevant food chain information is not available within 24 hours of an animal's arrival at the slaughterhouse, all meat from the animal is to be declared unfit for human consumption. If the animal has not yet been slaughtered, it is to be killed separately from other animals.
4. When the accompanying records, documentation or other information shows that:
 - (a) animals come from a holding or an area subject to a movement prohibition or other restriction for reasons of animal or public health;
 - (b) rules on the use of veterinary medicinal products have not been complied with;or
 - (c) any other condition which might adversely affect human or animal health is present, animals may not be accepted for slaughter other than in accordance with procedures laid down under Community legislation to eliminate human or animal health risks.

If the animals are already present at the slaughterhouse, they must be killed separately and declared unfit for human consumption, taking precautions to safeguard animal and public health where appropriate. Whenever the official veterinarian considers it necessary, official controls are to be carried out on the holding of provenance.

5. The competent authority is to take appropriate action if it discovers that the accompanying records, documentation or other information do not correspond with the true situation on the holding of provenance or the true condition of the animals or aim deliberately to mislead the official veterinarian. The competent authority is to take action against the food business operator responsible for the holding of provenance of the animals, or any other person involved. This action may consist in particular of extra controls. The food business operator responsible for the holding of provenance or any other person involved are to bear the costs of such extra controls.

CHAPTER III: DECISIONS CONCERNING LIVE ANIMALS

1. The official veterinarian is to verify compliance with the food business operator's duty pursuant to Regulation (EC) No 853/2004 to ensure that animals accepted for slaughter for human consumption are properly identified. The official veterinarian is to ensure that animals whose identity is not reasonably ascertainable are killed separately and declared unfit for human consumption. Whenever the official veterinarian considers it necessary, official controls are to be carried out on the holding of provenance.
2. When there are overriding animal welfare considerations, horses may undergo slaughter at the slaughterhouse even if the legally required information concerning their identity has not been supplied. However, this information must be supplied before the carcass may be declared fit for human consumption. These requirements also apply in the case of emergency slaughter of horses outside the slaughterhouse.
3. The official veterinarian is to verify compliance with the food business operator's duty under Regulation (EC) No 853/2004 to ensure that animals that have such hide, skin or fleece conditions that there is an unacceptable risk of contamination of the meat during slaughter are not slaughtered for human consumption unless they are cleaned beforehand.
4. Animals with a disease or condition that may be transmitted to animals or humans through handling or eating meat and, in general, animals showing clinical signs of systemic disease or emaciation, are not to be slaughtered for human consumption. Such animals must be killed separately, under conditions such that other animals or carcasses can not be contaminated, and declared unfit for human consumption.
5. The slaughter of animals suspected of having a disease or condition that may adversely affect human or animal health is to be deferred. Such animals are to undergo detailed ante-mortem examination in order to make a diagnosis. In addition, the official veterinarian may decide that sampling and laboratory examinations are to take place to supplement post-mortem inspection. If necessary, the animals are to be slaughtered separately or at the end of normal slaughtering, taking all necessary precautions to avoid contamination of other meat.
6. Animals that might contain residues of veterinary medicinal products in excess of the levels laid down in accordance with Community legislation, or residues of forbidden substances, are to be dealt with in accordance with Directive 96/23/EC.

7. The official veterinarian is to impose the conditions under which animals are to be dealt with under a specific scheme for the eradication or control of a specific disease, such as brucellosis or tuberculosis, or zoonotic agents such as salmonella, under his/her direct supervision. The competent authority is to determine the conditions under which such animals may be slaughtered. These conditions must have the aim of minimising contamination of other animals and the meat of other animals.
8. Animals that are presented to a slaughterhouse for slaughter must as a general rule be slaughtered there. However, in exceptional circumstances, such as a serious breakdown of the slaughter facilities, the official veterinarian may allow direct movements to another slaughterhouse.

CHAPTER IV: DECISIONS CONCERNING ANIMAL WELFARE

1. When the rules concerning the protection of animals at the time of slaughter or killing are not respected, the official veterinarian is to verify that the food business operator immediately takes necessary corrective measures and prevents recurrence.
2. The official veterinarian is to take a proportionate and progressive approach to enforcement action, ranging from issuing directions to slowing down and stopping production, depending on the nature and gravity of the problem.
3. Where appropriate, the official veterinarian is to inform other competent authorities of welfare problems.
4. When the official veterinarian discovers that rules concerning the protection of animals during transport are not being respected, he or she is to take necessary measures in accordance with the relevant Community legislation.
5. When:
 - (a) an official auxiliary is carrying out checks on animal welfare pursuant to Sections III or IV;
 - and
 - (b) those checks identify non-compliance with the rules on the protection of animals,the official auxiliary is immediately to inform the official veterinarian and, if necessary in cases of urgency, is to take the necessary measures referred to in paragraphs 1 to 4 pending the arrival of the official veterinarian.

CHAPTER V: DECISIONS CONCERNING MEAT

1. Meat is to be declared unfit for human consumption if it:
 - (a) derives from animals that have not undergone ante-mortem inspection, except for hunted wild game;
 - (b) derives from animals the offal of which has not undergone post-mortem inspection, unless otherwise provided for under this Regulation or Regulation (EC) No 853/2004;
 - (c) derives from animals which are dead before slaughter, stillborn, unborn or slaughtered under the age of seven days;
 - (d) results from the trimming of sticking points;
 - (e) derives from animals affected by an OIE List A or, where appropriate, OIE List B disease, unless otherwise provided for in Section IV;
 - (f) derives from animals affected by a generalised disease, such as generalised septicaemia, pyaemia, toxæmia or viraemia;
 - (g) is not in conformity with microbiological criteria laid down under Community legislation to determine whether food may be placed on the market;
 - (h) exhibits parasitic infestation, unless otherwise provided for in Section IV;
 - (i) contains residues or contaminants in excess of the levels laid down in Community legislation. Any overshooting of the relevant level should lead to additional analyses whenever appropriate;

- (j) without prejudice to more specific Community legislation, derives from animals or carcasses containing residues of forbidden substances or from animals that have been treated with forbidden substances;
 - (k) consists of the liver and kidneys of animals more than two years old from regions where implementation of plans approved in accordance with Article 5 of Directive 96/23/EC has revealed the generalised presence of heavy metals in the environment;
 - (l) has been treated illegally with decontaminating substances;
 - (m) has been treated illegally with ionising or UV-rays;
 - (n) contains foreign bodies (except, in the case of wild game, material used to hunt the animal);
 - (o) exceeds the maximum permitted radioactivity levels laid down under Community legislation;
 - (p) indicates patho-physiological changes, anomalies in consistency, insufficient bleeding (except for wild game) or organoleptic anomalies, in particular a pronounced sexual odour;
 - (q) derives from emaciated animals;
 - (r) contains specified risk material, except as provided for under Community legislation;
 - (s) shows soiling, faecal or other contamination;
 - (t) consists of blood that may constitute a risk to public or animal health owing to the health status of any animal from which it derives or contamination arising during the slaughter process;
 - (u) in the opinion of the official veterinarian, after examination of all the relevant information, it may constitute a risk to public or animal health or is for any other reason not suitable for human consumption.
2. The official veterinarian may impose requirements concerning the use of meat derived from animals having undergone emergency slaughter outside the slaughterhouse.

SECTION III: RESPONSIBILITIES AND FREQUENCY OF CONTROLS

CHAPTER I: OFFICIAL AUXILIARIES

Official auxiliaries may assist the official veterinarian with all tasks, subject to the following restrictions and to any specific rules laid down in Section IV:

- 1. in relation to auditing tasks, official auxiliaries may only collect information regarding good hygienic practices and HACCP-based procedures;
 - 2. in relation to ante-mortem inspection and checks concerning the welfare of animals, official auxiliaries may only make an initial check of animals and help with purely practical tasks;
- and
- 3. in relation to post-mortem inspection, the official veterinarian must regularly check the work of official auxiliaries and, in the case of animals having undergone emergency slaughter outside the slaughterhouse, carry out the inspection personally.

CHAPTER II: FREQUENCY OF CONTROLS

- 1. The competent authority is to ensure that at least one official veterinarian is present:
 - (a) in slaughterhouses, throughout both ante-mortem and post-mortem inspection;and
 - (b) in game handling establishments, throughout post-mortem inspection.

2. However, the competent authority may adapt this approach in certain slaughterhouses and game handling establishments identified on the basis of a risk analysis and in accordance with criteria laid down in accordance with Article 18, point 3, if there are any. In such cases:

- (a) the official veterinarian need not be present at the time of ante-mortem inspection in the slaughterhouse if:
 - (i) an official veterinarian or an approved veterinarian carried out ante-mortem inspection at the holding of provenance, checked the food chain information and communicated the results of the check to the official auxiliary at the slaughterhouse,
 - (ii) the official auxiliary at the slaughterhouse is satisfied that the food chain information does not point to any possible problem for food safety and that the animal's general state of health and welfare is satisfactory,and
 - (iii) the official veterinarian regularly satisfies himself/herself that the official auxiliary is carrying out such checks properly;
- (b) the official veterinarian need not be present at all times during post-mortem inspection if:
 - (i) an official auxiliary carries out post-mortem inspection and puts aside meat with abnormalities and all other meat from the same animal,
 - (ii) the official veterinarian subsequently inspects all such meat,and
 - (iii) the official auxiliary documents his/her procedures and findings in a manner that allows the official veterinarian to be satisfied that standards are being met.

However, in the case of poultry and lagomorphs, the official auxiliary may discard meat with abnormalities and, subject to Section IV, the official veterinarian need not systematically inspect all such meat.

3. The flexibility provided for in paragraph 2 does not apply:

- (a) to animals that have undergone emergency slaughter;
- (b) to animals suspected of having a disease or condition that may adversely affect human health;
- (c) to bovine animals from herds that have not been declared officially free of tuberculosis;
- (d) to bovine, ovine and caprine animals from herds that have not been declared officially free of brucellosis;
- (e) in the case of an outbreak of a disease listed on OIE List A or, where appropriate, OIE List B. This concerns animals susceptible to the particular disease in question that come from the particular region as defined in Article 2 of Council Directive 64/432/EEC ⁽¹⁾;
- (f) when stricter controls are necessary to take account of emerging diseases or particular OIE List B diseases.

4. In cutting plants, the competent authority is to ensure that an official veterinarian or an official auxiliary is present when meat is being worked on with a frequency appropriate to achieving the objectives of this Regulation.

⁽¹⁾ OJ L 21, 29.7.1964, p. 1977/64. Directive as last amended by Commission Regulation (EC) No 21/2004 (OJ L 5, 9.1.2004, p. 8).

CHAPTER III: INVOLVEMENT OF SLAUGHTERHOUSE STAFF

A. SPECIFIC TASKS CONCERNING THE PRODUCTION OF MEAT FROM POULTRY AND LAGOMORPHS

The Member States may permit slaughterhouse staff to take over the activities of the official auxiliaries in controlling the production of poultry and rabbit meat under the following conditions:

- (a) Where the establishment has used good hygiene practice in accordance with Article 4(4) of this Regulation and the HACCP procedure for at least 12 months, the competent authority may authorise staff of the establishment who have been trained in the same way as the official assistants and have passed the same examination to carry out tasks of the official auxiliaries and form part of the competent authority's independent inspection team, under the supervision, direction and responsibility of the official veterinarian. In these circumstances, the official veterinarian shall be present at ante-mortem and post-mortem examinations, shall supervise these activities and carry out regular performance tests to ensure that the performance of the slaughterhouse tasks meets the specific criteria laid down by the competent authority, and shall document the results of those performance tests. Detailed rules for the performance tests shall be laid down in accordance with the procedure set out in Article 18. Where the level of hygiene of the establishment is affected by the work of this staff, where this staff does not carry out the tasks properly or where in general this staff carries out its work in a manner that the competent authority considers unsatisfactory, this staff shall be replaced by official auxiliaries.

Responsibilities for production and inspection in the establishment must be kept separate and any establishment wishing to use the establishment's own inspectors must possess internationally recognised certification.

- (b) The competent authority of the Member State shall decide, in principle and on a case-by-case basis, whether to permit the implementation of the system described above. Where the Member State decides in principle in favour of this system, it shall inform the Commission of that decision and its associated conditions. For food business operators in a Member State implementing the system, the actual use of the system is optional. Food business operators shall not be forced by the competent authority to introduce the system described here. Where the competent authority is not convinced that the food business operator satisfies the requirements, the system shall not be implemented in that establishment. In order to assess this, the competent authority shall carry out an analysis of the production and inspection records, the type of activities undertaken in the establishment, the history of compliance with rules, the expertise, professional attitude and sense of responsibility of the slaughterhouse staff in regard to food safety, together with other relevant information.

B. SPECIFIC SAMPLING AND TESTING TASKS

Slaughterhouse staff who have received specific training, under the supervision of the official veterinarian, may, under the responsibility and the supervision of the official veterinarian, carry out specific sampling and testing tasks in respect of animals of all species.

CHAPTER IV: PROFESSIONAL QUALIFICATIONS

A. OFFICIAL VETERINARIANS

1. The competent authority may appoint only veterinarians who have passed a test meeting the requirements of paragraph 2 as official veterinarians.
2. The competent authority must make arrangements for the test. The test is to confirm knowledge of the following subjects to the extent necessary depending on the veterinarian's background and qualifications:
 - (a) national and Community legislation on veterinary public health, food safety, animal health, animal welfare and pharmaceutical substances;
 - (b) principles of the common agricultural policy, market measures, export refunds and fraud detection (including the global context: WTO, SPS, Codex Alimentarius, OIE);
 - (c) essentials of food processing and food technology;

- (d) principles, concepts and methods of good manufacturing practice and quality management;
 - (e) pre-harvest quality management (good farming practices);
 - (f) promotion and use of food hygiene, food related safety (good hygiene practices);
 - (g) principles, concepts and methods of risk-analysis;
 - (h) principles, concepts and methods of HACCP, use of HACCP throughout the food production food chain;
 - (i) prevention and control of food-borne hazards related to human health;
 - (j) population dynamics of infection and intoxication;
 - (k) diagnostic epidemiology;
 - (l) monitoring and surveillance systems;
 - (m) auditing and regulatory assessment of food safety management systems;
 - (n) principles and diagnostic applications of modern testing methods;
 - (o) information and communication technology as related to veterinary public health;
 - (p) data-handling and applications of biostatistics;
 - (q) investigations of outbreaks of food-borne diseases in humans;
 - (r) relevant aspects concerning TSEs;
 - (s) animal welfare at the level of production, transport and slaughter;
 - (t) environmental issues related to food production (including waste management);
 - (u) precautionary principle and consumer concerns;
- and
- (v) principles of training of personnel working in the production chain.

Candidates may acquire the required knowledge as part of their basic veterinary training, or through training undertaken, or professional experience acquired, after qualifying as veterinarians. The competent authority may arrange for different tests to take account of candidates' background. However, when the competent authority is satisfied that a candidate has acquired all the required knowledge as part of a university degree, or through continuing education resulting in a postgraduate qualification, it may waive the requirement for a test.

3. The veterinarian is to have aptitude for multidisciplinary cooperation.
4. In addition, each official veterinarian is to undergo practical training for a probationary period of at least 200 hours before starting to work independently. During this period the probationer is to work under the supervision of existing official veterinarians in slaughterhouses, cutting plants, inspection posts for fresh meat and on holdings. The training is to concern the auditing of food safety management systems in particular.
5. The official veterinarian is to maintain up-to-date knowledge and to keep abreast of new developments through regular continuing education activities and professional literature. The official veterinarian is, wherever possible, to undertake annual continuing education activities.

6. Veterinarians already appointed as official veterinarians must have adequate knowledge of the subjects mentioned in paragraph 2. Where necessary, they are to acquire this knowledge through continuing education activities. The competent authority is to make adequate provision in this regard.
7. Notwithstanding paragraphs 1 to 6, Member States may lay down specific rules for official veterinarians working on a part-time basis who are responsible for inspecting small businesses

B. OFFICIAL AUXILIARIES

1. The competent authority may appoint as official auxiliaries only persons who have undergone training and passed a test in accordance with the following requirements.
2. The competent authority must make arrangements for such tests. To be eligible for these tests, candidates must prove that they have received:
 - (a) at least 500 hours of theoretical training and at least 400 hours of practical training, covering the areas specified in paragraph 5;

and
 - (b) such additional training as is required to enable official auxiliaries to undertake their duties competently.
3. The practical training referred to in paragraph 2(a) is to take place in slaughterhouses and cutting plants, under the supervision of an official veterinarian, and on holdings and in other relevant establishments.
4. Training and tests are to concern principally red meat or poultrymeat. However, persons who undergo training for one of the two categories and passed the test need only undergo abridged training to pass the test for the other category. Training and test should cover wild game, farmed game and lagomorphs, where appropriate.
5. Training for official auxiliaries is to cover, and tests are to confirm knowledge of, the following subjects:
 - (a) in relation to holdings:
 - (i) theoretical part:
 - familiarity with the farming industry organisation, production methods, international trade etc.,
 - good livestock husbandry practices,
 - basic knowledge of diseases, in particular zoonoses — viruses, bacteria, parasites etc.,
 - monitoring for disease, use of medicines and vaccines, residue testing,
 - hygiene and health inspection,
 - animal welfare on the farm and during transport,
 - environmental requirements — in buildings, on farms and in general,
 - relevant laws, regulations and administrative provisions,
 - consumer concerns and quality control;
 - (ii) practical part:
 - visits to holdings of different types and using different rearing methods,

- visits to production establishments,
- observation of the loading and unloading of animals,
- laboratory demonstrations,
- veterinary checks,
- documentation;

(b) in relation to slaughterhouses and cutting plants:

(i) theoretical part:

- familiarity with the meat industry organisation, production methods, international trade and slaughter and cutting technology,
- basic knowledge of hygiene and good hygienic practices, and in particular industrial hygiene, slaughter, cutting and storage hygiene, hygiene of work,
- HACCP and the audit of HACCP-based procedures,
- animal welfare on unloading after transport and at the slaughterhouse,
- basic knowledge of the anatomy and physiology of slaughtered animals,
- basic knowledge of the pathology of slaughtered animals,
- basic knowledge of the pathological anatomy of slaughtered animals,
- relevant knowledge concerning TSEs and other important zoonoses and zoonotic agents,
- knowledge of methods and procedures for the slaughter, inspection, preparation, wrapping, packaging and transport of fresh meat,
- basic knowledge of microbiology,
- ante-mortem inspection,
- examination for trichinosis,
- post-mortem inspection,
- administrative tasks,
- knowledge of the relevant laws, regulations and administrative provisions,
- sampling procedure,
- fraud aspects;

(ii) practical part:

- animal identification,
- age checks,
- inspection and assessment of slaughtered animals,

- post-mortem inspection in a slaughterhouse,
 - examination for trichinosis,
 - identification of animal species by examination of typical parts of the animal,
 - identifying and commenting on parts of slaughtered animals in which changes have occurred,
 - hygiene control, including the audit of the good hygiene practices and the HACCP-based procedures,
 - recording the results of ante-mortem inspection,
 - sampling,
 - traceability of meat,
 - documentation.
6. Official auxiliaries are to maintain up-to-date knowledge and to keep abreast of new developments through regular continuing education activities and professional literature. The official auxiliary is, wherever possible, to undertake annual continuing education activities.
7. Persons already appointed as official auxiliaries must have adequate knowledge of the subjects mentioned in paragraph 5. Where necessary, they are to acquire this knowledge through continuing education activities. The competent authority is to make adequate provision in this regard.
8. However, when official auxiliaries carry out only sampling and analysis in connection with examinations for trichinosis, the competent authority need only ensure that they receive training appropriate to these tasks.

SECTION IV: SPECIFIC REQUIREMENTS

CHAPTER I: DOMESTIC BOVINE ANIMALS

A. BOVINE ANIMALS UNDER SIX WEEKS OLD

Carcases and offal of bovine animals under six weeks old are to undergo the following post-mortem inspection procedures:

1. visual inspection of the head and throat; incision and examination of the retropharyngeal lymph nodes (*Lnn retropharyngeales*); inspection of the mouth and fauces; palpation of the tongue; removal of the tonsils;
2. visual inspection of the lungs, trachea and oesophagus; palpation of the lungs; incision and examination of the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales and mediastinales*). The trachea and the main branches of the bronchi must be opened lengthwise and the lungs must be incised in their posterior third, perpendicular to their main axes; these incisions are not necessary where the lungs are excluded from human consumption;
3. visual inspection of the pericardium and heart, the latter being incised lengthwise so as to open the ventricles and cut through the interventricular septum;
4. visual inspection of the diaphragm;
5. visual inspection of the liver and the hepatic and pancreatic lymph nodes, (*Lnn portales*); palpation and, if necessary, incision of the liver and its lymph nodes;
6. visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales and caudales*); palpation and, if necessary, incision of the gastric and mesenteric lymph nodes;

7. visual inspection and, if necessary, palpation of the spleen;
8. visual inspection of the kidneys; incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);
9. visual inspection of the pleura and peritoneum;
10. visual inspection and palpation of the umbilical region and the joints. In the event of doubt, the umbilical region must be incised and the joints opened; the synovial fluid must be examined.

B. BOVINE ANIMALS OVER SIX WEEKS OLD

Carcases and offal of bovine animals over six weeks old are to undergo the following post-mortem inspection procedures:

1. visual inspection of the head and throat; incision and examination of the sub-maxillary, retropharyngeal and parotid lymph nodes (*Lnn. retropharyngiales, mandibulares and parotidei*); examination of the external masseters, in which two incisions must be made parallel to the mandible, and the internal masseters (internal pterygoid muscles), which must be incised along one plane. The tongue must be freed to permit a detailed visual inspection of the mouth and the fauces and must itself be visually inspected and palpated. The tonsils must be removed;
2. inspection of the trachea and oesophagus; visual examination and palpation of the lungs; incision and examination of the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales and mediastinales*). The trachea and the main branches of the bronchi must be opened lengthways and the lungs must be incised in their posterior third, perpendicular to their main axes; these incisions are not necessary where the lungs are excluded from human consumption;
3. visual inspection of the pericardium and heart, the latter being incised lengthways so as to open the ventricles and cut through the interventricular septum;
4. visual inspection of the diaphragm;
5. visual inspection and palpation of the liver and the hepatic and pancreatic lymph nodes, (*Lnn. portales*); incision of the gastric surface of the liver and at the base of the caudate lobe to examine the bile ducts;
6. visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales and caudales*); palpation and, if necessary, incision of the gastric and mesenteric lymph nodes;
7. visual inspection and, if necessary, palpation of the spleen;
8. visual inspection of the kidneys and incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);
9. visual inspection of the pleura and the peritoneum;
10. visual inspection of the genital organs (except for the penis, if already discarded);
11. visual inspection and, if necessary, palpation and incision of the udder and its lymph nodes (*Lnn. supramammarii*). In cows, each half of the udder must be opened by a long, deep incision as far as the lactiferous sinuses (*sinus lactiferes*) and the lymph nodes of the udder must be incised, except when the udder is excluded from human consumption.

CHAPTER II: DOMESTIC SHEEP AND GOATS

Carcases and offal of sheep and goats are to undergo the following post-mortem inspection procedures:

1. visual inspection of the head after flaying and, in the event of doubt, examination of the throat, mouth, tongue and retropharyngeal and parotid lymph nodes. Without prejudice to animal-health rules, these examinations are not necessary if the competent authority is able to guarantee that the head, including the tongue and the brains, will be excluded from human consumption;
2. visual inspection of the lungs, trachea and oesophagus; palpation of the lungs and the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales and mediastinales*); in the event of doubt, these organs and lymph nodes must be incised and examined;
3. visual inspection of the pericardium and heart; in the event of doubt, the heart must be incised and examined;
4. visual inspection of the diaphragm;
5. visual inspection of the liver and the hepatic and pancreatic lymph nodes, (*Lnn portales*); palpation of the liver and its lymph nodes; incision of the gastric surface of the liver to examine the bile ducts;
6. visual inspection of the gastro-intestinal tract, the mesentery and the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales and caudales*);
7. visual inspection and, if necessary, palpation of the spleen;
8. visual inspection of the kidneys; incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);
9. visual inspection of the pleura and peritoneum;
10. visual inspection of the genital organs (except for the penis, if already discarded);
11. visual inspection of the udder and its lymph nodes;
12. visual inspection and palpation of the umbilical region and joints of young animals. In the event of doubt, the umbilical region must be incised and the joints opened; the synovial fluid must be examined.

CHAPTER III: DOMESTIC SOLIPEDS

Carcases and offal of solipeds are to undergo the following post-mortem inspection procedures:

1. visual inspection of the head and, after freeing the tongue, the throat; palpation and, if necessary, incision of the sub-maxillary, retropharyngeal and parotid lymph nodes (*Lnn retropharyngiales, mandibulares and parotidei*). The tongue must be freed to permit a detailed visual inspection of the mouth and the fauces and must itself be visually examined and palpated. The tonsils must be removed;
2. visual inspection of the lungs, trachea and oesophagus; palpation of the lungs; palpation and, if necessary, incision of the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales and mediastinales*). The trachea and the main branches of the bronchi must be opened lengthwise and the lungs must be incised in their posterior third, perpendicular to their main axes; however, these incisions are not necessary where the lungs are excluded from human consumption;
3. visual inspection of the pericardium and the heart, the latter being incised lengthwise so as to open the ventricles and cut through the interventricular septum;
4. visual inspection of the diaphragm;
5. visual inspection, palpation and, if necessary, incision of the liver and the hepatic and pancreatic lymph nodes, (*Lnn portales*);
6. visual inspection of the gastro-intestinal tract, the mesentery and the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales and caudales*); incision, if necessary, of the gastric and mesenteric lymph nodes;
7. visual inspection and, if necessary, palpation of the spleen;

8. visual inspection and palpation of the kidneys; incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);
9. visual inspection of the pleura and peritoneum;
10. visual inspection of the genital organs of stallions (except for the penis, if already discarded) and mares;
11. visual inspection of the udder and its lymph nodes (*Lnn. supramammarii*) and, if necessary, incision of the supramammary lymph nodes;
12. visual inspection and palpation of the umbilical region and joints of young animals. In the event of doubt, the umbilical region must be incised and the joints opened; the synovial fluid must be examined;
13. all grey or white horses must be inspected for melanosis and melanomata by examination of the muscles and lymph nodes (*Lnn. subrhomboidei*) of the shoulders beneath the scapular cartilage after loosening the attachment of one shoulder. The kidneys must be exposed and examined by incision through the entire kidney.

CHAPTER IV: DOMESTIC SWINE

A. ANTE-MORTEM INSPECTION

1. The competent authority may decide that pigs intended for slaughter are to be submitted to ante-mortem inspection at the holding of provenance. In that case, slaughter of a lot of pigs from a holding may be authorised only if:
 - (a) the health certificate provided for in Chapter X, Part A, accompanies them;
 - and
 - (b) the requirements of paragraphs 2 to 5 are complied with.
2. Ante-mortem inspection at the holding of provenance is to comprise:
 - (a) checks on records or documentation at the holding, including food chain information;
 - (b) the examination of the pigs to determine whether:
 - (i) they have a disease or condition which may be transmitted to animals or humans through handling or eating the meat, or are behaving, individually or collectively, in a manner indicating that such a disease may occur,
 - (ii) they show disturbance of general behaviour or signs of disease which may make the meat unfit for human consumption,
 - or
 - (iii) there is evidence or reasons to suspect that they may contain chemical residues in excess of the levels laid down in Community legislation, or residues of forbidden substances.
3. An official veterinarian or an approved veterinarian is to carry out ante-mortem inspection at the holding. The pigs are to be sent directly to slaughter and not to be mixed with other pigs.
4. Ante-mortem inspection at the slaughterhouse need cover only:
 - (a) a control of the animals' identification;
 - and
 - (b) a screening to ascertain whether animal welfare rules have been complied with and whether signs of any condition which might adversely affect human or animal health are present. An official auxiliary may carry out this screening.
5. When pigs are not slaughtered within three days of the issue of the health certificate provided for in paragraph 1(a):
 - (a) if the pigs have not left the holding of provenance for the slaughterhouse, they are to be re-examined and a new health certificate issued;

- (b) if the pigs are already en route for or at the slaughterhouse, slaughter may be authorised once the reason for the delay has been assessed, provided that the pigs undergo a further veterinary ante-mortem inspection.

B. POST-MORTEM INSPECTION

1. Carcasses and offal of pigs other than those referred to in paragraph 2 are to undergo the following post-mortem inspection procedures:
 - (a) visual inspection of the head and throat; incision and examination of the submaxillary lymph nodes (*Lnn mandibulares*); visual inspection of the mouth, fauces and tongue;
 - (b) visual inspection of the lungs, trachea and oesophagus; palpation of the lungs and the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales and mediastinales*). The trachea and the main branches of the bronchi must be opened lengthwise and the lungs must be incised in their posterior third, perpendicular to their main axes; these incisions are not necessary where the lungs are excluded from human consumption;
 - (c) visual inspection of the pericardium and heart, the latter being incised lengthwise so as to open the ventricles and cut through the interventricular septum;
 - (d) visual inspection of the diaphragm;
 - (e) visual inspection of the liver and the hepatic and pancreatic lymph nodes, (*Lnn portales*); palpation of the liver and its lymph nodes;
 - (f) visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales and caudales*); palpation and, if necessary, incision of the gastric and mesenteric lymph nodes;
 - (g) visual inspection and, if necessary, palpation of the spleen;
 - (h) visual inspection of the kidneys; incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);
 - (i) visual inspection of the pleura and peritoneum;
 - (j) visual inspection of the genital organs (except for the penis, if already discarded);
 - (k) visual inspection of the udder and its lymph nodes (*Lnn. supramammarii*); incision of the supramammary lymph nodes in sows;
 - (l) visual inspection and palpation of the umbilical region and joints of young animals; in the event of doubt, the umbilical region must be incised and the joints opened.
2. The competent authority may decide, on the basis of epidemiological or other data from the holding, that fattening pigs housed under controlled housing conditions in integrated production systems since weaning need, in some or all of the cases referred to in paragraph 1, only undergo visual inspection.

CHAPTER V: POULTRY

A. ANTE-MORTEM INSPECTION

1. The competent authority may decide that poultry intended for slaughter are to be submitted to ante-mortem inspection at the holding of provenance. In that case, slaughter of a flock of birds from a holding may be authorised only if:
 - (a) the health certificate provided for in Chapter X, Part A, accompanies them:
and
 - (b) the requirements of paragraphs 2 to 5 are complied with.
2. Ante-mortem inspection on the holding of provenance is to comprise:
 - (a) checks on records or documentation at the holding, including food chain information;

- (b) a flock inspection, to determine whether the birds:
 - (i) have a disease or condition which may be transmitted to animals or humans through handling or eating the meat, or are behaving in a manner indicating that such a disease may occur,
 - (ii) show disturbance of general behaviour or signs of disease which may make the meat unfit for human consumption,or
 - (iii) show evidence that they may contain chemical residues in excess of the levels laid down in Community legislation, or residues of forbidden substances.
- 3. An official veterinarian or an approved veterinarian is to carry out ante-mortem inspection at the holding.
- 4. Ante-mortem inspection at the slaughterhouse need only cover:
 - (a) a control of the animals' identification;
 - and
 - (b) a screening to ascertain whether animal welfare rules have been complied with and whether signs of any condition which might adversely affect human or animal health are present. An official auxiliary may carry out this screening.
- 5. When birds are not slaughtered within three days of the issue of the health certificate referred to in paragraph 1(a):
 - (a) if the flock has not left the holding of provenance for the slaughterhouse, it is to be re-examined and a new health certificate issued;
 - (b) if the flock is already en route for or at the slaughterhouse, slaughter may be authorised once the reason for the delay has been assessed, provided that the flock is re-examined.
- 6. When ante-mortem inspection is not carried out at the holding, the official veterinarian is to carry out a flock inspection at the slaughterhouse.
- 7. If the birds show clinical symptoms of a disease, they may not be slaughtered for human consumption. However, killing of these birds on the slaughter line may take place at the end of the normal slaughter process, if precautions are taken to avoid the risk of spreading pathogenic organisms and to clean and disinfect the facilities immediately after killing.
- 8. In the case of poultry reared for the production of 'foie gras' and delayed eviscerated poultry slaughtered at the holding of provenance, ante-mortem inspection is to be carried out in accordance with paragraphs 2 and 3. A certificate conforming to the model set out in Part C is to accompany the uneviscerated carcasses to the slaughterhouse or cutting plant.

B. POST-MORTEM INSPECTION

- 1. All birds are to undergo post-mortem inspection in accordance with Sections I and III. In addition, the official veterinarian is personally to carry out the following checks:
 - (a) daily inspection of the viscera and body cavities of a representative sample of birds;
 - (b) a detailed inspection of a random sample, from each batch of birds having the same origin, of parts of birds or entire birds declared unfit for human consumption following post-mortem inspection;and
 - (c) any further investigations necessary when there is reason to suspect that the meat from the birds concerned could be unfit for human consumption.
- 2. In the case of poultry reared for the production of 'foie gras' and delayed eviscerated poultry obtained at the holding of provenance, post-mortem inspection is to include a check on the certificate accompanying the carcasses. When such carcasses are transported directly from the holding to a cutting plant, post-mortem inspection is to take place at the cutting plant.

C. SPECIMEN HEALTH CERTIFICATE

HEALTH CERTIFICATE

**for poultry intended for the production of foie gras and delayed eviscerated
poultry slaughtered at the holding of provenance**

Competent service:

No:

1. Identification of uneviscerated carcasses

Species:

Number:

2. Provenance of uneviscerated carcasses

Address of holding:

3. Destination of uneviscerated carcasses

The uneviscerated carcasses will be transported to the following cutting plant:

.....

4. Declaration

I, the undersigned, declare that:

- the uneviscerated carcasses described above are of birds which were examined before slaughter on the abovementioned holding at (time) on (date) and found to be healthy;
- the records and documentation concerning these animals satisfied the legal requirements and do not prohibit slaughter of the birds.

Done at:

(Place)

on:

(Date)

Stamp

.....
(Signature of the official or approved veterinarian)

CHAPTER VI: FARMED LAGOMORPHS

The requirements for poultry are to apply to farmed lagomorphs.

CHAPTER VII: FARMED GAME**A. Ante-mortem inspection**

1. Ante-mortem inspection may be carried out at the holding of provenance when the requirements of Annex III, Section III, to Regulation (EC) No 853/2004 are satisfied. In this case, an official veterinarian or an approved veterinarian is to carry out ante-mortem inspection.
2. Ante-mortem inspection at the holding is to include checks on the records or documentation at the holding, including food chain information.
3. When ante-mortem inspection takes place no more than three days before the arrival of the animals at the slaughterhouse, and animals are delivered to the slaughterhouse live, ante-mortem inspection at the slaughterhouse need only cover:
 - (a) a control of the animals' identification;
and
 - (b) a screening to ascertain whether animal welfare rules have been complied with and whether signs of any condition which might adversely affect human or animal health are present.
4. A certificate conforming to the specimen in Chapter X, Part A, is to accompany live animals inspected at the holding. A certificate conforming to the specimen in Chapter X, Part B, is to accompany animals inspected and slaughtered at the holding.

B. Post-mortem inspection

1. This inspection is to include palpation and, where judged necessary, incision of those parts of the animal which have undergone any change or are suspect for any other reason.
2. Post-mortem inspection procedures described for bovine and ovine animals, domestic swine and poultry are to be applied to the corresponding species of farmed game.
3. When the animals have been slaughtered at the holding, the official veterinarian at the slaughterhouse is to check the certificate accompanying them.

CHAPTER VIII: WILD GAME**A. Post-mortem inspection**

1. Wild game is to be inspected as soon as possible after admission to the game handling establishment.
2. The official veterinarian is to take account of the declaration or information that the trained person involved in hunting the animal has provided in accordance with Regulation (EC) No 853/2004.
3. During post-mortem inspection, the official veterinarian is to carry out:
 - (a) a visual examination of the carcase, its cavities and, where appropriate, organs with a view to:
 - (i) detecting any abnormalities not resulting from the hunting process. For this purpose, the diagnosis may be based on any information that the trained person has provided concerning the behaviour of the animal before killing,
 - (ii) checking that death was not caused by reasons other than hunting.

If an assessment cannot be made on the basis of visual examination alone, a more extensive inspection must be carried out in a laboratory;
 - (b) an investigation of organoleptic abnormalities;
 - (c) palpation of organs, where appropriate;

- (d) where there are serious grounds for suspecting the presence of residues or contaminants, an analysis by sampling of residues not resulting from the hunting process, including environmental contaminants. When a more extensive inspection is made on the basis of such suspicions, the veterinarian must wait until that inspection has been concluded before assessing all the game killed during a specific hunt, or those parts suspected of showing the same abnormalities;
- (e) examination for characteristics indicating that the meat presents a health risk, including:
 - (i) abnormal behaviour or disturbance of the general condition of the live animal, as reported by the hunter,
 - (ii) the generalised presence of tumours or abscesses affecting different internal organs or muscles,
 - (iii) arthritis, orchitis, pathological changes in the liver or the spleen, inflammation of the intestines or the umbilical region,
 - (iv) the presence of foreign bodies not resulting from the hunting process in the body cavities, stomach or intestines or in the urine, where the pleura or peritoneum are discoloured (when relevant viscera are present),
 - (v) the presence of parasites,
 - (vi) formation of a significant amount of gas in the gastro-intestinal tract with discolouring of the internal organs (when these viscera are present),
 - (vii) significant abnormalities of colour, consistency or odour of muscle tissue or organs,
 - (viii) aged open fractures,
 - (ix) emaciation and/or general or localised oedema,
 - (x) recent pleural or peritoneal adhesions.and
 - (xi) other obvious extensive changes, such as putrefaction.
- 4. Where the official veterinarian so requires, the vertebral column and the head are to be split lengthwise.
- 5. In the case of small wild game not eviscerated immediately after killing, the official veterinarian is to carry out a post-mortem inspection on a representative sample of animals from the same source. Where inspection reveals a disease transmissible to man or any of the characteristics listed in paragraph 3(e), the official veterinarian is to carry out more checks on the entire batch to determine whether it must be declared unfit for human consumption or whether each carcass must be inspected individually.
- 6. In the event of doubt, the official veterinarian may perform any further cuts and inspections of the relevant parts of the animals necessary to reach a final diagnosis.

B. Decisions following controls

In addition to the cases provided for in Section II, Chapter V, meat presenting during post-mortem inspection any of the characteristics listed in paragraph 3(e) of Part A is to be declared unfit for human consumption.

CHAPTER IX: SPECIFIC HAZARDS

A. Transmissible spongiform encephalopathies

Official controls carried out in relation to TSEs are to take account of the requirements of Regulation (EC) No 999/2001 and other relevant Community legislation.

B. Cysticercosis

1. The post-mortem inspection procedures described in Chapters I and IV are the minimum requirements for the examination for cysticercosis in bovine animals over six weeks old and swine. In addition, specific serological tests may be used. In the case of bovines over six weeks old, incision of the masseters at post-mortem inspection is not compulsory when a specific serological test is used. The same applies when bovine animals over six weeks old have been raised on a holding officially certified to be free of cysticercosis.
2. Meat infected with cysticercus is to be declared unfit for human consumption. However, when the animal is not generally infected with cysticercus, the parts not infected may be declared fit for human consumption after having undergone a cold treatment.

C. Trichinosis

1. Carcasses of swine (domestic, farmed game and wild game), solipeds and other species susceptible to trichinosis are to be examined for trichinosis in accordance with applicable Community legislation, unless that legislation provides otherwise.
2. Meat from animals infected with trichinae is to be declared unfit for human consumption.

D. Glanders

1. Where appropriate, solipeds are to be examined for glanders. Examination for glanders in solipeds is to include a careful examination of mucous membranes from the trachea, larynx, nasal cavities and sinuses and their ramifications, after splitting the head in the median plane and excising the nasal septum.
2. Meat from horses in which glanders has been diagnosed are to be declared unfit for human consumption.

E. Tuberculosis

1. When animals have reacted positively or inconclusively to tuberculin, or there are other grounds for suspecting infection, they are to be slaughtered separately from other animals, taking precautions to avoid the risk of contamination of other carcasses, the slaughter line and staff present in the slaughterhouse.
2. All meat from animals in which post-mortem inspection has revealed localised tuberculous lesions in a number of organs or a number of areas of the carcass is to be declared unfit for human consumption. However, when a tuberculous lesion has been found in the lymph nodes of only one organ or part of the carcass, only the affected organ or part of the carcass and the associated lymph nodes need be declared unfit for human consumption.

F. Brucellosis

1. When animals have reacted positively or inconclusively to a brucellosis test, or there are other grounds for suspecting infection, they are to be slaughtered separately from other animals, taking precautions to avoid the risk of contamination of other carcasses, the slaughter line and staff present in the slaughterhouse.
2. Meat from animals in which post-mortem inspection has revealed lesions indicating acute infection with brucellosis is to be declared unfit for human consumption. In the case of animals reacting positively or inconclusively to a brucellosis test, the udder, genital tract and blood must be declared unfit for human consumption even if no such lesion is found.

CHAPTER X: SPECIMEN HEALTH CERTIFICATE

A. SPECIMEN HEALTH CERTIFICATE FOR LIVE ANIMALS

HEALTH CERTIFICATE**for live animals transported from the holding to the slaughterhouse**

Competent service:

No:

1. Identification of the animals

Species:

Number of animals:

Identification marking:

2. Provenance of the animals

Address of holding of provenance:

Identification of house (*):

3. Destination of the animals

The animals will be transported to the following slaughterhouse:

by the following means of transport:

4. Other relevant information

.....

5. Declaration

I, the undersigned, declare that:

— the animals described above were examined before slaughter at the abovementioned holding at (time) on
..... (date) and were found to be healthy,— the records and documentation concerning these animals satisfied the legal requirements and do not prohibit
slaughter of the animals.

Done at:

(Place)

on:

(Date)

Stamp

.....

(Signature of official or approved veterinarian)

(*) optional

B. SPECIMEN HEALTH CERTIFICATE FOR ANIMALS SLAUGHTERED AT THE HOLDING

HEALTH CERTIFICATE**for animals slaughtered at the holding**

Competent service:

No:

1. Identification of the animals

Species:

Number of animals:

Identification marking:

2. Provenance of the animals

Address of holding of provenance:

Identification of house (*):

3. Destination of the animals

The animals will be transported to the following slaughterhouse:

.....

by the following means of transport:

4. Other relevant information

.....

5. Declaration

I, the undersigned, declare that:

— the animals described above were examined before slaughter at the abovementioned holding at (time) on (date) and were found to be healthy,

— they were slaughtered at the holding at (time) on (date) and slaughter and bleeding were carried out correctly,

— the records and documentation concerning these animals satisfied the legal requirements and did not prohibit slaughter of the animals.

Done at:

(Place)

on:

(Date)

Stamp

.....
(Signature of official or approved veterinarian)

(*) optional

ANNEX II

LIVE BIVALVE MOLLUSCS

CHAPTER I: SCOPE

This Annex applies to live bivalve molluscs and, by analogy, to live echinoderms, live tunicates and live marine gastropods.

CHAPTER II: OFFICIAL CONTROLS CONCERNING LIVE BIVALVE MOLLUSCS FROM CLASSIFIED PRODUCTION AREAS

A. CLASSIFICATION OF PRODUCTION AND RELAYING AREAS

1. The competent authority must fix the location and boundaries of production and relaying areas that it classifies. It may, where appropriate, do so in cooperation with the food business operator.
2. The competent authority must classify production areas from which it authorises the harvesting of live bivalve molluscs as being of one of three categories according to the level of faecal contamination. It may, where appropriate, do so in cooperation with the food business operator.
3. The competent authority may classify as being of Class A areas from which live bivalve molluscs may be collected for direct human consumption. Live bivalve molluscs taken from these areas must meet the health standards for live bivalve molluscs laid down in Annex III, Section VII, Chapter V, of Regulation (EC) No 853/2004.
4. The competent authority may classify as being of Class B areas from which live bivalve molluscs may be collected, but placed on the market for human consumption only after treatment in a purification centre or after relaying so as to meet the health standards referred to in paragraph 3. Live bivalve molluscs from these areas must not exceed the limits of a five-tube, three dilution Most Probable Number (MPN) test of 4 600 *E.coli* per 100 g of flesh and intravalvular liquid.
5. The competent authority may classify as being of Class C areas from which live bivalve molluscs may be collected but placed on the market only after relaying over a long period so as to meet the health standards referred to in paragraph 3. Live bivalve molluscs from these areas must not exceed the limits of a five-tube, three dilution MPN test of 46 000 *E.coli* per 100 g of flesh and intravalvular liquid.
6. If the competent authority decides in principle to classify a production or relaying area, it must:
 - (a) make an inventory of the sources of pollution of human or animal origin likely to be a source of contamination for the production area;
 - (b) examine the quantities of organic pollutants which are released during the different periods of the year, according to the seasonal variations of both human and animal populations in the catchment area, rainfall readings, waste-water treatment, etc.;
 - (c) determine the characteristics of the circulation of pollutants by virtue of current patterns, bathymetry and the tidal cycle in the production area;and
 - (d) establish a sampling programme of bivalve molluscs in the production area which is based on the examination of established data, and with a number of samples, a geographical distribution of the sampling points and a sampling frequency which must ensure that the results of the analysis are as representative as possible for the area considered.

B. MONITORING OF CLASSIFIED RELAYING AND PRODUCTION AREAS

1. Classified relaying and production areas must be periodically monitored to check:
 - (a) that there is no malpractice with regard to the origin, provenance and destination of live bivalve molluscs;

- (b) the microbiological quality of live bivalve molluscs in relation to the production and relaying areas;
 - (c) for the presence of toxin-producing plankton in production and relaying waters and biotoxins in live bivalve molluscs;
 - and
 - (d) for the presence of chemical contaminants in live bivalve molluscs.
2. To implement paragraph 1(b), (c) and (d), sampling plans must be drawn up providing for such checks to take place at regular intervals, or on a case-by-case basis if harvesting periods are irregular. The geographical distribution of the sampling points and the sampling frequency must ensure that the results of the analysis are as representative as possible for the area considered.
3. Sampling plans to check the microbiological quality of live bivalve molluscs must take particular account of:
- (a) the likely variation in faecal contamination;
 - and
 - (b) the parameters referred to in paragraph 6 of Part A.
4. Sampling plans to check for the presence of toxin-producing plankton in production and relaying waters and for biotoxins in live bivalve molluscs must take particular account of possible variations in the presence of plankton containing marine biotoxins. Sampling must comprise:
- (a) periodic sampling to detect changes in the composition of plankton containing toxins and their geographical distribution. Results suggesting an accumulation of toxins in mollusc flesh must be followed by intensive sampling;
 - (b) periodic toxicity tests using those molluscs from the affected area most susceptible to contamination.
5. The sampling frequency for toxin analysis in the molluscs is, as a general rule, to be weekly during the periods at which harvesting is allowed. This frequency may be reduced in specific areas, or for specific types of molluscs, if a risk assessment on toxins or phytoplankton occurrence suggests a very low risk of toxic episodes. It is to be increased where such an assessment suggests that weekly sampling would not be sufficient. The risk assessment is to be periodically reviewed in order to assess the risk of toxins occurring in the live bivalve molluscs from these areas.
6. When knowledge of toxin accumulation rates is available for a group of species growing in the same area, a species with the highest rate may be used as an indicator species. This will allow the exploitation of all species in the group if toxin levels in the indicator species are below the regulatory limits. When toxin levels in the indicator species are above the regulatory limits, harvesting of the other species is only to be allowed if further analysis on the other species shows toxin levels below the limits.
7. With regard to the monitoring of plankton, the samples are to be representative of the water column and to provide information on the presence of toxic species as well as on population trends. If any changes in toxic populations that may lead to toxin accumulation are detected, the sampling frequency of molluscs is to be increased or precautionary closures of the areas are to be established until results of toxin analysis are obtained.
8. Sampling plans to check for the presence of chemical contaminants must enable the detection of any overshooting of the levels laid down in Commission Regulation (EC) No 466/2001⁽¹⁾.

C. DECISIONS AFTER MONITORING

1. Where the results of sampling show that the health standards for molluscs are exceeded, or that there may be otherwise a risk to human health, the competent authority must close the production area concerned, preventing the

⁽¹⁾ OJ L 77, 16.3.2001, p. 1. Regulation as last amended by Regulation (EC) No 655/2004 (OJ L 104, 8.4.2004, p. 48).

harvesting of live bivalve molluscs. However, the competent authority may reclassify a production area as being of Class B or C if it meets the relevant criteria set out in Part A and presents no other risk to human health.

2. The competent authority may re-open a closed production area only if the health standards for molluscs once again comply with Community legislation. If the competent authority closes a production because of the presence of plankton or excessive levels of toxins in molluscs, at least two consecutive results below the regulatory limit separated at least 48 hours are necessary to re-open it. The competent authority may take account of information on phytoplankton trends when taking this decision. When there are robust data on the dynamic of the toxicity for a given area, and provided that recent data on decreasing trends of toxicity are available, the competent authority may decide to re-open the area with results below the regulatory limit obtained from one single sampling.

D. ADDITIONAL MONITORING REQUIREMENTS

1. The competent authority is to monitor classified production areas from which it has forbidden the harvesting of bivalve molluscs or subjected harvesting to special conditions, to ensure that products harmful to human health are not placed on the market.
2. In addition to the monitoring of relaying and production zones referred to in paragraph 1 of Part B, a control system must be set up comprising laboratory tests to verify food business operators' compliance with the requirements for the end product at all stages of production, processing and distribution. This control system is, in particular, to verify that the levels of marine biotoxins and contaminants do not exceed safety limits and that the microbiological quality of the molluscs does not constitute a hazard to human health.

E. RECORDING AND EXCHANGE OF INFORMATION

The competent authority must:

- (a) establish and keep up to date a list of approved production and relaying areas, with details of their location and boundaries, as well as the class in which the area is classified, from which live bivalve molluscs may be taken in accordance with the requirements of this Annex. This list must be communicated to interested parties affected by this Annex, such as producers, gatherers and operators of purification centres and dispatch centres;
 - (b) immediately inform the interested parties affected by this Annex, such as producers, gatherers and operators of purification centres and dispatch centres, about any change of the location, boundaries or class of a production area, or its closure, be it temporary or final;
- and
- (c) act promptly where the controls prescribed in this Annex indicate that a production area must be closed or reclassified or can be re-opened.

F. FOOD BUSINESS OPERATORS' OWN CHECKS

To decide on the classification, opening or closure of production areas, the competent authority may take into account the results of controls that food business operators or organisations representing food business operators have carried out. In that event, the competent authority must have designated the laboratory carrying out the analysis and, if necessary, sampling and analysis must have taken place in accordance with a protocol that the competent authority and the food business operators or organisation concerned have agreed.

CHAPTER III: OFFICIAL CONTROLS CONCERNING PECTINIDAE HARVESTED OUTSIDE CLASSIFIED PRODUCTION AREAS

Official controls on pectinidae harvested outside classified production areas are to be carried out in fish auctions, dispatch centres and processing establishments. Such official controls are to verify compliance with the health standards for live bivalve molluscs laid down in Annex III, Section VII, Chapter V, to Regulation (EC) No 853/2004 as well as compliance with other requirements of Annex III, Section VII, Chapter IX to that Regulation.

ANNEX III

FISHERY PRODUCTS

CHAPTER I: OFFICIAL CONTROLS OF PRODUCTION AND PLACING ON THE MARKET

1. Official controls on the production and placing on the market of fishery products are to include, in particular:
 - (a) a regular check on the hygiene conditions of landing and first sale;
 - (b) inspections at regular intervals of vessels and establishments on land, including fish auctions and wholesale markets, to check, in particular:
 - (i) where appropriate, whether the conditions for approval are still fulfilled,
 - (ii) whether the fishery products are handled correctly,
 - (iii) for compliance with hygiene and temperature requirements,and
 - (iv) the cleanliness of establishments, including vessels, and their facilities and equipment, and staff hygiene;and
 - (c) checks on storage and transport conditions.
2. However, subject to paragraph 3, official controls of vessels:
 - (a) may be carried out when vessels call at a port in a Member State;
 - (b) concern all vessels landing fishery products at ports in the Community, irrespective of flag;and
- (c) may, if necessary, when the competent authority of the Member State the flag of which the vessel is flying carries out the official control, be carried out while the vessel is at sea or when it is in a port in another Member State or in a third country.
3.
 - (a) In the case of an inspection of a factory or freezer vessel flying the flag of a Member State carried out with a view to the approval of the vessel, the competent authority of the Member State the flag of which the vessel is flying is to carry out inspections in such a manner as to comply with the requirements of Article 3, particularly the time limits of Article 3(2). If necessary, that competent authority may inspect the vessel while it is at sea or when it is in a port in another Member State or in a third country.
 - (b) When the competent authority of the Member State the flag of which the vessel is flying has granted the vessel conditional approval in accordance with Article 3, that competent authority may authorise a competent authority of:
 - (i) another Member State,or
 - (ii) a third country that appears on a list of third countries from which imports of fishery products are permitted drawn up in accordance with Article 11, to carry out a follow-up inspection with a view to granting full approval or prolonging conditional approval in accordance with Article 3(1)(b) or to keeping approval under review in accordance with Article 3(4). If necessary, that competent authority may inspect the vessel while it is at sea or when it is in a port in another Member State or in a third country.
4. When the competent authority of a Member State authorises the competent authority of another Member State or of a third country to carry out inspections on its behalf in accordance with paragraph 3, the two competent authorities are to agree on the conditions governing such inspections. These conditions are to ensure, in particular, that the competent authority of the Member State the flag of which the vessel is flying receives reports on the results of inspections and on any suspected non-compliance without delay, so as to enable it to take the necessary measures.

CHAPTER II: OFFICIAL CONTROLS OF FISHERY PRODUCTS

Official controls of fishery products are to include at least the following elements.

A. ORGANOLEPTIC EXAMINATIONS

Random organoleptic checks must be carried out at all stages of production, processing and distribution. One aim of these checks is to verify compliance with the freshness criteria established in accordance with Community legislation. In particular, this includes verifying, at all stages of production, processing and distribution, that fishery products at least exceed the baselines of freshness criteria established in accordance with Community legislation.

B. FRESHNESS INDICATORS

When the organoleptic examination reveals any doubt as to the freshness of the fishery products, samples may be taken and subjected to laboratory tests to determine the levels of total volatile basic nitrogen (TVB-N) and trimethylamine nitrogen (TMA-N).

The competent authority is to use the criteria laid down under Community legislation.

When the organoleptic examination gives cause to suspect the presence of other conditions which may affect human health, appropriate samples are to be taken for verification purposes.

C. HISTAMINE

Random testing for histamine is to be carried out to verify compliance with the permitted levels laid down under Community legislation.

D. RESIDUES AND CONTAMINANTS

Monitoring arrangements are to be set up to control the levels of residues and contaminants in accordance with Community legislation.

E. MICROBIOLOGICAL CHECKS

Where necessary, microbiological checks are to be performed in accordance with the relevant rules and criteria laid down under Community legislation.

F. PARASITES

Random testing is to take place to verify compliance with Community legislation on parasites.

G. POISONOUS FISHERY PRODUCTS

Checks are to take place to ensure that the following fishery products are not placed on the market:

1. poisonous fish of the following families are not placed on the market: *Tetraodontidae*, *Molidae*, *Diodontidae* and *Canthigasteridae*;

and
2. fishery products containing biotoxins such as *Ciguatera* or other toxins dangerous to human health. However, fishery products derived from bivalve molluscs, echinoderms, tunicates and marine gastropods may be placed on the market if they have been produced in accordance with Section VII of Annex III to Regulation (EC) No 853/2004 and comply with the standards laid down in Chapter V, point 2, of that section.

CHAPTER III: DECISIONS AFTER CONTROLS

Fishery products are to be declared unfit for human consumption if:

1. organoleptic, chemical, physical or microbiological checks or checks for parasites have shown that they are not in compliance with the relevant Community legislation;
2. they contain in their edible parts contaminants or residues in excess of the limits laid down in Community legislation or at levels where the calculated dietary intake would exceed the acceptable daily or weekly intake for humans;

-
3. they derive from:
- (i) poisonous fish,
 - (ii) fishery products not complying with the requirement of part G, point 2, of Chapter II concerning biotoxins,
- or
- (iii) bivalve molluscs, echinoderms, tunicates or marine gastropods containing marine biotoxins in total quantities exceeding the limits referred to in Regulation (EC) No 853/2004;
- or
4. the competent authority considers that they may constitute a risk to public or animal health or are for any other reason not suitable for human consumption.
-

ANNEX IV

RAW MILK AND DAIRY PRODUCTS**CHAPTER I: CONTROL OF MILK PRODUCTION HOLDINGS**

1. Animals on milk production holdings must be subject to official controls to verify that the health requirements for raw milk production, and in particular the health status of the animals and the use of veterinary medicinal products, are being complied with.

These controls may take place at the occasion of veterinary checks carried out pursuant to Community provisions on animal or public health or animal welfare and may be carried out by an approved veterinarian.

2. If there are grounds for suspecting that the animal health requirements are not being complied with, the general health status of the animals is to be checked.
3. Milk production holdings are to undergo official controls to verify that hygiene requirements are being complied with. These official controls may involve inspections and/or the monitoring of controls that professional organisations carry out. If it is shown that the hygiene is inadequate, the competent authority is to verify that appropriate steps are taken to correct the situation.

CHAPTER II: CONTROL OF RAW MILK UPON COLLECTION

1. The competent authority is to monitor the checks carried out in accordance with Annex III, Section IX, Chapter I, Part III, to Regulation (EC) No 853/2004.
 2. If the food business operator has not corrected the situation within three months of first notifying the competent authority of non-compliance with the criteria with regard to plate count and somatic cell count, delivery of raw milk from the production holding is to be suspended or — in accordance with a specific authorisation of, or general instructions from, the competent authority — subjected to requirements concerning its treatment and use necessary to protect public health. This suspension or these requirements are to remain in place until the food business operator has proved that the raw milk again complies with the criteria.
-

ANNEX V

**ESTABLISHMENTS NOT SUBJECT TO THE LISTING REQUIREMENT
OF ARTICLE 12(1)**

The following third-country establishments need not appear on lists drawn up and updated in accordance with Article 12(4):

1. establishments handling products of animal origin for which Annex III to Regulation (EC) No 853/2004 does not lay down requirements;
 2. establishments carrying out only primary production;
 3. establishments carrying out only transport operations;
 4. establishments carrying out only the storage of products of animal origin not requiring temperature-controlled storage conditions.
-

ANNEX VI

REQUIREMENTS FOR CERTIFICATES ACCOMPANYING IMPORTS

1. The representative of the competent authority of the third country of dispatch issuing a certificate to accompany a consignment of products of animal origin destined for the Community must sign the certificate and ensure that it bears an official stamp. This requirement applies to each sheet of the certificate if it consists of more than one. In the case of factory vessels, the competent authority may authorise the captain or another ship's officer to sign the certificate.
 2. Certificates must be drawn up in the official language or languages of the third country of dispatch and the Member State in which the border inspection takes place, or be accompanied by a certified translation into that language or languages. If the Member State of destination so requests, certificates must also be accompanied by a certified translation into the official language or languages of that Member State. However, a Member State may consent to the use of an official Community language other than its own.
 3. The original version of the certificate must accompany consignments on entry into the Community.
 4. Certificates must consist of:
 - (a) a single sheet of paper;
or
 - (b) two or more pages that are part of an integrated and indivisible sheet of paper;
or
 - (c) a sequence of pages numbered so as to indicate that it is a particular page in a finite sequence (for example, 'page 2 of four pages').
 5. Certificates must bear a unique identifying number. Where the certificate consists of a sequence of pages, each page must indicate this number.
 6. The certificate must be issued before the consignment to which it relates leaves the control of the competent authority of the third country of dispatch.
-

CORRIGENDA

Corrigendum to Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs*(Official Journal of the European Union L 139 of 30 April 2004)*

Regulation (EC) No 852/2004 should read as follows:

**REGULATION (EC) No 852/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 29 April 2004
on the hygiene of foodstuffs**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 95 and 152(4)(b) thereof,

Having regard to the proposal from the Commission ⁽¹⁾,Having regard to the opinion of the European Economic and Social Committee ⁽²⁾,

Having consulted the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁽³⁾,

Whereas:

- (1) The pursuit of a high level of protection of human life and health is one of the fundamental objectives of food law, as laid down in Regulation (EC) No 178/2002 ⁽⁴⁾. That Regulation also lays down other common principles and definitions for national and Community food law, including the aim of achieving free movement of food within the Community.

- (2) Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs ⁽⁵⁾ laid down the general rules of hygiene for foodstuffs and the procedures for verification of compliance with these rules.

- (3) Experience has shown that these rules and procedures constitute a sound basis for ensuring food safety. In the context of the common agricultural policy, many directives have been adopted to establish specific health rules for the production and placing on the market of the products listed in Annex I to the Treaty. These health rules have reduced trade barriers for the products concerned, contributing to the creation of the internal market while ensuring a high level of protection of public health.

- (4) With regard to public health, these rules and procedures contain common principles, in particular in relation to the manufacturers' and competent authorities' responsibilities, structural, operational and hygiene requirements for establishments, procedures for the approval of establishments, requirements for storage and transport and health marks.

- (5) These principles constitute a common basis for the hygienic production of all food, including products of animal origin listed in Annex I to the Treaty.

- (6) In addition to this common basis, specific hygiene rules are necessary for certain foodstuffs. Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin ⁽⁶⁾ lays down these rules.

⁽¹⁾ OJ C 365 E, 19.12.2000, p. 43.

⁽²⁾ OJ C 155, 29.5.2001, p. 39.

⁽³⁾ Opinion of the European Parliament of 15 May 2002 (OJ C 180 E, 31.7.2003, p. 267), Council Common Position of 27 October 2003 (OJ C 48 E, 24.2.2004, p. 1), Position of the European Parliament of 30 March 2004 (not yet published in the Official Journal) and Council Decision of 16 April 2004.

⁽⁴⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1). Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

⁽⁵⁾ OJ L 175, 19.7.1993, p. 1. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

⁽⁶⁾ See page 22 of this Official Journal.

- (7) The principal objective of the new general and specific hygiene rules is to ensure a high level of consumer protection with regard to food safety.
- (8) An integrated approach is necessary to ensure food safety from the place of primary production up to and including placing on the market or export. Every food business operator along the food chain should ensure that food safety is not compromised.
- (9) Community rules should not apply either to primary production for private domestic use, or to the domestic preparation, handling or storage of food for private domestic consumption. Moreover, they should apply only to undertakings, the concept of which implies a certain continuity of activities and a certain degree of organisation.
- (10) Food hazards present at the level of primary production should be identified and adequately controlled to ensure the achievement of the objectives of this Regulation. However, in the case of the direct supply of small quantities of primary products, by the food business operator producing them, to the final consumer or to a local retail establishment, it is appropriate to protect public health through national law, in particular because of the close relationship between the producer and the consumer.
- (11) The application of hazard analysis and critical control point (HACCP) principles to primary production is not yet generally feasible. However, guides to good practice should encourage the use of appropriate hygiene practices at farm level. Where necessary, specific hygiene rules for primary production should supplement these guides. It is appropriate for the hygiene requirements applicable to primary production and associated operations to differ from those for other operations.
- (12) Food safety is a result of several factors: legislation should lay down minimum hygiene requirements; official controls should be in place to check food business operators' compliance and food business operators should establish and operate food safety programmes and procedures based on the HACCP principles.
- (13) Successful implementation of the procedures based on the HACCP principles will require the full cooperation and commitment of food business employees. To this end, employees should undergo training. The HACCP system is an instrument to help food business operators attain a higher standard of food safety. The HACCP system should not be regarded as a method of self-regulation and should not replace official controls.
- (14) While the requirement of establishing procedures based on the HACCP principles should not initially apply to primary production, the feasibility of its extension will be one element of the review that the Commission will carry out following implementation of this Regulation. It is, however, appropriate for Member States to encourage operators at the level of primary production to apply such principles as far as possible.
- (15) The HACCP requirements should take account of the principles contained in the *Codex Alimentarius*. They should provide sufficient flexibility to be applicable in all situations, including in small businesses. In particular, it is necessary to recognise that, in certain food businesses, it is not possible to identify critical control points and that, in some cases, good hygienic practices can replace the monitoring of critical control points. Similarly, the requirement of establishing 'critical limits' does not imply that it is necessary to fix a numerical limit in every case. In addition, the requirement of retaining documents needs to be flexible in order to avoid undue burdens for very small businesses.
- (16) Flexibility is also appropriate to enable the continued use of traditional methods at any of the stages of production, processing or distribution of food and in relation to structural requirements for establishments. Flexibility is particularly important for regions that are subject to special geographical constraints, including the outermost regions referred to in Article 299(2) of the Treaty. However, flexibility should not compromise food hygiene objectives. Moreover, since all food produced in accordance with the hygiene rules will be in free circulation throughout the Community, the procedure allowing Member States to exercise flexibility should be fully transparent. It should provide, where necessary to resolve disagreements, for discussion within the Standing Committee on the Food Chain and Animal Health established by Regulation (EC) No 178/2002.
- (17) The setting of objectives such as pathogen reduction targets or performance standards may guide the implementation of hygiene rules. It is therefore necessary to provide procedures for that purpose. Such objectives would supplement existing food law, such as Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food ⁽¹⁾, which provides for the establishment of maximum tolerances for specific contaminants, and Regulation (EC) No 178/2002, which prohibits the placing on the market of unsafe food and provides a uniform basis for the use of the precautionary principle.
- ⁽¹⁾ OJ L 37, 13.2.1993, p. 1. Regulation as amended by Regulation (EC) No 1882/2003.

- (18) To take account of technical and scientific progress, close and effective cooperation should be ensured between the Commission and the Member States within the Standing Committee on the Food Chain and Animal Health. This Regulation takes account of international obligations laid down in the WTO Sanitary and Phytosanitary Agreement and the international food safety standards contained in the *Codex Alimentarius*.
- (19) The registration of establishments and the cooperation of food business operators are necessary to allow the competent authorities to perform official controls efficiently.
- (20) The traceability of food and food ingredients along the food chain is an essential element in ensuring food safety. Regulation (EC) No 178/2002 contains rules to ensure the traceability of food and food ingredients and provides a procedure for the adoption of implementing rules to apply these principles in respect of specific sectors.
- (21) Food imported into the Community is to comply with the general requirements laid down in Regulation (EC) No 178/2002 or satisfy rules that are equivalent to Community rules. The present Regulation defines certain specific hygiene requirements for food imported into the Community.
- (22) Food exported to third countries from the Community is to comply with the general requirements laid down in Regulation (EC) No 178/2002. The present Regulation defines certain specific hygiene requirements for food exported from the Community.
- (23) Scientific advice should underpin Community legislation on food hygiene. To this end, the European Food Safety Authority should be consulted whenever necessary.
- (24) Since this Regulation replaces Directive 93/43/EEC, the latter should be repealed.
- (25) The requirements of this Regulation should not apply until all parts of the new legislation on food hygiene have entered into force. It is also appropriate to provide for at least 18 months to elapse between entry into force and the application of the new rules, to allow the affected industries time to adapt.

- (26) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ⁽¹⁾.

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

1. This Regulation lays down general rules for food business operators on the hygiene of foodstuffs, taking particular account of the following principles:
- (a) primary responsibility for food safety rests with the food business operator;
 - (b) it is necessary to ensure food safety throughout the food chain, starting with primary production;
 - (c) it is important, for food that cannot be stored safely at ambient temperatures, particularly frozen food, to maintain the cold chain;
 - (d) general implementation of procedures based on the HACCP principles, together with the application of good hygiene practice, should reinforce food business operators' responsibility;
 - (e) guides to good practice are a valuable instrument to aid food business operators at all levels of the food chain with compliance with food hygiene rules and with the application of the HACCP principles;
 - (f) it is necessary to establish microbiological criteria and temperature control requirements based on a scientific risk assessment;
 - (g) it is necessary to ensure that imported foods are of at least the same hygiene standard as food produced in the Community, or are of an equivalent standard.

This Regulation shall apply to all stages of production, processing and distribution of food and to exports, and without prejudice to more specific requirements relating to food hygiene.

⁽¹⁾ OJ L 184, 17.7.1999, p. 23.

2. This Regulation shall not apply to:
- (a) primary production for private domestic use;
 - (b) the domestic preparation, handling or storage of food for private domestic consumption;
 - (c) the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer;
 - (d) collection centres and tanneries which fall within the definition of food business only because they handle raw material for the production of gelatine or collagen.
3. Member States shall establish, under national law, rules governing the activities referred to in paragraph 2(c). Such national rules shall ensure the achievement of the objectives of this Regulation.
- (i) 'clean water' means clean seawater and fresh water of a similar quality;
 - (j) 'wrapping' means the placing of a foodstuff in a wrapper or container in direct contact with the foodstuff concerned, and the wrapper or container itself;
 - (k) 'packaging' means the placing of one or more wrapped foodstuffs in a second container, and the latter container itself;
 - (l) 'hermetically sealed container' means a container that is designed and intended to be secure against the entry of hazards;
 - (m) 'processing' means any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes;
 - (n) 'unprocessed products' means foodstuffs that have not undergone processing, and includes products that have been divided, parted, severed, sliced, boned, minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep-frozen or thawed;
 - (o) 'processed products' means foodstuffs resulting from the processing of unprocessed products. These products may contain ingredients that are necessary for their manufacture or to give them specific characteristics.

Article 2

Definitions

1. For the purposes of this Regulation:
- (a) 'food hygiene', hereinafter called 'hygiene', means the measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use;
 - (b) 'primary products' means products of primary production including products of the soil, of stock farming, of hunting and fishing;
 - (c) 'establishment' means any unit of a food business;
 - (d) 'competent authority' means the central authority of a Member State competent to ensure compliance with the requirements of this Regulation or any other authority to which that central authority has delegated that competence; it shall also include, where appropriate, the corresponding authority of a third country;
 - (e) 'equivalent' means, in respect of different systems, capable of meeting the same objectives;
 - (f) 'contamination' means the presence or introduction of a hazard;
 - (g) 'potable water' means water meeting the minimum requirements laid down in Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption ⁽¹⁾;
 - (h) 'clean seawater' means natural, artificial or purified seawater or brackish water that does not contain micro-organisms, harmful substances or toxic marine plankton in quantities
2. The definitions laid down in Regulation (EC) No 178/2002 shall also apply.
3. In the Annexes to this Regulation the terms 'where necessary', 'where appropriate', 'adequate' and 'sufficient' shall mean respectively where necessary, where appropriate, adequate or sufficient to achieve the objectives of this Regulation.

CHAPTER II

FOOD BUSINESS OPERATORS' OBLIGATIONS

Article 3

General obligation

Food business operators shall ensure that all stages of production, processing and distribution of food under their control satisfy the relevant hygiene requirements laid down in this Regulation.

⁽¹⁾ OJ L 330, 5.12.1998, p. 32. Directive as amended by Regulation (EC) No 1882/2003.

Article 4

General and specific hygiene requirements

1. Food business operators carrying out primary production and those associated operations listed in Annex I shall comply with the general hygiene provisions laid down in part A of Annex I and any specific requirements provided for in Regulation (EC) No 853/2004.

2. Food business operators carrying out any stage of production, processing and distribution of food after those stages to which paragraph 1 applies shall comply with the general hygiene requirements laid down in Annex II and any specific requirements provided for in Regulation (EC) No 853/2004.

3. Food business operators shall, as appropriate, adopt the following specific hygiene measures:

- (a) compliance with microbiological criteria for foodstuffs;
- (b) procedures necessary to meet targets set to achieve the objectives of this Regulation;
- (c) compliance with temperature control requirements for foodstuffs;
- (d) maintenance of the cold chain;
- (e) sampling and analysis.

4. The criteria, requirements and targets referred to in paragraph 3 shall be adopted in accordance with the procedure referred to in Article 14(2).

Associated sampling and analysis methods shall be laid down in accordance with the same procedure.

5. When this Regulation, Regulation (EC) No 853/2004 and their implementing measures do not specify sampling or analysis methods, food business operators may use appropriate methods laid down in other Community or national legislation or, in the absence of such methods, methods that offer equivalent results to those obtained using the reference method, if they are scientifically validated in accordance with internationally recognised rules or protocols.

6. Food business operators may use the guides provided for in Articles 7, 8 and 9 as an aid to compliance with their obligations under this Regulation.

Article 5

Hazard analysis and critical control points

1. Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.

2. The HACCP principles referred to in paragraph 1 consist of the following:

- (a) identifying any hazards that must be prevented, eliminated or reduced to acceptable levels;
 - (b) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;
 - (c) establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;
 - (d) establishing and implementing effective monitoring procedures at critical control points;
 - (e) establishing corrective actions when monitoring indicates that a critical control point is not under control;
 - (f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively;
- and
- (g) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).

When any modification is made in the product, process, or any step, food business operators shall review the procedure and make the necessary changes to it.

3. Paragraph 1 shall apply only to food business operators carrying out any stage of production, processing and distribution of food after primary production and those associated operations listed in Annex I.

4. Food business operators shall:

- (a) provide the competent authority with evidence of their compliance with paragraph 1 in the manner that the competent authority requires, taking account of the nature and size of the food business;

- (b) ensure that any documents describing the procedures developed in accordance with this Article are up-to-date at all times;
- (c) retain any other documents and records for an appropriate period.

5. Detailed arrangements for the implementation of this Article may be laid down in accordance with the procedure referred to in Article 14(2). Such arrangements may facilitate the implementation of this Article by certain food business operators, in particular by providing for the use of procedures set out in guides for the application of HACCP principles, in order to comply with paragraph 1. Such arrangements may also specify the period during which food business operators shall retain documents and records in accordance with paragraph 4(c).

Article 6

Official controls, registration and approval

1. Food business operators shall cooperate with the competent authorities in accordance with other applicable Community legislation or, if it does not exist, with national law.
2. In particular, every food business operator shall notify the appropriate competent authority, in the manner that the latter requires, of each establishment under its control that carries out any of the stages of production, processing and distribution of food, with a view to the registration of each such establishment.

Food business operators shall also ensure that the competent authority always has up-to-date information on establishments, including by notifying any significant change in activities and any closure of an existing establishment.

3. However, food business operators shall ensure that establishments are approved by the competent authority, following at least one on-site visit, when approval is required:

- (a) under the national law of the Member State in which the establishment is located;
- (b) under Regulation (EC) No 853/2004;

or

- (c) by a decision adopted in accordance with the procedure referred to in Article 14(2).

Any Member State requiring the approval of certain establishments located on its territory under national law, as provided for in subparagraph (a), shall inform the Commission and other Member States of the relevant national rules.

CHAPTER III

GUIDES TO GOOD PRACTICE

Article 7

Development, dissemination and use of guides

Member States shall encourage the development of national guides to good practice for hygiene and for the application of HACCP principles in accordance with Article 8. Community guides shall be developed in accordance with Article 9.

The dissemination and use of both national and Community guides shall be encouraged. Nevertheless, food business operators may use these guides on a voluntary basis.

Article 8

National guides

1. When national guides to good practice are developed, they shall be developed and disseminated by food business sectors:

- (a) in consultation with representatives of parties whose interests may be substantially affected, such as competent authorities and consumer groups;
- (b) having regard to relevant codes of practice of the *Codex Alimentarius*;

and

- (c) when they concern primary production and those associated operations listed in Annex I, having regard to the recommendations set out in Part B of Annex I.

2. National guides may be developed under the aegis of a national standards institute referred to in Annex II to Directive 98/34/EC⁽¹⁾.

3. Member States shall assess national guides in order to ensure that:

- (a) they have been developed in accordance with paragraph 1;
- (b) their contents are practicable for the sectors to which they refer;

and

⁽¹⁾ Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations (OJ L 204, 21.7.1998, p. 37). Directive as last amended by the 2003 Act of Accession.

- (c) they are suitable as guides to compliance with Articles 3, 4 and 5 in the sectors and for the foodstuffs covered.

4. Member States shall forward to the Commission national guides complying with the requirements of paragraph 3. The Commission shall set up and run a registration system for such guides and make it available to Member States.

5. Guides to good practice drawn up pursuant to Directive 93/43/EEC shall continue to apply after the entry into force of this Regulation, provided that they are compatible with its objectives.

Article 9

Community guides

1. Before Community guides to good practice for hygiene or for the application of the HACCP principles are developed, the Commission shall consult the Committee referred to in Article 14. The objective of this consultation shall be to consider the case for such guides, their scope and subject matter.

2. When Community guides are prepared, the Commission shall ensure that they are developed and disseminated:

- (a) by or in consultation with appropriate representatives of European food business sectors, including SMEs, and other interested parties, such as consumer groups;
- (b) in collaboration with parties whose interests may be substantially affected, including competent authorities;
- (c) having regard to relevant codes of practice of the *Codex Alimentarius*;

and

- (d) when they concern primary production and those associated operations listed in Annex I, having regard to the recommendations set out in Part B of Annex I.

3. The Committee referred to in Article 14 shall assess draft Community guides in order to ensure that:

- (a) they have been developed in accordance with paragraph 2;
- (b) their contents are practicable for the sectors to which they refer throughout the Community;

and

- (c) they are suitable as guides to compliance with Articles 3, 4 and 5 in the sectors and for the foodstuffs covered.

4. The Commission shall invite the Committee referred to in Article 14 periodically to review any Community guides prepared in accordance with this Article, in cooperation with the bodies mentioned in paragraph 2.

The aim of this review shall be to ensure that the guides remain practicable and to take account of technological and scientific developments.

5. The titles and references of Community guides prepared in accordance with this Article shall be published in the C series of the *Official Journal of the European Union*.

CHAPTER IV

IMPORTS AND EXPORTS

Article 10

Imports

As regards the hygiene of imported food, the relevant requirements of food law referred to in Article 11 of Regulation (EC) No 178/2002 shall include the requirements laid down in Articles 3 to 6 of this Regulation.

Article 11

Exports

As regards the hygiene of exported or re-exported food, the relevant requirements of food law referred to in Article 12 of Regulation (EC) No 178/2002 shall include the requirements laid down in Articles 3 to 6 of this Regulation.

CHAPTER V

FINAL PROVISIONS

Article 12

Implementing measures and transitional arrangements

Implementing measures and transitional arrangements may be laid down in accordance with the procedure referred to in Article 14(2).

Article 13

Amendment and adaptation of Annexes I and II

1. Annexes I and II may be adapted or updated in accordance with the procedure referred to in Article 14(2), taking into account:

- (a) the need to revise the recommendations set out in Annex I, Part B, paragraph 2;

- (b) the experience gained from the implementation of HACCP-based systems pursuant to Article 5;
- (c) technological developments and their practical consequences and consumer expectations with regard to food composition;
- (d) scientific advice, particularly new risk assessments;
- (e) microbiological and temperature criteria for foodstuffs.

2. Derogations from Annexes I and II may be granted, in particular in order to facilitate the implementation of Article 5 for small businesses, in accordance with the procedure referred to in Article 14(2), taking into account the relevant risk factors, provided that such derogations do not affect the achievement of the objectives of this Regulation.

3. Member States may, without compromising achievement of the objectives of this Regulation, adopt, in accordance with paragraphs 4 to 7 of this Article, national measures adapting the requirements laid down in Annex II.

- 4. (a) The national measures referred to in paragraph 3 shall have the aim of:
 - (i) enabling the continued use of traditional methods, at any of the stages of production, processing or distribution of food;

or

 - (ii) accommodating the needs of food businesses situated in regions that are subject to special geographical constraints.
- (b) In other cases, they shall apply only to the construction, layout and equipment of establishments.

5. Any Member State wishing to adopt national measures as referred to in paragraph 3 shall notify the Commission and other Member States. The notification shall:

- (a) provide a detailed description of the requirements that that Member State considers need to be adapted and the nature of the adaptation sought;
- (b) describe the foodstuffs and establishments concerned;
- (c) explain the reasons for the adaptation, including, where relevant, by providing a summary of the hazard analysis carried out and any measures to be taken to ensure that the adaptation will not compromise the objectives of this Regulation;

and

- (d) give any other relevant information.

6. The other Member States shall have three months from the receipt of a notification referred to in paragraph 5 to send written comments to the Commission. In the case of the adaptations arising from paragraph 4(b), this period shall, at the request of any Member State, be extended to four months. The Commission may, and when it receives written comments from one or more Member States shall, consult Member States within the committee referred to in Article 14(1). The Commission may decide, in accordance with the procedure referred to in Article 14(2), whether the envisaged measures may be implemented, subject, if necessary, to appropriate amendments. Where appropriate, the Commission may propose general measures in accordance with paragraph 1 or 2.

7. A Member State may adopt national measures adapting the requirements of Annex II only:

- (a) in compliance with a decision adopted in accordance with paragraph 6;

or

- (b) if, one month after the expiry of the period referred to in paragraph 6, the Commission has not informed Member States that it has received written comments or that it intends to propose the adoption of a decision in accordance with paragraph 6.

Article 14

Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its Rules of Procedure.

Article 15

Consultation of the European Food Safety Authority

The Commission shall consult the European Food Safety Authority on any matter falling within the scope of this Regulation that could have a significant impact on public health and, in particular, before proposing criteria, requirements or targets in accordance with Article 4(4).

Article 16**Report to the European Parliament and the Council**

1. The Commission shall, not later than 20 May 2009, submit a report to the European Parliament and the Council.
2. The report shall, in particular, review the experience gained from the application of this Regulation and consider whether it would be desirable and practicable to provide for the extension of the requirements of Article 5 to food business operators carrying out primary production and those associated operations listed in Annex I.
3. The Commission shall, if appropriate, accompany the report with relevant proposals.

Article 17**Repeal**

1. Directive 93/43/EEC shall be repealed with effect from the date of application of this Regulation.
2. References to the repealed Directive shall be construed as being made to this Regulation.
3. However, decisions adopted pursuant to Articles 3(3) and 10 of Directive 93/43/EEC shall remain in force pending their replacement by decisions adopted in accordance with this Regulation or Regulation (EC) No 178/2002. Pending the setting of the criteria or requirements referred to in Article 4(3)(a) to (e) of this Regulation, Member States may maintain any national rules establishing such criteria or requirements that they had adopted in accordance with Directive 93/43/EEC.

4. Pending the application of new Community legislation laying down rules for official controls on food, Member States shall take all appropriate measures to ensure the fulfilment of the obligations laid down in or under this Regulation.

Article 18**Entry into force**

This Regulation shall enter into force on the 20th day after that of its publication in the *Official Journal of the European Union*.

It shall apply 18 months after the date on which all of the following acts have entered into force:

- (a) Regulation (EC) No 853/2004;
- (b) Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption ⁽¹⁾;
- and
- (c) Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption ⁽²⁾.

However, it shall apply no earlier than 1 January 2006.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 29 April 2004.

For the European Parliament
The President
P. COX

For the Council
The President
P. M. McDOWELL

⁽¹⁾ See page 83 of this Official Journal.

⁽²⁾ OJ L 157, 30.4.2004, p. 33.

ANNEX I

PRIMARY PRODUCTION

PART A: GENERAL HYGIENE PROVISIONS FOR PRIMARY PRODUCTION AND ASSOCIATED OPERATIONS

I. *Scope*

1. This Annex applies to primary production and the following associated operations:
 - (a) the transport, storage and handling of primary products at the place of production, provided that this does not substantially alter their nature;
 - (c) the transport of live animals, where this is necessary to achieve the objectives of this Regulation;and
 - (c) in the case of products of plant origin, fishery products and wild game, transport operations to deliver primary products, the nature of which has not been substantially altered, from the place of production to an establishment.

II. *Hygiene provisions*

2. As far as possible, food business operators are to ensure that primary products are protected against contamination, having regard to any processing that primary products will subsequently undergo.
3. Notwithstanding the general duty laid down in paragraph 2, food business operators are to comply with appropriate Community and national legislative provisions relating to the control of hazards in primary production and associated operations, including:
 - (a) measures to control contamination arising from the air, soil, water, feed, fertilisers, veterinary medicinal products, plant protection products and biocides and the storage, handling and disposal of waste;and
 - (b) measures relating to animal health and welfare and plant health that have implications for human health, including programmes for the monitoring and control of zoonoses and zoonotic agents.
4. Food business operators rearing, harvesting or hunting animals or producing primary products of animal origin are to take adequate measures, as appropriate:
 - (a) to keep any facilities used in connection with primary production and associated operations, including facilities used to store and handle feed, clean and, where necessary after cleaning, to disinfect them in an appropriate manner;
 - (b) to keep clean and, where necessary after cleaning, to disinfect, in an appropriate manner, equipment, containers, crates, vehicles and vessels;
 - (c) as far as possible to ensure the cleanliness of animals going to slaughter and, where necessary, production animals;
 - (d) to use potable water, or clean water, whenever necessary to prevent contamination;
 - (e) to ensure that staff handling foodstuffs are in good health and undergo training on health risks;
 - (f) as far as possible to prevent animals and pests from causing contamination;

- (g) to store and handle waste and hazardous substances so as to prevent contamination;
 - (h) to prevent the introduction and spread of contagious diseases transmissible to humans through food, including by taking precautionary measures when introducing new animals and reporting suspected outbreaks of such diseases to the competent authority;
 - (i) to take account of the results of any relevant analyses carried out on samples taken from animals or other samples that have importance to human health;
 - and
 - (j) to use feed additives and veterinary medicinal products correctly, as required by the relevant legislation.
5. Food business operators producing or harvesting plant products are to take adequate measures, as appropriate:
- (a) to keep clean and, where necessary after cleaning, to disinfect, in an appropriate manner, facilities, equipment, containers, crates, vehicles and vessels;
 - (b) to ensure, where necessary, hygienic production, transport and storage conditions for, and the cleanliness of, plant products;
 - (c) to use potable water, or clean water, whenever necessary to prevent contamination;
 - (d) to ensure that staff handling foodstuffs are in good health and undergo training on health risks;
 - (e) as far as possible to prevent animals and pests from causing contamination;
 - (f) to store and handle wastes and hazardous substances so as to prevent contamination;
 - (g) to take account of the results of any relevant analyses carried out on samples taken from plants or other samples that have importance to human health;
 - and
 - (h) to use plant protection products and biocides correctly, as required by the relevant legislation.
6. Food business operators are to take appropriate remedial action when informed of problems identified during official controls.

III. *Record-keeping*

7. Food business operators are to keep and retain records relating to measures put in place to control hazards in an appropriate manner and for an appropriate period, commensurate with the nature and size of the food business. Food business operators are to make relevant information contained in these records available to the competent authority and receiving food business operators on request.
8. Food business operators rearing animals or producing primary products of animal origin are, in particular, to keep records on:
- (a) the nature and origin of feed fed to the animals;
 - (b) veterinary medicinal products or other treatments administered to the animals, dates of administration and withdrawal periods;
 - (c) the occurrence of diseases that may affect the safety of products of animal origin;

- (d) the results of any analyses carried out on samples taken from animals or other samples taken for diagnostic purposes, that have importance for human health;
 - and
 - (e) any relevant reports on checks carried out on animals or products of animal origin.
9. Food business operators producing or harvesting plant products are, in particular, to keep records on:
- (a) any use of plant protection products and biocides;
 - (b) any occurrence of pests or diseases that may affect the safety of products of plant origin;
 - and
 - (c) the results of any relevant analyses carried out on samples taken from plants or other samples that have importance to human health.
10. The food business operators may be assisted by other persons, such as veterinarians, agronomists and farm technicians, with the keeping of records.

PART B: RECOMMENDATIONS FOR GUIDES TO GOOD HYGIENE PRACTICE

1. National and Community guides referred to in Articles 7 to 9 of this Regulation should contain guidance on good hygiene practice for the control of hazards in primary production and associated operations.
 2. Guides to good hygiene practice should include appropriate information on hazards that may arise in primary production and associated operations and actions to control hazards, including relevant measures set out in Community and national legislation or national and Community programmes. Examples of such hazards and measures may include:
 - (a) the control of contamination such as mycotoxins, heavy metals and radioactive material;
 - (b) the use of water, organic waste and fertilisers;
 - (c) the correct and appropriate use of plant protection products and biocides and their traceability;
 - (d) the correct and appropriate use of veterinary medicinal products and feed additives and their traceability;
 - (e) the preparation, storage, use and traceability of feed;
 - (f) the proper disposal of dead animals, waste and litter;
 - (g) protective measures to prevent the introduction of contagious diseases transmissible to humans through food, and any obligation to notify the competent authority;
 - (h) procedures, practices and methods to ensure that food is produced, handled, packed, stored and transported under appropriate hygienic conditions, including effective cleaning and pest-control;
 - (i) measures relating to the cleanliness of slaughter and production animals;
 - (j) measures relating to record-keeping.
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ANNEX II

**GENERAL HYGIENE REQUIREMENTS FOR ALL FOOD BUSINESS OPERATORS
(EXCEPT WHEN ANNEX I APPLIES)**

INTRODUCTION

Chapters V to XII apply to all stages of production, processing and distribution of food and the remaining Chapters apply as follows:

- Chapter I applies to all food premises, except premises to which Chapter III applies
- Chapter II applies to all rooms where food is prepared, treated or processed, except dining areas and premises to which Chapter III applies
- Chapter III applies to those premises listed in the heading to the Chapter
- Chapter IV applies to all transportation.

CHAPTER I

General requirements for food premises (other than those specified in chapter iii)

1. Food premises are to be kept clean and maintained in good repair and condition.
2. The layout, design, construction, siting and size of food premises are to:
 - (a) permit adequate maintenance, cleaning and/or disinfection, avoid or minimise air-borne contamination, and provide adequate working space to allow for the hygienic performance of all operations;
 - (b) be such as to protect against the accumulation of dirt, contact with toxic materials, the shedding of particles into food and the formation of condensation or undesirable mould on surfaces;
 - (c) permit good food hygiene practices, including protection against contamination and, in particular, pest control;and
 - (d) where necessary, provide suitable temperature-controlled handling and storage conditions of sufficient capacity for maintaining foodstuffs at appropriate temperatures and designed to allow those temperatures to be monitored and, where necessary, recorded.
3. An adequate number of flush lavatories are to be available and connected to an effective drainage system. Lavatories are not to open directly into rooms in which food is handled.
4. An adequate number of washbasins is to be available, suitably located and designated for cleaning hands. Washbasins for cleaning hands are to be provided with hot and cold running water, materials for cleaning hands and for hygienic drying. Where necessary, the facilities for washing food are to be separate from the hand-washing facility.
5. There is to be suitable and sufficient means of natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area is to be avoided. Ventilation systems are to be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.
6. Sanitary conveniences are to have adequate natural or mechanical ventilation.

7. Food premises are to have adequate natural and/or artificial lighting.
8. Drainage facilities are to be adequate for the purpose intended. They are to be designed and constructed to avoid the risk of contamination. Where drainage channels are fully or partially open, they are to be so designed as to ensure that waste does not flow from a contaminated area towards or into a clean area, in particular an area where foods likely to present a high risk to the final consumer are handled.
9. Where necessary, adequate changing facilities for personnel are to be provided.
10. Cleaning agents and disinfectants are not to be stored in areas where food is handled.

CHAPTER II

Specific requirements in rooms where foodstuffs are prepared, treated or processed (excluding dining areas and those premises specified in chapter III)

1. In rooms where food is prepared, treated or processed (excluding dining areas and those premises specified in Chapter III, but including rooms contained in means of transport) the design and layout are to permit good food hygiene practices, including protection against contamination between and during operations. In particular:
 - (a) floor surfaces are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials unless food business operators can satisfy the competent authority that other materials used are appropriate. Where appropriate, floors are to allow adequate surface drainage;
 - (b) wall surfaces are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials and require a smooth surface up to a height appropriate for the operations unless food business operators can satisfy the competent authority that other materials used are appropriate;
 - (c) ceilings (or, where there are no ceilings, the interior surface of the roof) and overhead fixtures are to be constructed and finished so as to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable mould and the shedding of particles;
 - (d) windows and other openings are to be constructed to prevent the accumulation of dirt. Those which can be opened to the outside environment are, where necessary, to be fitted with insect-proof screens which can be easily removed for cleaning. Where open windows would result in contamination, windows are to remain closed and fixed during production;
 - (e) doors are to be easy to clean and, where necessary, to disinfect. This will require the use of smooth and non-absorbent surfaces unless food business operators can satisfy the competent authority that other materials used are appropriate;and
 - (f) surfaces (including surfaces of equipment) in areas where foods are handled and in particular those in contact with food are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of smooth, washable corrosion-resistant and non-toxic materials, unless food business operators can satisfy the competent authority that other materials used are appropriate.
2. Adequate facilities are to be provided, where necessary, for the cleaning, disinfecting and storage of working utensils and equipment. These facilities are to be constructed of corrosion-resistant materials, be easy to clean and have an adequate supply of hot and cold water.

3. Adequate provision is to be made, where necessary, for washing food. Every sink or other such facility provided for the washing of food is to have an adequate supply of hot and/or cold potable water consistent with the requirements of Chapter VII and be kept clean and, where necessary, disinfected.

CHAPTER III

Requirements for movable and/or temporary premises (such as marquees, market stalls, mobile sales vehicles), premises used primarily as a private dwelling-house but where foods are regularly prepared for placing on the market and vending machines

1. Premises and vending machines are, so far as is reasonably practicable, to be so sited, designed, constructed and kept clean and maintained in good repair and condition as to avoid the risk of contamination, in particular by animals and pests.
2. In particular, where necessary:
 - (a) appropriate facilities are to be available to maintain adequate personal hygiene (including facilities for the hygienic washing and drying of hands, hygienic sanitary arrangements and changing facilities);
 - (b) surfaces in contact with food are to be in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of smooth, washable, corrosion-resistant and non-toxic materials, unless food business operators can satisfy the competent authority that other materials used are appropriate;
 - (c) adequate provision is to be made for the cleaning and, where necessary, disinfecting of working utensils and equipment;
 - (d) where foodstuffs are cleaned as part of the food business' operations, adequate provision is to be made for this to be undertaken hygienically;
 - (e) an adequate supply of hot and/or cold potable water is to be available;
 - (f) adequate arrangements and/or facilities for the hygienic storage and disposal of hazardous and/or inedible substances and waste (whether liquid or solid) are to be available;
 - (g) adequate facilities and/or arrangements for maintaining and monitoring suitable food temperature conditions are to be available;
 - (h) foodstuffs are to be so placed as to avoid the risk of contamination so far as is reasonably practicable.

CHAPTER IV

Transport

1. Conveyances and/or containers used for transporting foodstuffs are to be kept clean and maintained in good repair and condition to protect foodstuffs from contamination and are, where necessary, to be designed and constructed to permit adequate cleaning and/or disinfection.
2. Receptacles in vehicles and/or containers are not to be used for transporting anything other than foodstuffs where this may result in contamination.
3. Where conveyances and/or containers are used for transporting anything in addition to foodstuffs or for transporting different foodstuffs at the same time, there is, where necessary, to be effective separation of products.

4. Bulk foodstuffs in liquid, granulate or powder form are to be transported in receptacles and/or containers/tankers reserved for the transport of foodstuffs. Such containers are to be marked in a clearly visible and indelible fashion, in one or more Community languages, to show that they are used for the transport of foodstuffs, or are to be marked 'for foodstuffs only'.
5. Where conveyances and/or containers have been used for transporting anything other than foodstuffs or for transporting different foodstuffs, there is to be effective cleaning between loads to avoid the risk of contamination.
6. Foodstuffs in conveyances and/or containers are to be so placed and protected as to minimise the risk of contamination.
7. Where necessary, conveyances and/or containers used for transporting foodstuffs are to be capable of maintaining foodstuffs at appropriate temperatures and allow those temperatures to be monitored.

CHAPTER V

Equipment requirements

1. All articles, fittings and equipment with which food comes into contact are to:
 - (a) be effectively cleaned and, where necessary, disinfected. Cleaning and disinfection are to take place at a frequency sufficient to avoid any risk of contamination;
 - (b) be so constructed, be of such materials and be kept in such good order, repair and condition as to minimise any risk of contamination;
 - (c) with the exception of non-returnable containers and packaging, be so constructed, be of such materials and be kept in such good order, repair and condition as to enable them to be kept clean and, where necessary, to be disinfected;and
 - (d) be installed in such a manner as to allow adequate cleaning of the equipment and the surrounding area.
2. Where necessary, equipment is to be fitted with any appropriate control device to guarantee fulfilment of this Regulation's objectives.
3. Where chemical additives have to be used to prevent corrosion of equipment and containers, they are to be used in accordance with good practice.

CHAPTER VI

Food waste

1. Food waste, non-edible by-products and other refuse are to be removed from rooms where food is present as quickly as possible, so as to avoid their accumulation.
2. Food waste, non-edible by-products and other refuse are to be deposited in closable containers, unless food business operators can demonstrate to the competent authority that other types of containers or evacuation systems used are appropriate. These containers are to be of an appropriate construction, kept in sound condition, be easy to clean and, where necessary, to disinfect.
3. Adequate provision is to be made for the storage and disposal of food waste, non-edible by-products and other refuse. Refuse stores are to be designed and managed in such a way as to enable them to be kept clean and, where necessary, free of animals and pests.
4. All waste is to be eliminated in a hygienic and environmentally friendly way in accordance with Community legislation applicable to that effect, and is not to constitute a direct or indirect source of contamination.

CHAPTER VII

Water supply

1. (a) There is to be an adequate supply of potable water, which is to be used whenever necessary to ensure that foodstuffs are not contaminated;
- (b) Clean water may be used with whole fishery products. Clean seawater may be used with live bivalve molluscs, echinoderms, tunicates and marine gastropods; clean water may also be used for external washing. When such water is used, adequate facilities are to be available for its supply.
2. Where non-potable water is used, for example for fire control, steam production, refrigeration and other similar purposes, it is to circulate in a separate duly identified system. Non-potable water is not to connect with, or allow reflux into, potable water systems.
3. Recycled water used in processing or as an ingredient is not to present a risk of contamination. It is to be of the same standard as potable water, unless the competent authority is satisfied that the quality of the water cannot affect the wholesomeness of the foodstuff in its finished form.
4. Ice which comes into contact with food or which may contaminate food is to be made from potable water or, when used to chill whole fishery products, clean water. It is to be made, handled and stored under conditions that protect it from contamination.
5. Steam used directly in contact with food is not to contain any substance that presents a hazard to health or is likely to contaminate the food.
6. Where heat treatment is applied to foodstuffs in hermetically sealed containers it is to be ensured that water used to cool the containers after heat treatment is not a source of contamination for the foodstuff.

CHAPTER VIII

Personal hygiene

1. Every person working in a food-handling area is to maintain a high degree of personal cleanliness and is to wear suitable, clean and, where necessary, protective clothing.
2. No person suffering from, or being a carrier of a disease likely to be transmitted through food or afflicted, for example, with infected wounds, skin infections, sores or diarrhoea is to be permitted to handle food or enter any food-handling area in any capacity if there is any likelihood of direct or indirect contamination. Any person so affected and employed in a food business and who is likely to come into contact with food is to report immediately the illness or symptoms, and if possible their causes, to the food business operator.

CHAPTER IX

Provisions applicable to foodstuffs

1. A food business operator is not to accept raw materials or ingredients, other than live animals, or any other material used in processing products, if they are known to be, or might reasonably be expected to be, contaminated with parasites, pathogenic microorganisms or toxic, decomposed or foreign substances to such an extent that, even after the food business operator had hygienically applied normal sorting and/or preparatory or processing procedures, the final product would be unfit for human consumption.
2. Raw materials and all ingredients stored in a food business are to be kept in appropriate conditions designed to prevent harmful deterioration and protect them from contamination.

3. At all stages of production, processing and distribution, food is to be protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state.
4. Adequate procedures are to be in place to control pests. Adequate procedures are also to be in place to prevent domestic animals from having access to places where food is prepared, handled or stored (or, where the competent authority so permits in special cases, to prevent such access from resulting in contamination).
5. Raw materials, ingredients, intermediate products and finished products likely to support the reproduction of pathogenic micro-organisms or the formation of toxins are not to be kept at temperatures that might result in a risk to health. The cold chain is not to be interrupted. However, limited periods outside temperature control are permitted, to accommodate the practicalities of handling during preparation, transport, storage, display and service of food, provided that it does not result in a risk to health. Food businesses manufacturing, handling and wrapping processed foodstuffs are to have suitable rooms, large enough for the separate storage of raw materials from processed material and sufficient separate refrigerated storage.
6. Where foodstuffs are to be held or served at chilled temperatures they are to be cooled as quickly as possible following the heat-processing stage, or final preparation stage if no heat process is applied, to a temperature which does not result in a risk to health.
7. The thawing of foodstuffs is to be undertaken in such a way as to minimise the risk of growth of pathogenic micro-organisms or the formation of toxins in the foods. During thawing, foods are to be subjected to temperatures that would not result in a risk to health. Where run-off liquid from the thawing process may present a risk to health it is to be adequately drained. Following thawing, food is to be handled in such a manner as to minimise the risk of growth of pathogenic microorganisms or the formation of toxins.
8. Hazardous and/or inedible substances, including animal feed, are to be adequately labelled and stored in separate and secure containers.

CHAPTER X

Provisions applicable to the wrapping and packaging of foodstuffs

1. Material used for wrapping and packaging are not to be a source of contamination.
2. Wrapping materials are to be stored in such a manner that they are not exposed to a risk of contamination.
3. Wrapping and packaging operations are to be carried out so as to avoid contamination of the products. Where appropriate and in particular in the case of cans and glass jars, the integrity of the container's construction and its cleanliness is to be assured.
4. Wrapping and packaging material re-used for foodstuffs is to be easy to clean and, where necessary, to disinfect.

CHAPTER XI

Heat treatment

The following requirements apply only to food placed on the market in hermetically sealed containers:

1. any heat treatment process used to process an unprocessed product or to process further a processed product is:
 - (a) to raise every party of the product treated to a given temperature for a given period of time;
 - and
 - (b) to prevent the product from becoming contaminated during the process;

2. to ensure that the process employed achieves the desired objectives, food business operators are to check regularly the main relevant parameters (particularly temperature, pressure, sealing and microbiology), including by the use of automatic devices;
3. the process used should conform to an internationally recognised standard (for example, pasteurisation, ultra high temperature or sterilisation).

CHAPTER XII

Training

Food business operators are to ensure:

1. that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity;
 2. that those responsible for the development and maintenance of the procedure referred to in Article 5(1) of this Regulation or for the operation of relevant guides have received adequate training in the application of the HACCP principles;
- and
3. compliance with any requirements of national law concerning training programmes for persons working in certain food sectors.
-

I

(Acts whose publication is obligatory)

**REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 28 January 2002**

**laying down the general principles and requirements of food law, establishing the European Food
Safety Authority and laying down procedures in matters of food safety**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE
EUROPEAN UNION,

Having regard to the Treaty establishing the European
Community, and in particular Articles 37, 95, 133 and Article
152(4)(b) thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the opinion of the Economic and Social
Committee ⁽²⁾,

Having regard to the opinion of the Committee of the
Regions ⁽³⁾,

Acting in accordance with the procedure laid down in Article
251 of the Treaty ⁽⁴⁾,

Whereas:

- (1) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.
- (2) A high level of protection of human life and health should be assured in the pursuit of Community policies.
- (3) The free movement of food and feed within the Community can be achieved only if food and feed safety requirements do not differ significantly from Member State to Member State.
- (4) There are important differences in relation to concepts, principles and procedures between the food laws of

the Member States. When Member States adopt measures governing food, these differences may impede the free movement of food, create unequal conditions of competition, and may thereby directly affect the functioning of the internal market.

- (5) Accordingly, it is necessary to approximate these concepts, principles and procedures so as to form a common basis for measures governing food and feed taken in the Member States and at Community level. It is however necessary to provide for sufficient time for the adaptation of any conflicting provisions in existing legislation, both at national and Community level, and to provide that, pending such adaptation, the relevant legislation be applied in the light of the principles set out in the present Regulation.
- (6) Water is ingested directly or indirectly like other foods, thereby contributing to the overall exposure of a consumer to ingested substances, including chemical and microbiological contaminants. However, as the quality of water intended for human consumption is already controlled by Council Directives 80/778/EEC ⁽⁵⁾ and 98/83/EC ⁽⁶⁾, it suffices to consider water after the point of compliance referred to in Article 6 of Directive 98/83/EC.
- (7) Within the context of food law it is appropriate to include requirements for feed, including its production and use where that feed is intended for food-producing animals. This is without prejudice to the similar requirements which have been applied so far and which will be applied in the future in feed legislation applicable to all animals, including pets.
- (8) The Community has chosen a high level of health protection as appropriate in the development of food law, which it applies in a non-discriminatory manner whether food or feed is traded on the internal market or internationally.

⁽¹⁾ OJ C 96 E, 27.3.2001, p. 247.

⁽²⁾ OJ C 155, 29.5.2001, p. 32.

⁽³⁾ Opinion delivered on 14 June 2001 (not yet published in the Official Journal).

⁽⁴⁾ Opinion of the European Parliament of 12 June 2001 (not yet published in the Official Journal), Council Common Position of 17 September 2001 (not yet published in the Official Journal) and Decision of the European Parliament of 11 December 2001 (not yet published in the Official Journal). Council Decision of 21 January 2002.

⁽⁵⁾ OJ L 229, 30.8.1980, p. 11. Directive repealed by Directive 98/83/EC.

⁽⁶⁾ OJ L 330, 5.12.1998, p. 32.

- (9) It is necessary to ensure that consumers, other stakeholders and trading partners have confidence in the decision-making processes underpinning food law, its scientific basis and the structures and independence of the institutions protecting health and other interests.
- (10) Experience has shown that it is necessary to adopt measures aimed at guaranteeing that unsafe food is not placed on the market and at ensuring that systems exist to identify and respond to food safety problems in order to ensure the proper functioning of the internal market and to protect human health. Similar issues relating to feed safety should be addressed.
- (11) In order to take a sufficiently comprehensive and integrated approach to food safety, there should be a broad definition of food law covering a wide range of provisions with a direct or indirect effect on the safety of food and feed, including provisions on materials and articles in contact with food, animal feed and other agricultural inputs at the level of primary production.
- (12) In order to ensure the safety of food, it is necessary to consider all aspects of the food production chain as a continuum from and including primary production and the production of animal feed up to and including sale or supply of food to the consumer because each element may have a potential impact on food safety.
- (13) Experience has shown that for this reason it is necessary to consider the production, manufacture, transport and distribution of feed given to food-producing animals, including the production of animals which may be used as feed on fish farms, since the inadvertent or deliberate contamination of feed, and adulteration or fraudulent or other bad practices in relation to it, may give rise to a direct or indirect impact on food safety.
- (14) For the same reason, it is necessary to consider other practices and agricultural inputs at the level of primary production and their potential effect on the overall safety of food.
- (15) Networking of laboratories of excellence, at regional and/or interregional level, with the aim of ensuring continuous monitoring of food safety, could play an important role in the prevention of potential health risks for citizens.
- (16) Measures adopted by the Member States and the Community governing food and feed should generally be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.
- Recourse to a risk analysis prior to the adoption of such measures should facilitate the avoidance of unjustified barriers to the free movement of foodstuffs.
- (17) Where food law is aimed at the reduction, elimination or avoidance of a risk to health, the three interconnected components of risk analysis — risk assessment, risk management, and risk communication — provide a systematic methodology for the determination of effective, proportionate and targeted measures or other actions to protect health.
- (18) In order for there to be confidence in the scientific basis for food law, risk assessments should be undertaken in an independent, objective and transparent manner, on the basis of the available scientific information and data.
- (19) It is recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls.
- (20) The precautionary principle has been invoked to ensure health protection in the Community, thereby giving rise to barriers to the free movement of food or feed. Therefore it is necessary to adopt a uniform basis throughout the Community for the use of this principle.
- (21) In those specific circumstances where a risk to life or health exists but scientific uncertainty persists, the precautionary principle provides a mechanism for determining risk management measures or other actions in order to ensure the high level of health protection chosen in the Community.
- (22) Food safety and the protection of consumer's interests is of increasing concern to the general public, non-governmental organisations, professional associations, international trading partners and trade organisations. It is necessary to ensure that consumer confidence and the confidence of trading partners is secured through the open and transparent development of food law and through public authorities taking the appropriate steps to inform the public where there are reasonable grounds to suspect that a food may present a risk to health.

- (23) The safety and confidence of consumers within the Community, and in third countries, are of paramount importance. The Community is a major global trader in food and feed and, in this context, it has entered into international trade agreements, it contributes to the development of international standards which underpin food law, and it supports the principles of free trade in safe feed and safe, wholesome food in a non-discriminatory manner, following fair and ethical trading practices.
- (24) It is necessary to ensure that food and feed exported or re-exported from the Community complies with Community law or the requirements set up by the importing country. In other circumstances, food and feed can only be exported or re-exported if the importing country has expressly agreed. However, it is necessary to ensure that even where there is agreement of the importing country, food injurious to health or unsafe feed is not exported or re-exported.
- (25) It is necessary to establish the general principles upon which food and feed may be traded and the objectives and principles for the contribution of the Community to developing international standards and trade agreements.
- (26) Some Member States have adopted horizontal legislation on food safety imposing, in particular, a general obligation on economic operators to market only food that is safe. However, these Member States apply different basic criteria for establishing whether a food is safe. Given these different approaches, and in the absence of horizontal legislation in other Member States, barriers to trade in foods are liable to arise. Similarly such barriers may arise to trade in feed.
- (27) It is therefore necessary to establish general requirements for only safe food and feed to be placed on the market, to ensure that the internal market in such products functions effectively.
- (28) Experience has shown that the functioning of the internal market in food or feed can be jeopardised where it is impossible to trace food and feed. It is therefore necessary to establish a comprehensive system of traceability within food and feed businesses so that targeted and accurate withdrawals can be undertaken or information given to consumers or control officials, thereby avoiding the potential for unnecessary wider disruption in the event of food safety problems.
- (29) It is necessary to ensure that a food or feed business including an importer can identify at least the business from which the food, feed, animal or substance that may be incorporated into a food or feed has been supplied, to ensure that on investigation, traceability can be assured at all stages.
- (30) A food business operator is best placed to devise a safe system for supplying food and ensuring that the food it supplies is safe; thus, it should have primary legal responsibility for ensuring food safety. Although this principle exists in some Member States and areas of food law, in other areas this is either not explicit or else responsibility is assumed by the competent authorities of the Member State through the control activities they carry out. Such disparities are liable to create barriers to trade and distort competition between food business operators in different Member States.
- (31) Similar requirements should apply to feed and feed business operators.
- (32) The scientific and technical basis of Community legislation relating to the safety of food and feed should contribute to the achievement of a high level of health protection within the Community. The Community should have access to high-quality, independent and efficient scientific and technical support.
- (33) The scientific and technical issues in relation to food and feed safety are becoming increasingly important and complex. The establishment of a European Food Safety Authority, hereinafter referred to as 'the Authority', should reinforce the present system of scientific and technical support which is no longer able to respond to increasing demands on it.
- (34) Pursuant to the general principles of food law, the Authority should take on the role of an independent scientific point of reference in risk assessment and in so doing should assist in ensuring the smooth functioning of the internal market. It may be called upon to give opinions on contentious scientific issues, thereby enabling the Community institutions and Member States to take informed risk management decisions necessary to ensure food and feed safety whilst helping avoid the fragmentation of the internal market through the adoption of unjustified or unnecessary obstacles to the free movement of food and feed.
- (35) The Authority should be an independent scientific source of advice, information and risk communication in order to improve consumer confidence; nevertheless, in order to promote coherence between the risk assessment, risk management and risk communication functions, the link between risk assessors and risk managers should be strengthened.

- (36) The Authority should provide a comprehensive independent scientific view of the safety and other aspects of the whole food and feed supply chains, which implies wide-ranging responsibilities for the Authority. These should include issues having a direct or indirect impact on the safety of the food and feed supply chains, animal health and welfare, and plant health. However, it is necessary to ensure that the Authority focuses on food safety, so its mission in relation to animal health, animal welfare and plant health issues that are not linked to the safety of the food supply chain should be limited to the provision of scientific opinions. The Authority's mission should also cover scientific advice and scientific and technical support on human nutrition in relation to Community legislation and assistance to the Commission at its request on communication linked to Community health programmes.
- (37) Since some products authorised under food law such as pesticides or additives in animal feed may involve risks to the environment or to the safety of workers, some environmental and worker protection aspects should also be assessed by the Authority in accordance with the relevant legislation.
- (38) In order to avoid duplicated scientific assessments and related scientific opinions on genetically modified organisms (GMOs), the Authority should also provide scientific opinions on products other than food and feed relating to GMOs as defined by Directive 2001/18/EC⁽¹⁾ and without prejudice to the procedures established therein.
- (39) The Authority should contribute through the provision of support on scientific matters, to the Community's and Member States' role in the development and establishment of international food safety standards and trade agreements.
- (40) The confidence of the Community institutions, the general public and interested parties in the Authority is essential. For this reason, it is vital to ensure its independence, high scientific quality, transparency and efficiency. Cooperation with Member States is also indispensable.
- (41) To that effect the Management Board should be appointed in such a way as to secure the highest standard of competence, a broad range of relevant expertise, for instance in management and in public administration, and the broadest possible geographic distribution within the Union. This should be facilitated by a rotation of the different countries of origin of the members of the Management Board without any post being reserved for nationals of any specific Member State.
- (42) The Authority should have the means to perform all the tasks required to enable it to carry out its role.
- (43) The Management Board should have the necessary powers to establish the budget, check its implementation, draw up internal rules, adopt financial regulations, appoint members of the Scientific Committee and Scientific Panels and appoint the Executive Director.
- (44) The Authority should cooperate closely with competent bodies in the Member States if it is to operate effectively. An Advisory Forum should be created in order to advise the Executive Director, to constitute a mechanism of exchange of information, and to ensure close cooperation in particular with regard to the networking system. Cooperation and appropriate exchange of information should also minimise the potential for diverging scientific opinions.
- (45) The Authority should take over the role of the Scientific Committees attached to the Commission in issuing scientific opinions in its field of competence. It is necessary to reorganise these Committees to ensure greater scientific consistency in relation to the food supply chain and to enable them to work more effectively. A Scientific Committee and Permanent Scientific Panels should therefore be set up within the Authority to provide these opinions.
- (46) In order to guarantee independence, members of the Scientific Committee and Panels should be independent scientists recruited on the basis of an open application procedure.
- (47) The Authority's role as an independent scientific point of reference means that a scientific opinion may be requested not only by the Commission, but also by the European Parliament and the Member States. In order to ensure the manageability and consistency of the process of scientific advice, the Authority should be able to refuse or amend a request providing justification for this and on the basis of predetermined criteria. Steps should also be taken to help avoid diverging scientific opinions and, in the event of diverging scientific opinions between scientific bodies, procedures should be in place to resolve the divergence or provide the risk managers with a transparent basis of scientific information.
- ⁽¹⁾ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

- (48) The Authority should also be able to commission scientific studies necessary for the accomplishment of its duties, while ensuring that the links established by it with the Commission and the Member States prevent duplication of effort. It should be done in an open and transparent fashion and the Authority should take into account existing Community expertise and structures.
- (49) The lack of an effective system of collection and analysis at Community level of data on the food supply chain is recognised as a major shortcoming. A system for the collection and analysis of relevant data in the fields covered by the Authority should therefore be set up, in the form of a network coordinated by the Authority. A review of Community data collection networks already existing in the fields covered by the Authority is called for.
- (50) Improved identification of emerging risks may in the long term be a major preventive instrument at the disposal of the Member States and the Community in the exercise of its policies. It is therefore necessary to assign to the Authority an anticipatory task of collecting information and exercising vigilance and providing evaluation of and information on emerging risks with a view to their prevention.
- (51) The establishment of the Authority should enable Member States to become more closely involved in scientific procedures. There should therefore be close cooperation between the Authority and the Member States for this purpose. In particular, the Authority should be able to assign certain tasks to organisations in the Member States.
- (52) It is necessary to ensure that a balance is struck between the need to use national organisations to carry out tasks for the Authority and the need to ensure for the purposes of overall consistency that such tasks are carried out in line with the criteria established for such tasks. Existing procedures for the allocation of scientific tasks to the Member States, in particular with regard to the evaluation of dossiers presented by industry for the authorisation of certain substances, products or procedures, should be re-examined within a year with the objective of taking into account the establishment of the Authority and the new facilities it offers, the evaluation procedures remaining at least as stringent as before.
- (53) The Commission remains fully responsible for communicating risk management measures. The appropriate information should therefore be exchanged between the Authority and the Commission. Close cooperation between the Authority, the Commission and the Member States is also necessary to ensure the coherence of the global communication process.
- (54) The independence of the Authority and its role in informing the public mean that it should be able to communicate autonomously in the fields falling within its competence, its purpose being to provide objective, reliable and easily understandable information.
- (55) Appropriate cooperation with the Member States and other interested parties is necessary in the specific field of public information campaigns to take into account any regional parameters and any correlation with health policy.
- (56) In addition to its operating principles based on independence and transparency, the Authority should be an organisation open to contacts with consumers and other interested groups.
- (57) The Authority should be financed by the general budget of the European Union. However, in the light of experience acquired, in particular with regard to the processing of authorisation dossiers presented by industry, the possibility of fees should be examined within three years following the entry into force of this Regulation. The Community budgetary procedure remains applicable as far as any subsidies chargeable to the general budget of the European Union are concerned. Moreover, the auditing of accounts should be undertaken by the Court of Auditors.
- (58) It is necessary to allow for the participation of European countries which are not members of the European Union and which have concluded agreements obliging them to transpose and implement the body of Community law in the field covered by this Regulation.
- (59) A system for rapid alert already exists in the framework of Council Directive 92/59/EEC of 29 June 1992 on general product safety⁽¹⁾. The scope of the existing system includes food and industrial products but not feed. Recent food crises have demonstrated the need to set up an improved and broadened rapid alert system covering food and feed. This revised system should be managed by the Commission and include as members of the network the Member States, the Commission and the Authority. The system should not cover the Community arrangements for the early exchange of information in the event of a radiological emergency as defined in Council Decision 87/600/Euratom⁽²⁾.
- (60) Recent food safety incidents have demonstrated the need to establish appropriate measures in emergency situations ensuring that all foods, whatever their type and origin, and all feed should be subject to common measures in the event of a serious risk to human health, animal health or the environment. Such a comprehensive approach to emergency food safety measures should allow effective action to be taken and avoid artificial disparities in the treatment of a serious risk in relation to food or feed.

⁽¹⁾ OJ L 228, 11.8.1992, p. 24.

⁽²⁾ OJ L 371, 30.12.1987, p. 76.

- (61) Recent food crises have also shown the benefits to the Commission of having properly adapted, more rapid procedures for crisis management. These organisational procedures should make it possible to improve coordination of effort and to determine the most effective measures on the basis of the best scientific information. Therefore, revised procedures should take into account the Authority's responsibilities and should provide for its scientific and technical assistance in the form of advice in the event of a food crisis.
- (62) In order to ensure a more effective, comprehensive approach to the food chain, a Committee on the Food Chain and Animal Health should be established to replace the Standing Veterinary Committee, the Standing Committee for Foodstuffs and the Standing Committee for Feedingstuffs. Accordingly, Council Decisions 68/361/EEC ⁽¹⁾, 69/414/EEC ⁽²⁾, and 70/372/EEC ⁽³⁾, should be repealed. For the same reason the Committee on the Food Chain and Animal Health should also replace the Standing Committee on Plant Health in relation to its competence (for Directives 76/895/EEC ⁽⁴⁾, 86/362/EEC ⁽⁵⁾, 86/363/EEC ⁽⁶⁾, 90/642/EEC ⁽⁷⁾ and 91/414/EEC ⁽⁸⁾) on plant protection products and the setting of maximum residue levels.
- (63) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ⁽⁹⁾.
- (64) It is necessary that operators should have sufficient time to adapt to some of the requirements established by the present Regulation and that the European Food Safety Authority should commence its operations on 1 January 2002.
- (65) It is important to avoid confusion between the missions of the Authority and the European Agency for the Evaluation of Medicinal Products (EMA) established by Council Regulation (EEC) No 2309/93 ⁽¹⁰⁾. Consequently, it is necessary to establish that this Regulation is without prejudice to the competence conferred on the EMA by Community legislation, including powers conferred by Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin ⁽¹¹⁾.
- (66) It is necessary and appropriate for the achievement of the basic objectives of this Regulation to provide for the approximation of the concepts, principles and procedures forming a common basis for food law in the Community and to establish a European Food Safety Authority. In accordance with the principle of proportionality as set out in Article 5 of the Treaty, this Regulation does not go beyond what is necessary in order to achieve the objectives pursued.

HAVE ADOPTED THIS REGULATION:

CHAPTER I

SCOPE AND DEFINITIONS

Article 1

Aim and scope

1. This Regulation provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the internal market.

It establishes common principles and responsibilities, the means to provide a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food and feed safety.

2. For the purposes of paragraph 1, this Regulation lays down the general principles governing food and feed in general, and food and feed safety in particular, at Community and national level.

It establishes the European Food Safety Authority.

It lays down procedures for matters with a direct or indirect impact on food and feed safety.

⁽¹⁾ OJ L 255, 18.10.1968, p. 23.

⁽²⁾ OJ L 291, 19.11.1969, p. 9.

⁽³⁾ OJ L 170, 3.8.1970, p. 1.

⁽⁴⁾ OJ L 340, 9.12.1976, p. 26. Directive as last amended by Commission Directive 2000/57/EC (OJ L 244, 29.9.2000, p. 76).

⁽⁵⁾ OJ L 221, 7.8.1986, p. 37. Directive as last amended by Commission Directive 2001/57/EC (OJ L 208, 1.8.2001, p. 36).

⁽⁶⁾ OJ L 221, 7.8.1986, p. 43. Directive as last amended by Commission Directive 2001/57/EC.

⁽⁷⁾ OJ L 350, 14.12.1990, p. 71. Directive as last amended by Commission Directive 2001/57/EC.

⁽⁸⁾ OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2001/49/EC (OJ L 176, 29.6.2001, p. 61).

⁽⁹⁾ OJ L 184, 17.7.1999, p. 23.

⁽¹⁰⁾ OJ L 214, 24.8.1993, p. 1. Regulation amended by Commission Regulation (EC) No 649/98 (OJ L 88, 24.3.1998, p. 7).

⁽¹¹⁾ OJ L 224, 18.8.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 1553/2001 (OJ L 205, 31.7.2001, p. 16).

3. This Regulation shall apply to all stages of production, processing and distribution of food and feed. It shall not apply to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption.

Article 2

Definition of 'food'

For the purposes of this Regulation, 'food' (or 'foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.

'Food' shall not include:

- (a) feed;
- (b) live animals unless they are prepared for placing on the market for human consumption;
- (c) plants prior to harvesting;
- (d) medicinal products within the meaning of Council Directives 65/65/EEC⁽¹⁾ and 92/73/EEC⁽²⁾;
- (e) cosmetics within the meaning of Council Directive 76/768/EEC⁽³⁾;
- (f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC⁽⁴⁾;
- (g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971;
- (h) residues and contaminants.

Article 3

Other definitions

For the purposes of this Regulation:

- 1. 'food law' means the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level; it covers any stage of production, processing and distribution

of food, and also of feed produced for, or fed to, food-producing animals;

- 2. 'food business' means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food;
- 3. 'food business operator' means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control;
- 4. 'feed' (or 'feedingstuff') means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals;
- 5. 'feed business' means any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed including any producer producing, processing or storing feed for feeding to animals on his own holding;
- 6. 'feed business operator' means the natural or legal persons responsible for ensuring that the requirements of food law are met within the feed business under their control;
- 7. 'retail' means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets;
- 8. 'placing on the market' means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves;
- 9. 'risk' means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard;
- 10. 'risk analysis' means a process consisting of three interconnected components: risk assessment, risk management and risk communication;
- 11. 'risk assessment' means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation;
- 12. 'risk management' means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options;

⁽¹⁾ OJ 22, 9.2.1965, p. 369. Directive as last amended by Directive 93/39/EEC (OJ L 214, 24.8.1993, p. 22).

⁽²⁾ OJ L 297, 13.10.1992, p. 8.

⁽³⁾ OJ L 262, 27.9.1976, p. 169. Directive as last amended by Commission Directive 2000/41/EC (OJ L 145, 20.6.2000, p. 25).

⁽⁴⁾ OJ L 359, 8.12.1989, p. 1. Directive as last amended by Directive 92/41/EEC (OJ L 158, 11.6.1992, p. 30).

13. 'risk communication' means the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions;
14. 'hazard' means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect;
15. 'traceability' means the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution;
16. 'stages of production, processing and distribution' means any stage, including import, from and including the primary production of a food, up to and including its storage, transport, sale or supply to the final consumer and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale and supply of feed;
17. 'primary production' means the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products;
18. 'final consumer' means the ultimate consumer of a food-stuff who will not use the food as part of any food business operation or activity.

CHAPTER II

GENERAL FOOD LAW

Article 4

Scope

1. This Chapter relates to all stages of the production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals.
2. The principles laid down in Articles 5 to 10 shall form a general framework of a horizontal nature to be followed when measures are taken.
3. Existing food law principles and procedures shall be adapted as soon as possible and by 1 January 2007 at the latest in order to comply with Articles 5 to 10.
4. Until then, and by way of derogation from paragraph 2, existing legislation shall be implemented taking account of the principles laid down in Articles 5 to 10.

SECTION 1

GENERAL PRINCIPLES OF FOOD LAW

Article 5

General objectives

1. Food law shall pursue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade, taking account of, where appropriate, the protection of animal health and welfare, plant health and the environment.

2. Food law shall aim to achieve the free movement in the Community of food and feed manufactured or marketed according to the general principles and requirements in this Chapter.

3. Where international standards exist or their completion is imminent, they shall be taken into consideration in the development or adaptation of food law, except where such standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food law or where there is a scientific justification, or where they would result in a different level of protection from the one determined as appropriate in the Community.

Article 6

Risk analysis

1. In order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.
2. Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.
3. Risk management shall take into account the results of risk assessment, and in particular, the opinions of the Authority referred to in Article 22, other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 7(1) are relevant, in order to achieve the general objectives of food law established in Article 5.

Article 7

Precautionary principle

1. In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

2. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.

Article 8

Protection of consumers' interests

1. Food law shall aim at the protection of the interests of consumers and shall provide a basis for consumers to make informed choices in relation to the foods they consume. It shall aim at the prevention of:

- (a) fraudulent or deceptive practices;
- (b) the adulteration of food; and
- (c) any other practices which may mislead the consumer.

SECTION 2

PRINCIPLES OF TRANSPARENCY

Article 9

Public consultation

There shall be open and transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food law, except where the urgency of the matter does not allow it.

Article 10

Public information

Without prejudice to the applicable provisions of Community and national law on access to documents, where there are reasonable grounds to suspect that a food or feed may present

a risk for human or animal health, then, depending on the nature, seriousness and extent of that risk, public authorities shall take appropriate steps to inform the general public of the nature of the risk to health, identifying to the fullest extent possible the food or feed, or type of food or feed, the risk that it may present, and the measures which are taken or about to be taken to prevent, reduce or eliminate that risk.

SECTION 3

GENERAL OBLIGATIONS OF FOOD TRADE

Article 11

Food and feed imported into the Community

Food and feed imported into the Community for placing on the market within the Community shall comply with the relevant requirements of food law or conditions recognised by the Community to be at least equivalent thereto or, where a specific agreement exists between the Community and the exporting country, with requirements contained therein.

Article 12

Food and feed exported from the Community

1. Food and feed exported or re-exported from the Community for placing on the market of a third country shall comply with the relevant requirements of food law, unless otherwise requested by the authorities of the importing country or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country.

In other circumstances, except in the case where foods are injurious to health or feeds are unsafe, food and feed can only be exported or re-exported if the competent authorities of the country of destination have expressly agreed, after having been fully informed of the reasons for which and the circumstances in which the food or feed concerned could not be placed on the market in the Community.

2. Where the provisions of a bilateral agreement concluded between the Community or one of its Member States and a third country are applicable, food and feed exported from the Community or that Member State to that third country shall comply with the said provisions.

Article 13**International standards**

Without prejudice to their rights and obligations, the Community and the Member States shall:

- (a) contribute to the development of international technical standards for food and feed and sanitary and phytosanitary standards;
- (b) promote the coordination of work on food and feed standards undertaken by international governmental and non-governmental organisations;
- (c) contribute, where relevant and appropriate, to the development of agreements on recognition of the equivalence of specific food and feed-related measures;
- (d) give particular attention to the special development, financial and trade needs of developing countries, with a view to ensuring that international standards do not create unnecessary obstacles to exports from developing countries;
- (e) promote consistency between international technical standards and food law while ensuring that the high level of protection adopted in the Community is not reduced.

SECTION 4**GENERAL REQUIREMENTS OF FOOD LAW****Article 14****Food safety requirements**

1. Food shall not be placed on the market if it is unsafe.
2. Food shall be deemed to be unsafe if it is considered to be:
 - (a) injurious to health;
 - (b) unfit for human consumption.
3. In determining whether any food is unsafe, regard shall be had:
 - (a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and
 - (b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.

4. In determining whether any food is injurious to health, regard shall be had:

- (a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;
- (b) to the probable cumulative toxic effects;
- (c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.

5. In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.

6. Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.

7. Food that complies with specific Community provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.

8. Conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe.

9. Where there are no specific Community provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof.

Article 15**Feed safety requirements**

1. Feed shall not be placed on the market or fed to any food-producing animal if it is unsafe.
2. Feed shall be deemed to be unsafe for its intended use if it is considered to:
 - have an adverse effect on human or animal health;
 - make the food derived from food-producing animals unsafe for human consumption.

3. Where a feed which has been identified as not satisfying the feed safety requirement is part of a batch, lot or consignment of feed of the same class or description, it shall be presumed that all of the feed in that batch, lot or consignment is so affected, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment fails to satisfy the feed safety requirement.

4. Feed that complies with specific Community provisions governing feed safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.

5. Conformity of a feed with specific provisions applicable to that feed shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the feed is unsafe.

6. Where there are no specific Community provisions, feed shall be deemed to be safe when it conforms to the specific provisions of national law governing feed safety of the Member State in whose territory the feed is in circulation, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof.

Article 16

Presentation

Without prejudice to more specific provisions of food law, the labelling, advertising and presentation of food or feed, including their shape, appearance or packaging, the packaging materials used, the manner in which they are arranged and the setting in which they are displayed, and the information which is made available about them through whatever medium, shall not mislead consumers.

Article 17

Responsibilities

1. Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.

2. Member States shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution.

For that purpose, they shall maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on food and feed safety and risk, food and feed safety surveillance and other

monitoring activities covering all stages of production, processing and distribution.

Member States shall also lay down the rules on measures and penalties applicable to infringements of food and feed law. The measures and penalties provided for shall be effective, proportionate and dissuasive.

Article 18

Traceability

1. The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution.

2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed.

To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.

3. Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand.

4. Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions.

5. Provisions for the purpose of applying the requirements of this Article in respect of specific sectors may be adopted in accordance with the procedure laid down in Article 58(2).

Article 19

Responsibilities for food: food business operators

1. If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection.

2. A food business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the food-safety requirements and shall participate in contributing to the safety of the food by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.

3. A food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health. Operators shall inform the competent authorities of the action taken to prevent risks to the final consumer and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a food.

4. Food business operators shall collaborate with the competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied.

Article 20

Responsibilities for feed: feed business operators

1. If a feed business operator considers or has reason to believe that a feed which it has imported, produced, processed, manufactured or distributed does not satisfy the feed safety requirements, it shall immediately initiate procedures to withdraw the feed in question from the market and inform the competent authorities thereof. In these circumstances or, in the case of Article 15(3), where the batch, lot or consignment does not satisfy the feed safety requirement, that feed shall be destroyed, unless the competent authority is satisfied otherwise. The operator shall effectively and accurately inform users of the

feed of the reason for its withdrawal, and if necessary, recall from them products already supplied when other measures are not sufficient to achieve a high level of health protection.

2. A feed business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the feed shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the feed-safety requirements and shall participate in contributing to the safety of food by passing on relevant information necessary to trace a feed, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.

3. A feed business operator shall immediately inform the competent authorities if it considers or has reason to believe that a feed which it placed on the market may not satisfy the feed safety requirements. It shall inform the competent authorities of the action taken to prevent risk arising from the use of that feed and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a feed.

4. Feed business operators shall collaborate with the competent authorities on action taken in order to avoid risks posed by a feed which they supply or have supplied.

Article 21

Liability

The provisions of this Chapter shall be without prejudice to Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products ⁽¹⁾.

CHAPTER III

EUROPEAN FOOD SAFETY AUTHORITY

SECTION 1

MISSION AND TASKS

Article 22

Mission of the Authority

1. A European Food Safety Authority, hereinafter referred to as the 'Authority', is hereby established.

2. The Authority shall provide scientific advice and scientific and technical support for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety. It shall provide independent information on all matters within these fields and communicate on risks.

3. The Authority shall contribute to a high level of protection of human life and health, and in this respect take account of animal health and welfare, plant health and the environment, in the context of the operation of the internal market.

⁽¹⁾ OJ L 210, 7.8.1985, p. 29. Directive as last amended by Directive 1999/34/EC of the European Parliament and of the Council (OJ L 141, 4.6.1999, p. 20).

4. The Authority shall collect and analyse data to allow the characterisation and monitoring of risks which have a direct or indirect impact on food and feed safety.

5. The mission of the Authority shall also include the provision of:

- (a) scientific advice and scientific and technical support on human nutrition in relation to Community legislation and, at the request of the Commission, assistance concerning communication on nutritional issues within the framework of the Community health programme;
- (b) scientific opinions on other matters relating to animal health and welfare and plant health;
- (c) scientific opinions on products other than food and feed relating to genetically modified organisms as defined by Directive 2001/18/EC and without prejudice to the procedures established therein.

6. The Authority shall provide scientific opinions which will serve as the scientific basis for the drafting and adoption of Community measures in the fields falling within its mission.

7. The Authority shall carry out its tasks in conditions which enable it to serve as a point of reference by virtue of its independence, the scientific and technical quality of the opinions it issues and the information it disseminates, the transparency of its procedures and methods of operation, and its diligence in performing the tasks assigned to it.

It shall act in close cooperation with the competent bodies in the Member States carrying out similar tasks to these of the Authority.

8. The Authority, Commission and Member States shall cooperate to promote the effective coherence between risk assessment, risk management and risk communication functions.

9. The Member States shall cooperate with the Authority to ensure the accomplishment of its mission.

Article 23

Tasks of the Authority

The tasks of the Authority shall be the following:

- (a) to provide the Community institutions and the Member States with the best possible scientific opinions in all cases provided for by Community legislation and on any question within its mission;
- (b) to promote and coordinate the development of uniform risk assessment methodologies in the fields falling within its mission;
- (c) to provide scientific and technical support to the Commission in the areas within its mission and, when so requested, in the interpretation and consideration of risk assessment opinions;

(d) to commission scientific studies necessary for the accomplishment of its mission;

(e) to search for, collect, collate, analyse and summarise scientific and technical data in the fields within its mission;

(f) to undertake action to identify and characterise emerging risks, in the fields within its mission;

(g) to establish a system of networks of organisations operating in the fields within its mission and be responsible for their operation;

(h) to provide scientific and technical assistance, when requested to do so by the Commission, in the crisis management procedures implemented by the Commission with regard to the safety of food and feed;

(i) to provide scientific and technical assistance, when requested to do so by the Commission, with a view to improving cooperation between the Community, applicant countries, international organisations and third countries, in the fields within its mission;

(j) to ensure that the public and interested parties receive rapid, reliable, objective and comprehensible information in the fields within its mission;

(k) to express independently its own conclusions and orientations on matters within its mission;

(l) to undertake any other task assigned to it by the Commission within its mission.

SECTION 2

ORGANISATION

Article 24

Bodies of the Authority

The Authority shall comprise:

- (a) a Management Board;
- (b) an Executive Director and his staff;
- (c) an Advisory Forum;
- (d) a Scientific Committee and Scientific Panels.

Article 25

Management Board

1. The Management Board shall be composed of 14 members appointed by the Council in consultation with the European Parliament from a list drawn up by the Commission which includes a number of candidates substantially higher than the number of members to be appointed, plus a representative of the Commission. Four of the members shall have their background in organisations representing consumers and other interests in the food chain.

The list drawn up by the Commission, accompanied by the relevant documentation, shall be forwarded to the European Parliament. As soon as possible and within three months of such communication, the European Parliament may make its views available for consideration by the Council, which will then appoint the Management Board.

The members of the Board shall be appointed in such a way as to secure the highest standards of competence, a broad range of relevant expertise and, consistent with these, the broadest possible geographic distribution within the Union.

2. Members' term of office shall be four years, and may be renewed once. However, for the first mandate, this period shall be six years for half of the members.

3. The Management Board shall adopt the Authority's internal rules on the basis of a proposal by the Executive Director. These rules shall be made public.

4. The Management Board shall elect one of its members as its Chair for a two-year period, which shall be renewable.

5. The Management Board shall adopt its rules of procedure.

Unless otherwise provided, the Management Board shall act by a majority of its members.

6. The Management Board shall meet at the invitation of the Chair or at the request of at least a third of its members.

7. The Management Board shall ensure that the Authority carries out its mission and performs the tasks assigned to it under the conditions laid down in this Regulation.

8. Before 31 January each year, the Management Board shall adopt the Authority's programme of work for the coming year. It shall also adopt a revisable multi-annual programme. The Management Board shall ensure that these programmes are consistent with the Community's legislative and policy priorities in the area of food safety.

Before 30 March each year, the Management Board shall adopt the general report on the Authority's activities for the previous year.

9. The Management Board, having received the Commission's approval and the opinion of the Court of Auditors, shall adopt the Authority's financial regulation which specifies in particular the procedure for drawing up and implementing the Authority's budget, in accordance with Article 142 of the Financial Regulation of 21 December 1977 applicable to the general budget of the European Communities ⁽¹⁾ and with the legislative requirements concerning investigations conducted by the European Anti-Fraud Office.

10. The Executive Director shall take part in the meetings of the Management Board, without voting rights, and shall provide the Secretariat. The Management Board shall invite the Chair of the Scientific Committee to attend its meetings without voting rights.

Article 26

Executive Director

1. The Executive Director shall be appointed by the Management Board, on the basis of a list of candidates proposed by the Commission after an open competition, following publication in the *Official Journal of the European Communities* and elsewhere of a call for expressions of interest, for a period of five years which shall be renewable. Before appointment the candidate nominated by the Management Board shall be invited without delay to make a statement before the European Parliament and answer questions put by members of this institution. The Executive Director may be removed from office by a majority of the Management Board.

2. The Executive Director shall be the legal representative of the Authority and shall be responsible for:

- (a) the day-to-day administration of the Authority;
- (b) drawing up a proposal for the Authority's work programmes in consultation with the Commission;
- (c) implementing the work programmes and the decisions adopted by the Management Board;
- (d) ensuring the provision of appropriate scientific, technical and administrative support for the Scientific Committee and the Scientific Panels;
- (e) ensuring that the Authority carries out its tasks in accordance with the requirements of its users, in particular with regard to the adequacy of the services provided and the time taken;
- (f) the preparation of the statement of revenue and expenditure and the execution of the budget of the Authority;
- (g) all staff matters;
- (h) developing and maintaining contact with the European Parliament, and for ensuring a regular dialogue with its relevant committees.

3. Each year, the Executive Director shall submit to the Management Board for approval:

- (a) a draft general report covering all the activities of the Authority in the previous year;
- (b) draft programmes of work;
- (c) the draft annual accounts for the previous year;
- (d) the draft budget for the coming year.

The Executive Director shall, following adoption by the Management Board, forward the general report and the programmes to the European Parliament, the Council, the Commission and the Member States, and shall have them published.

4. The Executive Director shall approve all financial expenditure of the Authority and report on the Authority's activities to the Management Board.

⁽¹⁾ OJ L 356, 31.12.1977, p. 1. Regulation as last amended by Regulation (EC, ECSC, Euratom) No 762/2001 (OJ L 111, 20.4.2001, p. 1).

Article 27

Advisory Forum

1. The Advisory Forum shall be composed of representatives from competent bodies in the Member States which undertake tasks similar to those of the Authority, on the basis of one representative designated by each Member State. Representatives may be replaced by alternates, appointed at the same time.
2. Members of the Advisory Forum may not be members of the Management Board.
3. The Advisory Forum shall advise the Executive Director in the performance of his duties under this Regulation, in particular in drawing up a proposal for the Authority's work programme. The Executive Director may also ask the Advisory Forum for advice on the prioritisation of requests for scientific opinions.
4. The Advisory Forum shall constitute a mechanism for an exchange of information on potential risks and the pooling of knowledge. It shall ensure close cooperation between the Authority and the competent bodies in the Member States in particular on the following items:
 - (a) avoidance of duplication of the Authority's scientific studies with Member States, in accordance with Article 32;
 - (b) in those circumstances identified in Article 30(4), where the Authority and a national body are obliged to cooperate;
 - (c) in the promoting of the European networking of organisations operating within the fields of the Authority's mission, in accordance with Article 36(1);
 - (d) where the Authority or a Member State identifies an emerging risk.
5. The Advisory Forum shall be chaired by the Executive Director. It shall meet regularly at the invitation of the Chair or at the request of at least a third of its members, and not less than four times per year. Its operational procedures shall be specified in the Authority's internal rules and shall be made public.
6. The Authority shall provide the technical and logistic support necessary for the Advisory Forum and provide the Secretariat for its meetings.
7. Representatives of the Commission's departments may participate in the work of the Advisory Forum. The Executive Director may invite representatives of the European Parliament and from other relevant bodies to take part.

Where the Advisory Forum discusses the matters referred to in Article 22(5)(b), representatives from competent bodies in the Member States which undertake tasks similar to those referred to in Article 22(5)(b) may participate in the work of the Advisory Forum, on the basis of one representative designated by each Member State.

Article 28

Scientific Committee and Scientific Panels

1. The Scientific Committee and permanent Scientific Panels shall be responsible for providing the scientific opinions of the Authority, each within their own spheres of competence, and shall have the possibility, where necessary, of organising public hearings.
 2. The Scientific Committee shall be responsible for the general coordination necessary to ensure the consistency of the scientific opinion procedure, in particular with regard to the adoption of working procedures and harmonisation of working methods. It shall provide opinions on multisectoral issues falling within the competence of more than one Scientific Panel, and on issues which do not fall within the competence of any of the Scientific Panels.
- Where necessary, and particularly in the case of subjects which do not fall within the competence of any of the Scientific Panels, the Scientific Committee shall set up working groups. In such cases, it shall draw on the expertise of those working groups when establishing scientific opinions.
3. The Scientific Committee shall be composed of the Chairs of the Scientific Panels and six independent scientific experts who do not belong to any of the Scientific Panels.
 4. The Scientific Panels shall be composed of independent scientific experts. When the Authority is established, the following Scientific Panels shall be set up:
 - (a) the Panel on food additives, flavourings, processing aids and materials in contact with food;
 - (b) the Panel on additives and products or substances used in animal feed;
 - (c) the Panel on plant health, plant protection products and their residues;
 - (d) the Panel on genetically modified organisms;
 - (e) the Panel on dietetic products, nutrition and allergies;
 - (f) the Panel on biological hazards;
 - (g) the Panel on contaminants in the food chain;
 - (h) the Panel on animal health and welfare.

The number and names of the Scientific Panels may be adapted in the light of technical and scientific development by the Commission, at the Authority's request, in accordance with the procedure referred to in Article 58(2).

5. The members of the Scientific Committee who are not members of Scientific Panels and the members of the Scientific Panels shall be appointed by the Management Board, acting upon a proposal from the Executive Director, for a three-year term of office, which shall be renewable, following publication in the *Official Journal of the European Communities*, in relevant leading scientific publications and on the Authority's website of a call for expressions of interest.

6. The Scientific Committee and the Scientific Panels shall each choose a Chair and two Vice-Chairs from among their members.

7. The Scientific Committee and the Scientific Panels shall act by a majority of their members. Minority opinions shall be recorded.

8. The representatives of the Commission's departments shall be entitled to be present in the meetings of the Scientific Committee, the Scientific Panels and their working groups. If invited to do so, they may assist for the purposes of clarification or information but shall not seek to influence discussions.

9. The procedures for the operation and cooperation of the Scientific Committee and the Scientific Panels shall be laid down in the Authority's internal rules.

These procedures shall relate in particular to:

- (a) the number of times that a member can serve consecutively on a Scientific Committee or Scientific Panel;
- (b) the number of members in each Scientific Panel;
- (c) the procedure for reimbursing the expenses of members of the Scientific Committee and the Scientific Panels;
- (d) the manner in which tasks and requests for scientific opinions are assigned to the Scientific Committee and the Scientific Panels;
- (e) the creation and organisation of the working groups of the Scientific Committee and the Scientific Panels, and the possibility of external experts being included in those working groups;
- (f) the possibility of observers being invited to meetings of the Scientific Committee and the Scientific Panels;
- (g) the possibility of organising public hearings.

SECTION 3

OPERATION

Article 29

Scientific opinions

1. The Authority shall issue a scientific opinion:

- (a) at the request of the Commission, in respect of any matter within its mission, and in all cases where Community legislation makes provision for the Authority to be consulted;
- (b) on its own initiative, on matters falling within its mission.

The European Parliament or a Member State may request the Authority to issue a scientific opinion on matters falling within its mission.

2. Requests referred to in paragraph 1 shall be accompanied by background information explaining the scientific issue to be addressed and the Community interest.

3. Where Community legislation does not already specify a time limit for the delivery of a scientific opinion, the Authority shall issue scientific opinions within the time limit specified in the requests for opinions, except in duly justified circumstances.

4. Where different requests are made on the same issues or where the request is not in accordance with paragraph 2, or is unclear, the Authority may either refuse, or propose amendments to a request for an opinion in consultation with the institution or Member State(s) that made the request. Justifications for the refusal shall be given to the institution or Member State(s) that made the request.

5. Where the Authority has already delivered a scientific opinion on the specific topic in a request, it may refuse the request if it concludes there are no new scientific elements justifying the re-examination. Justifications for the refusal shall be given to the institution or Member State(s) that made the request.

6. The implementing rules for the application of this Article shall be established by the Commission after consulting the Authority, in accordance with the procedure provided for in Article 58(2). These rules shall specify in particular:

- (a) the procedure to be applied by the Authority to the requests referred to it;
- (b) the guidelines governing the scientific evaluation of substances, products or processes which are subject under Community legislation to a system of prior authorisation or entry on a positive list, in particular where Community legislation makes provision for, or authorises, a dossier to be presented for this purpose by the applicant.

7. The Authority's internal rules shall specify requirements in regard to format, explanatory background and publication of a scientific opinion.

Article 30

Diverging scientific opinions

1. The Authority shall exercise vigilance in order to identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks.

2. Where the Authority identifies a potential source of divergence, it shall contact the body in question to ensure that all relevant scientific information is shared and in order to identify potentially contentious scientific issues.

3. Where a substantive divergence over scientific issues has been identified and the body in question is a Community agency or one of the Commission's Scientific Committees, the Authority and the body concerned shall be obliged to co-operate with a view to either resolving the divergence or presenting a joint document to the Commission clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. This document shall be made public.

4. Where a substantive divergence over scientific issues has been identified and the body in question is a Member State body, the Authority and the national body shall be obliged to cooperate with a view to either resolving the divergence or preparing a joint document clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. This document shall be made public.

Article 31

Scientific and technical assistance

1. The Authority may be requested by the Commission to provide scientific or technical assistance in any field within its mission. The tasks of providing scientific and technical assistance shall consist of scientific or technical work involving the application of well-established scientific or technical principles which does not require scientific evaluation by the Scientific Committee or a Scientific Panel. Such tasks may include in particular assistance to the Commission for the establishment or evaluation of technical criteria and also assistance to the Commission in the development of technical guidelines.

2. Where the Commission refers a request for scientific or technical assistance to the Authority, it shall specify, in agreement with the Authority, the time limit within which the task must be completed.

Article 32

Scientific studies

1. Using the best independent scientific resources available, the Authority shall commission scientific studies necessary for the performance of its mission. Such studies shall be commissioned in an open and transparent fashion. The Authority shall seek to avoid duplication with Member State or Community research programmes and shall foster cooperation through appropriate coordination.

2. The Authority shall inform the European Parliament, the Commission and the Member States of the results of its scientific studies.

Article 33

Collection of data

1. The Authority shall search for, collect, collate, analyse and summarise relevant scientific and technical data in the

fields within its mission. This shall involve in particular the collection of data relating to:

- (a) food consumption and the exposure of individuals to risks related to the consumption of food;
- (b) incidence and prevalence of biological risk;
- (c) contaminants in food and feed;
- (d) residues.

2. For the purposes of paragraph 1, the Authority shall work in close cooperation with all organisations operating in the field of data collection, including those from applicant countries, third countries or international bodies.

3. The Member States shall take the necessary measures to enable the data they collect in the fields referred to in paragraphs 1 and 2 to be transmitted to the Authority.

4. The Authority shall forward to the Member States and the Commission appropriate recommendations which might improve the technical comparability of the data it receives and analyses, in order to facilitate consolidation at Community level.

5. Within one year following the date of entry into force of this Regulation, the Commission shall publish an inventory of data collection systems existing at Community level in the fields within the mission of the Authority.

The report, which shall be accompanied, where appropriate, by proposals, shall indicate in particular:

- (a) for each system, the role which should be assigned to the Authority, and any modifications or improvements which might be required to enable the Authority to carry out its mission, in cooperation with the Member States;
- (b) the shortcomings which should be remedied to enable the Authority to collect and summarise at Community level relevant scientific and technical data in the fields within its mission.

6. The Authority shall forward the results of its work in the field of data collection to the European Parliament, the Commission and the Member States.

Article 34

Identification of emerging risks

1. The Authority shall establish monitoring procedures for systematically searching for, collecting, collating and analysing information and data with a view to the identification of emerging risks in the fields within its mission.

2. Where the Authority has information leading it to suspect an emerging serious risk, it shall request additional information from the Member States, other Community agencies and the Commission. The Member States, the Community agencies concerned and the Commission shall reply as a matter of urgency and forward any relevant information in their possession.

3. The Authority shall use all the information it receives in the performance of its mission to identify an emerging risk.

4. The Authority shall forward the evaluation and information collected on emerging risks to the European Parliament, the Commission and the Member States.

Article 35

Rapid alert system

To enable it to perform its task of monitoring the health and nutritional risks of foods as effectively as possible, the Authority shall be the recipient of any messages forwarded via the rapid alert system. It shall analyse the content of such messages with a view to providing the Commission and the Member States with any information required for the purposes of risk analysis.

Article 36

Networking of organisations operating in the fields within the Authority's mission

1. The Authority shall promote the European networking of organisations operating in the fields within the Authority's mission. The aim of such networking is, in particular, to facilitate a scientific cooperation framework by the coordination of activities, the exchange of information, the development and implementation of joint projects, the exchange of expertise and best practices in the fields within the Authority's mission.

2. The Management Board, acting on a proposal from the Executive Director, shall draw up a list to be made public of competent organisations designated by the Member States which may assist the Authority, either individually or in networks, with its mission. The Authority may entrust to these organisations certain tasks, in particular preparatory work for scientific opinions, scientific and technical assistance, collection of data and identification of emerging risks. Some of these tasks may be eligible for financial support.

3. The implementing rules for the application of paragraphs 1 and 2 shall be laid down by the Commission, after consulting the Authority, in accordance with the procedure referred to in Article 58(2). Those rules shall specify, in particular, the criteria for inclusion of an institute on the list of competent organisations designated by the Member States, arrangements for setting out harmonised quality requirements and the financial rules governing any financial support.

4. Within one year following the entry into force of this Regulation, the Commission shall publish an inventory of Community systems existing in the fields within the mission of the Authority which make provision for Member States to carry out certain tasks in the field of scientific evaluation, in particular the examination of authorisation dossiers. The report, which shall be accompanied, where appropriate, by proposals, shall indicate in particular, for each system, any modifications or improvements which might be required to

enable the Authority to carry out its mission, in cooperation with the Member States.

SECTION 4

INDEPENDENCE, TRANSPARENCY, CONFIDENTIALITY AND COMMUNICATION

Article 37

Independence

1. The members of the Management Board, the members of the Advisory Forum and the Executive Director shall undertake to act independently in the public interest.

For this purpose, they shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made annually in writing.

2. The members of the Scientific Committee and the Scientific Panels shall undertake to act independently of any external influence.

For this purpose, they shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made annually in writing.

3. The members of the Management Board, the Executive Director, the members of the Advisory Forum, the members of the Scientific Committee and the Scientific Panels, as well as external experts participating in their working groups shall declare at each meeting any interests which might be considered prejudicial to their independence in relation to the items on the agenda.

Article 38

Transparency

1. The Authority shall ensure that it carries out its activities with a high level of transparency. It shall in particular make public without delay:

- (a) agendas and minutes of the Scientific Committee and the Scientific Panels;
- (b) the opinions of the Scientific Committee and the Scientific Panels immediately after adoption, minority opinions always being included;
- (c) without prejudice to Articles 39 and 41, the information on which its opinions are based;
- (d) the annual declarations of interest made by members of the Management Board, the Executive Director, members of the Advisory Forum and members of the Scientific Committee and Scientific Panels, as well as the declarations of interest made in relation to items on the agendas of meetings;

- (e) the results of its scientific studies;
- (f) the annual report of its activities;
- (g) requests from the European Parliament, the Commission or a Member State for scientific opinions which have been refused or modified and the justifications for the refusal or modification.

2. The Management Board shall hold its meetings in public unless, acting on a proposal from the Executive Director, it decides otherwise for specific administrative points of its agenda, and may authorise consumer representatives or other interested parties to observe the proceedings of some of the Authority's activities.

3. The Authority shall lay down in its internal rules the practical arrangements for implementing the transparency rules referred to in paragraphs 1 and 2.

Article 39

Confidentiality

1. By way of derogation from Article 38, the Authority shall not divulge to third parties confidential information that it receives for which confidential treatment has been requested and justified, except for information which must be made public if circumstances so require, in order to protect public health.

2. Members of the Management Board, the Executive Director, members of the Scientific Committee and Scientific Panels as well as external experts participating in their working groups, members of the Advisory Forum and members of the staff of the Authority, even after their duties have ceased, shall be subject to the requirements of confidentiality pursuant to Article 287 of the Treaty.

3. The conclusions of the scientific opinions delivered by the Authority relating to foreseeable health effects shall on no account be kept confidential.

4. The Authority shall lay down in its internal rules the practical arrangements for implementing the confidentiality rules referred to in paragraphs 1 and 2.

Article 40

Communications from the Authority

1. The Authority shall communicate on its own initiative in the fields within its mission without prejudice to the Commission's competence to communicate its risk management decisions.

2. The Authority shall ensure that the public and any interested parties are rapidly given objective, reliable and easily accessible information, in particular with regard to the results of its work. In order to achieve these objectives, the Authority shall develop and disseminate information material for the general public.

3. The Authority shall act in close collaboration with the Commission and the Member States to promote the necessary coherence in the risk communication process.

The Authority shall publish all opinions issued by it in accordance with Article 38.

4. The Authority shall ensure appropriate cooperation with the competent bodies in the Member States and other interested parties with regard to public information campaigns.

Article 41

Access to documents

1. The Authority shall ensure wide access to the documents which it possesses.

2. The Management Board, acting on a proposal from the Executive Director, shall adopt the provisions applicable to access to the documents referred to in paragraph 1, taking full account of the general principles and conditions governing the right of access to the Community institutions' documents.

Article 42

Consumers, producers and other interested parties

The Authority shall develop effective contacts with consumer representatives, producer representatives, processors and any other interested parties.

SECTION 5

FINANCIAL PROVISIONS

Article 43

Adoption of the Authority's budget

1. The revenues of the Authority shall consist of a contribution from the Community and, from any State with which the Community has concluded the agreements referred to in Article 49, and charges for publications, conferences, training and any other similar activities provided by the Authority.

2. The expenditure of the Authority shall include the staff, administrative, infrastructure and operational expenses, and expenses resulting from contracts entered into with third parties or resulting from the financial support referred to in Article 36.

3. In good time, before the date referred to in paragraph 5, the Executive Director shall draw up an estimate of the Authority's revenue and expenditure for the coming financial year, and shall forward it to the Management Board, accompanied by a provisional list of posts.

4. Revenue and expenditure shall be in balance.

5. By 31 March each year at the latest, the Management Board shall adopt the draft estimates including the provisional list of posts accompanied by the preliminary work programme and forward them to the Commission, and the States with which the Community has concluded the agreements referred to in Article 49. On the basis of that draft, the Commission shall enter the relevant estimates in the preliminary draft general budget of the European Union to be put before the Council pursuant to Article 272 of the Treaty.

6. After the adoption of the general budget of the European Union by the budgetary authority, the Management Board shall adopt the Authority's final budget and work programme, adjusting them where necessary to the Community's contribution. It shall forward them without delay to the Commission and the budgetary authority.

Article 44

Implementation of the Authority's budget

1. The Executive Director shall implement the Authority's budget.

2. Control of commitment and payment of all expenditure and control of the existence and recovery of all the Authority's revenue shall be carried out by the Commission's financial controller.

3. By 31 March each year at the latest, the Executive Director shall forward to the Commission, the Management Board and the Court of Auditors the detailed accounts for all the revenue and expenditure in respect of the previous financial year.

The Court of Auditors shall examine the accounts in accordance with Article 248 of the Treaty. It shall publish each year a report on the Authority's activities.

4. The European Parliament, acting on a recommendation from the Council, shall give a discharge to the Authority's Executive Director in respect of the implementation of the budget.

Article 45

Fees received by the Authority

Within three years following the date of entry into force of this Regulation and after consulting the Authority, the Member States and the interested parties, the Commission shall publish a report on the feasibility and advisability of presenting a legislative proposal under the co-decision procedure and in accordance with the Treaty and for other services provided by the Authority.

SECTION 6

GENERAL PROVISIONS

Article 46

Legal personality and privileges

1. The Authority shall have legal personality. In all Member States it shall enjoy the widest powers granted by law to legal

persons. In particular, it may acquire and dispose of movable and immovable property and institute legal proceedings.

2. The Protocol on the privileges and immunities of the European Communities shall apply to the Authority.

Article 47

Liability

1. The contractual liability of the Authority shall be governed by the law applicable to the contract in question. The Court of Justice of the European Communities shall have jurisdiction to give judgment pursuant to any arbitration clause contained in a contract concluded by the Authority.

2. In the case of non-contractual liability, the Authority shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by it or its servants in the performance of their duties. The Court of Justice shall have jurisdiction in any dispute relating to compensation for such damage.

3. The personal liability of its servants towards the Authority shall be governed by the relevant provisions applying to the staff of the Authority.

Article 48

Staff

1. The staff of the Authority shall be subject to the rules and regulations applicable to officials and other staff of the European Communities.

2. In respect of its staff, the Authority shall exercise the powers which have been devolved to the appointing authority.

Article 49

Participation of third countries

The Authority shall be open to the participation of countries which have concluded agreements with the European Community by virtue of which they have adopted and apply Community legislation in the field covered by this Regulation.

Arrangements shall be made under the relevant provisions of those agreements, specifying in particular the nature, extent and manner in which these countries will participate in the Authority's work, including provisions relating to participation in the networks operated by the Authority, inclusion in the list of competent organisations to which certain tasks may be entrusted by the Authority, financial contributions and staff.

CHAPTER IV

RAPID ALERT SYSTEM, CRISIS MANAGEMENT AND EMERGENCIES

SECTION 1

RAPID ALERT SYSTEM

Article 50

Rapid alert system

1. A rapid alert system for the notification of a direct or indirect risk to human health deriving from food or feed is hereby established as a network. It shall involve the Member States, the Commission and the Authority. The Member States, the Commission and the Authority shall each designate a contact point, which shall be a member of the network. The Commission shall be responsible for managing the network.

2. Where a member of the network has any information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed, this information shall be immediately notified to the Commission under the rapid alert system. The Commission shall transmit this information immediately to the members of the network.

The Authority may supplement the notification with any scientific or technical information, which will facilitate rapid, appropriate risk management action by the Member States.

3. Without prejudice to other Community legislation, the Member States shall immediately notify the Commission under the rapid alert system of:

- (a) any measure they adopt which is aimed at restricting the placing on the market or forcing the withdrawal from the market or the recall of food or feed in order to protect human health and requiring rapid action;
- (b) any recommendation or agreement with professional operators which is aimed, on a voluntary or obligatory basis, at preventing, limiting or imposing specific conditions on the placing on the market or the eventual use of food or feed on account of a serious risk to human health requiring rapid action;
- (c) any rejection, related to a direct or indirect risk to human health, of a batch, container or cargo of food or feed by a competent authority at a border post within the European Union.

The notification shall be accompanied by a detailed explanation of the reasons for the action taken by the competent authorities of the Member State in which the notification was issued. It shall be followed, in good time, by supplementary information, in particular where the measures on which the notification is based are modified or withdrawn.

The Commission shall immediately transmit to members of the network the notification and supplementary information received under the first and second subparagraphs.

Where a batch, container or cargo is rejected by a competent authority at a border post within the European Union, the Commission shall immediately notify all the border posts within the European Union, as well as the third country of origin.

4. Where a food or feed which has been the subject of a notification under the rapid alert system has been dispatched to a third country, the Commission shall provide the latter with the appropriate information.

5. The Member States shall immediately inform the Commission of the action implemented or measures taken following receipt of the notifications and supplementary information transmitted under the rapid alert system. The Commission shall immediately transmit this information to the members of the network.

6. Participation in the rapid alert system may be opened up to applicant countries, third countries or international organisations, on the basis of agreements between the Community and those countries or international organisations, in accordance with the procedures defined in those agreements. The latter shall be based on reciprocity and shall include confidentiality measures equivalent to those applicable in the Community.

Article 51

Implementing measures

The measures for implementing Article 50 shall be adopted by the Commission, after discussion with the Authority, in accordance with the procedure referred to in Article 58(2). These measures shall specify, in particular, the specific conditions and procedures applicable to the transmission of notifications and supplementary information.

Article 52

Confidentiality rules for the rapid alert system

1. Information, available to the members of the network, relating to a risk to human health posed by food and feed shall in general be available to the public in accordance with the information principle provided for in Article 10. In general, the public shall have access to information on product identification, the nature of the risk and the measure taken.

However, the members of the network shall take steps to ensure that members of their staff are required not to disclose information obtained for the purposes of this Section which by its nature is covered by professional secrecy in duly justified cases, except for information which must be made public, if circumstances so require, in order to protect human health.

2. Protection of professional secrecy shall not prevent the dissemination to the competent authorities of information relevant to the effectiveness of market surveillance and enforcement activities in the field of food and feed. The authorities receiving information covered by professional secrecy shall ensure its protection in conformity with paragraph 1.

SECTION 2

EMERGENCIES

Article 53

Emergency measures for food and feed of Community origin or imported from a third country

1. Where it is evident that food or feed originating in the Community or imported from a third country is likely to constitute a serious risk to human health, animal health or the environment, and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, the Commission, acting in accordance with the procedure provided for in Article 58(2) on its own initiative or at the request of a Member State, shall immediately adopt one or more of the following measures, depending on the gravity of the situation:

- (a) in the case of food or feed of Community origin:
 - (i) suspension of the placing on the market or use of the food in question;
 - (ii) suspension of the placing on the market or use of the feed in question;
 - (iii) laying down special conditions for the food or feed in question;
 - (iv) any other appropriate interim measure;
- (b) in the case of food or feed imported from a third country:
 - (i) suspension of imports of the food or feed in question from all or part of the third country concerned and, where applicable, from the third country of transit;
 - (ii) laying down special conditions for the food or feed in question from all or part of the third country concerned;
 - (iii) any other appropriate interim measure.

2. However, in eMERGENCIES, the Commission may provisionally adopt the measures referred to in paragraph 1 after consulting the Member State(s) concerned and informing the other Member States.

As soon as possible, and at most within 10 working days, the measures taken shall be confirmed, amended, revoked or extended in accordance with the procedure referred to in Article 58(2), and the reasons for the Commission's decision shall be made public without delay.

Article 54

Other emergency measures

1. Where a Member State officially informs the Commission of the need to take emergency measures, and where the Commission has not acted in accordance with Article 53, the Member State may adopt interim protective measures. In this event, it shall immediately inform the other Member States and the Commission.

2. Within 10 working days, the Commission shall put the matter before the Committee set up in Article 58(1) in accordance with the procedure provided for in Article 58(2) with a view to the extension, amendment or abrogation of the national interim protective measures.

3. The Member State may maintain its national interim protective measures until the Community measures have been adopted.

SECTION 3

CRISIS MANAGEMENT

Article 55

General plan for crisis management

1. The Commission shall draw up, in close cooperation with the Authority and the Member States, a general plan for crisis management in the field of the safety of food and feed (hereinafter referred to as 'the general plan').

2. The general plan shall specify the types of situation involving direct or indirect risks to human health deriving from food and feed which are not likely to be prevented, eliminated or reduced to an acceptable level by provisions in place or cannot adequately be managed solely by way of the application of Articles 53 and 54.

The general plan shall also specify the practical procedures necessary to manage a crisis, including the principles of transparency to be applied and a communication strategy.

Article 56**Crisis unit**

1. Without prejudice to its role of ensuring the application of Community law, where the Commission identifies a situation involving a serious direct or indirect risk to human health deriving from food and feed, and the risk cannot be prevented, eliminated or reduced by existing provisions or cannot adequately be managed solely by way of the application of Articles 53 and 54, it shall immediately notify the Member States and the Authority.

2. The Commission shall set up a crisis unit immediately, in which the Authority shall participate, and provide scientific and technical assistance if necessary.

Article 57**Tasks of the crisis unit**

1. The crisis unit shall be responsible for collecting and evaluating all relevant information and identifying the options available to prevent, eliminate or reduce to an acceptable level the risk to human health as effectively and rapidly as possible.

2. The crisis unit may request the assistance of any public or private person whose expertise it deems necessary to manage the crisis effectively.

3. The crisis unit shall keep the public informed of the risks involved and the measures taken.

CHAPTER V**PROCEDURES AND FINAL PROVISIONS****SECTION 1****COMMITTEE AND MEDIATION PROCEDURES****Article 58****Committee**

1. The Commission shall be assisted by a Standing Committee on the Food Chain and Animal Health, hereinafter referred to as the 'Committee', composed of representatives of the Member States and chaired by the representative of the Commission. The Committee shall be organised in sections to deal with all relevant matters.

2. Where reference is made to this paragraph, the procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Articles 7 and 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

Article 59**Functions assigned to the Committee**

The Committee shall carry out the functions assigned to it by this Regulation and by other relevant Community provisions, in the cases and conditions provided for in those provisions. It may also examine any issue falling under those provisions, either at the initiative of the Chairman or at the written request of one of its members.

Article 60**Mediation procedure**

1. Without prejudice to the application of other Community provisions, where a Member State is of the opinion that a measure taken by another Member State in the field of food safety is either incompatible with this Regulation or is likely to affect the functioning of the internal market, it shall refer the matter to the Commission, which will immediately inform the other Member State concerned.

2. The two Member States concerned and the Commission shall make every effort to solve the problem. If agreement cannot be reached, the Commission may request an opinion on any relevant contentious scientific issue from the Authority. The terms of that request and the time limit within which the Authority is requested to give its opinion shall be established by mutual agreement between the Commission and the Authority, after consulting the two Member States concerned.

SECTION 2**FINAL PROVISIONS****Article 61****Review clause**

1. Before 1 January 2005 and every six years thereafter, the Authority, in collaboration with the Commission, shall commission an independent external evaluation of its achievements on the basis of the terms of reference issued by the Management Board in agreement with the Commission. The evaluation will assess the working practices and the impact of the Authority. The evaluation will take into account the views of the stakeholders, at both Community and national level.

The Management Board of the Authority shall examine the conclusions of the evaluation and issue to the Commission such recommendations as may be necessary regarding changes in the Authority and its working practices. The evaluation and the recommendations shall be made public.

2. Before 1 January 2005, the Commission shall publish a report on the experience acquired from implementing Sections 1 and 2 of Chapter IV.

3. The reports and recommendations referred to in paragraphs 1 and 2 shall be forwarded to the Council and the European Parliament.

Article 62

References to the European Food Safety Authority and to the Standing Committee on the Food Chain and Animal Health

1. Every reference in Community legislation to the Scientific Committee on Food, the Scientific Committee on Animal Nutrition, the Scientific Veterinary Committee, the Scientific Committee on Pesticides, the Scientific Committee on Plants and the Scientific Steering Committee shall be replaced by a reference to the European Food Safety Authority.

2. Every reference in Community legislation to the Standing Committee on Foodstuffs, the Standing Committee for Feedingstuffs and the Standing Veterinary Committee shall be replaced by a reference to the Standing Committee on the Food Chain and Animal Health.

Every reference to the Standing Committee on Plant Health in Community legislation based upon and including Directives 76/895/EEC, 86/362/EEC, 86/363/EEC, 90/642/EEC and 91/414/EEC relating to plant protection products and the setting of maximum residue levels shall be replaced by a reference to the Standing Committee on the Food Chain and Animal Health.

3. For the purpose of paragraphs 1 and 2, 'Community legislation' shall mean all Community Regulations, Directives and Decisions.

4. Decisions 68/361/EEC, 69/414/EEC and 70/372/EEC are hereby repealed.

Article 63

Competence of the European Agency for the Evaluation of Medicinal Products

This Regulation shall be without prejudice to the competence conferred on the European Agency for the Evaluation of Medicinal Products by Regulation (EEC) No 2309/93, Regulation (EEC) No 2377/90, Council Directive 75/319/EEC⁽¹⁾ and Council Directive 81/851/EEC⁽²⁾.

Article 64

Commencement of the Authority's operation

The Authority shall commence its operations on 1 January 2002.

Article 65

Entry into force

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Communities*.

Articles 11 and 12 and Articles 14 to 20 shall apply from 1 January 2005.

Articles 29, 56, 57 and 60 and Article 62(1) shall apply as from the date of appointment of the members of the Scientific Committee and of the Scientific Panels which shall be announced by means of a notice in the 'C' series of the Official Journal.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 28 January 2002.

For the European Parliament

The President

P. COX

For the Council

The President

J. PIQUÉ I CAMPS

⁽¹⁾ OJ L 147, 9.6.1975, p. 13. Directive amended by Directive 2001/83/EC of the European Parliament and of the Council (OJ L 311, 28.11.2001, p. 67).

⁽²⁾ OJ L 317, 6.11.1981, p. 1. Directive amended by Directive 2001/82/EC of the European Parliament and of the Council (OJ L 311, 28.11.2001, p. 1).

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(Acts whose publication is obligatory)

COMMISSION REGULATION (EC) No 2073/2005

of 15 November 2005

on microbiological criteria for foodstuffs

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs⁽¹⁾, and in particular Articles 4(4) and 12 thereof,

Whereas:

- (1) A high level of protection of public health is one of the fundamental objectives of food law, as laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety⁽²⁾. Microbiological hazards in foodstuffs form a major source of food-borne diseases in humans.
- (2) Foodstuffs should not contain micro-organisms or their toxins or metabolites in quantities that present an unacceptable risk for human health.
- (3) Regulation (EC) No 178/2002 lays down general food safety requirements, according to which food must not be placed on the market if it is unsafe. Food business operators have an obligation to withdraw unsafe food from the market. In order to contribute to the protection of public health and to prevent differing interpretations, it is appropriate to establish harmonised safety criteria on the acceptability of food, in particular as regards the presence of certain pathogenic micro-organisms.

- (4) Microbiological criteria also give guidance on the acceptability of foodstuffs and their manufacturing, handling and distribution processes. The use of microbiological criteria should form an integral part of the implementation of HACCP-based procedures and other hygiene control measures.

- (5) The safety of foodstuffs is mainly ensured by a preventive approach, such as implementation of good hygiene practice and application of procedures based on hazard analysis and critical control point (HACCP) principles. Microbiological criteria can be used in validation and verification of HACCP procedures and other hygiene control measures. It is therefore appropriate to set microbiological criteria defining the acceptability of the processes, and also food safety microbiological criteria setting a limit above which a foodstuff should be considered unacceptably contaminated with the micro-organisms for which the criteria are set.

- (6) According to Article 4 of Regulation (EC) No 852/2004, food business operators are to comply with microbiological criteria. This should include testing against the values set for the criteria through the taking of samples, the conduct of analyses and the implementation of corrective actions, in accordance with food law and the instructions given by the competent authority. It is therefore appropriate to lay down implementing measures concerning the analytical methods, including, where necessary, the measurement uncertainty, the sampling plan, the microbiological limits, the number of analytical units that should comply with these limits. Furthermore, it is appropriate to lay down implementing measures concerning the foodstuff to which the criterion applies, the points of the food chain where the criterion applies, as well as the actions to be taken when the criterion is not met. The measures to be taken by the food business operators in order to ensure compliance with criteria defining the acceptability of a process may include, among other things, controls of raw materials, hygiene, temperature and shelf-life of the product.

⁽¹⁾ OJ L 139, 30.4.2004, p. 1, corrected by OJ L 226, 25.6.2004, p. 3.

⁽²⁾ OJ L 31, 1.2.2002, p. 1. Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

- (7) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules ⁽¹⁾ requires the Member States to ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency. Those controls should take place at appropriate stages of the production, processing and distribution of food to ensure that the criteria laid down in this Regulation are complied with by food business operators.
- (8) The Communication from the Commission on the Community Strategy for setting microbiological criteria for foodstuffs ⁽²⁾ describes the strategy to lay down and revise the criteria in Community legislation, as well as the principles for the development and application of the criteria. This strategy should be applied when microbiological criteria are laid down.
- (9) The Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) issued an opinion on 23 September 1999 on the evaluation of microbiological criteria for food products of animal origin for human consumption. It highlighted the relevance of basing microbiological criteria on formal risk assessment and internationally approved principles. The opinion recommends that microbiological criteria should be relevant and effective in relation to consumer health protection. The SCVPH proposed, while awaiting formal risk assessments, certain revised criteria as interim measures.
- (10) The SCVPH issued at the same time a separate opinion on *Listeria monocytogenes*. That opinion recommended that it be an objective to keep the concentration of *Listeria monocytogenes* in food below 100 cfu/g. The Scientific Committee on Food (SCF) agreed with these recommendations in its opinion of 22 June 2000.
- (11) The SCVPH adopted an opinion on *Vibrio vulnificus* and *Vibrio parahaemolyticus* on 19 and 20 September 2001. It concluded that currently available scientific data do not support setting specific criteria for pathogenic *V. vulnificus* and *parahaemolyticus* in seafood. However, it recommended that codes of practice should be established to ensure that good hygiene practice has been applied.
- (12) The SCVPH issued an opinion on Norwalk-like viruses (NLVs, noroviruses) on 30-31 January 2002. In that opinion it concluded that the conventional faecal indicators are unreliable for demonstrating the presence or absence of NLVs and that the reliance on faecal bacterial indicator removal for determining shellfish purification times is unsafe practice. It also recommended using *E. coli* rather than faecal coliforms to indicate faecal contamination in shellfish harvesting areas, when applying bacterial indicators.
- (13) On 27 February 2002 the SCF adopted an opinion on specifications for gelatine in terms of consumer health. It concluded that the microbiological criteria set in Chapter 4 of Annex II to Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A(I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC ⁽³⁾ in terms of consumer health were excessive, and considered it sufficient to apply a mandatory microbiological criterion for salmonella only.
- (14) The SCVPH issued an opinion on verotoxigenic *E. coli* (VTEC) in foodstuffs on 21 and 22 January 2003. In its opinion it concluded that applying an end-product microbiological standard for VTEC O157 is unlikely to deliver meaningful reductions in the associated risk for the consumers. However, microbiological guidelines aimed at reducing the faecal contamination along the food chain can contribute to a reduction in public health risks, including VTEC. The SCVPH identified the following food categories where VTEC represents a hazard to public health: raw or undercooked beef and possibly meat from other ruminants, minced meat and fermented beef and products thereof, raw milk and raw milk products, fresh produce, in particular sprouted seeds, and unpasteurised fruit and vegetable juices.
- (15) On 26 and 27 March 2003 the SCVPH adopted an opinion on staphylococcal enterotoxins in milk products, particularly in cheeses. It recommended revising the criteria for coagulase-positive staphylococci in cheeses, in raw milk intended for processing and in powdered milk. In addition, criteria for staphylococcal enterotoxins should be laid down for cheeses and powdered milk.

⁽¹⁾ OJ L 165, 30.4.2004, p. 1, corrected by OJ L 191, 28.5.2004, p. 1.

⁽²⁾ SANCO/1252/2001 Discussion paper on strategy for setting microbiological criteria for foodstuffs in Community legislation, p. 34.

⁽³⁾ OJ L 62, 15.3.1993, p. 49. Directive as last amended by Commission Regulation (EC) No 445/2004 (OJ L 72, 11.3.2004, p. 60).

- (16) The SCVPH adopted an opinion on salmonellae in foodstuffs on 14 and 15 April 2003. According to the opinion, food categories possibly posing a high risk to public health include raw meat and some products intended to be eaten raw, raw and undercooked products of poultry meat, eggs and products containing raw eggs, unpasteurised milk and some products thereof. Sprouted seeds and unpasteurised fruit juices are also of concern. It recommended that the decision on the need for microbiological criteria should be taken on the basis of its ability to protect the consumers and its feasibility.
- (17) The Scientific Panel on Biological Hazards (BIOHAZ Panel) of the European Food Safety Authority (EFSA) issued an opinion on the microbiological risks in infant formulae and follow-on formulae on 9 September 2004. It concluded that *Salmonella* and *Enterobacter sakazakii* are the micro-organisms of greatest concern in infant formulae, formulae for special medical purposes and follow-on formulae. The presence of these pathogens constitutes a considerable risk if conditions after reconstitution permit multiplication. Enterobacteriaceae, which are more often present, could be used as an indicator for risk. Monitoring and testing of Enterobacteriaceae was recommended in both the manufacturing environment and the finished product by the EFSA. However, besides pathogenic species the family Enterobacteriaceae includes also environmental species, which often appear in the food manufacturing environment without posing any health hazard. Therefore, the family Enterobacteriaceae can be used for routine monitoring, and if they are present testing of specific pathogens can be started.
- (18) International guidelines for microbiological criteria in respect of many foodstuffs have not yet been established. However, the Commission has followed the Codex Alimentarius guideline 'Principles for the establishment and application of microbiological criteria for foods CAC/GL 21 — 1997' and in addition, the advice of the SCVPH and the SCF in laying down microbiological criteria. Existing Codex specifications in respect of dried milk products, foods for infants and children and the histamine criterion for certain fish and fishery products have been taken account. The adoption of Community criteria should benefit trade by providing harmonised microbiological requirements for foodstuffs and replacing national criteria.
- (19) The microbiological criteria set for certain categories of food of animal origin in Directives that were repealed by Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC⁽¹⁾ should be revised and certain new criteria set in the light of the scientific advice.
- (20) The microbiological criteria laid down in Commission Decision 93/51 EEC of 15 December 1992 on the microbiological criteria applicable to the production of cooked crustaceans and molluscan shellfish⁽²⁾ are incorporated in this Regulation. It is therefore appropriate to repeal that Decision. Since Commission Decision 2001/471/EC of 8 June 2001 laying down rules for the regular checks on the general hygiene carried out by the operators in establishments according to Directive 64/433/EEC on health conditions for the production and marketing of fresh meat and Directive 71/118/EEC on health problems affecting the production and placing on the market of fresh poultrymeat⁽³⁾ is repealed with effect from the 1 January 2006, it is appropriate to incorporate microbiological criteria set for carcasses in this Regulation.
- (21) The producer or manufacturer of a food product has to decide whether the product is ready to be consumed as such, without the need to cook or otherwise process it in order to ensure its safety and compliance with the microbiological criteria. According to Article 3 of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs⁽⁴⁾, the instructions for use of a foodstuff are compulsory on the labelling when it would be impossible to make appropriate use of the foodstuff in the absence of such instructions. Such instructions should be taken into account by food business operators when deciding appropriate sampling frequencies for the testing against microbiological criteria.
- (22) Sampling of the production and processing environment can be a useful tool to identify and prevent the presence of pathogenic micro-organisms in foodstuffs.
- (23) Food business operators should decide themselves the necessary sampling and testing frequencies as part of their procedures based on HACCP principles and other hygiene control procedures. However, it may be necessary in certain cases to set harmonised sampling frequencies at Community level, particularly in order to ensure the same level of controls to be performed throughout the Community.
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- (¹) OJ L 157, 30.4.2004, p. 33, corrected by OJ L 195, 2.6.2004, p. 12.
- (²) OJ L 13, 21.1.1993, p. 11.
- (³) OJ L 165, 21.6.2001, p. 48. Decision as amended by Decision 2004/379/EC (OJ L 144, 30.4.2004, p. 1).
- (⁴) OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15).

(24) Test results are dependent on the analytical method used, and therefore a given reference method should be associated with each microbiological criterion. However, food business operators should have the possibility to use analytical methods other than the reference methods, in particular more rapid methods, as long as the use of these alternative methods provides equivalent results. Moreover, a sampling plan needs to be defined for each criterion in order to ensure harmonised implementation. It is nevertheless necessary to allow the use of other sampling and testing schemes, including the use of alternative indicator organisms, on condition that these schemes provide equivalent guarantees of food safety.

(25) Trends in test results should be analysed, as they are able to reveal unwanted developments in the manufacturing process enabling the food business operator to take corrective actions before the process is out of control.

(26) The microbiological criteria set in this Regulation should be open to review and revised or supplemented, if appropriate, in order to take into account developments in the field of food safety and food microbiology. This includes progress in science, technology and methodology, changes in prevalence and contamination levels, changes in the population of vulnerable consumers, as well as the possible outputs from risk assessments.

(27) In particular, criteria for pathogenic viruses in live bivalve molluscs should be established when the analytical methods are developed sufficiently. There is a need for development of reliable methods for other microbial hazards too, e.g. *Vibrio parahaemolyticus*.

(28) It has been demonstrated that the implementation of control programmes can markedly contribute to a reduction of the prevalence of salmonella in production animals and products thereof. The purpose of Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents⁽¹⁾ is to ensure that proper and effective measures are taken to control salmonella at relevant stages of the food chain. Criteria for meat and products thereof should take into account the expected improvement in the salmonella situation at the level of primary production.

(29) For certain food safety criteria, it is appropriate to grant the Member States a transitional derogation, enabling them to comply with less stringent criteria but provided that the foodstuffs would only be marketed on the

national market. The Member States should notify the Commission and other Member States where this transitional derogation is used.

(30) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Subject-matter and scope

This Regulation lays down the microbiological criteria for certain micro-organisms and the implementing rules to be complied with by food business operators when implementing the general and specific hygiene measures referred to in Article 4 of Regulation (EC) No 852/2004. The competent authority shall verify compliance with the rules and criteria laid down in this Regulation in accordance with Regulation (EC) No 882/2004, without prejudice to its right to undertake further sampling and analyses for the purpose of detecting and measuring other micro-organisms, their toxins or metabolites, either as a verification of processes, for food suspected of being unsafe, or in the context of a risk analysis.

This Regulation shall apply without prejudice to other specific rules for the control of micro-organisms laid down in Community legislation and in particular the health standards for foodstuffs laid down in Regulation (EC) No 853/2004 of the European Parliament and of the Council⁽²⁾, the rules on parasites laid down under Regulation (EC) No 854/2004 of the European Parliament and of the Council⁽³⁾ and the microbiological criteria laid down under Council Directive 80/777/EEC⁽⁴⁾.

Article 2

Definitions

The following definitions shall apply:

- (a) 'micro-organisms' means bacteria, viruses, yeasts, moulds, algae, parasitic protozoa, microscopic parasitic helminths, and their toxins and metabolites;
- (b) 'microbiological criterion' means a criterion defining the acceptability of a product, a batch of foodstuffs or a process, based on the absence, presence or number of micro-organisms, and/or on the quantity of their toxins/metabolites, per unit(s) of mass, volume, area or batch;

⁽¹⁾ OJ L 325, 12.12.2003, p. 1.

⁽²⁾ OJ L 139, 30.4.2004, p. 55, corrected by OJ L 226, 25.6.2004, p. 22.

⁽³⁾ OJ L 139, 30.4.2004, p. 206, corrected by OJ L 226, 25.6.2004, p. 83.

⁽⁴⁾ OJ L 229, 30.8.1980, p. 1.

- (c) 'food safety criterion' means a criterion defining the acceptability of a product or a batch of foodstuff applicable to products placed on the market;
- (d) 'process hygiene criterion' a criterion indicating the acceptable functioning of the production process. Such a criterion is not applicable to products placed on the market. It sets an indicative contamination value above which corrective actions are required in order to maintain the hygiene of the process in compliance with food law;
- (e) 'batch' means a group or set of identifiable products obtained from a given process under practically identical circumstances and produced in a given place within one defined production period;
- (f) 'shelf-life' means either the period corresponding to the period preceding the 'use by' or the minimum durability date, as defined respectively in Articles 9 and 10 of Directive 2000/13/EC;
- (g) 'ready-to-eat food' means food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing effective to eliminate or reduce to an acceptable level micro-organisms of concern;
- (h) 'food intended for infants' means food specifically intended for infants, as defined in Commission Directive 91/321/EEC ⁽¹⁾;
- (i) 'food intended for special medical purposes' means dietary food for special medical purposes, as defined in Commission Directive 1999/21/EC ⁽²⁾;
- (j) 'sample' means a set composed of one or several units or a portion of matter selected by different means in a population or in an important quantity of matter, which is intended to provide information on a given characteristic of the studied population or matter and to provide a basis for a decision concerning the population or matter in question or concerning the process which has produced it;
- (k) 'representative sample' means a sample in which the characteristics of the batch from which it is drawn are maintained. This is in particular the case of a simple random sample where each of the items or increments of the batch has been given the same probability of entering the sample;
- (l) 'compliance with microbiological criteria' means obtaining satisfactory or acceptable results set in Annex I when testing against the values set for the criteria through the

taking of samples, the conduct of analyses and the implementation of corrective action, in accordance with food law and the instructions given by the competent authority.

Article 3

General requirements

1. Food business operators shall ensure that foodstuffs comply with the relevant microbiological criteria set out in Annex I. To this end the food business operators at each stage of food production, processing and distribution, including retail, shall take measures, as part of their procedures based on HACCP principles together with the implementation of good hygiene practice, to ensure the following:

- (a) that the supply, handling and processing of raw materials and foodstuffs under their control are carried out in such a way that the process hygiene criteria are met,
- (b) that the food safety criteria applicable throughout the shelf-life of the products can be met under reasonably foreseeable conditions of distribution, storage and use.

2. As necessary, the food business operators responsible for the manufacture of the product shall conduct studies in accordance with Annex II in order to investigate compliance with the criteria throughout the shelf-life. In particular, this applies to ready-to-eat foods that are able to support the growth of *Listeria monocytogenes* and that may pose a *Listeria monocytogenes* risk for public health.

Food businesses may collaborate in conducting those studies.

Guidelines for conducting those studies may be included in the guides to good practice referred to in Article 7 of Regulation (EC) No 852/2004.

Article 4

Testing against criteria

1. Food business operators shall perform testing as appropriate against the microbiological criteria set out in Annex I, when they are validating or verifying the correct functioning of their procedures based on HACCP principles and good hygiene practice.

2. Food business operators shall decide the appropriate sampling frequencies, except where Annex I provides for specific sampling frequencies, in which case the sampling frequency shall be at least that provided for in Annex I. Food business operators shall make this decision in the context of their procedures based on HACCP principles and good

⁽¹⁾ OJ L 175, 4.7.1991, p. 35.

⁽²⁾ OJ L 91, 7.4.1999, p. 29.

hygiene practice, taking into account the instructions for use of the foodstuff.

The frequency of sampling may be adapted to the nature and size of the food businesses, provided that the safety of foodstuffs will not be endangered.

Article 5

Specific rules for testing and sampling

1. The analytical methods and the sampling plans and methods in Annex I shall be applied as reference methods.

2. Samples shall be taken from processing areas and equipment used in food production, when such sampling is necessary for ensuring that the criteria are met. In that sampling the ISO standard 18593 shall be used as a reference method.

Food business operators manufacturing ready-to-eat foods, which may pose a *Listeria monocytogenes* risk for public health, shall sample the processing areas and equipment for *Listeria monocytogenes* as part of their sampling scheme.

Food business operators manufacturing dried infant formulae or dried foods for special medical purposes intended for infants below six months which pose an *Enterobacter sakazakii* risk shall monitor the processing areas and equipment for Enterobacteriaceae as part of their sampling scheme.

3. The number of sample units of the sampling plans set out in Annex I may be reduced if the food business operator can demonstrate by historical documentation that he has effective HACCP-based procedures.

4. If the aim of the testing is to specifically assess the acceptability of a certain batch of foodstuffs or a process, the sampling plans set out in Annex I shall be respected as a minimum.

5. Food business operators may use other sampling and testing procedures, if they can demonstrate to the satisfaction of the competent authority that these procedures provide at least equivalent guarantees. Those procedures may include use of alternative sampling sites and use of trend analyses.

Testing against alternative micro-organisms and related microbiological limits as well as testing of analytes other than microbiological ones shall be allowed only for process hygiene criteria.

The use of alternative analytical methods is acceptable when the methods are validated against the reference method in

Annex I and if a proprietary method, certified by a third party in accordance with the protocol set out in EN/ISO standard 16140 or other internationally accepted similar protocols, is used.

If the food business operator wishes to use analytical methods other than those validated and certified as described in paragraph 3 the methods shall be validated according to internationally accepted protocols and their use authorised by the competent authority.

Article 6

Labelling requirements

1. When the requirements for *Salmonella* in minced meat, meat preparations and meat products intended to be eaten cooked of all species set down in Annex I are fulfilled, the batches of those products placed on the market must be clearly labelled by the manufacturer in order to inform the consumer of the need for thorough cooking prior to consumption.

2. As from 1 January 2010 labelling as referred to in paragraph 1 in respect of minced meat, meat preparations and meat products made from poultrymeat will no longer be required.

Article 7

Unsatisfactory results

1. When the results of testing against the criteria set out in Annex I are unsatisfactory, the food business operators shall take the measures laid down in paragraphs 2 to 4 of this Article together with other corrective actions defined in their HACCP-based procedures and other actions necessary to protect the health of consumers.

In addition, they shall take measures to find the cause of the unsatisfactory results in order to prevent the recurrence of the unacceptable microbiological contamination. Those measures may include modifications to the HACCP-based procedures or other food hygiene control measures in place.

2. When testing against food safety criteria set out in Chapter 1 of Annex I provides unsatisfactory results, the product or batch of foodstuffs shall be withdrawn or recalled in accordance with Article 19 of Regulation (EC) No 178/2002. However, products placed on the market, which are not yet at retail level and which do not fulfil the food safety criteria, may be submitted to further processing by a treatment eliminating the hazard in question. This treatment may only be carried out by food business operators other than those at retail level.

The food business operator may use the batch for purposes other than those for which it was originally intended, provided that this use does not pose a risk for public or animal health and provided that this use has been decided within the procedures based on HACCP principles and good hygiene practice and authorised by the competent authority.

3. A batch of mechanically separated meat (MSM) produced with the techniques referred to in Chapter III, paragraph 3, in Section V of Annex III to Regulation (EC) No 853/2004, with unsatisfactory results in respect of the *Salmonella* criterion, may be used in the food chain only to manufacture heat-treated meat products in establishments approved in accordance with Regulation (EC) No 853/2004.

4. In the event of unsatisfactory results as regards process hygiene criteria the actions laid down in Annex I, Chapter 2 shall be taken.

Article 8

Transitional derogation

1. A transitional derogation is granted until 31 December 2009 at the latest pursuant to Article 12 of Regulation (EC) No 852/2004 as regards compliance with the value set in Annex I to this Regulation for *Salmonella* in minced meat, meat preparations and meat products intended to be eaten cooked placed on the national market of a Member State.

2. The Member States using this possibility shall notify the Commission and other Member States thereof. The Member State shall:

- (a) guarantee that the appropriate means, including labelling and a special mark, which cannot be confused with the identification mark provided for in Annex II, Section I to Regulation (EC) No 853/2004, are in place to ensure that the derogation applies only to the products concerned when placed on the domestic market, and that products dispatched for intra-Community trade comply with the criteria laid down in Annex I;

- (b) provide that the products to which such transitional derogation applies shall be clearly labelled that they must be thoroughly cooked prior to consumption;
- (c) undertake that when testing against the *Salmonella* criterion pursuant to Article 4, and for the result to be acceptable as regards such transitional derogation, no more than one out of five sample units shall be found to be positive.

Article 9

Analyses of trends

Food business operators shall analyse trends in the test results. When they observe a trend towards unsatisfactory results, they shall take appropriate actions without undue delay to remedy the situation in order to prevent the occurrence of microbiological risks.

Article 10

Review

This Regulation shall be reviewed taking into account progress in science, technology and methodology, emerging pathogenic micro-organisms in foodstuffs, and information from risk assessments. In particular, the criteria and conditions concerning the presence of salmonella in carcasses of cattle, sheep, goats, horses, pigs and poultry shall be revised in the light of the changes observed in salmonella prevalence.

Article 11

Repeal

Decision 93/51/EEC is repealed.

Article 12

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2006.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 15 November 2005.

For the Commission

Markos KYPRIANOU

Member of the Commission

ANNEX I

Microbiological criteria for foodstuffs

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Chapter 1. Food safety criteria

Food category	Micro-organisms/their toxins, metabolites	Sampling-plan ⁽¹⁾		Limits ⁽²⁾		Analytical reference method ⁽³⁾	Stage where the criterion applies
		n	c	m	M		
1.1. Ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes ⁽⁴⁾	<i>Listeria monocytogenes</i>	10	0	Absence in 25 g		EN/ISO 11290-1	Products placed on the market during their shelf-life
1.2. Ready-to-eat foods able to support the growth of <i>L. monocytogenes</i> , other than those intended for infants and for special medical purposes	<i>Listeria monocytogenes</i>	5	0	100 cfu/g ⁽⁵⁾		EN/ISO 11290-2 ⁽⁶⁾	Products placed on the market during their shelf-life
		5	0	Absence in 25 g ⁽⁷⁾		EN/ISO 11290-1	Before the food has left the immediate control of the food business operator, who has produced it
1.3. Ready-to-eat foods unable to support the growth of <i>L. monocytogenes</i> , other than those intended for infants and for special medical purposes ⁽⁴⁾ ⁽⁸⁾	<i>Listeria monocytogenes</i>	5	0	100 cfu/g		EN/ISO 11290-2 ⁽⁶⁾	Products placed on the market during their shelf-life
1.4. Minced meat and meat preparations intended to be eaten raw	<i>Salmonella</i>	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.5. Minced meat and meat preparations made from poultry meat intended to be eaten cooked	<i>Salmonella</i>	5	0	From 1.1.2006 Absence in 10 g From 1.1.2010 Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.6. Minced meat and meat preparations made from other species than poultry intended to be eaten cooked	<i>Salmonella</i>	5	0	Absence in 10 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.7. Mechanically separated meat (MSM) ⁽⁹⁾	<i>Salmonella</i>	5	0	Absence in 10 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.8. Meat products intended to be eaten raw, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	<i>Salmonella</i>	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life

Food category	Micro-organisms/their toxins, metabolites	Sampling-plan ⁽¹⁾		Limits ⁽²⁾		Analytical reference method ⁽³⁾	Stage where the criterion applies
		n	c	m	M		
1.9. Meat products made from poultry meat intended to be eaten cooked	<i>Salmonella</i>	5	0	From 1.1.2006 Absence in 10 g From 1.1.2010 Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.10. Gelatine and collagen	<i>Salmonella</i>	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.11. Cheeses, butter and cream made from raw milk or milk that has undergone a lower heat treatment than pasteurisation ⁽¹⁰⁾	<i>Salmonella</i>	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.12. Milk powder and whey powder ⁽¹⁰⁾	<i>Salmonella</i>	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.13. Ice cream ⁽¹¹⁾ , excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	<i>Salmonella</i>	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.14. Egg products, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	<i>Salmonella</i>	5	0	Absence in 25g		EN/ISO 6579	Products placed on the market during their shelf-life
1.15. Ready-to-eat foods containing raw egg, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	<i>Salmonella</i>	5	0	Absence in 25 g or ml		EN/ISO 6579	Products placed on the market during their shelf-life
1.16. Cooked crustaceans and molluscan shell-fish	<i>Salmonella</i>	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.17. Live bivalve molluscs and live echinoderms, tunicates and gastropods	<i>Salmonella</i>	5	0	Absence in 25g		EN/ISO 6579	Products placed on the market during their shelf-life

Food category	Micro-organisms/their toxins, metabolites	Sampling-plan ⁽¹⁾		Limits ⁽²⁾		Analytical reference method ⁽³⁾	Stage where the criterion applies
		n	c	m	M		
1.18. Sprouted seeds (ready-to-eat) ⁽¹²⁾	<i>Salmonella</i>	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.19. Pre-cut fruit and vegetables (ready-to-eat)	<i>Salmonella</i>	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.20. Unpasteurised fruit and vegetable juices (ready-to-eat)	<i>Salmonella</i>	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.21. Cheeses, milk powder and whey powder, as referred to in the coagulase-positive staphylococci criteria in Chapter 2.2 of this Annex	Staphylococcal enterotoxins	5	0	Not detected in 25g		European screening method of the CRL for Milk ⁽¹³⁾	Products placed on the market during their shelf-life
1.22. Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age, as referred to in the Enterobacteriaceae criterion in Chapter 2.2 of this Annex	<i>Salmonella</i>	30	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.23. Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age, as referred to in the Enterobacteriaceae criterion in Chapter 2.2 of this Annex	<i>Enterobacter sakazakii</i>	30	0	Absence in 10 g		ISO/DTS 22964	Products placed on the market during their shelf-life
1.24. Live bivalve molluscs and live echinoderms, tunicates and gastropods	<i>E.coli</i> ⁽¹⁴⁾	1 ⁽¹⁵⁾	0	230 MPN/100g of flesh and intra-valvular liquid		ISO TS 16649-3	Products placed on the market during their shelf-life
1.25. Fishery products from fish species associated with a high amount of histidine ⁽¹⁶⁾	Histamine	9 ⁽¹⁷⁾	2	100 mg/kg	200 mg/kg	HPLC ⁽¹⁸⁾	Products placed on the market during their shelf-life

Food category	Micro-organisms/their toxins, metabolites	Sampling-plan ⁽¹⁾		Limits ⁽²⁾		Analytical reference method ⁽³⁾	Stage where the criterion applies
		n	c	m	M		
1.26. Fishery products which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with a high amount of histidine ⁽¹⁶⁾	Histamine	9	2	200 mg/kg	400 mg/kg	HPLC ⁽¹⁸⁾	Products placed on the market during their shelf-life

⁽¹⁾ n = number of units comprising the sample; c = number of sample units giving values over m or between m and M.

⁽²⁾ For points 1.1-1.24 m=M.

⁽³⁾ The most recent edition of the standard shall be used.

⁽⁴⁾ Regular testing against the criterion is not useful in normal circumstances for the following ready-to-eat foods:

- those which have received heat treatment or other processing effective to eliminate *L. monocytogenes*, when recontamination is not possible after this treatment (e.g. products heat treated in their final package),
- fresh, uncut and unprocessed vegetables and fruits, excluding sprouted seeds,
- bread, biscuits and similar products,
- bottled or packed waters, soft drinks, beer, cider, wine, spirits and similar products,
- sugar, honey and confectionery, including cocoa and chocolate products,
- live bivalve molluscs.

⁽⁵⁾ This criterion applies if the manufacturer is able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit 100 cfu/g throughout the shelf-life. The operator may fix intermediate limits during the process that should be low enough to guarantee that the limit of 100 cfu/g is not exceeded at the end of the shelf-life.

⁽⁶⁾ 1 ml of inoculum is plated on a Petri dish of 140 mm diameter or on three Petri dishes of 90 mm diameter.

⁽⁷⁾ This criterion applies to products before they have left the immediate control of the producing food business operator, when he is not able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit of 100 cfu/g throughout the shelf-life.

⁽⁸⁾ Products with pH ≤ 4,4 or a_w ≤ 0,92, products with pH ≤ 5,0 and a_w ≤ 0,94, products with a shelf-life of less than five days are automatically considered to belong to this category. Other categories of products can also belong to this category, subject to scientific justification.

⁽⁹⁾ This criterion applies to mechanically separated meat (MSM) produced with the techniques referred to in Chapter III, paragraph 3, in section V of Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin.

⁽¹⁰⁾ Excluding products when the manufacturer can demonstrate to the satisfaction of the competent authorities that, due to the ripening time and a_w of the product where appropriate, there is no salmonella risk.

⁽¹¹⁾ Only ice creams containing milk ingredients.

⁽¹²⁾ Preliminary testing of the batch of seeds before starting the sprouting process or the sampling to be carried out at the stage where the highest probability of finding *Salmonella* is expected.

⁽¹³⁾ Reference: Hennekinne et al., J. AOAC Internat. Vol. 86, No 2, 2003.

⁽¹⁴⁾ *E. coli* is used here as an indicator of faecal contamination.

⁽¹⁵⁾ A pooled sample comprising a minimum of 10 individual animals.

⁽¹⁶⁾ Particularly fish species of the families: *Scombridae*, *Clupeidae*, *Engraulidae*, *Coryfenidae*, *Pomatomidae*, *Scombresosidae*.

⁽¹⁷⁾ Single samples may be taken at retail level. In such a case the presumption laid down in Article 14(6) of Regulation (EC) No 178/2002, according to which the whole batch should be deemed unsafe, shall not apply.

⁽¹⁸⁾ References: 1. Malle P., Valle M., Bouquelet S. Assay of biogenic amines involved in fish decomposition. J. AOAC Internat. 1996, 79, 43-49.

2. Duflos G., Dervin C., Malle P., Bouquelet S. Relevance of matrix effect in determination of biogenic amines in plaice (*Pleuronectes platessa*) and whiting (*Merlangius merlangus*). J. AOAC Internat. 1999, 82, 1097-1101.

Interpretation of the test results

The limits given refer to each sample unit tested, excluding live bivalve molluscs and live echinoderms, tunicates and gastropods in relation to testing *E. coli*, where the limit refers to a pooled sample.

The test results demonstrate the microbiological quality of the batch tested ⁽¹⁾.

L. monocytogenes in ready-to-eat foods intended for infants and for special medical purposes:

- satisfactory, if all the values observed indicate the absence of the bacterium,
- unsatisfactory, if the presence of the bacterium is detected in any of the sample units.

L. monocytogenes in ready-to-eat foods able to support the growth of *L. monocytogenes* before the food has left the immediate control of the producing food business operator when he is not able to demonstrate that the product will not exceed the limit of 100 cfu/g throughout the shelf-life:

- satisfactory, if all the values observed indicate the absence of the bacterium,
- unsatisfactory, if the presence of the bacterium is detected in any of the sample units.

L. monocytogenes in other ready-to-eat foods and *E. coli* in live bivalve molluscs:

- satisfactory, if all the values observed are \leq the limit,
- unsatisfactory, if any of the values are $>$ the limit.

Salmonella in different food categories:

- satisfactory, if all the values observed indicate the absence of the bacterium,
- unsatisfactory, if the presence of the bacterium is detected in any of the sample units.

⁽¹⁾ The test results can be used also for demonstrating the effectiveness of the HACCP or good hygiene procedure of the process.

Staphylococcal enterotoxins in dairy products:

- satisfactory, if in all the sample units the enterotoxins are not detected,
- unsatisfactory, if the enterotoxins are detected in any of the sample units.

Enterobacter sakazakii in dried infant formulae and dried dietary foods for special medical purposes intended for infants below 6 months of age:

- satisfactory, if all the values observed indicate the absence of the bacterium,
- unsatisfactory, if the presence of the bacterium is detected in any of the sample units.

Histamine in fishery products from fish species associated with a high amount of histidine:

- satisfactory, if the following requirements are fulfilled:
 1. the mean value observed is $\leq m$
 2. a maximum of c/n values observed are between m and M
 3. no values observed exceed the limit of M ,
- unsatisfactory, if the mean value observed exceeds m or more than c/n values are between m and M or one or more of the values observed are $>M$.

Chapter 2. Process hygiene criteria

2.1. Meat and products thereof

Food category	Micro-organisms	Sampling plan ⁽¹⁾		Limits ⁽²⁾		Analytical reference method ⁽³⁾	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.1.1. Carcases of cattle, sheep, goats and horses ⁽⁴⁾	Aerobic colony count			3,5 log cfu/cm ² daily mean log	5,0 log cfu/cm ² daily mean log	ISO 4833	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
	Enterobacteriaceae			1,5 log cfu/cm ² daily mean log	2,5 log cfu/cm ² daily mean log	ISO 21528-2	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
2.1.2. Carcases of pigs ⁽⁴⁾	Aerobic colony count			4,0 log cfu/cm ² daily mean log	5,0 log cfu/cm ² daily mean log	ISO 4833	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
	Enterobacteriaceae			2,0 log cfu/cm ² daily mean log	3,0 log cfu/cm ² daily mean log	ISO 21528-2	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
2.1.3. Carcases of cattle, sheep, goats and horses	<i>Salmonella</i>	50 ⁽⁵⁾	2 ⁽⁶⁾	Absence in the area tested per carcase		EN/ISO 6579	Carcases after dressing but before chilling	Improvements in slaughter hygiene, review of process controls and of origin of animals
2.1.4. Carcases of pig	<i>Salmonella</i>	50 ⁽⁵⁾	5 ⁽⁶⁾	Absence in the area tested per carcase		EN/ISO 6579	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls, origin of animals and of the biosecurity measures in the farms of origin
2.1.5. Poultry carcases of broilers and turkeys	<i>Salmonella</i>	50 ⁽⁵⁾	7 ⁽⁶⁾	Absence in 25 g of a pooled sample of neck skin		EN/ISO 6579	Carcases after chilling	Improvements in slaughter hygiene and review of process controls, origin of animals and biosecurity measures in the farms of origin

Food category	Micro-organisms	Sampling plan ⁽¹⁾		Limits ⁽²⁾		Analytical reference method ⁽³⁾	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.1.6. Minced meat	Aerobic colony count ⁽⁷⁾	5	2	5x10 ⁵ cfu/g	5x10 ⁶ cfu/g	ISO 4833	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
	<i>E.coli</i> ⁽⁸⁾	5	2	50 cfu/g	500 cfu/g	ISO 16649-1 or 2	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
2.1.7. Mechanically separated meat (MSM) ⁽⁹⁾	Aerobic colony count	5	2	5x10 ⁵ cfu/g	5x10 ⁶ cfu/g	ISO 4833	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
	<i>E.coli</i> ⁽⁸⁾	5	2	50 cfu/g	500 cfu/g	ISO 16649-1 or 2	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
2.1.8. Meat preparations	<i>E.coli</i> ⁽⁸⁾	5	2	500 cfu/g or cm ²	5 000 cfu/g or cm ²	ISO 16649-1 or 2	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials

⁽¹⁾ n = number of units comprising the sample; c = number of sample units giving values between m and M.

⁽²⁾ For points 2.1.3 — 2.1.5 m=M.

⁽³⁾ The most recent edition of the standard shall be used.

⁽⁴⁾ The limits (m and M) apply only to samples taken by the destructive method. The daily mean log is calculated by first taking a log value of each individual test result and then calculating the mean of these log values.

⁽⁵⁾ The 50 samples are derived from 10 consecutive sampling sessions in accordance with the sampling rules and frequencies laid down in this Regulation.

⁽⁶⁾ The number of samples where the presence of salmonella is detected. The c value is subject to review in order to take into account the progress made in reducing the salmonella prevalence. Member States or regions having low salmonella prevalence may use lower c values even before the review.

⁽⁷⁾ This criterion does not apply to minced meat produced at retail level when the shelf-life of the product is less than 24 hours.

⁽⁸⁾ *E. coli* is used here as an indicator of faecal contamination.

⁽⁹⁾ These criteria apply to mechanically separated meat (MSM) produced with the techniques referred to in Chapter III, paragraph 3, in section V of Annex III of Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin.

Interpretation of the test results

The limits given refer to each sample unit tested, excluding testing of carcasses where the limits refer to pooled samples.

The test results demonstrate the microbiological quality of the process tested.

Enterobacteriaceae and aerobic colony count in carcasses of cattle, sheep, goats, horses and pigs:

- satisfactory, if the daily mean log is $< m$,
- acceptable, if the daily mean log is between m and M ,
- unsatisfactory, if the daily mean log is $> M$.

Salmonella in carcasses:

- satisfactory, if the presence of *Salmonella* is detected in a maximum of c/n samples,
- unsatisfactory, if the presence of *Salmonella* is detected in more than c/n samples.

After each sampling session, the results of the last ten sampling sessions are assessed in order to obtain the n number of samples.

E. coli and aerobic colony count in minced meat, meat preparations and mechanically separated meat (MSM):

- satisfactory, if all the values observed are $< m$,
- acceptable, if a maximum of c/n values are between m and M , and the rest of the values observed are $< m$,
- unsatisfactory, if one or more of the values observed are $> M$ or more than c/n values are between m and M .

2.2. Milk and dairy products

Food category	Micro-organisms	Sampling plan ⁽¹⁾		Limits ⁽²⁾		Analytical reference method ⁽³⁾	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.2.1. Pasteurised milk and other pasteurised liquid dairy products ⁽⁴⁾	Enterobacteriaceae	5	2	<1 cfu/ml	5 cfu/ml	ISO 21528-1	End of the manufacturing process	Check on the efficiency of heat-treatment and prevention of recontamination as well as the quality of raw materials
2.2.2. Cheeses made from milk or whey that has undergone heat treatment	<i>E.coli</i> ⁽⁵⁾	5	2	100 cfu/g	1 000 cfu/g	ISO 16649- 1 or 2	At the time during the manufacturing process when the <i>E. coli</i> count is expected to be highest ⁽⁶⁾	Improvements in production hygiene and selection of raw materials
2.2.3. Cheeses made from raw milk	Coagulase-positive staphylococci	5	2	10 ⁴ cfu/g	10 ⁵ cfu/g	EN/ISO 6888-2	At the time during the manufacturing process when the number of staphylococci is expected to be highest	Improvements in production hygiene and selection of raw materials. If values > 10 ⁵ cfu/g are detected, the cheese batch has to be tested for staphylococcal enterotoxins.
2.2.4. Cheeses made from milk that has undergone a lower heat treatment than pasteurisation ⁽⁷⁾ and ripened cheeses made from milk or whey that has undergone pasteurisation or a stronger heat treatment ⁽⁷⁾	Coagulase-positive staphylococci	5	2	100 cfu/g	1 000 cfu/g	EN/ISO 6888-1 or 2		
2.2.5. Unripened soft cheeses (fresh cheeses) made from milk or whey that has undergone pasteurisation or a stronger heat treatment ⁽⁷⁾	Coagulase-positive staphylococci	5	2	10 cfu/g	100 cfu/g	EN/ISO 6888-1 or 2	End of the manufacturing process	Improvements in production hygiene. If values > 10 ⁵ cfu/g are detected, the cheese batch has to be tested for staphylococcal enterotoxins.
2.2.6. Butter and cream made from raw milk or milk that has undergone a lower heat treatment than pasteurisation	<i>E.coli</i> ⁽⁵⁾	5	2	10 cfu/g	100 cfu/g	ISO 16649- 1 or 2	End of the manufacturing process	Improvements in production hygiene and selection of raw materials

Food category	Micro-organisms	Sampling plan ⁽¹⁾		Limits ⁽²⁾		Analytical reference method ⁽³⁾	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.2.7. Milk powder and whey powder ⁽⁴⁾	Enterobacteriaceae	5	0	10 cfu/g		ISO 21528- 1	End of the manufacturing process	Check on the efficiency of heat treatment and prevention of recontamination
	Coagulase-positive staphylococci	5	2	10 cfu/g	100 cfu/g	EN/ISO 6888-1 or 2	End of the manufacturing process	Improvements in production hygiene. If values > 10 ⁵ cfu/g are detected, the batch has to be tested for staphylococcal enterotoxins.
2.2.8. Ice cream ⁽⁵⁾ and frozen dairy desserts	Enterobacteriaceae	5	2	10 cfu/g	100 cfu/g	ISO 21528- 2	End of the manufacturing process	Improvements in production hygiene
2.2.9. Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age	Enterobacteriaceae	10	0	Absence in 10 g		ISO 21528- 1	End of the manufacturing process	Improvements in production hygiene to minimise contamination. If Enterobacteriaceae are detected in any of the sample units, the batch has to be tested for <i>E. sakazakii</i> and <i>Salmonella</i>

⁽¹⁾ n = number of units comprising the sample; c = number of sample units giving values between m and M.

⁽²⁾ For point 2.2.7 m=M.

⁽³⁾ The most recent edition of the standard shall be used.

⁽⁴⁾ The criterion does not apply to products intended for further processing in the food industry.

⁽⁵⁾ *E. coli* is used here as an indicator for the level of hygiene.

⁽⁶⁾ For cheeses which are not able to support the growth of *E. coli*, the *E. coli* count is usually the highest at the beginning of the ripening period, and for cheeses which are able to support the growth of *E. coli*, it is normally at the end of the ripening period.

⁽⁷⁾ Excluding cheeses where the manufacturer can demonstrate, to the satisfaction of the competent authorities, that the product does not pose a risk of staphylococcal enterotoxins.

⁽⁸⁾ Only ice creams containing milk ingredients.

Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.

Enterobacteriaceae in dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age:

- satisfactory, if all the values observed indicate the absence of the bacterium,
- unsatisfactory, if the presence of the bacterium is detected in any of the sample units

E. coli, enterobacteriaceae (other food categories) and coagulase-positive staphylococci:

- satisfactory, if all the values observed are $< m$,
- acceptable, if a maximum of c/n values are between m and M , and the rest of the values observed are $< m$,
- unsatisfactory, if one or more of the values observed are $> M$ or more than c/n values are between m and M .

2.3. Egg products

Food category	Micro-organisms	Sampling plan ⁽¹⁾		Limits		Analytical reference method ⁽²⁾	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.3.1. Egg products	Enterobacteriaceae	5	2	10 cfu/g or ml	100 cfu/g or ml	ISO 21528-2	End of the manufacturing process	Checks on the efficiency of the heat treatment and prevention of recontamination

⁽¹⁾ n = number of units comprising the sample; c = number of sample units giving values between m and M.

⁽²⁾ The most recent edition of the standard shall be used.

Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.

Enterobacteriaceae in egg products:

- satisfactory, if all the values observed are < m,
- acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m,
- unsatisfactory, if one or more of the values observed are >M or more than c/n values are between m and M.

2.4. Fishery products

Food category	Micro-organisms	Sampling plan ⁽¹⁾		Limits		Analytical reference method ⁽²⁾	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.4.1. Shelled and shucked products of cooked crustaceans and molluscan shellfish	<i>E.coli</i>	5	2	1 cfu/g	10 cfu/g	ISO TS 16649-3	End of the manufacturing process	Improvements in production hygiene
	Coagulase-positive staphylococci	5	2	100 cfu/g	1 000 cfu/g	EN/ISO 6888-1 or 2	End of the manufacturing process	Improvements in production hygiene

⁽¹⁾ n = number of units comprising the sample; c = number of sample units giving values between m and M.

⁽²⁾ The most recent edition of the standard shall be used.

Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.

E. coli in shelled and shucked products of cooked crustaceans and molluscan shellfish:

- satisfactory, if all the values observed are $\leq m$,
- acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are $\leq m$,
- unsatisfactory, if one or more of the values observed are $>M$ or more than c/n values are between m and M.

Coagulase-positive staphylococci in shelled and cooked crustaceans and molluscan shellfish:

- satisfactory, if all the values observed are $< m$,
- acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are $< m$,
- unsatisfactory, if one or more of the values observed are $>M$ or more than c/n values are between m and M.

2.5. Vegetables, fruits and products thereof

Food category	Micro-organisms	Sampling plan ⁽¹⁾		Limits		Analytical reference method ⁽²⁾	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.5.1. Pre-cut fruit and vegetables (ready-to-eat)	<i>E.coli</i>	5	2	100 cfu/g	1 000 cfu/g	ISO 16649- 1 or 2	Manufacturing process	Improvements in production hygiene, selection of raw materials
2.5.2. Unpasteurised fruit and vegetable juices (ready-to-eat)	<i>E.coli</i>	5	2	100 cfu/g	1 000 cfu/g	ISO 16649- 1 or 2	Manufacturing process	Improvements in production hygiene, selection of raw materials

⁽¹⁾ n = number of units comprising the sample; c = number of sample units giving values between m and M.

⁽²⁾ The most recent edition of the standard shall be used.

Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.

E. coli in pre-cut fruit and vegetables (ready-to-eat) and in unpasteurised fruit and vegetable juices (ready-to-eat):

- satisfactory, if all the values observed are $\leq m$,
- acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are $\leq m$,
- unsatisfactory, if one or more of the values observed are $>M$ or more than c/n values are between m and M.



United States Department of Agriculture

Food Safety and
Inspection Service

OCT 21 2015

1400 Independence
Avenue, SW.
Washington, D.C.
20250

Dr. Per S. Henriksen
Chief Veterinary Officer
Ministry of Food, Agriculture and Fisheries
Danish Veterinary and Food Administration
Mørkhøj Bygade 19
DK-2860 Søborg
Denmark

Dear Dr. Henriksen:

The Food Safety and Inspection Service (FSIS) has concluded its review of Denmark's September 2013 submission to conduct a visual post-mortem inspection that omits the palpation of the lungs, the liver, and their associated lymph nodes of market hogs that are raised indoors. This submission has been determined to meet United States levels of protection and is therefore equivalent.

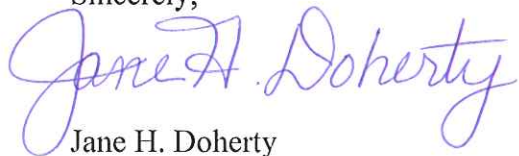
Previously, FSIS has made equivalence determinations for other aspects of Denmark's visual post-mortem inspection system for market hogs. On December 24, 2008, FSIS approved a submission to omit the palpation and incision of mandibular lymph nodes, and on February 29, 2012, a second submission was approved to omit the palpation and incision of mesenteric lymph nodes. These combined equivalence determinations will allow Denmark to perform a full carcass visual post-mortem inspection on indoor raised market hogs.

Visual post-mortem inspection will still allow veterinary inspectors to palpate and incise lymph nodes and organs (as occurs in traditional inspection) at their discretion. Each herd of market hogs that arrives at establishments to be slaughtered is accompanied by historical "Supply-Chain Information." Supply-Chain Information consists of paperwork that documents the health status and history of each herd, complete traceback information, as well as details about the originating farm, such as history of disease, use of medications and other on farm practices that contribute to maintenance of the herd's health. This documentation, as well as any ante-mortem inspection observances, will influence the veterinary inspector's decision whether to perform visual inspection or traditional inspection.

FSIS' reviews were conducted using submitted material provided by Denmark, such as detailed descriptions of their proposed systems, and in-depth risk assessments. These risk assessments considered various food safety hazards such as the risk of exposure to pathogenic organisms, pathology, animal disease, and a study comparing the performance of visual inspection to that of traditional inspection.

Thank you for your assistance and cooperation during the review process. Please feel free to contact me at telephone number 202-708-8769, or by email at Jane.Doherty@fsis.usda.gov if you have any questions.

Sincerely,



Jane H. Doherty
International Coordination Executive
Office of International Coordination



United States Department of Agriculture

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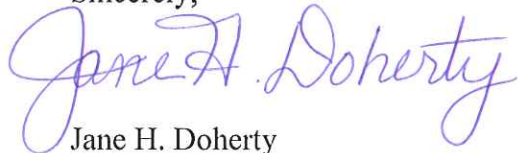
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Sincerely,



Jane H. Doherty
International Coordination Executive
Office of International Coordination



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

Dr. Peter W. de Leeuw
Chief Veterinary Officer
Ministry of Agriculture, Nature and Food Quality
PO Box 19506
2500 CM The Hague
Netherlands

JUL 16 2008

Dear Dr. de Leeuw:

I am writing to inform you of the equivalence decision made by this office with regard to your request for use of an alternative post-mortem inspection procedure for market hogs. In the submission, the Netherlands requested an equivalence determination for:

- Supply Chain Inspection

As part of the equivalence determination process, the Food Safety and Inspection Service (FSIS) establishes criteria for determining whether an alternative sanitary measure will ensure the same level of public health protection as the FSIS requirement. Accordingly, FSIS applied the following equivalence criteria for making an equivalence determination regarding the use of an alternative post-mortem inspection procedure for market hogs:

- The government inspection service administers an inspection program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass.
- The government inspection system requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market hog carcasses presented for inspection.
- The incidence of diseases in market hogs, such as TB, is no higher than the incidence in the United States.
- The market swine must be born and raised in the country.
- The government inspection service must implement a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects).

Based on the information provided, FSIS determined that Netherland's use of an alternative post-mortem inspection procedure for market hogs meets the established criteria. Therefore, FSIS is granting the government of the Netherlands approval to use supply chain inspection for the purposes of post-mortem inspection of the meat products exported to the United States.

If you have any questions regarding these equivalence determinations or need additional information, please contact me by telephone at 202-720-3781, by fax at 202-690-4040, or by electronic mail at sally.white@fsis.usda.gov.

Sincerely,

A handwritten signature in cursive script that reads "Sally White".

Sally White
Director
International Equivalence Staff
Office of International Affairs

CC:



Steve Huete, Attaché, US Embassy, The Hague
Fritz Thissen, Agricultural Counselor, Netherlands Embassy, Wash DC
Canice Nolan, Agric. / Consumer Affairs, EU Mission to the U.S., Wash DC
Bernard Van Goethem, Acting Director, Directorate E, European Commission, Brussels
Debra Henke, Minister-Counselor, US Mission to the EU in Brussels
OSTA/ FAS
David Young, Europe Area Director, FAS
Ann Ryan, State Department
Alfred Almanza, Administrator, FSIS
William James, Assistant Administrator, OIA, FSIS
Donald Smart, Director, IAS, OIA, FSIS
Clark Danford, Director, IEPS, OIA
Sally White, Director, IES, OIA
Director, FCPS, OIA
Robert Tuverson, Director, IID, OIA
Lisa Wallenda Picard, OA
David Smith, IES, OIA
Mary Stanley, OAA
Rick Harries, OAA
Yolande Mitchell, FCPS, OIA
Country File

FSIS:OIA:IES:TFurey:720.5123:07/09/08:NL – Supply Chain Inspection

A handwritten signature in black ink, appearing to be 'Furey', is written below the distribution list.



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FILE ASSURANCE CHECKLIST

CERTIFICATION STATEMENT

The contents of this file has been reviewed in accordance with the Equivalence Management Controls established by the International Equivalence Staff (IES) as certified by the Senior Equivalence Officer assigned to the file and reviewed by the Director, IES, Office of International Affairs.

COUNTRY

TYPE OF FILE

- ☒ ON-GOING EQUIVALENCE DETERMINATION
- ☐ INITIAL EQUIVALENCE DETERMINATION
- ☐ ANNUAL ON-SITE AUDIT
- ☐ OTHER

CERTIFIED BY

M. J. ...

SENIOR EQUIVALENCE OFFICER, IES

DATE: 11/17/06

REVIEWED BY

Sally White

DIRECTOR, IES

DATE: 11/17/06

DECISION MEMORANDUM

ISSUE:

The Netherlands has developed a system for inspection of market hogs which emphasizes ante-mortem animal disease detection (tuberculosis) by serology on-farm instead of post-mortem inspection for gross lesions at slaughter.

BACKGROUND:

The Netherlands has implemented a Supply Chain Inspection system. This system allows inspection of market hogs raised under an integrated quality control program coupled with a system of on-farm testing, and on-site verification at the slaughter establishment for checking the accuracy of visually inspected carcasses and organs to ensure that passed carcasses and parts are wholesome and not adulterated.

A team of FSIS experts met and reviewed the Netherlands Supply Chain Inspection system, the Netherlands reference materials, and information presented by the Netherlands officials during FSIS-Netherlands bilateral meeting of November 1-2, 2006. The FSIS team also reviewed the two FSIS inspection procedures (traditional inspection and HACCP-Based Inspection Model Project-HIMP) employed in establishments slaughtering market age hogs and compared these two inspection procedures with the Netherlands' post-mortem inspection procedure. These two FSIS inspection procedures were used to develop the equivalence criteria used to evaluate the Netherlands' request.

SUMMARY OF SUPPLY CHAIN INSPECTION

The following is a summary of the Netherlands' inspection procedures used in establishments operating under Supply Chain Inspection:

Ante-mortem Inspection

Ante-mortem inspection on all swine is performed by the official veterinarian using traditional inspection procedures, which are equivalent to FSIS' traditional inspection procedures.

Post-mortem Inspection

Post-mortem inspection is performed by official auxiliaries (contract inspectors) located at fixed inspection stations for head, viscera and carcass inspection.

- Head Inspection
 - Visual inspection of the head and throat, including the mandibular lymph nodes
 - Visual inspection of the mouth, fauces, and tongue

- Viscera Inspection
 - Visual inspection of the lungs, trachea, and esophagus
 - Visual inspection of the pericardium and heart
 - Visual inspection of the liver and hepatic and pancreatic (portal) lymph nodes
 - Visual inspection of the gastro-intestinal tract, mesentery, gastric and mesenteric lymph nodes
 - Visual inspection of the spleen
 - Visual inspection of genital organs
- Carcass Inspection
 - Visual inspection of the carcass
 - Visual inspection of the pleura and peritoneum (lining of chest and abdominal cavities)
 - Visual inspection of the kidneys
 - Visual inspection of the diaphragm
 - Visual inspection of the udder and its lymph nodes
 - Visual inspection of the umbilical region and joints of young animals

SUMMARY OF FSIS TRADITIONAL INSPECTION

The following is a summary of the FSIS inspection procedures in establishments operating under the traditional swine inspection system.

Ante-mortem Inspection

All swine offered for slaughter in an official establishment are examined and inspected on the day of and before slaughter by an FSIS inspector. Ante-mortem inspection is made in pens on the premises of the establishment. All animals are examined and inspected at rest and in motion; both sides are inspected and observed. Each head, viscera and carcass is inspected as described below.

Post –mortem Inspection

FSIS inspectors are located at fixed inspection stations in order to perform inspection of the head, viscera and carcass.

- Head Inspection
 - Observe head and cut surfaces – eyes, fat, cheek muscles, and other tissues for abnormalities
 - Incise and observe mandibular lymph nodes
- Viscera Inspection
 - Observe eviscerated carcass, viscera and parietal (top) surface of spleen
 - Observe and palpate mesenteric lymph nodes
 - Palpate portal lymph nodes

- Observe dorsal (curved) surface of lungs
 - Palpate bronchial lymph nodes
 - Observe mediastinal lymph nodes
 - Turn lungs over and observe ventral (flat) surfaces
 - Observe heart
 - Observe dorsal (curved) surface of liver
 - Turn liver over and observe ventral (flat) surface
- Carcass Inspection
 - Observe back of carcass (turn carcass or use mirror).
 - Observe front and inside of carcass, including:
 - Cut surfaces
 - All body cavities
 - Lumbar region
 - Neck region
 - Grasp, turn, and observe the kidneys

SUMMARY OF FSIS HIMP INSPECTION

The following is a summary of the FSIS inspection procedures in establishments operating under HIMP.

FSIS conducts three types of inspection activities; Systems Inspection, Carcass Inspection and Verification Inspection in HIMP establishments. Systems Inspection involves the evaluation of in-plant inspection findings and is intended to determine the effectiveness of the overall design and execution of all establishment slaughter processes under the HACCP and process control plans. Carcass Inspection involves the examination of each carcass and its parts to determine if they are unadulterated. Verification Inspection involves the evaluation of the effectiveness of the establishment's HACCP and process control plan in meeting the relevant performance standards. Inspection procedures under HIMP were developed to reduce reliance on organoleptic inspection, to shift to prevention-oriented inspection systems based on risk assessment, and to redeploy inspection resources in a manner that better protects the public from food-borne diseases.

System Inspection - The System Inspector (SI) is either the Inspector in Charge (IIC) or the Supervisory Veterinary Medical Officer (SVMO). The SI has overall responsibility to assure that the plant and inspection personnel effectively conduct the required activities under HIMP, as designed.

Specifically, the System Inspector:

- Determines, or assigns to the verification inspector (VI), the daily random sampling schedule.
- Monitors and determines the effectiveness of ante-mortem verification inspection.
- Monitors and determines the effectiveness of the establishment's ante-mortem sorting.

- Determines final disposition of animals designated by the VI as “suspects” at ante-mortem.
- Monitors and determines the effectiveness of the establishment’s post-mortem sorting and dispositions.
- Determines final disposition on carcasses retained by the carcass inspector (CI) or VI on post-mortem.
- Records nonconformance findings on the appropriate HIMP form.
- Determines if the establishment is meeting relevant performance standards.
- Assesses the overall design and execution of the establishment’s HACCP and process control procedures.
- Assures that all adulterated products are condemned in accordance with applicable regulations.
- Determines when unscheduled verification sampling is warranted.
- Maintains communication with the VI and CIs to facilitate coordination of all ante-mortem and post-mortem findings.

Carcass Inspection - The Carcass Inspectors (CI) are stationed at fixed locations on the post-mortem line to determine whether a product is adulterated or unadulterated. They inspect each carcass and part on the line, as well as evaluate the on-going effectiveness of the establishment’s food safety and other consumer protection processes.

Specifically, the CI:

- Determines whether each carcass and its parts are adulterated or unadulterated.
- Takes appropriate action to prevent adulterated product from entering into human food channels.
- Notifies the establishment personnel, VI and/or SI of carcass and/or parts defect findings.
- Retains carcasses and parts for further disposition by the SI if food safety and other conditions are identified that could result in condemnation.

Verification Inspection - The Verification Inspector (VI) does not have a fixed position on the line, and can move freely.

Specifically, the VI:

- Observes and evaluates the effectiveness of the establishment’s HACCP and process control plans, including the examination of records, to determine whether the establishment is in compliance with applicable regulatory requirements.
- Records all findings of noncompliance with applicable performance standards.
- Investigates potential process control problems.
- Notifies the SI if the process control plan is not being met or if performance standards have been exceeded.
- Retains carcasses and parts for further disposition by the SI if food safety and other conditions are identified that could result in condemnation.

The following is a summary of tasks performed by the CI and VI during ante-mortem and post-mortem inspection in HIMP establishments.

Ante-mortem inspection

The VI conducts ante-mortem inspection of all animals at rest and 5-10 percent of animals in motion.

- Retains animals for further disposition by the SI, if the animal is suspected of having a condition that could result in condemnation.
- Documents ante-mortem findings on the appropriate HIMP form.

The Systems Inspector monitors and determines the effectiveness of the establishment's ante-mortem sorting.

- Monitors and determines the effectiveness of ante-mortem verification inspection.
- Determines final disposition of animals designated by the VI as "suspects" at ante-mortem.

Post-mortem inspection

Post-mortem inspection is performed by the CI for the head, viscera and carcass.

Head Inspection

Establishments must incise the mandibular lymph nodes before presenting the carcass for inspection.

The CI observes the head, including:

- Incised mandibular lymph nodes
- Cut surfaces, eyes, fat, cheek muscles, and other tissues

Viscera Inspection

The CI observes the viscera, including:

- Spleen
- Mesenteric and portal lymph nodes
- Liver
- Lungs
- Bronchial and mediastinal lymph nodes
- Heart

Carcass Inspection

The CI observes the carcass, including:

- Cut surfaces
- All body cavities
- Lumbar region
- Neck region
- Kidneys

COMPARISON: FSIS INSPECTION AND SUPPLY CHAIN INSPECTION PROCEDURES

Netherlands uses a combination of pre-slaughter data collection and post-mortem inspection to ensure the identification and removal of unhealthy animals, adulterated carcasses and parts and resulting products from the food supply. Pre-slaughter data collection is done through a system called the IKB Varkens (IKB) program which is an integrated quality assurance program with comprehensive controls over the production chain in addition to national and EU requirements for feed, hygiene, the use of veterinary drugs, transport of animals, and animal welfare. The IKB requires transfer of animal health records from the farm to both the establishment and inspection officials to reduce animal diseases to provide greater assurance that only wholesome meat products are produced. All market hogs receive ante-mortem and post-mortem visual inspection of the head, viscera, and carcass.

FSIS' post-mortem inspection procedures in the traditional inspection are similar to the Netherlands' post-mortem inspection procedures except FSIS inspectors incise and observe mandibular lymph nodes, observe and palpate portal and bronchial lymph nodes, turn and observe both surfaces of liver and lungs and kidneys.

FSIS post-mortem inspection procedures under HIMP are similar to the Netherlands ante-mortem and post-mortem inspection except that FSIS requires the establishment to incise mandibular lymph nodes. FSIS verifies the accuracy of establishment procedures by system inspection and verification inspection procedures. In addition both systems have inspection verification procedures.

FSIS FOOD SAFETY MEASURE:

The purpose of post-mortem inspection of livestock is to protect the public health by ensuring that carcasses and parts that enter commerce are wholesome and not adulterated. To achieve this goal, in swine slaughter establishments operating under traditional inspection or in those establishments operating under the HACCP-Based Inspection Models Project (HIMP), FSIS inspectors perform ante-mortem and post-mortem inspection procedures to detect diseases, abnormalities, and contamination of livestock carcasses and parts.

In establishments operating under HIMP, FSIS requires that the establishment implement ante-mortem and post-mortem sorting procedures and present to FSIS only normal and healthy-appearing animals and carcasses and parts that are wholesome and free of defects. HIMP also requires additional FSIS verification procedures to ensure that the establishment produces only safe, wholesome products.

OBJECTIVE:

FSIS inspectors conduct ante-mortem inspection of live swine and post-mortem inspection of carcasses and parts on a carcass by carcass basis. In market age swine, FSIS performs

inspection under either the traditional inspection system or under the HIMP inspection system. In both cases, inspection procedures are intended to identify and remove unwholesome and adulterated carcasses and parts from the food supply.

EQUIVALENCE CRITERIA AND EVALUATION:

The government inspection service administers an inspection program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass.

Netherlands uses a combination of pre-slaughter data collection and post-mortem inspection to ensure the identification and removal of diseased carcasses and parts from the food supply.

Research in the Netherlands has shown that the prevalence of *M. avium* at the farm level has decreased between 1998 and 2003. Actually, *M. avium* has not been detected in a targeted surveillance in the 2003 prevalence study by Komijn *et al.* In a prevalence study performed in 1996, 0.27% of slaughter pigs were found to have *Mycobacterium avium* subsp *avium* isolated from lesions in the mandibular lymph nodes. In a 2004 study, nine pig farms were selected based on risk. These farms had a recent history of having a high percentage of lesions in the mandibular lymph nodes. From a sample pool of 160 pigs, one had a lesion in the mesenteric lymph nodes, and ninety-eight pigs had lesions in the mandibular lymph nodes. All lesions were negative for *Mycobacterium avium* subsp *avium*. From these data, it is presumed that the prevalence of *Mycobacterium avium* subsp. *avium* is very low, thus forming the scientific basis for the change in the control of *M. avium* in pork.

Other studies also conducted in the Netherlands have shown that, in slaughter establishments with a high degree of control of fecal contamination, *Salmonella* contamination of carcasses is related to cross-contamination in the slaughterhouse rather than to *Salmonella* present in the intestine. An effective control of cross-contamination is therefore crucial to decrease *Salmonella* contamination of carcasses. The incisions made during the traditional post-mortem inspection contribute to the cross-contamination of *Salmonella*. Omitting these incisions will reduce the risk of cross-contamination.

Information from the reviewed studies and other documents provided by the Netherlands, coupled with the pilot study, shows that reduction in human health hazards predominately lies in the hygiene control programs that are implemented throughout the entire production process (farm to table). This supports their use of a “hands-off” system in the slaughter line and, instead, focuses on risk factors prior to post-mortem inspection.

The government inspection system requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market hog carcasses presented for inspection.

Netherlands has implemented a system of Supply Chain Inspection, which allows visual inspection of market hogs raised under the IKB Varkens (IKB) program. The Dutch IKB program is an integrated quality assurance program with comprehensive controls over the production chain in addition to national and EU requirements for feed, hygiene, the use of veterinary drugs, transport of animals, and animal welfare. The IKB program integrates the swine production process from breeding farm to slaughterhouse. The IKB provides requirements for the transfer of animal health records from the farm to the establishment, qualifications for veterinary practitioners, lists of approved veterinary drugs, feed control practices, and hygiene codes for farms, transporters and processors. The goal of an integrated animal health program is to reduce the occurrence of animal diseases and to provide greater assurance of wholesome meat products.

In addition to the IKB program, the Netherlands also requires swine farms to be subjected to ongoing serological surveillance for *M. avium* as a requirement for participation in Supply Chain inspection. Farms are categorized according to risk of *M. avium* infection based on the results of ongoing sampling results. If a farm has 18 consecutive negative results (sampled from 6 pigs in each of 3 deliveries), it is assigned a neutral risk. Afterwards, when the farm has 18 consecutive negative samples (collected from 2 pigs per herd), it is assigned a low risk. Ongoing monitoring of the low risk category of a farm is conducted by collecting 2 samples from each herd for serological testing. In the event of a positive result the farm loses its' low risk status, and becomes either high risk or neutral risk. If both results are positive the farm will be re-classified as high risk.

Only neutral and low risk farms are eligible to participate in visual inspection. Swine from high risk farms are subject to traditional inspection. In addition, animal health authorities assist the farms in identifying and reducing risk factors for *M. avium* infection.

The incidence of diseases in market hogs, such as TB, is no higher than the incidence in the United States.

The incidence of swine tuberculosis is lower in the Netherlands than the incidence of the disease in animals in the United States. Diseases that produce lesions in the mesenteric lymph nodes, such as tuberculosis, are very rare in the Netherlands.

The market swine must be born and raised in the country.

The swine must be born and raised in the Dutch Territories. In the Netherlands, swine are born and raised on large farms under controlled conditions. Improvements in animal husbandry, preventive medicine, and disease control programs have led to a significant rise in the slaughter of animals at a much younger age, in relatively uniform groups. These young animals have a lower incidence of diseases. However, some countries in Europe have a much higher prevalence of *M. avium*. Therefore, swine slaughtered for export to the United States must be born and raised in the Dutch Territories.

The government inspection service must implement a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects).

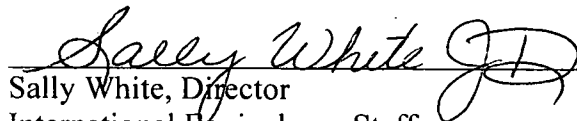
In all slaughterhouses, verification of visual inspection takes place on a daily basis (minimum once a day) and is carried out by the official veterinarian. The location of the verification activities is the on-line inspection platform next to the on-line inspection station. The results of this verification are documented, and the information is used to evaluate performance of online inspectors. These verification activities can be split into two basic standards, 1) standards for inspection procedures and 2) standards for inspection decisions. The official veterinarian verifies appropriate performance of inspection procedures by periodically observing inspectors. Inspectors are required to perform inspection procedures correctly and completely. The standard for the official veterinarian's verification is a maximum of 5% incorrect procedures. The official veterinarian also conducts verification of inspection decisions by periodically observing carcasses and organs for any pathological lesions or hygiene defects. For food safety conditions (feces, ingesta, septicemia-toxemia, cysticercosis), there is zero tolerance. For non-food safety defects, there is a cumulative maximum of 6% of missed pathological abnormalities (2% standard for the carcass, 2% for the stomach/intestines, and 2% for the organs). The inspectors will rail out forty carcasses four times per day, and forty plucks two times per day for verification. The Official Veterinarian also performs verification activities. Two times per day forty carcasses are railed out for the Official Veterinarian to perform verification of the inspection activities of the inspector to ensure that they are making the correct dispositions. The same procedure is conducted once per day on organs from forty carcasses.

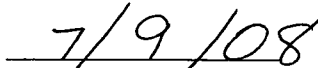
In cases where inspectors are not performing as required, the official veterinarian will take corrective actions.

RECOMMENDATION:


FSIS has determined that the alternate post-mortem procedure for market age hogs submitted by the Netherlands is equivalent to the FSIS post-mortem procedure for market age hogs. Therefore, the Netherlands' equivalence request should be granted.

DECISION CONFIRMATION AND APPROVAL:


Sally White, Director
International Equivalence Staff
Office of International Affairs, FSIS


Date

CONCURRENCE:


Dr. William James
Assistant Administrator
Office of International Affairs, FSIS


Date

**EQUIVALENCE DETERMINATION
ALTERNATE POST-MORTEM INSPECTION PROCEDURE FOR MARKET AGE
HOGS
November 3, 2006
Minutes**

PARTICIPANTS:

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David Smith, Staff Officer, IES, OIA
Scott Seebom, Staff Officer, TSC, OPPED

DOCUMENTS REVIEWED:

FSIS DOCUMENTS

1. Federal Meat Inspection Regulations, Parts 309, 310 and 311
2. Federal Meat Inspection Regulations, Part 303.2
3. HACCP-Based Inspection Models Project for Market Hogs (6/21/06)

NETHERLANDS DOCUMENTS

1. (Draft) Final Report on the data analysis from the "Visual Inspection Pilot."
2. Opinion of the Scientific Committee on Veterinary Measures Relating to Public Health on Revision of Meat Inspection Procedures.
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5. Regulations Governing the IKB Pigs Scheme for Pig Farmers. Netherlands documentation.
6. Certification Criteria for IKB Pigs Scheme. Netherlands documentation.
7. Recognition Terms for IKB Varkens Certifying Bodies. Netherlands documentation.
8. Post-Mortem Inspection in Fattening Pigs – Visual Inspection and Traditional. Netherlands documentation.
9. Answers to Questions FSIS to the Netherlands. Netherlands documentation.
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Equivalence Request: FSIS has received a request from the Netherlands to use an alternate post-mortem inspection procedure for market hogs—visual inspection of the carcass and viscera. The procedure does not require incising of the mandibular lymph nodes, palpation of the mesenteric, portal and bronchial lymph nodes, turning of lungs and liver, and grasping and turning of kidneys. The Netherlands has implemented a system of “Food Chain Inspection.” This system allows visual inspection of market hogs raised under an integrated quality control program coupled with a system of verification for checking the accuracy of visually inspected carcasses and organs to ensure that passed carcasses and parts are wholesome and not adulterated.

The team of FSIS experts met and reviewed the Netherlands visual inspection procedures, the Netherlands reference materials, and information presented by the Netherlands officials during FSIS-Netherlands bilateral meeting of November 1-2, 2006. The FSIS team also reviewed the two FSIS inspection procedures (traditional inspection and HACCP-Based Inspection Model Project-HIMP) employed in establishments slaughtering market hogs and compared these two inspection procedures with the Netherlands’ visual post-mortem inspection procedure. These two FSIS inspection procedures will be used to develop equivalence criteria to evaluate the Netherlands’ request.

The following is a summary of the Netherlands’ inspection procedures used in establishments operating under visual inspection.

ANTE-MORTEM INSPECTION

Ante-mortem inspection on all swine is performed by the official veterinarian using traditional inspection procedures, which are equivalent to FSIS’s traditional inspection procedures.

POST-MORTEM INSPECTION

Post-mortem inspection is performed by official auxiliaries (contract inspectors) located at fixed inspection stations for head, viscera and carcass inspection.

Head Inspection

- Visual inspection of the head and throat, including the mandibular lymph nodes
- Visual inspection of the mouth, fauces, and tongue

Viscera and carcass inspection

- Visual inspection of the lungs, trachea, and esophagus
- Visual inspection of the pericardium and heart

- Visual inspection of the liver and hepatic and pancreatic (portal) lymph nodes
- Visual inspection of the gastro-intestinal tract, mesentery, gastric and mesenteric lymph nodes
- Visual inspection of the spleen
- Visual inspection of genital organs

Carcass Inspection

- Visual inspection of the carcass
- Visual inspection of the pleura and peritoneum (lining of chest and abdominal cavities)
- Visual inspection of the kidneys
- Visual inspection of the diaphragm
- Visual inspection of the udder and its lymph nodes
- Visual inspection of the umbilical region and joints of young animals

The following is a summary of the FSIS inspection procedures in establishments operating under the traditional swine inspection system.

ANTE-MORTEM INSPECTION

All swine offered for slaughter in an official establishment are examined and inspected on the day of and before slaughter by an FSIS inspector. Ante-mortem inspection is made in pens on the premises of the establishment. All animals are examined and inspected at rest and in motion; both sides are inspected and observed. Each head, viscera and carcass is inspected as described below.

POST-MORTEM INSPECTION

FSIS inspectors are located at fixed inspection stations in order to perform inspection of the head, viscera and carcass.

Head Inspection

- Observe head and cut surfaces – eyes, fat, cheek muscles, and other tissues for abnormalities.
- Incise and observe mandibular lymph nodes.

Viscera Inspection

- Observe eviscerated carcass, viscera and parietal (top) surface of spleen.
- Observe and palpate mesenteric lymph nodes.
- Palpate portal lymph nodes.
- Observe dorsal (curved) surface of lungs.
- Palpate bronchial lymph nodes.
- Observe mediastinal lymph nodes.
- Turn lungs over and observe ventral (flat) surfaces.
- Observe heart.
- Observe dorsal (curved) surface of liver.

- Turn liver over and observe ventral (flat) surface.

Carcass Inspection

Observe back of carcass (turn carcass or use mirror).

- Observe front and inside of carcass, including.
 - Cut surfaces
 - All body cavities
 - Lumbar region
 - Neck region
 - Grasp, turn, and observe the kidneys

The following is a summary of the FSIS inspection procedures in establishments operating under HIMP

FSIS conducts three types of inspection activities; Systems Inspection, Carcass Inspection and Verification Inspection in HIMP establishments. Systems Inspection involves the evaluation of in-plant inspection findings and is intended to determine the effectiveness of the overall design and execution of all establishment slaughter processes under the HACCP and process control plans. Carcass Inspection involves the examination of each carcass and its parts to determine if they are unadulterated. Verification Inspection involves the evaluation of the effectiveness of the establishment's HACCP and process control plan in meeting the relevant performance standards. Inspection procedures under HIMP were developed to reduce reliance on organoleptic inspection, to shift to prevention-oriented inspection systems based on risk assessment, and to redeploy inspection resources in a manner that better protects the public from food-borne diseases.

System Inspection - The System Inspector (SI) is either the Inspector in Charge (IIC) or the Supervisory Veterinary Medical Officer (SVMO). The SI has overall responsibility to assure that the plant and inspection personnel effectively conduct the required activities under HIMP, as designed.

Specifically, the System Inspector:

- Determines, or assigns to the verification inspector (VI), the daily random sampling schedule.
- Monitors and determines the effectiveness of ante-mortem verification inspection.
- Monitors and determines the effectiveness of the establishment's ante-mortem sorting.
- Determines final disposition of animals designated by the VI as "suspects" at ante-mortem.
- Monitors and determines the effectiveness of the establishment's post-mortem sorting and dispositions.
- Determines final disposition on carcasses retained by the carcass inspector (CI) or VI on post-mortem.
- Records nonconformance findings on the appropriate HIMP form.
- Determines if the establishment is meeting relevant performance standards.
- Assesses the overall design and execution of the establishment's HACCP and process control procedures.

- Assures that all adulterated products are condemned in accordance with applicable regulations.
- Determines when unscheduled verification sampling is warranted.
- Maintains communication with the VI and CIs to facilitate coordination of all ante-mortem and post-mortem findings.

Carcass Inspection - The Carcass Inspectors (CI) are stationed at fixed locations on the post-mortem line to determine whether a product is adulterated or unadulterated. They inspect each carcass and part on the line, as well as evaluate the on-going effectiveness of the establishment's food safety and other consumer protection processes.

Specifically, the CI:

- Determines whether each carcass and its parts are adulterated or unadulterated.
- Takes appropriate action to prevent adulterated product from entering into human food channels.
- Notifies the establishment personnel, VI and/or SI of carcass and/or parts defect findings.
- Retains carcasses and parts for further disposition by the SI if food safety and other conditions are identified that could result in condemnation.

Verification Inspection - The Verification Inspector (VI) does not have a fixed position on the line, and can move freely.

Specifically, the VI:

- Observes and evaluates the effectiveness of the establishment's HACCP and process control plans, including the examination of records, to determine whether the establishment is in compliance with applicable regulatory requirements.
- Records all findings of noncompliance with applicable performance standards.
- Investigates potential process control problems.
- Notifies the SI if the process control plan is not being met or if performance standards have been exceeded.
- Retains carcasses and parts for further disposition by the SI if food safety and other conditions are identified that could result in condemnation.

The following is a summary of tasks performed by the CI and VI during ante-mortem and post-mortem inspection in HIMP establishments.

Ante-mortem inspection

The VI conducts ante-mortem inspection of all animals at rest and 5-10 percent of animals in motion.

- Retains animals for further disposition by the SI, if the animal is suspected of having a condition that could result in condemnation.
- Documents ante-mortem findings on the appropriate HIMP form.

The Systems Inspector monitors and determines the effectiveness of the establishment's ante-mortem sorting.

- Monitors and determines the effectiveness of ante-mortem verification inspection.
- Determines final disposition of animals designated by the VI as "suspects" at ante-mortem.

Post-mortem inspection

Post-mortem inspection is performed by the CI for the head, viscera and carcass.

Head Inspection

Establishments must incise the mandibular lymph nodes before presenting the carcass for inspection.

The CI observes the head, including:

- Incised mandibular lymph nodes
- Cut surfaces, eyes, fat, cheek muscles, and other tissues

Viscera Inspection

The CI observes the viscera, including:

- Spleen
- Mesenteric and portal lymph nodes
- Liver
- Lungs
- Bronchial and mediastinal lymph nodes
- Heart

Carcass Inspection

The CI observes the carcass, including:

- Cut surfaces
- All body cavities
- Lumbar region
- Neck region
- Kidneys

Development of Equivalence Criteria

The team developed equivalence criteria for visual inspection after review of the FSIS inspection procedures (later described in the minutes) and the Netherlands' proposal, taking into account the FSIS food safety measure and objective of the measure.

FSIS food safety measure: The purpose of post-mortem inspection of livestock is to protect the public health by ensuring that carcasses and parts that enter commerce are wholesome and not adulterated. To achieve this goal, in swine slaughter establishments operating under traditional inspection or in swine slaughter establishments operating under the HACCP-Based Inspection Models Project (HIMP), FSIS inspectors perform ante-

mortem and post-mortem inspection procedures to detect diseases, abnormalities, and contamination of livestock carcasses and parts.

In establishments operating under HIMP, FSIS requires that the establishment implement ante-mortem and post-mortem sorting procedures and present to FSIS only normal and healthy-appearing animals and carcasses and parts that are wholesome and free of defects. HIMP also requires additional FSIS verification procedures to ensure that the establishment produces only safe, wholesome products.

Objective: FSIS inspectors conduct ante-mortem inspection of live swine and post-mortem inspection of carcasses and parts on a carcass by carcass basis. In market age swine, FSIS performs inspection under either the traditional inspection system or under the HIMP inspection system. In both cases, inspection procedures are intended to identify and remove unwholesome and adulterated carcasses and parts from the food supply.

Comparison of the Netherlands visual inspection procedures with the FSIS inspection procedures.

Netherlands uses a combination of pre-slaughter data collection and post-mortem inspection to ensure the identification and removal of unhealthy animals, adulterated carcasses and parts and resulting products from the food supply. Pre-slaughter data collection is done through a system of "Food Chain Inspection" called the IKB Varkens (IKB) program which is an integrated quality assurance program with comprehensive controls over the production chain in addition to national and EU requirements for feed, hygiene, the use of veterinary drugs, transport of animals, and animal welfare. The IKB requires transfer of animal health records from the farm to both the establishment and inspection officials to reduce animal diseases to provide greater assurance that only wholesome meat products are produced. All market hogs receive ante-mortem and post-mortem visual inspection of the head, viscera, and carcass.

FSIS' post-mortem inspection procedures in the traditional inspection are similar to the Netherlands' visual post-mortem inspection procedures except FSIS inspectors incise and observe mandibular lymph nodes, observe and palpate portal and bronchial lymph nodes, turn and observe both surfaces of liver and lungs and kidneys.

FSIS post-mortem inspection procedures under HIMP are similar to the Netherlands visual ante-mortem and post-mortem inspection except that FSIS requires the establishment to incise mandibular lymph nodes. FSIS verifies the accuracy of establishment procedures by system inspection and verification inspection procedures. In addition both systems have inspection verification procedures.

EQUIVALENCE CRITERIA FOR AN ALTERNATE POST-MORTEM INSPECTION PROCEDURE FOR MARKET HOGS

Criteria used to determine whether an alternative post-mortem inspection procedure for market hogs is equivalent to the US inspection procedure for market hogs are set forth below:

1. The government inspection service administers an inspection program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass.
2. The government inspection system requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market hog carcasses presented for inspection.
3. The incidence of diseases in market hogs, such as TB, is no higher than the incidence in the United States.
4. The market swine must be born and raised in the country.
5. The government inspection service must implement a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects).

APPLICATION OF EQUIVALENCE CRITERIA FOR ALTERNATE POST-MORTEM INSPECTION PROCEDURE FOR MARKET HOGS

1. **The government inspection service administers an inspection program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass.** Netherlands uses a combination of pre-slaughter data collection and post-mortem inspection to ensure the identification and removal of diseased carcasses and parts from the food supply.

Research in the Netherlands has shown that the prevalence of *M. avium* at the farm level has decreased between 1998 and 2003. Actually, *M. avium* has not been detected in a targeted surveillance in the 2003 prevalence study by Komijn *et al.* In a prevalence study performed in 1996, 0.8% of slaughter pigs were found, upon post mortem inspection, to have lesions in the mandibular lymph nodes. Of these, 20% were found to have *Mycobacterium avium* subsp *avium*. In a 2004 study, nine pig farms were selected based on risk. These farms had a recent history of having a high percentage of lesions in the mandibular lymph nodes. From a sample pool of 160 pigs, one had a lesion in the mesenteric lymph nodes, and ninety-eight pigs had lesions in the mandibular lymph nodes. All lesions were negative for *Mycobacterium avium* subsp *avium*. From these data, it is presumed that the prevalence of *Mycobacterium avium* subsp. *avium* is very low, thus forming the scientific basis for the change in the control of *M. avium* in pork.

Other studies also conducted in the Netherlands have shown that, in slaughter establishments with a high degree of control of fecal contamination, *Salmonella* contamination of carcasses is related to cross-contamination in the slaughterhouse

rather than to *Salmonella* present in the intestine. An effective control of cross-contamination is therefore crucial to decrease *Salmonella* contamination of carcasses. The incisions made during the traditional post-mortem inspection contribute to the cross-contamination of *Salmonella*. Omitting these incisions will reduce the risk of cross-contamination.

Information from the reviewed studies and other documents provided by the Netherlands coupled with the pilot study shows that reduction in human health hazards predominately lies in the hygiene control programs that are implemented throughout the entire production process (farm to table). This supports their use of a “hands-off” system in the slaughter line and, instead, focusing on controlling risk factors prior to post-mortem inspection.

2. **The government inspection system requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market hog carcasses presented for inspection.** Netherlands has implemented a system of “Food Chain Inspection,” which allows visual inspection of market hogs raised under the IKB Varkens (IKB) program. The Dutch IKB program is an integrated quality assurance program with comprehensive controls over the production chain in addition to national and EU requirements for feed, hygiene, the use of veterinary drugs, transport of animals, and animal welfare. The IKB program integrates the swine production process from breeding farm to slaughterhouse. The IKB provides requirements for the transfer of animal health records from the farm to the establishment, qualifications for veterinary practitioners, lists of approved veterinary drugs, feed control practices, and hygiene codes for farms, transporters and processors. The goal of an integrated animal health program is to reduce the occurrence of animal diseases and to provide greater assurance of wholesome meat products.

In addition to the IKB program, the Netherlands also requires swine farms to be subjected to ongoing serological surveillance for *M. avium* as a requirement for participation in visual inspection. Farms are categorized according to risk of *M. avium* infection based on the results of ongoing sampling results. If a farm has 18 consecutive negative results (sampled from no more than 6 pigs in each of 3 deliveries), it is assigned a neutral risk. When the farm has 18 additional negative samples (collected from 2 pigs in each of 9 deliveries), it is assigned a low risk. When a farm has a single positive result or two intermediate results within 18 samples, it is placed in the high risk category. Only neutral and low risk farms are eligible to participate in visual inspection. Swine from high risk farms are subject to traditional inspection. In addition, animal health authorities assist the farms in identifying and reducing risk factors for *M. avium* infection.

3. **The incidence of diseases in market hogs, such as TB, is no higher than the incidence in the United States.** The incidence of swine tuberculosis is lower in the Netherlands than the incidence of the disease in animals in the United States.

Diseases that produce lesions in the mesenteric lymph nodes, such as tuberculosis, are very rare in the Netherlands.

4. **The market swine must be born and raised in the country.** The swine must be born and raised in the Dutch Territories. In the Netherlands, swine are born and raised on large farms under controlled conditions. Improvements in animal husbandry, preventive medicine, and disease control programs have led to a significant rise in the slaughter of animals at a much younger age, in relatively uniform groups. These young animals have a lower incidence of diseases. However, some countries in Europe have a much higher prevalence of *M. avium*. Therefore, swine slaughtered for export to the United States must be born and raised in the Dutch Territories.
5. **The government inspection service must implement a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects).** In all slaughterhouses, verification of visual inspection takes place on a daily basis (minimum once a day) and is carried out by the official veterinarian. The location of the verification activities is the on-line inspection platform next to the on-line inspection station. The results of this verification are documented, and the information is used to evaluate performance of online inspectors. These verification activities can be split into two basic standards, 1) standards for inspection procedures and 2) standards for inspection decisions. The official veterinarian verifies appropriate performance of inspection procedures by periodically observing inspectors. Inspectors are required to perform inspection procedures correctly and completely. The standard for the official veterinarian's verification is a maximum of 5% incorrect procedures. The official veterinarian also conducts verification of inspection decisions by periodically observing carcasses and organs for any pathological lesions or hygiene defects. For food safety conditions (feces, ingesta, septicemia-toxemia, cysticercosis), there is zero tolerance. For non-food safety defects, there is a cumulative maximum of 6% of missed pathological abnormalities (2% standard for the carcass, 2% for the stomach/intestines, and 2% for the organs). The number of carcasses plus stomach-intestines plus organs to be verified on a daily basis is distributed over the day with a minimum of 2 batches and a minimum of 50 pigs. In cases where inspectors are not performing as required, the official veterinarian will take corrective actions.

<u>Name</u>	<u>Signatures</u>	<u>Date</u>
Ghias Mughal, Senior Staff Officer, IES, OIA	<i>Ghias Mughal</i>	11/3/06
Nancy Goodwin, Senior Staff Officer, IES, OIA	<i>Nancy Goodwin</i>	11/3/06
David Smith, Staff Officer, IES, OIA	<i>David Smith</i>	11/3/06
Scott Seebohm, Staff Officer, TSC, OPPED	<i>Scott Seebohm</i>	11/3/06

DECISION MEMORANDUM

ISSUE:

FSIS has received a request from the Netherlands to use an alternate post-mortem inspection procedure for market hogs—visual inspection of the carcass and viscera. The procedure does not require incising of the mandibular lymph nodes, palpation of the mesenteric, portal and bronchial lymph nodes, turning of lungs and liver, and grasping and turning of kidneys.

BACKGROUND:

The Netherlands has implemented a system of “Supply Chain Inspection.” This system allows visual inspection of market hogs raised under an integrated quality control program coupled with a system of verification for checking the accuracy of visually inspected carcasses and organs to ensure that passed carcasses and parts are wholesome and not adulterated.

A team of FSIS experts met and reviewed the Netherlands’ visual inspection procedures, the Netherlands’ reference materials, and information presented by Netherlands’ officials during the FSIS-Netherlands bilateral meeting of November 1-2, 2006. The FSIS team also reviewed the two FSIS inspection procedures (Traditional Inspection and HACCP-Based Inspection Models Project (HIMP)) employed in establishments slaughtering market-age hogs and compared these two inspection procedures with the Netherlands’ visual post-mortem inspection procedure. These two FSIS inspection procedures were used to develop the equivalence criteria used to evaluate the Netherlands’ request.

The following is a summary of the Netherlands’ visual inspection procedure pilot tested in an establishment which is not certified for export to the United States.

ANTE-MORTEM INSPECTION

Ante-mortem inspection on all market hogs is performed by the official veterinarian using traditional inspection procedures, which are equivalent to FSIS’ traditional inspection procedures.

POST-MORTEM INSPECTION

Visual post-mortem inspection of the head, viscera and carcass is performed by official auxiliaries (contract inspectors) located at three fixed inspection stations.

Head Inspection

- Visual inspection of the head and throat, including the mandibular lymph nodes
- Visual inspection of the mouth, fauces, and tongue

Viscera Inspection

- Visual inspection of the lungs, trachea, and esophagus
- Visual inspection of the pericardium and heart
- Visual inspection of the liver and hepatic and pancreatic (portal) lymph nodes
- Visual inspection of the gastro-intestinal tract, mesentery, gastric and mesenteric lymph nodes
- Visual inspection of the spleen
- Visual inspection of the genital organs

Carcass Inspection

- Visual inspection of the carcass
- Visual inspection of the pleura and peritoneum (linings of chest and abdominal cavities)
- Visual inspection of the kidneys
- Visual inspection of the diaphragm
- Visual inspection of the udder and its lymph nodes
- Visual inspection of the umbilical region and joints of young animals

The following is a summary of FSIS' inspection procedures in establishments operating under traditional inspection for market hogs.

ANTE-MORTEM INSPECTION

All market hogs offered for slaughter in an official establishment are examined and inspected on the day of and before slaughter by an FSIS inspector. Ante-mortem inspection is made in pens on the premises of the establishment. All animals are examined and inspected at rest and in motion; both sides are inspected and observed. After slaughter, each head, viscera and carcass is inspected as described below.

POST-MORTEM INSPECTION

FSIS inspectors are located at fixed inspection stations to perform inspection of the head, viscera and carcass.

Head Inspection

- Observe the head and cut surfaces – eyes, fat, cheek muscles, and other tissues for abnormalities
- Incise and observe the mandibular lymph nodes

Viscera Inspection

- Observe the eviscerated carcass, viscera and parietal (top) surface of spleen
- Observe and palpate the mesenteric lymph nodes
- Palpate the portal lymph nodes
- Observe the dorsal (curved) surface of lungs
- Palpate the bronchial lymph nodes
- Observe the mediastinal lymph nodes

- Turn the lungs over and observe ventral (flat) surfaces
- Observe the heart
- Observe the dorsal (curved) surface of liver
- Turn the liver over and observe ventral (flat) surface

Carcass Inspection

- Observe the back of the carcass (turn carcass or use mirror)
- Observe the front and inside of the carcass, including:
 - Cut surfaces
 - All body cavities
 - Lumbar region
 - Neck region
- Grasp, turn and observe the kidneys

The following is a summary of the FSIS inspection procedures in establishments operating under HIMP.

FSIS conducts three types of inspection activities in the HIMP establishments; Systems Inspection, Carcass Inspection and Verification Inspection. Systems Inspection involves the evaluation of in-plant inspection findings and is intended to determine the effectiveness of the overall design and execution of all establishment slaughter processes under HACCP and process control plans. Carcass Inspection involves the examination of each carcass and its parts to determine if they are adulterated. Verification Inspection involves the evaluation of the effectiveness of the establishment's HACCP plan and process control plan in meeting the relevant performance standards. Inspection procedures under HIMP were developed to reduce reliance on organoleptic inspection, to shift to prevention-oriented inspection systems based on risk assessment, and to redeploy inspection resources in a manner that better protects the public from food-borne diseases.

System Inspection - The System Inspector (SI) is either the Inspector in Charge (IIC) or the Supervisory Veterinary Medical Officer (SVMO). The SI has overall responsibility to assure that the plant and inspection personnel effectively conduct the required activities under HIMP, as designed.

Specifically, the System Inspector:

- Determines, or assigns to the verification inspector (VI), the daily random sampling schedule.
- Monitors and determines the effectiveness of ante-mortem verification inspection.
- Monitors and determines the effectiveness of the establishment's ante-mortem sorting.
- Determines final disposition of animals designated by the VI as "suspects" at ante-mortem.
- Monitors and determines the effectiveness of the establishment's post-mortem sorting and dispositions.
- Determines final disposition of carcasses retained by the Carcass Inspector or VI on post-mortem inspection.
- Records nonconformance findings on the appropriate HIMP form.

- Determines if the establishment is meeting relevant performance standards.
- Assesses the overall design and execution of the establishment's HACCP plan and process control procedures.
- Assures that all adulterated products are condemned in accordance with applicable regulations.
- Determines when unscheduled verification sampling is warranted.
- Maintains communication with the VI and CIs to facilitate coordination of all ante-mortem and post-mortem findings.

Carcass Inspection - The Carcass Inspectors (CI) are stationed at fixed locations on the post-mortem line to determine whether a product is adulterated or unadulterated. They inspect each carcass and part on the line, as well as evaluate the on-going effectiveness of the establishment's food safety and other consumer protection processes.

Specifically, the CI:

- Determines whether each carcass and its parts are adulterated or unadulterated.
- Takes appropriate action to prevent adulterated product from entering into human food channels.
- Notifies the establishment personnel, VI and/or SI of carcass and/or parts defect findings.
- Retains carcasses and parts for further disposition by the SI if food safety and other conditions are identified that could result in condemnation.

Verification Inspection - The Verification Inspector (VI) does not have a fixed position on the line and can move freely throughout the plant.

Specifically, the VI:

- Observes and evaluates the effectiveness of the establishment's HACCP plan and process control plans, including the examination of records, to determine whether the establishment is in compliance with applicable regulatory requirements.
- Records all findings of noncompliance with applicable performance standards.
- Investigates potential process control problems.
- Notifies the SI if the process control plan is not being met or if performance standards have been exceeded.
- Retains carcasses and parts for further disposition by the SI if food safety and other conditions are identified that could result in condemnation.

The following is a summary of tasks performed by the CI and VI during ante-mortem and post-mortem inspection in the HIMP establishments.

Ante-mortem inspection

The VI conducts ante-mortem inspection of all animals at rest and 5-10 percent of animals in motion and retains animals for further disposition by the SI, if the animals are suspected of having a condition that could result in condemnation.

Post-mortem inspection

Post-mortem inspection is performed by the CI for the head, viscera and carcass.

Head Inspection

Establishments must incise the mandibular lymph nodes before presenting the carcass for inspection.

The CI observes the head, including:

- Incised mandibular lymph nodes
- Cut surfaces, eyes, fat, cheek muscles, and other tissues

Viscera Inspection

The CI observes the viscera, including:

- Spleen
- Mesenteric and portal lymph nodes
- Liver
- Lungs
- Bronchial and mediastinal lymph nodes
- Heart

Carcass Inspection

The CI observes the carcass, including:

- Cut surfaces
- All body cavities
- Lumbar region
- Neck region
- Kidneys

Comparison of the Netherlands Visual Inspection Procedures with the FSIS Inspection Procedures

Netherlands uses a combination of pre-slaughter data collection and post-mortem inspection to ensure the identification and removal of unhealthy animals, adulterated carcasses and parts and resulting products from the food supply. Pre-slaughter data collection is done through a system of “Supply Chain Inspection” called the IKB Varkens (IKB) program which is an integrated quality assurance program with comprehensive controls over the production chain in addition to national and EU requirements for feed, hygiene, the use of veterinary drugs, transport of animals, and animal welfare. The IKB requires transfer of animal health records from the farm to both the establishment and inspection officials to provide greater assurance that only wholesome meat products are produced. All market hogs receive ante-mortem and post-mortem visual inspection of the head, viscera, and carcass.

FSIS’ post-mortem inspection procedures under traditional inspection are similar to the Netherlands’ visual post-mortem inspection procedures except FSIS inspectors incise and

observe mandibular lymph nodes, observe and palpate portal and bronchial lymph nodes, and turn and observe both surfaces of the liver, the lungs and the kidneys.

FSIS post-mortem inspection procedures under HIMP are similar to the Netherlands visual ante-mortem and post-mortem inspection except that FSIS requires the establishment to incise mandibular lymph nodes. FSIS verifies the accuracy of establishment procedures by system inspection and verification inspection procedures. In addition both systems have inspection verification procedures.

FSIS FOOD SAFETY MEASURE:

The purpose of post-mortem inspection of livestock is to protect the public health by ensuring that carcasses and parts that enter commerce are wholesome and not adulterated. To achieve this goal, in market hogs slaughter establishments operating under traditional inspection or in those establishments operating under HIMP, FSIS inspectors perform ante-mortem and post-mortem inspection procedures to detect diseases, abnormalities, and contamination of livestock carcasses and parts.

In establishments operating under HIMP, FSIS requires that the establishment implement ante-mortem and post-mortem sorting procedures and present to FSIS only normal and healthy-appearing animals and carcasses and parts that are wholesome and free of defects. HIMP also requires additional FSIS verification procedures to ensure that the establishment produces only safe, wholesome products.

OBJECTIVE:

For market hogs slaughtered in the United States, FSIS requires that ante-mortem inspection of live market hogs and post-mortem inspection of carcasses and parts be conducted on a carcass-by-carcass basis. In market hogs, FSIS performs post-mortem inspection under the traditional inspection system or the HIMP inspection system. Post-mortem inspection procedures under traditional inspection include incision, observation and palpation, as applicable, of the head, viscera and carcass. Under HIMP, FSIS post-mortem inspection procedures involve only a visual inspection, with no incisions or palpation. In both cases, inspection procedures are intended to identify and remove unwholesome and adulterated carcasses and parts from the food supply.

EQUIVALENCE CRITERIA:

The criteria used by FSIS to determine whether the Netherlands' alternative post-mortem inspection procedure is equivalent to the FSIS post-mortem procedure are set forth below:

1. The government inspection service administers an inspection program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass.

2. The government inspection system requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market hog carcasses presented for inspection.
3. The incidence of diseases in market hogs, such as Tuberculosis (TB), is no higher than the incidence in the United States.
4. The market hogs must be born and raised in the country.
5. The government inspection service must implement a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects).

EQUIVALENCE EVALUATION:

Application of Equivalence Criteria for an Alternate Post-Mortem Inspection Procedure for Market Hogs

1. The Netherlands' inspection service administers a program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass. This determination is based on the following information: The Netherlands uses a combination of pre-slaughter data collection and post-mortem inspection to ensure the identification and removal of sick animals and diseased carcasses and parts from the food supply.

In January 2006, the Netherlands Ministries of Agriculture, Nature and Food Quality and Health, Welfare and Sport and the Food and Consumer Product Safety Authority completed a pilot study in one market hog establishment that was intended to evaluate the effectiveness of visual inspection procedures through the use of pre-slaughter data and post-mortem inspection procedures. During this pilot study, epidemiological data or other history, such as data in regard to *M. avium*, was provided to the official veterinarian immediately prior to slaughter of the herd. After slaughter, each carcass first underwent a visual post-mortem inspection. The inspector did not palpate or make any incisions on the carcass at this point. If the inspector observed an abnormality on a carcass or the viscera, the carcass and viscera were railed out for traditional post-mortem examination. If an inspector did not detect any abnormalities, the carcass and viscera continued moving on the slaughter-line. The carcass then reached the inspector who incised the mandibular lymph nodes. If the inspector discovered abnormalities in the mandibular lymph nodes, the head and the viscera were rejected. The inspector would also rail out the carcass for further traditional post-mortem inspection, if needed. In addition, if the inspector performing visual inspection or the inspector performing traditional inspection detected any abnormality in any organ or carcass that required further examination, all viscera and the corresponding carcass were railed out.

Information from the published studies and other documents provided by the Netherlands, coupled with the pilot study, shows that reduction in human health hazards predominately lies in the hygiene control programs that are implemented throughout the entire production process (farm to table). This supports Netherlands' use of a "hands-off"

system in the slaughter line and, instead, focuses on risk factors prior to post-mortem inspection.

2. The Netherlands' inspection service requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market-age hog carcasses presented for inspection. This determination is based on the following information: The Netherlands has implemented a system known as "Supply Chain Inspection," which allows visual inspection of market hogs raised under the Dutch IKB Quality Assurance Program. The Dutch IKB program is an integrated quality assurance program with comprehensive controls over the production chain in addition to national and EU requirements for feed, hygiene, the use of veterinary drugs, transport of animals, and animal welfare. The IKB program integrates the market hogs production process from breeding farm to slaughterhouse, and provides requirements for the transfer of animal health records from the farm to the establishment, qualifications for veterinary practitioners, lists of approved veterinary drugs, feed control practices, and hygiene codes for farms, transporters and processors. The goal of an integrated animal health program is to reduce the occurrence of animal diseases and to provide greater assurance of wholesome meat products.

In addition to the IKB program, the Netherlands also requires market hogs farms to be subjected to ongoing serological surveillance for *M. avium* as a requirement for participation in visual inspection. Farms are categorized according to risk of *M. avium* infection based on the results of ongoing sampling results. If a farm has 18 consecutive negative results (sampled from no more than 6 pigs in each of 3 deliveries), it is assigned a neutral risk. When the farm has 18 additional negative samples (collected from 2 pigs in each of 9 deliveries), it is assigned a low risk. When a farm has a single positive result or two intermediate results within 18 samples, it is placed in the high risk category. Only neutral and low risk farms are eligible to participate in visual inspection. Market hogs from high risk farms are subject to traditional inspection. In addition, animal health authorities assist the farms in identifying and reducing risk factors for *M. avium* infection.

3 The incidence of diseases in market hogs, such as Tuberculosis (TB), is no higher than the incidence in the United States. FSIS slaughter data from July 2005-June 2006 showed no detection of TB lesions in market hogs. Research in the Netherlands has shown that the prevalence of *M. avium* at the farm level has decreased between 1998 and 2003. In a 2004 study, 2,116,536 market hogs were examined in the Netherlands for the presence of *M. avium*. Nine pig farms were selected based a recent history of having a high percentage of lesions in the mandibular lymph nodes. From a sample pool of 160 pigs, one had a lesion in the mesenteric lymph nodes, and 98 pigs had lesions in the mandibular lymph nodes. All lesions were negative for *M. avium* subsp *avium*. From these data, it is concluded that the prevalence of *M. avium* subsp. *avium* is very low, thus forming the scientific basis for the change in the control of *M. avium* in pork. From this information, FSIS concluded that the incidence of diseases in market hogs, such as Tuberculosis (TB), is no higher than the incidence in the United States

4. Market hogs slaughtered in the Netherlands are from animals born and raised only in the Netherlands. These animals are raised under controlled conditions, which have led to

a significant increase in the slaughter of animals at a much younger age and in relatively uniform groups. However, some countries in Europe have a much higher prevalence of *M. avium*. Therefore, market hogs slaughtered for export to the United States must be born and raised in the Netherlands.

5. The Netherlands' inspection service has implemented a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects). This determination is based on the following information: In the Netherlands', verification of visual inspection takes place on a daily basis (minimum once a day) and is carried out by the official veterinarian. The location of the verification activities is the on-line inspection platform next to the on-line inspection station.

These verification activities are split into two basic standards: 1) standards for inspection procedures and 2) standards for inspection decisions. All inspectors are required to perform inspection procedures correctly and completely. The official veterinarian verifies appropriate performance of inspection procedures by periodically observing inspectors. The standard for the official veterinarian's verification is a maximum of 5% incorrect procedures. The official veterinarian also conducts verification of inspection decisions by periodically observing carcasses and organs for any pathological lesions or hygiene defects. For food safety conditions (feces, ingesta, septicemia-toxemia, cysticercosis), there is zero tolerance. For non-food safety defects, there is a cumulative maximum of 4% of missed pathological abnormalities (2 % standard for the carcass and, 2 % for the stomach/intestines/organs). The number of carcasses plus stomach-intestines-organs to be verified on a daily basis is distributed over the day with a minimum of 2 batches and a minimum of 50 pigs. In cases where inspectors are not performing as required, the official veterinarian will take corrective actions. The results of this verification are documented, and the information is used to evaluate the performance of online inspectors. In addition, the Netherlands' inspection service has a program in place to conduct a system audit of the establishment on a regular basis.

RECOMMENDATION:

FSIS has determined that the alternate post-mortem procedure for market-age hogs submitted by the Netherlands is equivalent to the FSIS post-mortem procedure for market-age hogs. Therefore, the Netherlands' equivalence request should be granted.

DECISION CONFIRMATION AND APPROVAL:

Sally White JD 12/6/06

Sally White, Director
International Equivalence Staff
Office of International Affairs, FSIS

~~CONCURRENCE:~~

Dr. Uhm

~~Karen Stuck~~

Assistant Administrator
Office of International Affairs

7/8/08

Do not concur.
Issue is not sufficiently
characterized.

EQUIVALENCE CRITERIA FOR ALTERNATE POST-MORTEM INSPECTION PROCEDURE FOR MARKET HOGS

Criteria used to determine whether an alternative post-mortem inspection procedure for market hogs is equivalent to the US inspection procedure for market hogs are set forth below:

- 1. The government inspection service administers an inspection program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass.**
- 2. The government inspection system requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market hog carcasses presented for inspection.**
- 3. The incidence of diseases in market hogs, such as TB, is no higher than the incidence in the United States.**
- 4. The market swine must be born and raised in the country.**
- 5. The government inspection service must implement a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects).**

SUMMARY OF THE OF THE TELECONFERENCE

DATE: June 19, 2006

COUNTRY: Netherlands

FSIS PARTICIPANTS: Steve McDermott, Office of International Affairs, FSIS, Ghias Mughal, OIA, FSIS, Bobby Palesano, OPPED, FSIS, Karlease Kelly, OPPED, FSIS, Roger Wentzel, FAS, The Hague

NETHERLANDS PARTICIPANTS: Dr. M.J.B. (Martijn) Weijtens, Deputy CVO, LNV Ir. R.C.A. (Richard) Soons, Cluster Ketens, LNV, Dr. M. (Martin) Hennecken, Cluster Ketens, LNV, Inge Hardenberg, Cluster International, LNV, Ate Jelsma, VWA (Netherlands Food and Consumer Product Safety Authority), Dr. Bettine Murlat, VWA (Netherlands Food and Consumer Product Safety Authority), Prof. Dr. Bert Urlings, Director Quality and Environment, VION Food, Caroline Feitel, Royal Netherlands Embassy, Washington, DC

FOLLOWING AGENDA TOPICS WERE DISCUSSED:

- FSIS Strategic Implementation Plan for Strengthening Small and Very Small Plant Outreach: *Karlease Kelly*
- KDS Pilot : *Dr. Ate Jelsma, VWA and M.J.B. (Martijn) Weijtens Deputy CVO*
- HACCP-based Pork Chain Pilot Project: *Dr. Bert Urlings*
- FSIS project on Risk-Based Verification Audits of Foreign Countries Meat and Poultry Inspection Programs: *Steve McDermott*
- Update on Use of Alternate post mortem Inspection Procedure in market age swine in the Netherlands: *Ghias Mughal*
- FSIS Initiative of Enhanced Risk-Based Inspection System: *Bobby Palesano*

DISCUSSIONS:

FSIS informed the Netherlands' officials that visual inspection and the use of auxiliaries in slaughter establishments must not be implemented in the Netherlands establishments certified for export to the United States until FSIS has made an equivalence determination. FSIS stressed this point several times during the conference call including advising Caroline Feitel of the Netherlands' Embassy immediately after the completion of the conference call.

It was also agreed by the parties to have another conference call in a few weeks, on a mutually agreed date, to further discuss the KDS HACCP Pilot project relating to visual inspection and use of auxiliaries Project and its application in other swine establishments in the Netherlands.

Minutes by
Ghias Mughal
6/19/2006

SUMMARY OF MEETING

DATE: October 12, 2006

COUNTRY: Netherlands

FSIS PARTICIPANTS: Bill James, Deputy Assistant Administrator, OIA, Sally White, Director, IES, OIA, Steve McDermott, Deputy Director, IES, OIA Ghias Mughal, Senior Staff officer, IES, OIA; Nancy Goodwin, Senior Staff Officer, IES, OIA

NETHERLANDS AND EU PARTICIPANTS: Dr. M.J.B. (Martijn) Weijtens, Deputy CVO, LNV Ir. R.C.A., Dr. Jos Goebbles, Director, Inspections VWA & Food and Consumer Product Safety, Dr. Wolf – Martin Maier, Counselor Food Safety, Health and Consumer Affairs, EU Delegation, Washington, DC, Wim Tacken, Agricultural Counselor, Royal Netherlands Embassy, Washington, DC

- SUMMARY: This meeting took place at the request of Dr. Martin Weijtens, Deputy CVO to follow up on FSIS letter of Oct. 2, 2006 in which FSIS had asked Netherlands to suspend exports, from, young swine slaughter/processing, establishments in which Netherlands had implemented use of Visual Inspection or use of auxiliaries to conduct post mortem inspection.
 - Netherlands provided for explanation for implementation of Visual Inspection and stated that it was implemented in swine slaughter establishments because it provided extra food safety and it was found equivalent by other EU member States.
 - FSIS asked for further explanation on several issues such as:
 - Rate of condemnation was higher under the old system compared to results of the pilot which was attributed to variation seasonal changes and Netherlands reply was it is true that condemnations rate was higher in traditional inspection but those condemnations were for disease that were of no public health significance.
 - IKB scheme of quality control used in the Pilot which was not clearly defined in the submitted and more information would be helpful to FSIS. Netherlands agreed to send it.
 - Other FSIS questions related to getting further explanation or justification of conclusion drawn during the pilot and both parties agreed to have a follow up meeting of the Technical experts.
 - FSIS also requested Netherlands to provide a written response to FSIS' previous request for information on the type of verification that in-plant inspection officials will perform on the carcasses and viscera passed by the on-line inspectors performing visual inspection of mesenteric lymph nodes. Netherlands officials agreed to send this information in near future.

- THE SECOND ISSUE discussed during the meeting was the use of auxiliaries in establishments certified for export to the US.
- Netherlands explained that although the documents sent to FSIS for employment of auxiliaries referred to new EC Directives 852 and 854, the use of auxiliaries was really under provision of the EC 64/433 which had been previously deemed equivalent by FSIS and that has now been converted in to these new directives. They requested that FSIS reconsider their request and allow use of auxiliaries. Their role has been explained in the document “ The new Organization of the red meat Inspection System in the Netherlands 2006”
- FSIS re-examined the document in light of the Dutch explanation, looked at the relationship between the Netherlands Inspection Service (VWA) and contractors that employs the auxiliaries (KDS) and concluded that relationship between the VWA and KDS is clearly stated. It also narrates the financial structure, training of the auxiliaries and appears to provide adequate government (VWA) oversight on their daily activities.
- FSIS agreed to immediately permit VWA to use auxiliaries in establishments certified for export to the US and will follow verbal permission with written letter.
- Both parties agreed to have a meeting of the technical experts from both sides to resolve the issue of Visual Inspection of the young swine. This meeting was tentatively scheduled to take place in Washington, DC during the first week of November 2006

Minutes by:
 Ghias Mughal, IES, OIA
 10/13/06

Summary of FSIS Pre-Meeting on Visual Inspection in Market age swine

Date: October 31, 2006

Country: Netherlands

Participants: Sally White, Director, IES, OIA,
Steve McDermott, Deputy Director, IES, OIA
Ghias Mughal, Senior Staff Officer, IES, OIA
Nancy Goodwin, Senior Staff Officer, IES, OIA
David Smith, Staff Officer, IES, OIA
Scott Seebohm, Staff Officer, TSC, OPED

The following items were discussed:

1. Comparison Table: Swine Inspection Procedures
2. Netherlands responses to FSIS questions: "Answers to Questions FSIS to the Netherlands"

Clarification from the NL officials is needed on the following additional follow-up questions:

- Q. 1 The U.S. legal definition of adulteration includes both food safety and non-food safety criteria. How does the Netherlands inspection system address the issue of adulteration for non-food safety conditions?
- Q. 2 What are the provisions for government oversight of the IKB production scheme? When would the government get involved, and what actions could they take?
- Q. 3 OK
- Q. 4 The response to Question 4 refers to several reference documents not previously provided to FSIS. We request copies of the additional documents that are relevant to the response (in English, if possible)
- Q. 5 OK
- Q. 6 Need more specific explanation/clarification of how the Farm Risk Profile is calculated. How does it incorporate farm level information on *Salmonella* and *M. avium* ? What specific criteria are used to determine whether a slaughter lot is eligible for visual inspection?

- Q. 7 Need clarification on the verification procedures. Explain how, where, and when the procedures are accomplished.
During FSIS audits, where would FSIS auditors be able to find verification documents/records?
- Q. 8 It was not clear as to how the Farm Risk Profile considers *Salmonella* sample results? What criteria for these samples would dictate switching from visual to traditional inspection?
- Q. 9 When a group of pigs is sampled for antimicrobial residues, based on pathology levels (as described in response to Q6)? Need more information on the sampling procedures. Will all animals in the lot be sampled? If not, what method will be used to select sampled animals?
- Q 10. Response appears to address FSIS question. Need to get copies of the relevant references listed in the response to Q10 (in English, if possible).
- Q. 11 OK
- (Q12) Response appears to address FSIS question. Need to have get copies of the relevant references (in English, if possible).

Ghias Mughal
10-31-2006

DRAFT

MARKET HOGS



HIMP

(HACCP-BASED INSPECTION
MODELS PROJECT)

HIMP MARKET HOG INSPECTION

Background

FSIS collected data to determine the current food safety and other consumer protection achievements of the traditional inspection system in five market hog slaughter plants. The data were used to develop performance standards that volunteer plants in the HACCP-based Inspection Models Project (HIMP) must meet. The performance standards were published in a Federal Register Notice on November 2, 2000. A total of six performance standards were developed: three Food Safety categories (FS 1-3) and three Other Consumer Protection categories (OCP 1-3). The performance standards for the Food Safety categories (FS-1-3) were set at zero. The performance standards for the Other Consumer Protection categories (OCP 1-3) were based on the 75th percentile of the ranges of baseline data. (See Attachment 1)

Types of Inspection Activities

The Market Hog HIMP pilot consists of three types of inspection activities: system inspection, carcass inspection, and verification inspection. System inspection involves the evaluation of in-plant inspection findings and determines the effectiveness of the overall design and execution of all establishment slaughter processes under the HACCP and process control plans. Carcass inspection involves the examination of each carcass and its parts to determine that they are unadulterated. Verification inspection involves the evaluation of the effectiveness of the establishment's HACCP and Process Control plan in meeting the relevant performance standards. These three types of inspection are discussed in further detail below.

System Inspection - The System Inspector (SI) is either the Inspector in Charge (IIC) or the Supervisory Veterinary Medical Officer (SVMO). The SI has overall responsibility to assure that the plant and inspection personnel effectively conduct the required activities under the HIMP, as designed. The SI sends verification data to headquarters and provides overall feedback on how the project is working. Specifically, the SI:

- Determines (or assigns to the verification inspector (VI))* the daily random sampling schedule and provides the schedule to the VI.
- Monitors and determines the effectiveness of ante-mortem verification inspection.
- Monitors and determines the effectiveness of the establishment ante-mortem sorting.
- Determines final disposition of animals designated by the VI as "suspects" at ante-mortem.
- Monitors and determines the effectiveness of the establishment's post-mortem sorting and disposition.
- Determines final disposition on carcasses retained by the carcass inspector (CI) or VI on post-mortem.*
- Records FS-1 and FS-3 nonconformance findings on the appropriate HIMP form.
- Determines if the establishment is meeting relevant performance standards.
- Assesses the overall design and execution of the establishment's HACCP and process control procedures.
- Assures that all adulterated products are condemned in accordance with applicable regulations.
- Determines when unscheduled verification sampling is warranted.

- Maintains communication with the VI and CIs to facilitate coordination of all ante-mortem and post-mortem findings.

Carcass Inspection - The Carcass Inspectors (CI) are stationed at up to 3 fixed locations on the post-mortem line to determine whether a product is adulterated or unadulterated. They inspect each carcass and part on the line, as well as evaluate the on-going effectiveness of the establishment's food safety and other consumer protection processes. Specifically, the CIs:

- Determine whether each carcass and its parts are adulterated or unadulterated.
- Take appropriate action to prevent adulterated product from entering into human food channels.
- Notify the establishment personnel, VI and/or SI of carcass and/or parts defect findings.
- Examine sample sets when notified by the VI and verbally inform the VI during sampling when defects are found.
- Contact the SI if there are any concerns about process control.
- Retain carcasses and parts for further disposition by the SI if food safety and other conditions are identified that could result in condemnation.
- Maintain communication with the VI and SI to facilitate coordination of all post-mortem findings.

Verification Inspection - The Verification Inspector (VI) does not have a fixed position on the line, and can move freely. Specifically, the VI:

- Observes and evaluates the effectiveness of the establishment's HACCP and process control plans, including the examination of records, to determine whether the establishment is in compliance with applicable regulatory requirements.
- Conducts ante-mortem inspection of all animals at rest and 5-10 percent of animals in motion.
- Retains animals for further disposition by the SI, if the animal is suspected of having a condition that could result in condemnation.
- Documents ante-mortem findings on HIMP FORM 9.
- Takes verification samples to determine if establishment is complying with relevant performance standards, including scheduled and unscheduled sampling.
- Records all findings of noncompliance with applicable performance standards.
- Notifies the CI when verification samples are required and records the findings in each sample set during post-mortem. Evaluates the noncompliance findings and records in the appropriate category on HIMP form 7.
- Investigates potential process control problems.
- Notifies SI if the process control plan is not being met or if performance standards have been exceeded.
- Retains carcasses and parts for further disposition by the SI if food safety and other conditions are identified that could result in condemnation.
- Maintains communication with the CI and SI.

MARKET HOG INSPECTION STATION

Facilities required at each inspection station include:

1. The conveyor and/or rail shall be level for the entire length of the inspection station.
2. Floor space shall be adequate along the conveyor and rail.
3. Conveyor and rail stop/start switches shall be readily accessible.
4. A minimum of 50 foot-candles of shadow-free lighting shall exist at each inspection station.

Inspection Stations will be established at up to 3 locations:

FSIS personnel are responsible for inspecting each head, viscera, and carcass. These locations will be:

1. After the mandibular lymph node incision step and before the head removal step for the Head Inspection Station.
2. After the establishment's viscera sorting step and before the viscera harvesting step for the Viscera Inspection Station.
3. After the final trim and sorting step and before the carcass wash step for the Carcass Inspection Station.

Inspection locations may be combined if carcass and/or parts (head and viscera) can be inspected at a single location. (Example: combining the viscera with carcass inspection if they can be inspected at one location.). Proposals for less than three inspector locations must be presented to the HIMP Project Manager.

DOCUMENTATION

The forms used for the HIMP Market Hog project are:

- HIMP FORM-7, Postmortem Verification Inspection Activities
- HIMP FORM 8-1 OCP-1 25 Day Results
- HIMP FORM 8-2 OCP-2 25 Day Results
- HIMP FORM 8-3OCP-3 25 Day Results
- HIMP FORM-9 Ante-Mortem Verification Inspection Activities
- HIMP FORM-10 HIMP Verification/Corrective Action Log
- FSIS Form 5400-4 Noncompliance Record (NR)

•

FS-1 and FS-3 nonconformance documentation -

- The SI makes the final disposition on carcasses retained by inspection personnel on FS-1 and FS-3 categories and documents the FS-1 and FS-3 nonconformance on a NR as ISP code 03J01.
- If the SI finds additional noncompliance for **this specific slaughter production lot**, the SI will document the findings on separate NR's.
 - All findings must be taken into consideration after the NR is written. The SI also checks the plant's corrective actions. All findings and plant's corrective actions are to be documented on the NR.
- The 03J02 procedure is considered to be complete when inspection personnel have verified the establishment's pre-shipment review.
- The SI will inform the VI to document FS-1 non-conformances on the daily HIMP Form 7
- The SI will document FS-3 non-conformances on the HIMP form 9.

FS-2 nonconformance documentation -

- An FS-2 nonconformance is documented when feces, ingesta or milk are identified during verification activities.(according to the identification guidelines in FSIS Directive 6420.2).*
- The CI at the final carcass inspection station will follow FSIS Directive 6420.2 *Livestock Post-Mortem Inspection Activities-Enforcing the Zero Tolerances for Fecal Material, Ingesta, and Milk* Section II. B. 1 as it pertains to the final rail inspector.*
- The VI, when performing FS-2 verification, will document an FS-2 nonconformance on a NR as ISP code 03J01.
- If the VI finds additional noncompliance for **this specific slaughter production lot**, the VI will document their findings on additional NR's.
- All findings must be taken into consideration by the VI that found the noncompliance or another VI. The VI also checks the plant's corrective actions. All findings and plant's corrective actions are to be documented on the NR.
- The 03J02 procedure is considered to be complete when the VI has verified the establishment's pre-shipment review.
- The FS-2 nonconformance is also to be documented by the VI on HIMP FORM-7.

OCP nonconformance documentation –

The VI or SI will document the OCP nonconformance findings during the shift on Draft HIMP form 7.

- If the establishment exceeds the daily maximum limit (See Table 1) for a specific OCP category, the VI will notify the SI.
- At the end of each shift, the SI will document the number of defects and pass/fail for each OCP category on HIMP FORMS 8- 1 through 8-3.

VERIFICATION PROCEDURES

FSIS conducts verification inspection to assure that plants are meeting the performance standards. Verification inspection occurs in ante-mortem and post-mortem.

ANTE-MORTEM

- Establishment ante-mortem records for the FS-3 category are to be reviewed by the VI or SI.
- The VI or the SI will inspect 100% of live animals at rest that are presented by the establishment for slaughter.
- The SI (or assigns to VI) randomly selects ante-mortem sampling times throughout the shift. Ante-mortem sampling times can be scheduled if the entire kill is available prior to start of shift. Usually live animals continue to be shipped to the establishment throughout the day and it is not possible to schedule the times for random sampling. Therefore, it is left to the discretion of the SI to determine randomness of sampling throughout the shift when live animals are available.
- The VI or SI will inspect 5-10% of the live animals in motion randomly throughout the shift after establishment sorting for slaughter.
- The VI or SI will assess sorting activities and humane handling practices.
- The SI will assess plant activities at the suspect pen.
- The VI will retain as suspect for SI disposition any animal that could result in condemnation.
- FS-3 deficiency determined by the SI will be documented by the SI on a NR and the establishment follows HACCP procedures in 9 CFR 417.3.
- The SI will document or notify the VI to document any FS-3 deficiency on HIMP Form 9.
- Other deficiencies found on ante-mortem sampling by the VI will be reported to establishment and the SI (such as humane handling).
- A NR is to be documented for humane handling violation. The ISP procedure code for violations related to humane handling and slaughter is **04C02**. *

POST-MORTEM

The verification sampling procedures for both food safety and other consumer protection performance standards will be conducted on 24 randomly selected samples for each shift. This procedure can be conducted either off-line or on-line. If conducted on-line, the VI will identify the samples and have the CI's examine each part and carcass, starting with the head inspection station. The VI will follow the samples through the entire process and record all defects found during the CI examination. The VI will record a maximum of one defect in each performance standard category per sample unit (e.g., a sample having bile and a bruise on the carcass would be identified as 1 OCP-3 defect. A sample having arthritis and fecal contamination of the viscera would be identified as 1 OCP-1 and 1 OCP-2).

In addition, the VI or SI will review establishment post-mortem records for FS-1. The SI and/or VI will review other establishment post-mortem records.

1) General

- A sample consists of a carcass with corresponding head and viscera.
- The SI or the VI will notify the on-line CI when to inspect verification samples during the shift.
- The CI, when notified by the VI, will inspect the verification samples of the carcass with corresponding viscera and head per shift and verbally inform the VI of their findings during sampling.
- The 24 unit samples per shift may be taken in subsets.
 - Sample subsets may be randomly taken in one of the following manners:
 - 3 samples 8 times per shift.
 - 4 samples 6 times per shift.
 - 6 samples 4 times per shift.
 - 8 samples 3 times per shift.
- Any OCP defects, which are identified at the inspection stations, should be identified to the establishment but not scored toward plant performance unless it is part of a scheduled or unscheduled sample subset.
- Sample times and sample subsets are to be selected randomly prior to the start of the shift.
- The VI or SI will record findings on DRAFT HIMP Form-7. It is not necessary to record a specific condition within a performance standard category (i.e., localized lung or heart conditions would be recorded as a noncompliance of the OCP-1 performance standard category).
- If the establishment is engaged in product/process action at the time the random sample is to be taken, the VI will suspend random sampling until the establishment has completed its actions.

2. FS1 and FS 2

- Establishment post-mortem records for FS-1 and FS-2 categories are to be reviewed by the VI or SI in accordance with 9 CFR 417.8.
 - The CI, when notified by the VI, will examine the sample subsets for indications of FS-1 and FS-2 defects and verbally relay the information to the VI.
 - 1) FS-2 defects are recorded at the post-mortem rail inspection station.
 - 2) The CI will retain carcasses with potential FS-1 defects for final disposition by the SI. If the VI/SI finds additional non-compliance for this slaughter production lot, the VI/SI will document each additional FS-2 defect findings on separate NR's. *
 - 3) The CI at the Pre-Wash Verification Location Inspection Station will identify potential FS-1 and FS-2 defects. The CI will retain the carcass for final disposition by the SI. The CI will identify FS-2 defects and take the appropriate action consistent with established HACCP procedures. The VI/SI will document the FS-2 defect that was found by the CI on a NR. If the VI/SI finds additional non-compliance for this slaughter production lot, the VI/SI will document each additional FS-2 defect findings on separate NR's. *
- No carcasses are allowed to exhibit FS-2 defects at the post-mortem rail inspection station. The CI will follow instructions for "on-line inspection personnel" in FSIS Directive 6420.2. The CI will have the defect removed either by railing the carcass out or having it trimmed on-line. Notify the SI/VI for possible unscheduled verification sampling. *
- The SI will write a NR for FS-1 noncompliance.
- The VI will write a NR for FS-2 noncompliance observed during verification sampling in accordance with FSIS Directive 6420.2.*

3. OCP

- The CI or VI will retain a carcass for final disposition by the SI when OCP defects are found that could result in condemnation.
- If the VI or SI determines that defects in an OCP category exceed the performance standard as stated in Table 1, the VI or SI will check the establishment's process control records for the same time frame. If the establishment results show a potential or actual loss of control as defined in the establishment's process control plan (PCP), the VI or SI will check the establishment's records to determine whether corrective actions described in the PCP were taken.

TABLE 1: OCP Maximum defects allowed Per Shift

SAMPLE SIZE	24 SAMPLES (Head, Viscera, carcass)	UNSCHEDULED 27 SAMPLES	UNSCHEDULED 30 SAMPLES	UNSCHEDULED 33 SAMPLES
OCP-1	2	2	2	2
OCP-2	3	3	3	3
OCP-3	7	7	8	9

- If the establishment failed to take proper corrective action according to their PCP, the establishment should detail what new corrective and preventive action will be implemented to prevent recurrence. Any samples that exhibit defects in any of the OCP performance standard categories should be pointed out to establishment personnel.

Unscheduled Verification Inspection

When the SI determines that an unscheduled inspection should occur, the SI will notify the VI to conduct the inspection. Each unscheduled verification inspection will be three carcasses with corresponding viscera and head.

- Unscheduled verification sampling done at the direction of the SI will also be recorded on Draft HIMP Form 7.
- Unscheduled verification sampling will count toward the establishment's performance evaluation (See Table 1).
- The SI may call for unscheduled verification inspection because a CI has identified a potential problem.
- The SI may call for unscheduled verification inspection after the establishment has had sufficient opportunity to correct an establishment identified problem. This would confirm that the problem has been corrected.
- The establishment is notified of unscheduled verification inspection.
- The SI and/or VI will notify the establishment of the results of unscheduled verification sampling and establishment record examinations.

EXAMINATION OF PLANT SAMPLING RECORDS FOR OCP'S

- In addition to the 24 OCP samples, VI will review establishment's records for OCP sampling results at least three times per day.
- Examples of plant records evaluation may also include observations of the plant selecting samples and data recording procedures.
- The VI or SI should record the results on the Draft HIMP Form 10.
- The VI will notify the SI of any discrepancies in the record examination.

SI evaluation of OCP 1 through 3 for 25 day performance

- To evaluate whether the establishment maintains process control, the SI will track the performance of OCP 1 through 3 for a 25-day period using Draft HIMP Form 8-1 through 8-3 and Table 1.
- Each OCP will be tracked each shift and referenced to the Table 1 values.
- The SI will record that the plant passed or failed each of the 3 OCP categories on the appropriate HIMP form 8 and notify the plant of their findings.
- For an entire 25-day period, the maximum number of days on which the Table 1 performance standards can be exceeded is given in Table 2.

**TABLE 2: Maximum Days (OCP's)
(Number of Days Above maximum defects
allowed Per 25-Day Period)**

OCP-1	2 days
OCP-2	4 days
OCP-3	3 days

- If the plant exceeds the maximum days for any OCP category listed in table 2 for a 25-day period, at any point during the 25 days, the SI will write a NR coded 04C01. The plant should detail what new corrective and preventive actions are implemented to prevent recurrence. The plant will provide this information to the SI.

Note: A 25 day period will end at a full 25 days provided that the Table 2 Maximum Number of Days are not exceeded. If the Table 2 Maximum Number of Days are exceeded before 25 days are completed, e.g. on the 13th day, the period stops then while the plant responds as described above. A new 25-day period will begin when those conditions are satisfied.

Correlation

The SI and/or VI will meet regularly with plant management to conduct correlation activities during the transition period. Regular correlation will aid FSIS and the plant in establishing a common basis for both FS and OCP determinations.

Attachment 1**Model Performance Standards for Market Hogs Plants**

<u>Performance Standard Categories</u>	<u>Plant Performance Standards</u>
FS-1—Condition – Infectious (for example: septicemia/toxemia, pyemia, cysticercus)	Zero
FS-2 – Condition – Digestive Content/Milk (for example: fecal material, ingesta, milk)	Zero
FS-3 – Ante-mortem Suspect (for example: neurologic conditions, moribund, pyrexia, severe lameness)	Zero
OCP-1 – Carcass- Pathology* (for example: arthritis, emaciation, erysipelas, localized abscess, mastitis, metritis, mycobacteriosis [M Avium], neoplasms, pericarditis, pleuritis, pneumonia, uremia)	4.1%
OCP-2 – Visceral Pathology* (for example: cystic kidneys, enteritis/gastritis, fecal contamination of viscera, nephritis/pyelonephritis, parasites—other than Cysticercus, peritonitis)	7.2%
OCP-3 – Miscellaneous (for example: anemia, bile, bruise, edema, external mutilation, fractures, icterus, odor, skin lesions, scabs, toenails not removed)	20.5%

***Conditions exhibiting a septicemia or toxemia are considered food safety hazards**

PLANT PERFORMANCE

Ante-mortem Verification Inspection Activities (FS-3)

Shift: 1 2 Est. number: _____ Date: _____

Inspection Activity	1			2		
	Deficiency	FS-3	NR	Deficiency	FS-3	NR
Inspect 100% of hogs at rest						
Inspect 5-10% of hogs in motion, passed by plant for slaughter (at or after CCP location)						
Inspect suspects, as required (done by SI)						
Observe humane slaughter practices						
Examine Ante-mortem records						
Additional Comments:						

1. Circle **Shift**
2. Enter **Establishment #**
3. Enter **Date**
4. For each of the **Inspection Activities** listed, indicate if a **deficiency** is found. Also, indicate if the deficiency constitutes a **FS-3** and/or an **NR** by writing a **yes** or **no** in the space provided.

PLANT PERFORMANCE

Postmortem Verification Inspection Activities – FS and OCP Conditions

Date	Shift 1 2	Est #	Est. Name																								Unscheduled Verifications				
Performance Standard Categories			Scheduled Verification																								Total	Set 1	Set 2	Set 3	Total
FS-1 Condition – Infectious (SI ONLY) (for example: septicemia/toxemia, pyemia, cysticercosis) <div style="text-align: right;">Max 0</div>			1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24																												
FS-2 Condition – Digestive Content/Milk (Carcass only) (for example: fecal material, ingesta, milk) <div style="text-align: right;">Max 0</div>			1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24																												
OCP-1 Carcass – Pathology* (for example: arthritis, erysipelas, localized abscess, mastitis, metritis, mycobacteriosis, [M avium] neoplasms, pericarditis, pleuritis, pneumonia, (SI only emaciation, uremia) <div style="text-align: right;">Max 2</div>			1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24																												
OCP-2 Visceral – Pathology* (Head and Viscera) (for example: cystic kidneys, enteritis/gastritis, fecal contamination of viscera, nephritis/pyelonephritis, parasites - other than cysticercus, peritonitis) <div style="text-align: right;">Max 3</div>			1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24																												
OCP-3 Miscellaneous (for example: Anemia/Pale Soft Exudative pork, bile, bruise, edema, external mutilation, fractures, icterus, odor, skin lesions, scabs, toenails not removed) <div style="text-align: right;">Max 7</div>			1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24																												

* Conditions exhibiting a septicemia or toxemia are considered food safety hazards.

DRAFT 7 HIMP FORM 7 5/24/01
MARKET HOGS

1. Enter **Date**
2. Enter **Shift**
3. Enter **Establishment # and name**
4. For **FS** and **OCP** deficiencies, circle the number corresponding to the sample with the defect (condition). Enclose in brackets the sample subset (i.e. a three sample subset would be bracketed as [1 2 3] [4 5 6]...

A 4 sample subset may also be taken 6 times per shift, or 6 a sample subset 4 times per shift, or a 8 sample subset 3 times per shift.

Sample times and sample subsets are to be selected randomly **prior** to the start of the shift.

TABLE 1: OCP Maximum defects allowed Per Shift

SAMPLE SIZE	24 SAMPLES (Head, Viscera, carcass)	UNSCHEDULED 27 SAMPLES	UNSCHEDULED 30 SAMPLES	UNSCHEDULED 33 SAMPLES
OCP-1	2	2	2	2
OCP-2	3	3	3	3
OCP-3	7	7	8	9

EST. # _____

MARKET HOGS**DRAFT HIMP FORM 8-1**

5/10/01

OCP-1**25 Day Results**

Directions: Using the data from DRAFT HIMP Form 7 for OCP-1, determine plant performance per shift using Table 1. Record No. of Hogs with defects and indicate Pass or Fail for OCP-1 for each shift. The Maximum number of days on which this performance standard can be exceeded per 25 day window is given in Table 2.

Date of Collection	OCP-1	Date of Collection	OCP-1	Date of Collection	OCP-1
1		1		1	
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	
7		7		7	
8		8		8	
9		9		9	
10		10		10	
11		11		11	
12		12		12	
13		13		13	
14		14		14	
15		15		15	
16		16		16	
17		17		17	
18		18		18	
19		19		19	
20		20		20	
21		21		21	
22		22		22	
23		23		23	
24		24		24	
25		25		25	
TOTAL # PASSED		TOTAL # PASSED		TOTAL # PASSED	
TOTAL # FAILED		TOTAL # FAILED		TOTAL # FAILED	

TABLE 1: OCP-1 Performance Standard Per Shift (24 head, carcass, & viscera samples)

CONDITION	MAXIMUM DEFECTS ALLOWED
OCP-1	2

TABLE 2: Maximun # of Days OCP-1 is Allowed Above Performance Standard (Per 25-Day Period)

CONDITION	MAX. # DAYS PER 25 DAY PERIOD
OCP-1	2 days

EST. # _____

MARKET HOGS**DRAFT HIMP FORM 8-2**

5/10/01

OCP-2**25 Day Results**

Directions: Using the data from DRAFT HIMP Form 7 for OCP-2, determine plant performance per shift using Table 1. Record No. of Hogs with defects and indicate Pass or Fail for OCP-2 for each shift. The Maximum number of days on which this performance standard can be exceeded per 25 day window is given in Table 2.

Date of Collection	OCP-2	Date of Collection	OCP-2	Date of Collection	OCP-2
1		1		1	
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	
7		7		7	
8		8		8	
9		9		9	
10		10		10	
11		11		11	
12		12		12	
13		13		13	
14		14		14	
15		15		15	
16		16		16	
17		17		17	
18		18		18	
19		19		19	
20		20		20	
21		21		21	
22		22		22	
23		23		23	
24		24		24	
25		25		25	
TOTAL # PASSED		TOTAL # PASSED		TOTAL # PASSED	
TOTAL # FAILED		TOTAL # FAILED		TOTAL # FAILED	

TABLE 1: OCP-2 Performance Standard Per Shift (24 head, & viscera samples)

CONDITION	MAXIMUM DEFECTS ALLOWED
OCP-2	3

TABLE 2: Maximum # of Days OCP-2 is Allowed Above Performance Standard (Per 25-Day Period)

CONDITION	MAX. # DAYS PER 25 DAY PERIOD
OCP-2	4 days

EST. # _____

MARKET HOGS**DRAFT HIMP FORM 8-3**

5/10/01

OCP-3**25 Day Results**

Directions: Using the data from DRAFT HIMP Form 7 for OCP-3, determine plant performance per shift using Table 1. Record No. of Hogs with defects and indicate Pass or Fail for OCP-3 for each shift. The Maximum number of days on which this performance standard can be exceeded per 25 day window is given in Table 2.

Date of Collection	OCP-3	Date of Collection	OCP-3	Date of Collection	OCP-3
1		1		1	
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	
7		7		7	
8		8		8	
9		9		9	
10		10		10	
11		11		11	
12		12		12	
13		13		13	
14		14		14	
15		15		15	
16		16		16	
17		17		17	
18		18		18	
19		19		19	
20		20		20	
21		21		21	
22		22		22	
23		23		23	
24		24		24	
25		25		25	
TOTAL # PASSED		TOTAL # PASSED		TOTAL # PASSED	
TOTAL # FAILED		TOTAL # FAILED		TOTAL # FAILED	

TABLE 1: OCP-3 Performance Standard Per Shift (24 head, carcass, & viscera samples)

CONDITION	MAXIMUM DEFECTS ALLOWED
OCP-3	7

TABLE 2: Maximum # of Days OCP-3 is Allowed Above Performance Standard (Per 25-Day Period)

CONDITION	MAX. # DAYS PER 25 DAY PERIOD
OCP-3	3 days

Comparison Table: Swine Inspection

FSIS Swine Inspection Procedures (traditional): <ul style="list-style-type: none"> • Authority: 21 USC 604 (FMIA), 9 CFR 310.1 • Procedures: Slaughter Inspection Training Materials (1/14/2005) 	FSIS Swine Inspection Procedures for Plants Operating Under HIMP: <ul style="list-style-type: none"> • Authority: 21 USC 604 (FMIA), 9 CFR 303.2 	Netherlands Swine Inspection Procedures for Plants Operating Under Visual Inspection: <ul style="list-style-type: none"> • Authority: EC 854/2004 • Procedures: "The New Organization of the Red Meat Inspection System in the Netherlands (2006)" 	EU Swine Inspection Procedures (traditional): <ul style="list-style-type: none"> • Authority: EC 854/2004 • Procedures: Annex I; Sec IV; Chap IV: Domestic Swine, B.—Post mortem Inspection
General: <ul style="list-style-type: none"> • For all swine 			
	<ul style="list-style-type: none"> • For market hogs slaughtered in plants operating under the HACCP-based Inspection Models Project (HIMP). • Carcasses must be presented for inspection with the mandibular lymph nodes incised. 	<ul style="list-style-type: none"> • For fattening pigs housed under controlled housing in integrated production systems since weaning. • At the discretion of the competent authority based on epidemiological or other data from the holding [farm]. • Data from the farm must include food chain information, results of testing for <i>M. avium</i>, and certain additional requirements to control hazards in the food supply chain. 	<ul style="list-style-type: none"> • For all swine except those identified under paragraph (2).

Head Inspection: <ul style="list-style-type: none"> • Observe head and cut surfaces – eyes, fat, cheek muscles, and other tissues for abnormalities. • Incise and observe mandibular lymph nodes. 	<ul style="list-style-type: none"> • Visual inspection of the head and throat. • Visual inspection of the incised mandibular lymph nodes. • Visual inspection of mouth, fauces, tongue. 	<ul style="list-style-type: none"> • Visual inspection of the head and throat, including the mandibular lymph nodes. • Visual inspection of mouth, fauces, tongue. 	<ul style="list-style-type: none"> • Visual inspection of the head and throat. • Incision and examination of the submaxillary lymph nodes (Lnn mandibulares). • Visual inspection of the mouth, fauces and tongue.
Viscera Inspection: <ul style="list-style-type: none"> • Observe eviscerated carcass, viscera and parietal (top) surface of spleen. • Observe and palpate mesenteric lymph nodes. • Palpate portal lymph nodes. • Observe dorsal (curved) surface of lungs. • Palpate bronchial lymph nodes. • Observe mediastinal lymph nodes. • Turn lungs over and observe ventral (flat) surfaces. • Observe heart. • Observe dorsal (curved) surface of liver. • Turn liver over and observe ventral (flat) surface. 	<ul style="list-style-type: none"> • Visual inspection of the lungs, trachea, and oesophagus. • Visual inspection of the pericardium and heart. • Visual inspection of the liver and hepatic and pancreatic (portal) lymph nodes. • Visual inspection of the gastro-intestinal tract, mesentery, gastric and mesenteric lymph nodes. • Visual inspection of the spleen. 	<ul style="list-style-type: none"> • Visual inspection of the lungs, trachea, and oesophagus. • Visual inspection of the pericardium and heart. • Visual inspection of the liver and hepatic and pancreatic (portal) lymph nodes. • Visual inspection of the gastro-intestinal tract, mesentery, gastric and mesenteric lymph nodes. • Visual inspection of the spleen. • Visual inspection of genital organs. 	<ul style="list-style-type: none"> • Visual inspection of the lungs, trachea and oesophagus. • Palpation of the lungs and the bronchial and mediastinal lymph nodes (Lnn. bifurcationes, eparteriales and mediastinales). • The trachea and the main branches of the bronchi must be opened lengthwise and the lungs must be incised in their posterior third, perpendicular to their main axes; these incisions are not necessary where the lungs are excluded from human consumption. • Visual inspection of the liver and the hepatic and pancreatic lymph nodes, (Lnn portales). • Palpation of the liver and its lymph nodes. • Visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (Lnn gastrici, mesenterici, craniales and caudales). • Palpation and, if necessary,

			incision of the gastric and mesenteric lymph nodes. <ul style="list-style-type: none"> • Visual inspection and, if necessary, palpation of the spleen.
Carcass Inspection:			
<ul style="list-style-type: none"> • Observe back of carcass (turn carcass or use mirror). • Observe front and inside of carcass, including <ul style="list-style-type: none"> ○ Cut surfaces, ○ All body cavities, ○ Lumbar region, ○ Neck region. • Grasp, turn, and observe the kidneys. 	<ul style="list-style-type: none"> • Visual inspection of the carcass. • Visual inspection of the pleura and peritoneum [lining of chest and abdominal cavities]. • Visual inspection of the kidneys. • Visual inspection of the diaphragm. • Visual inspection of the udder and its lymph nodes. • Visual inspection of the umbilical region and joints of young animals. 	<ul style="list-style-type: none"> • Visual inspection of the carcass. • Visual inspection of the pleura and peritoneum [lining of chest and abdominal cavities]. • Visual inspection of the kidneys. • Visual inspection of the diaphragm. • Visual inspection of the udder and its lymph nodes. • Visual inspection of the umbilical region and joints of young animals. 	<ul style="list-style-type: none"> • Visual inspection of the carcass. • Visual inspection of the pleura and peritoneum. • Visual inspection of the kidneys. • Incision, if necessary, of the kidneys and the renal lymph nodes (Lnn. renales). • Visual inspection of the diaphragm. • Visual inspection of the udder and its lymph nodes (Lnn. supramammarii). • Incision of the supramammary lymph nodes in sows. • Visual inspection and palpation of the umbilical region and joints of young animals. • In the event of doubt, the umbilical region must be incised and the joints opened.

ANSWERS TO QUESTIONS FSIS TO THE NETHERLANDS

GENERAL

Before providing specific answers to the questions that have been asked by FSIS, it is important to take into account the following general remarks:

- Specific focus of the pilot project regarding visual inspection was to identify relevant risks for food safety resulting from the new method and to answer the question whether the level of food safety was (at least) the same as with the traditional method. Thus the focus was not a complete scientific comparison between two p.m. inspection methods, but a risk-based approach regarding food safety. Others have already carried out scientific research concerning public health aspects of post mortem inspection in market hogs.
- Several documents concerning visual meat inspection in the Netherlands have already been sent to FSIS this year. In these documents detailed information is available about the results of our pilot project and relevant procedures of meat inspection. When providing answers to the questions we will therefore refer to the relevant text in these documents. Furthermore we will include these reference documents with this report.

SPECIFIC

1. Question

The pilot study concludes that visual inspection failed to reject 9 of 174,250 (0052%) carcasses that were inspected. However, this also represents 9 of 43 (20.9%) carcasses rejected during the pilot study. Therefore visual inspection failed to detect a significant portion (21%) of carcasses affected with pathological conditions that warranted rejection. It appears that the Netherlands considers it acceptable to pass one fifth of all carcasses that should be condemned for pathology. Is this correct? Can human factors of visual-only inspection be an aggravating factor?

To put the question about the acceptability of missed pathological conditions into the right perspective, it is important to note the aim of the pilot project. The central question was whether the new method could be operated at (at least) the same level of food safety as the traditional method. So we have not done a complete scientific comparison between two methods of p.m. investigation. Such comparison has already been done in different scientific projects in several countries and these were summarized in the "Opinion on Meat Inspection Procedures" of the European "Scientific Committee on Veterinary Measures". An important conclusion has been that p.m. inspection of pigs from industrialized production in general will assist little in improving meat safety. Reduction of the prevalence of human hazards mainly lies in the hygiene control programs throughout the whole supply chain. This supports the importance of "hands-off" systems in the slaughter line and securing possible risks concerning meat safety by other means than p.m. inspection. That's why we focused on meat safety with a risk-based approach. So we have (for example) not examined the portion of carcasses that were passed by traditional investigation, but may have been rejected by visual inspection. This was not possible because of the logistical organization of the pilot where visual inspection was followed by traditional inspection, and visual inspection was a part of the traditional inspection.

From a risk point of view it is important to put the proportion of carcasses missed by visual inspection and rejected by traditional inspection into relation with the total number of inspected carcasses.

Besides we want to give you specific information regarding the 9 carcasses that have not been detected by the visual inspectors during the pilot:

The reasons for condemnation were:

- Serious generalised pathological conditions (2 carcasses) and icterus (1 carcass):

It is clear that these 3 carcasses should have been detected by the visual inspectors and cannot be seen as "missed by the system". It seems logical to look for the cause of these missed abnormalities primarily at the human level. As stated above we have not investigated the "human factor" of the traditional method but seen the small number of rejected carcasses in relation to the total number of inspected carcasses the human factor has to be taken into account with both, visual and traditional inspection methods.

- Positive bacteriological test on *arcanobacterium pyogenes* (3 carcasses):

- Positive bacteriological test on *haemolytic streptococci* (1 carcass):

From a public health view the question is, whether these 4 carcasses with a positive BE (bacteriological examination) do indeed represent a food safety risk? For a closer look at the bacteria's found and their relevance for food safety please see the answer to question 10.

- Failed bacteriological test (1 carcass):

It is difficult to say something about the carcass where the bacteriological test failed. The test may have been negative and consequently the carcass would have passed through.

- Positive test on antibiotics (1 carcass)

The carcass had been raised out for further testing because of inflammation of a carpus/ tarsus and multiple abscesses in the lung found by traditional inspection. The bacteriological test was negative.

¹ Opinion of the Scientific Committee on Veterinary Measures relating to Public Health on "Revision of meat inspection Procedures, 24-2-2000.

▪ Further remarks:

Figure 4 from the draft report (page 14, chapter 5.1) shows that in the beginning of the pilot project there were relatively more pathological findings not detected by the visual inspectors. Possibly it took some time before everyone was used to the new situation. This would be another, (specific) aspect of the "human factor".

As stated above it can be concluded from scientific literature that some findings will not be detected by visual inspection. During the pilot project we have tried to identify the relevant food safety risks and to secure them also by other means. But it is important to note that both, visual and traditional inspection methods have not a very high sensitivity with respect to the detection of possible food safety risks (opinion of the SC on revision of meat inspection procedures, 2000). This has been one of the main reasons for looking for ways to secure food safety risks by other means within the supply chain.

2. Question

The paper mentions that pigs from farms meeting requirements laid down in the Code of Practice of the IKB Scheme or an equivalent quality assurance scheme were used. Further information on the scheme is needed. For example, what records are available related to ongoing disease surveillance, treatment records, production methods to reduce exposure to specific pathogens, etc?

The Dutch IKB scheme is an integrated quality assurance scheme for production chain control with additional requirements on top of national and EU legislation for feed, hygiene, the use of veterinary drugs, transport and animal welfare. The integrated chain approach of the program means, that all activities in pork production are closely linked to one another, from breeders to pig farmers to slaughterhouses. The work carried out by vets, the requirements for veterinary medicines and the standards for animal feed and animal welfare are also covered within the program.

In addition, all of the professional contacts of pig farmers in the industry must comply with the requirements that are laid down in separate quality regulations: the Quality Regulations governing Livestock Trading, the Quality Regulations governing the Transport of Livestock, the Good Manufacturing Practice regulations for feed manufacturers and the Good Veterinary Practice regulations for Accredited Pig Veterinary Surgeons. Within the quality system there are regulations governing each type of establishment. These include both system requirements and product requirements. The system requirements relate to the established way of working (the manual) and the implementation of the system in practice. The product requirements relate to every link in the production chain. As far as animal health and food safety are concerned, these focus on aspects such as:

- Transfer of records on animal health
- GVP (Good Veterinary Practice) approved veterinarians
- Limited list of approved veterinary drugs compared with EU legislation
- Feed control according to food safety based GMP+ system including HACCP for pig feed
- Hygiene codes for farms, transport and processors

Data exchange animal health

Within the IKB system information about the state of health of an animal accompanies the animal in question to the next link in the chain. Both the breeder and the pig farmer record all important data concerning the health of their animals in an IKB farm logbook, i.e. identification and registration details, the origin of the sows and the fattening pigs and the length of time the animals have spent on the farm.

Other details that are recorded include any purchases, the nature of any health problems, every veterinary medicine administered, the date and duration of the treatment, the medicine dosage, the recommended withdrawal period and all vaccinations of piglets and fattening pigs. Both the breeder and the pig farmer keep copies of delivery documents. All data is kept for a minimum of 12 months.

At the slaughterhouse relevant data of post mortem inspection such as carcass lesions and organ lesions, as reported in the letter of 25-07-2006 from the Dutch Deputy Chief Veterinary Officer (reference 06.2092/IH), are collected and subsequently reported back to the farmer.

Good Veterinary Practice

Pig farmers may only make use of the services of vets who operate in accordance with the Code of Good Veterinary Practice (GVP) and are accredited pig veterinary surgeons. This Code is administered by an independent body, the Veterinary Quality Body (VKB), in collaboration with the Royal Netherlands Veterinary Association. The pig farmer concludes an exclusive contract with a GVP-certified pig veterinary surgeon. This Code contains guidelines for vets on how to handle animals carefully and in an ethical manner.

Approved medicines

Veterinary medicines may only be used on IKB pig farms if prescribed by a vet. Only veterinary medicines that appear on the 'positive list of veterinary medicines for IKB pig farms' may be used. The effect of this measure is that when an animal is slaughtered, there are no residues or injection marks in the meat. To guarantee that this is in fact the case, in a great many instances the withdrawal period is longer than the withdrawal period provided for by EU law. The requirements imposed on medicines on the positive list are more stringent than the statutory requirements. For example, the use of sulphonamides (sulpha drugs) is extremely restricted on the positive list.

The positive list indicates per product the active substance, the dosage form, the registration number, the registration holder, the product name and the withdrawal period in days. All veterinary medicines on the positive list have to undergo additional testing before they can be accepted on the list.

GMP+ Feed

Pigs on IKB farms may only be given feed that comes from companies that operate in accordance with the Code of Good Manufacturing Practice+ (GMP+Feed). The Code is a quality scheme that has been set up by the Product Board for Animal Feed. The Code contains regulations concerning the use of additives and veterinary medicines, the prevention of undesirable substances and controls on the microbiological condition of the feed. Quality assurance within the GMP+ scheme is based on the international standard HACCP, which has been prescribed in Europe for the food industry.

The aim of the IKB quality system is to provide guarantees in the areas of product safety, traceability and audits. IKB is a flexible system that is constantly being further developed, tightened up and adapted. It provides an infrastructure within which changes can be introduced relatively easily. This means that the system is capable of adapting to new developments.

Important changes were made in April 2003, when the IKB system was extended to include additional regulations covering the layout of pig units, hygiene, independent auditing (EN 45011) and ISO-based pig husbandry procedures. In April 2004 the IKB system was extended to include SAFE, a program of extensive testing for unauthorized substances in pig farming.

An English translation of the IKB Code of Practice for pig farmers is attached to this report.

3. Question

The paper did not provide adequate historical data to support that there are enhancements of visual-only inspection over traditional inspection. It was stated that total number of condemnations during the previous year differed significantly in comparison with data of the pilot. It was concluded that this difference could be explained by the fact that the supply of fattening pigs during the previous year did not match the supply during the pilot. This suggests and does support that source has a significant impact on "risk." More information is needed to support if such decisions can be maintained regularly and predictably in the future. It is difficult to make a comparison of inspection methods if the source animals are not from the same source.

It was concluded that comparison of results of visual inspection with historical data of traditional inspection was not preferable because of a possible bias. It couldn't be excluded that the type of fattening pigs that was inspected in the year before (and whose inspection results were the basis of the historical data) was different

from that inspected during the pilot². For this reason a comparison was made **within** the same group of animals, the fattening pigs that were presented for inspection during the pilot. All these animals underwent a double inspection regime, they were both visually and traditionally inspected. So for the duration of the pilot, source as a reason for bias could be effectively excluded.

Source cannot be excluded as a possible risk factor, but this aspect was – and had to be! – incorporated in the visual inspection pilot. For instance only fattening pigs from farms that met all the requirements (see below) were admitted to this double inspection regime. The justification of visual inspection lies in Regulation (EC) 854/2004 where it is stated that:

*'The competent authority may decide, on the basis of epidemiological or other data from the holding, that fattening pigs housed under controlled housing conditions in integrated production systems since weaning need, in some or all of the cases referred to in paragraph 1, only undergo visual inspection.'*³

The minimum requirements for participation in visual inspection are:

- it concerns only fattening pigs
- they may not have had outdoor access
- they should come from farms that have implemented the system of food chain information
- they should come from farms that have implemented pro-active measures against *Mycobacterium avium*
- they should have been raised under controlled housing conditions and in integrated systems of production.(IKB).

4. Question

The report indicates that decision making was made primarily on farm data and history. A serological test would need to be reliable as a predictor for evaluating the TB herd status. It was not clear if reliability and value of an antibody test for *M. avium* had been established. The report indicates that antibody testing should be, for the time being, be considered as the most sensible diagnostic tool. However, no specific data was presented supporting serological testing as an effective or practical herd monitoring tool for TB.

Before we address your specific questions regarding serological testing we want to give you some general information about the epidemiology of *Mycobacterium avium* in the Netherlands and relevant research that has been done regarding the relation between positive bacteriological tests with *M. avium*, the presence of macroscopic lesions in lymph nodes and serological conversion.

Furthermore, we will provide information about the procedures for serological testing of pigs within the chain supply chain inspection scheme and the follow-up of serological positive farms.

Mycobacterium avium is a bacterium that can cause harm to man. Several scientific publications and health statistics show the relevance of *M. avium*, see references (Inderlied et al, 1993, Wallace and Hannah 1988). The Dutch government and scientific research organizations have carried out already for years research into this bacterium. Results of the prevalence studies on *M. avium* in market hogs are published by Komijn et al (1999, and 2007), see the enclosures.

The Dutch pork producers aimed to contain the prevalence of *M. avium* through preventing the introduction of this bacterium at the hog farm. Measures to realize this were implemented in the IKB code of practice at farm level (see also respons to Question 2). Within the code of practice pest control and hygiene of feed and bedding material are most relevant with respect to the control of *M. avium* at farm level.

Research showed that the prevalence of *M. avium* at farm level has decreased between 1998 and 2003. Actually *M. avium* has not been detected in a targeted surveillance in the 2003 prevalence study of Komijn et al (publication accepted in 2006, will be published in 2007), thus the prevalence in the Netherlands is very low.

These data form the scientific basis for the change in the control of *M. avium* in pork.

In order to gain more insight in the development of granulomatous lesions in pigs an infection experiment was done (Wisselink et al, 2006). The results showed that all pigs inoculated with *M. avium* had one or more lymph nodes bacteriological positive with *M. avium* at slaughter age. From the pigs inoculated once below 5 weeks of

² See also: 'Final report on the data analysis from the 'Visual inspection Pilot', page 12 and further.

³ EC regulation 854/2004, Annex I, section IV, chapter IV, B Post-mortem inspection, paragraph 2

age 14 out of 16 showed granulomatous lesions in one or more lymph nodes. However only 2 out of 8 pigs inoculated 3 times (at 2½, 4½ and 18 weeks of age) showed granulomatous lesions. Of all pigs inoculated, 23 out of 32 showed seroconversion at market age, see table 1, 2 and 5.

Lipids of a *M. avium* strain harvested from pigs in the Netherlands (strain MAA 17404) were used to develop an antibody test. Polar lipids were used as antigen in the Elisa. The highest value of percentage positivity measured in known MMA-free pigs was 16%. See for the results of the serological test tables 3 to 5.

Table 1: Macroscopic evaluation of Lnn of pigs at 24 weeks of age after experimental infection with *Mycobacterium avium* subsp. *avium*

Group	Number pigs	age experimental infection (wks)			Lesions in lymphnodes	
		2,5	4	18	Mean (n)	pigs (n)
1	8	X			2,1	7
2	8		X		2,5	7
3	8			X	0	0
4	8	X	X	X	0,3	2

Table 2: Macroscopic lesions on lymphnodes in pigs after experimental infection with *Mycobacterium avium* subsp. *avium*

Group	Number pigs	Number of macroscopic lesions in lymphnodes per infection group:						
		Tonsil	Mand.	Mes.	Ing.	Trach.-br. (li)	Trach.-br. (re)	Retro-phar
1	8	1	3	6	0	2	2	3
2	8	0	7	7	0	0	2	4
3	8	0	0	0	0	0	0	0
4	8	0	0	2	0	0	0	0

Legenda: Mand = Lnn mandibularis; Mes = Lnn mesenterialis; Ing = Lnn inguinalis; Trach. br. = Lnn trachea-bronchialis; Retro-phar = Lnn retro-pharyngeal

Table 3: Sera originating of pigs that showed to be negative in bacteriological examination on *Mycobacterium avium* subsp. *avium* (MAA), tested in an ELISA with antibodies against the polar lipids of MAA

Percentage Positivity (serology)	Number of samples (%)
< 0%	80 (52.3)
0 - 5%	60 (39.2)
5 - 10%	10 (6.5)
10 - 15%	2 (1.3)
15 - 20%	1 (0.7)
> 25%	0 (0)
Totaal	153 (100)

Table 4: Test levels in percentage positivity (PP%) at different targeted levels of specificity

Specificity		Test levels (PP%)	
Mean	Range	Mean	Range
0.90	0.84 – 0.94	4.4	2.4 – 7.7
0.95	0.90 – 0.97	7.5	5.1 – 14.4
0.975	0.94 – 0.99	8.9	7.4 – *
0.99	0.96 – 1.00	12.3	8.8 – *

* dataset insufficient

Table 5: Evaluation of macroscopic lesions, bacteriological examination and serology of 32 pigs experimentally infected with MAA

Group	Number of pigs positive						
	Lymphnode lesions macroscopic			Lymphnode bacteriological			Serology (> 7,5 PP%)
	Mand.	Mes.	Mand.+ Mes.	Mand.	Mes.	Mand.+ Mes.	
1	3	6	7	5	8	8	8
2	7	7	7	8	7	8	5
3	0	0	0	8	5	8	2
4	0	2	2	7	7	8	8
Total	10	15	16	28	27	32	23

Legenda: Mand = Lnn mandibularis; Mes = Lnn mesenterialis

Procedures for testing of pig serum within the supply chain inspection

From each lot of pigs supplied to the slaughterhouse two or six blood samples are taken. A farm can only be qualified to deliver pigs that satisfy the requirements of supply chain inspection when at least 18 subsequent blood samples showed to be negative in the MAA-Elisa. Whenever one or more blood samples are positive the lots of pigs of that farm will be slaughtered at a slaughterhouse that conducts traditional meat inspection.

Follow up of *Mycobacterium avium* serological positive farms.

When lots of the same farm repeatedly have positive results when tested serologically for *M. avium* this could be indicative for the presence of *M. avium*. VION will assist the farm to become *M. avium* free again. In the traditional meat inspection incision of the lymphnodes occurs, additionally at this slaughterhouse of every market hog lot six blood samples are taken and analyzed for the presence of antibodies against *M. avium*.

The farms are being visited by a VION employee who, together with the farmer, will assess the risk factors for *M. avium*. The farmer is being encouraged to alter his management. If problems persist the farm is visited by a veterinarian who will conduct additional tests. These tests consist of tuberculation of the hogs and a further evaluation of the risk factors at the farm. If the extended evaluation of the risk factor shows indications for contamination routes, samples of the environment (e.g. soil, feed and water) are taken. Of the tuberculated hogs mesenteric lymphnodes are being sampled in the slaughterhouse and these are analyzed for the presence of *M. avium*.

References:

Inderlied CB, Kemper CA, Bermudez LE. The *Mycobacterium avium* complex. Clin Microbiol Rev. 1993 Jul;6(3):266-310. Review.

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Wallace JM, Hannah JB. *Mycobacterium avium* complex infection in patients with the acquired immunodeficiency syndrome. A clinicopathologic study. Chest. 1988 May;93(5):926-32.

Wisselink, HM, C van Solt-Smits, N Stockhofe-Zurwieden, H Bergen-Buys, P. Overduin, M van Prehn, D van Soelingen and J Thole. Comparison of visual and bacteriological examination of mandibular and mesenteric lymphnodes in pigs, experimentally infected with *Mycobacterium avium* subsp. *avium*. IPVS Conference Copenhagen 2007.

5. Question

It is not clear if visual inspection would be used for non-market weight hogs, such as sows and boars. Since the basis for deciding not to incise lymph nodes is based on epidemiological data of pigs raised since weaning, and TB, if present, is more or less likely to be seen in older animals, detection in sows might be more important in evaluating the risk of TB. Are incisions to be performed in older animals (non-market hogs)?

The visual inspection is not used for non market weight hogs, such as sows and boars. They follow the traditional inspection. Visual inspection can be only in place for fattening pigs kept under controlled housing conditions in integrated production systems in line with the legal European framework as mentioned in the answer to question no. 3.

6. Question

It is not clear if/how the Farm Risk Profile considers previous slaughter results? What criteria will be used to determine whether a particular slaughter lot requires more intensive inspection procedures? How rapidly will those criteria be re-evaluated based on information from previous slaughter lots (or even the current slaughter lot)? Is the data real time?

9. Question

Will verification testing for residues be based on history of treatment? It is not clear what value the history of "group treatments" has on supporting visual-only inspection to rule out whether non-TB abscesses or drug residues are likely to be present.

In the answer below we address question no 6 and no 9 at the same time:

The Farm Risk Profile (FRP) is an index used for estimating the risk of *Mycobacterium avium* in future market hog lots. The way the FRP is calculated is described in the answers to question 4.

To assess if a supplied lot needs to be analyzed in more detail for residues of anti-microbiological agents, the slaughter results of the previous slaughtered lots of the same farm are used.

If the percentage affected lungs and/or pleuritis of the farm (calculated over the last 4 weeks; if less then 2 deliveries in these last 4 weeks, then the last 2 deliveries of the farm to VION) is at least double the percentage of affected lungs and/or pleuritis in comparison to the slaughter plant average, the current lot is being sampled and analyzed for residues of anti-microbiological agents.

Because the percentage of affected lung/pleurisy is calculated over the last 4 weeks, seasonal changes are incorporated in the estimation.

The slaughter lesions found in a market hog lot is being presented to the farmer. VION uses an internet based application called Farmingnet. The data from lots slaughtered will be available to the farmer within 24 hours. Farmers can use this information to improve their management and the health of the pigs subsequently on the farm.

Table 1: VION Helmond versus National Plan at VION Helmond

Period: January untill June 2006

Animal species: market hogs

Total no. pigs slaughtered: n=697.394	positive NAT-screening	NAT post-screening kidney	NAT post-screening meat	Chemical analyses meat	
				<MRL	>MRL
Supply chain meat inspection (samples taken n=439)	36 (8,2 %) 26 x tetracycline 1x β -lactam 3x aminoglycoside 1x quinolonen 5x sulfonamiden	7 (1,6 %)	7 (1,6 %)	5 4xtetra 1xsulfa	2 1xtetra 1xsulfa
National Plan (n=147)	7 (4,8 %) 7xtetracyclines	2 (1,3 %)	2 (1,3 %)	1 1xtetra	1 1xtetra

NAT-screening: microbiological analyses pré-urine

NAT post-screening kidney: microbiological analyses kidney tissue

NAT post-screening meat: microbiological analyses muscular tissue

Chemical analyses: liquid chromatography in combination with mass-spectrometry or diode-array detection.

In table 1, the results of residue analyses due to supply chain meat inspection (targeted sampling) and the results of residue analyses of the National Plan random sampling (coordinated by the Government) are shown. It is concluded that because of the risk based approach of the supply chain meat inspection, the percentage of residues found in meat has increased in the targeted cohort.

Whenever values above MRL are detected, the agriculture police will take immediate action. In case of results of analyses of values below MRL, the Food Chain Information will be taken into account. A follow up to the farm will be initiated, in order to part he control of the absence of residues at a higher level.

6. Question

How will scheduling of verification procedures occur to ensure that visual inspection continues to protect food safety? Verification procedures should be initiated based on random and biased factors. Verification lots of market hogs where abscess/granulomas are observed in the mesenteric lymph nodes would be an excellent way to rule out M. avium lesions that might have been missed by not incising the mandibular lymph nodes.

In the case of the slaughterhouses in general and slaughterhouses which export to the USA specifically there are several types of verification:

- Permanent (daily) visual verification of hygienic process conditions by the VWA
- Permanent (daily) bacteriological verification of hygienic process conditions by the slaughterhouse, supervision by the VWA.

- Salmonella monitoring (USA-exporting slaughterhouses)
- Monitoring of residues in the framework of the National Plan (random sampling)

Also there are verifications on meat inspection:

General (all slaughterhouses):

1. Verification of quality of inspection (has the right decision been made by the on-line inspector) does take place on a daily basis (minimum once a day) and is carried out by the official veterinarian.
2. The location of the verification activities is the on-line inspection platform next to the on-line inspection.
3. The results of this verification are documented. This information will be used for verification of inspection performance of official auxiliaries that is set as a cumulative maximum of 6% of missed pathological abnormalities (2% standard for the carcass, 2% for the stomach/intestines, and 2% for the organs). In case of insufficient performance the official veterinarian will take action.
4. The number of carcasses + stomach-intestines + organs to be verified on a daily basis are calculated as the square-root of the number of slaughtered pigs, distributed over the day with a minimum of 2 batches and a minimum of 50 pigs.
5. No (normal) carcasses /stomach-intestines/ organs will be "railed out" for verification purposes; the verification occurs on-line next to the normal inspection, not off-line.

A detail description of the verification procedures on the quality level of the post mortem inspection as performed by the official auxiliaries is described below.

The standards can be distinguished into two basic elements, i.e. standards for inspection procedures and standards for inspection decisions:

Inspection procedures

The starting point is that inspection procedures have to be carried out in compliance with Regulation (EC) 854/2004. Verification of the execution of official controls has to be done on the inspection station. The standard for the correct execution of the inspection procedures is fixed at 5% per inspection position. By this standard is meant the maximum number of deviations of the number of inspection procedures. The size of the random sample is determined at \sqrt{n} (n =number of animals in a one-day production cycle) over two batches.

1. Inspection decisions

The verification of the correct execution of the inspection decisions distinguishes two parts, i.e. pathological abnormalities and hygienic slaughtering. The verification of pathological abnormalities takes place on the inspection station, as long as the carcass and the organs where running synchronically. The verification of hygienic slaughtering takes place between the trimming station and the end of the slaughtering line.

Pathological abnormalities

Regulation (EC) 854/2004, annex 1, section II, chapter V describes which pathological abnormalities are reason to declare meat unfit for human and/or animal consumption. The standard for missed pathological abnormalities is determined at 6% cumulative and is in fact a check on wrongly approved material. This standard consists for the traditional pm. inspection of a 2% standard for the carcass, 2% for the pluck, and 2% for the intestines. For the supply chain inspection this standard consist of a 2% standard for the carcass and a 2 standard for the plucks and intestines together. This cumulative standard is based on the fact that this was found to be very realistic in New Zealand. New Zealand is the only country that has experience in this area with meat.

The size of the random sample per inspection position to test the standard of 6% cumulative for traditional inspection and 4% cumulative for supply chain inspection is fixed at \sqrt{n} (n =number of animals in a one-day-production cycle) over two batches. If the result of \sqrt{n} exceeds 50, these batches will be divided in two batches of a minimum of 25 carcasses per inspection position. The cumulative standard of 6% for missed pathological abnormalities is a guidance standard for the assessment of the post mortem inspection quality.

Together with the size of the random sample, a statistically justifiable picture of the post mortem inspection quality is created.

Hygienic slaughtering

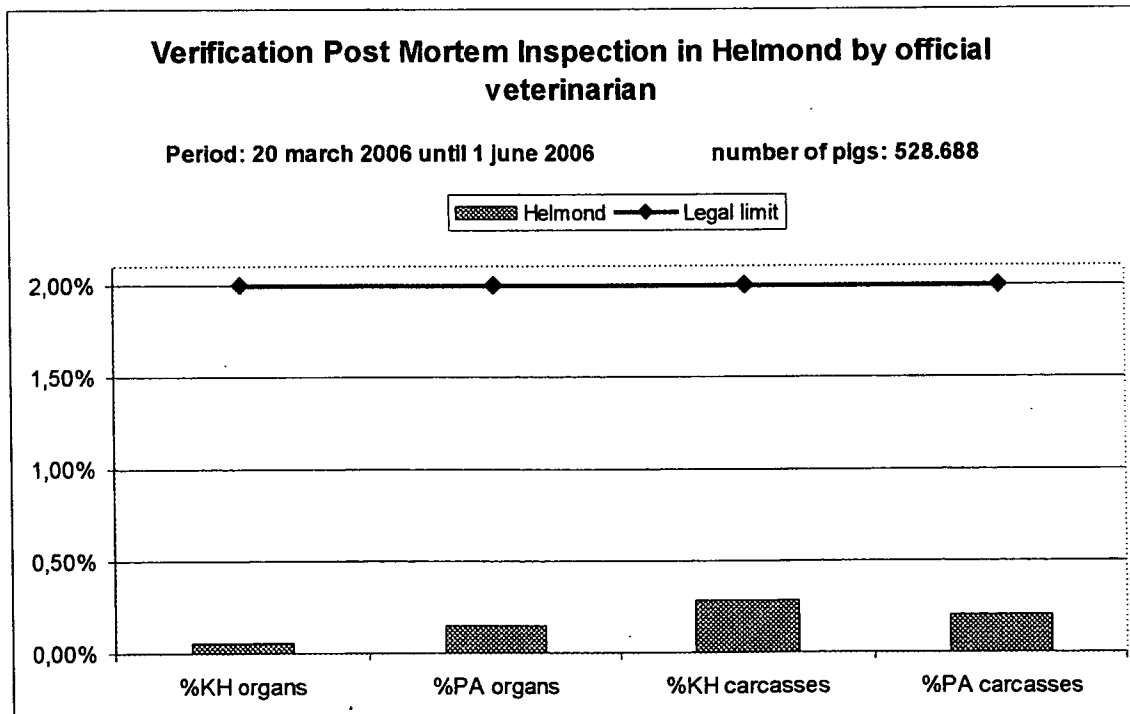
In the first place it needs to be clear that faecal contamination is a Critical Control Point in the HACCP-system (EC Regulation 852/2004, article 5). The slaughterhouse is responsible for the guaranteeing of this CCP.

In addition, slaughter animals with deviations as a result of errors in the slaughtering hygiene are offered for inspection, which require an inspection decision. The standard per carcass for slaughtering defects is fixed at 2% total and 0% for faecal contamination. The faecal contamination will always have to be 0% at the end of the slaughtering line! The size of the random sample to test the standards of 2% and 0% is fixed at $2\sqrt{n}$ (n =number of animals in a one-day-production cycle) over four batches. If the result of \sqrt{n} exceeds 50, these batches will be divided in four batches of a minimum of 25 carcasses.

Results of the verifications described above have shown that there are no indications that visual inspection is performing less on the basis of these results.⁴

In Annex 1 tables are presented of monthly summaries for verifications inspection procedures and inspection decisions. When comparing location Helmond (supply chain inspection) with VION location Boxtel (traditional inspection) it becomes clear that the level of inspection both for inspection procedures and inspection decisions was adequate.

In graph 1, the results of the verification of the p.m. inspection at VION Helmond are shown in detail. KH represents a wrong inspection performance or a wrong inspection decision. PA represents missed pathological abnormalities. The performance of the inspection meets the standards (<2% standard for plucks and intestines, <2% standard for carcasses, which makes total cumulative below 6 %) as in the verification procedure of the Food and Consumer Product Safety Authority (VWA).



Legenda: KH = wrong inspection performance or a wrong inspection decision; PA = missed pathological abnormalities

Graph 1 results of the verification of the p.m. Inspection at VION Helmond.

⁴ See Annex I

From this graph it becomes clear that visual inspection at VION location meets the VWA standards.

Verification procedures in the framework of supervision on the Vion supply chain inspection pilot project.:

In the supervision protocol activities of the VWA are two parts described in this protocol: VWA external and VWA internal with four types of supervision.

VWA external

1. Audits on the execution of protocols stated (external audits)
 - Audit on Food Chain Information submission
 - Audit on implementation at the slaughterhouse
2. Verification at slaughterhouse level
3. Verification at farm level

VWA internal

4. Audit on supervision carried out by the VWA as described here under 'internal audit'.

The verification procedures mentioned above are described in the Supervisory framework on the Vion chain management pilot project: see annex

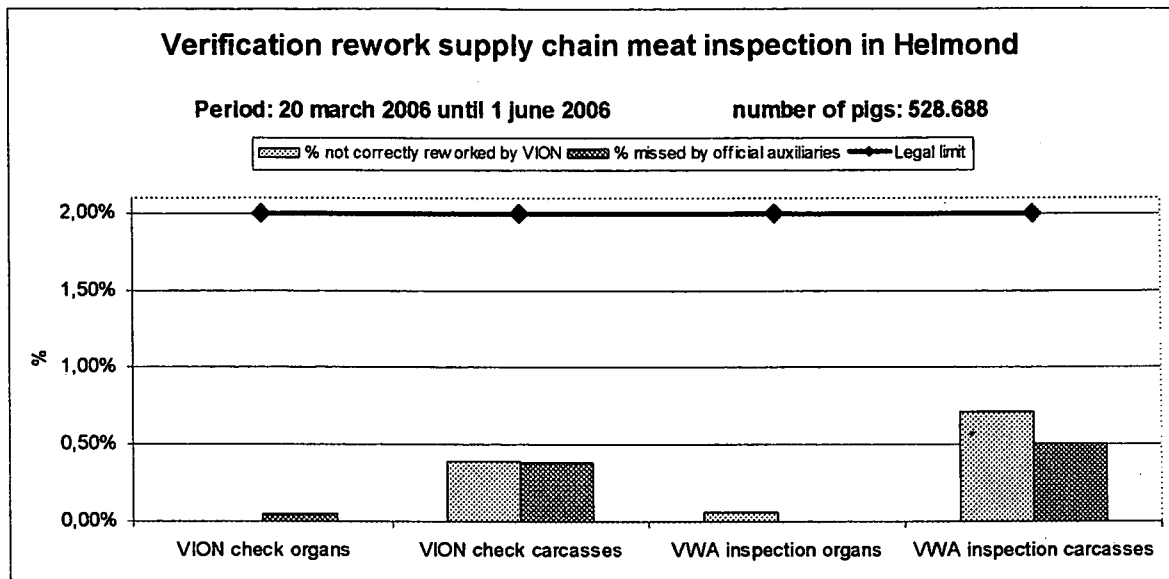
In addition to the standard procedures for all slaughterhouses, specifically in the case of supply chain inspection also verification is in place on the overall performance of inspections including handling and correction of all defects on the trimming station.

The performance standard is set at compliance levels of 98% a day and 98% a week of the checked carcasses to be up to specification. This standard is set up for the deviations marked by the official auxiliaries. Deviations which have not been marked by the official auxiliaries are registered and if needed corrected and will be passed on to the official veterinarian of the Dutch Product and Food Safety Authority, but will not count in the total score to determine the performance standard of the slaughterhouse.

When the above-mentioned performance standards are not met at the monitoring, next to above-mentioned measures (including additional instruction), the frequency will be increased. In the case of more than 2% deviations a day, the next day an additional check will be performed. When in 2 occasions (or more) with more than 2% deviations in a week, the frequency for checks on carcasses will be increased to 5 checks a day (in stead of 4 checks) for the period of 1 week and for the plucks and the organs, the frequency will be increased to 3 checks a day (in stead of 2 checks) for the period of 1 week.

The official veterinarian of the Food and Consumer Product Safety Authority will perform verification on above-mentioned working method. When deviations are found, VION will perform the same measures as if the deviation was observed by VION.

In the period of 20 March 2006 until 1 September 2006, it only occurred once, that 3 carcass had deviations after rework in one day. The correct measures were taken. In the same period, it did not occur that organs (plucks and intestines) showed deviations after rework.



Graph 2 Results of verification rework supply chain meat inspection at VION Helmond

8. Question

How does the Farm Risk Profile factor impact *M. avium*, *Salmonella*, etc. without validated blood testing or historical slaughter data under traditional inspection? It is reasonable to factor seasonal changes in calculating risk of disease (pneumonia) and need for additional residue testing.

This question has been dealt with in the answers to questions 4 and 6.

9. Question

Will verification testing for residues be based on history of treatment? It is not clear what value the history of "group treatments" has on supporting visual-only inspection to rule out whether non-TB abscesses or drug residues are likely to be present.

Please see answer to question no 6.

10. Question

A discussion on the impact of visual inspection on detection of endocarditis lesions and some of the causative agents has been provided in the draft report. Results indicate that inspectors will not be able to identify as many lesions as during traditional inspection. Although some possible reasons have been mentioned, further information and discussion on this issue are needed, especially discussion on *Strep. suis* and other microorganisms of zoonotic concern.

It is correct that not all endocarditis lesions will be detected by visual only p.m. inspection. However, scientific literature concludes that detecting large part of endocarditis lesions is possible with visual only inspection (especially by focussing on kidney infarcts). We have found support for that in our pilot as well. On the other hand it is important as well to note that also with standard incision of the heart it will not be possible to detect every case of endocarditis because of the speed of the slaughter line.

According to the risk-based approach as explained in answer to question 1 we carried out a risk analysis on endocarditis (appendix 2 of the data analysis report) with the following results:

- The prevalence of endocarditis is very low (0,005-0,007%), data source: pilot project + other meat inspection data (Netherlands, 2004)

- We also found that only 33-50% leads to condemnation of the carcass because a positive bacteriological test.
- The microorganisms usually associated with endocarditis (*E. rhusiopathiae*, *A. pyogenes* and Haemolytic streptococci) are not known as important food born zoonotic agents. But off-course this cannot be ruled out for a 100%.

When looking at the micro-organisms that can be found in association with endocarditis, *E. rhusiopathiae* en *Streptococcus suis II* are of zoonotic concern.

For *E. rhusiopathiae* it can be said that:

- Was not detected during the pilot and in the year before.
- Is not a big issue in Dutch pig husbandry (i.a. because of vaccination)
- Is mostly of zoonotic concern in contact infections (farmworkers, slaughterhouse employees)
- In some cases *E. rhusiopathiae* also gives generalised symptoms like the typical skin lesions. These carcasses will be detected with visual p.m. inspection.

For *Streptococcus suis* it can be said that:

- Especially *S. suis II* is a zoonotic micro organism.
- It is not known if *S. suis II* is associated with endocarditis in the market hogs in the Netherlands. Because further serotyping is not done streptococci isolated in slaughterhouses.
- *suis II* is known to give animal health problems in Dutch pig husbandry and would therefore be detected in the live animal at farm level or at ante-mortem.
- *suis II* is known as a relevant zoonotic risk for slaughterhouse employees, butchers, farm workers, because the infection occurs through contact.
- Foodborne infection can not be ruled out 100%, but is not likely.

For *A. pyogenes* can be said that:

- It's not seen as a zoonotic microorganism
- Is sporadically found in human
- There are no indications that food born infections are possible

In a risk-based approach we concluded that the risk of not detecting all endocarditis lesions is not relevant for food safety.

The conclusions we drew about the micro organisms mentioned above are based on our literature research (see below). Our conclusions are also supported by a literature research done on different microorganisms concerning meat inspection by the National Institute for Public Health and the Environment (RIVM) in 1989. They also concluded that *A. pyogenes*, *S. suis* and *E. rhusiopathiae* are not relevant as foodborne zoonotic microorganisms.

Literature:

1. W. Wouda et. al. , Endocarditis en vleeskeuring bij slachtvarkens, Tijdschrift voor Diergeneeskunde, deel 112, afl. 21, 1987, p. 1226-1235
2. Masanori Katsumi et. al, Bacterial Isolation from slaughtered pigs associated with endocarditis, especially the isolation of *Streptococcus suis*, Journal of veterinary medical science, vol. 59, 1997, p. 75-78
3. U. narucka et. al., Afwijkingen bij slachtdieren, Tijdschrift voor Diergeneeskunde, deel 110, afl. 19, 1985, p. 776-779
4. W. Wouda et. al. , Endocarditis en vleeskeuring bij slachtvarkens, Tijdschrift voor diergeneeskunde, deel 112, afl. 21, 1987, p. 1236-1242.
5. R. Fries und J. Leps, Die incision des herzens beim schwein, Fleischwirtschaft, vol 10, 2005, p. 116-119.

6. C. Tarrads et. al., Identification of Streptococcus suis Isolated from Swine: Proposal for Biochemical Parameters, journal of clinical microbiology, vol. 32, 1994, p. 578-580
 7. J.J. Staats et. al., Streptococcus Suis: past and present, Veterinary research communications, vol. 21, 1997, p. 381-407.
- Yu-Tsung Huang et. al., Streptococcus suis infection, Journal of Microbiol Immunol Infect, vol. 38, 2005, p. 306-313.

11. Question

It is not clear if farm workers are subject to health testing. This may be of concern in cases where there is a high turnover rate and there are migrant workers from other EU countries and non EU countries that work on farms. What is the normal turnover rate for the work force at the farms. There could be a potential risk of farm or abattoir workers introducing TB, especially drug-resistant TB, to livestock or food products.

In practice, most farmers work alone or have personnel which are contracted for a long period. Therefore, it rarely happens that new personal is hired (especially foreign personnel because of communication problems).

People from non EU countries are allowed to work in the Netherlands, provided that they have a working permit. This working permit is only given when strict conditions are met. One condition is that the employer can not find an employee in the Netherlands to fill in the job vacancy. When farmers do not act according this law, severe fines are given by the government.

People from other EU countries are allowed to work in the Netherlands, where they have to work according Dutch law. The Dutch law concerning labour, is supervised by the Labour Inspection of the Dutch Government. The Labour Inspection is authorized to sanction the concerning employer when the conditions are not met.

In addition, people who are working in the VION slaughter establishments have to fill in two documents:

1. a health declaration, provided with a signature of the employee and the medical doctor (see appendix 1).
2. the VION hygiene regulations, signed by the employee that he has read and understood the hygiene regulations. In these hygiene regulations is described how to deal with illness and injuries (see appendix 2)

According to public health regulations concerning Tuberculosis (TBC) in man in the Netherlands, TBC must be reported to the government when TBC has been diagnosed. When TBC has been diagnosed, the government will take immediate actions to control and eliminated the disease (as stated in a report of the National coordinator infectious disease control).

Appendix 1

2.6 Health declaration for persons working in the food industry

Name:
First name:
Date of birth:-.....-.....
Place of birth:
Address:

Have you ever suffered from, or do you still suffer from:

- | | | |
|----------------------------|--------------------------|---------------------------|
| A. typhoid fever | <input type="radio"/> no | <input type="radio"/> yes |
| B. paratyphoid fever | <input type="radio"/> no | <input type="radio"/> yes |
| C. tuberculosis | <input type="radio"/> no | <input type="radio"/> yes |
| D. infectious skin disease | <input type="radio"/> no | <input type="radio"/> yes |

If yes, which one:

- | | | |
|---------------------------------|--------------------------|---------------------------|
| E. any other infectious disease | <input type="radio"/> no | <input type="radio"/> yes |
|---------------------------------|--------------------------|---------------------------|

If yes, which one:

The undersigned states to have given the above information to the best of his/her knowledge.

The undersigned also states that during his/her employment he/she will immediately report to management and to ArboUnie (Working Conditions Union) when he/she is suffering or believes to be suffering from an infectious disease.

Town:
Date:-.....-.....
Signature:

Health certificate (to be completed by the physician)

The undersigned states to have no objections against issuing the "Health certificate food industry" on the basis of the supplied information.

The certificate is valid until.....

Name of physician.....

Town

Date

Signature

Appendix 2 Hygiene regulations VION (Pro-ALG-NL-10091)

Illness and injuries

- Infections, eczema, diarrhoea and contagious diseases which can be spread through food should be reported immediately to the management. The company management will assess availability for work, but if there is a risk of direct or indirect contamination of the product, no access to the production hall will be permitted. Reports will be handled confidentially.
- Cuts and grazes should be treated at once, using a blue, detectable plaster or bandage if necessary (preferably by a First Aid official). The loss of a blue plaster or bandage during production must be reported to the manager.
- In the case of cuts, grazes, etc. on hands or lower arms, wear a glove (Latex disposable gloves or examination glove).
- Always wear gloves if you have warts.
- If you have a cold, wash your hands after any contact with mucus/discharge (for example after coughing, sneezing); use disposable tissues.
- It is forbidden to bring personal medication into the production hall.
- Anyone who suffers from external bleeding, vomiting or other form of human discharge must be removed from the department immediately. If the product, workplace, tools or packaging material are contaminated/soiled in the process, the department manager must act according to PRO-ALG-NL-10034

12. Question

The report indicated that the supply of food chain information was at a high rate of compliance, but it did not indicate what information was provided. The report also indicated that visual inspection resulted in a minimal loss of food safety. Food safety improvements were based on increased risk based testing for residues (regardless of the new scheme). The claim that, omitting incision of mandibular lymph nodes reduced the spread of *Salmonella*, was not supported. The claim that the incision of mandibular lymph nodes to detect *M. avium* is "not very meaningful" is without support. Further information is needed.

The food chain information (FCI) that was presented along with the animals can be found in the VION procedure 'Food chain information (in regard to supply chain meat inspection)'⁵

This procedure was designed by VION on the basis of VWA-directives. Before implementation it was checked again by the VWA to see if it covered:

- Legal demands for FCI coming from Reg. (EC) 853/2004
- The specific information related to the *Mycobacterium avium* status of the holding⁶
- Information on possible risk factors like historic data of percentages of lung and liver inflammation and pleurisy, as it was suspected that the chance of finding antibiotics residues was higher in animals coming from holdings with higher percentages⁷. This assumption was confirmed later.⁸ The testing for antibiotic residues could of course also have been in place in the case of traditional inspection only but it was seen as a logic consequence of the broader concept of supply chain inspection which aims at improving food safety by reducing both sources of cross contamination and other hazards.

The influence of omitting the incisions of the mandibular lymph nodes on *Salmonella* contamination was tested. It proved to lead to a significant reduction of contamination.⁹

The conclusion on meaningfulness of incision of the mandibular lymph nodes for detecting *Mycobacterium avium* was based on a literature study¹⁰.

Finally, one of the three objectives of the pilot was to answer the question:

'Does the system safeguard that at least the same level of food safety is guaranteed?'¹¹

The evaluation of this question can be found in the 'Final report 'Pilot Pork Supply Chain Inspection VION' in the paragraph 'Evaluation food safety balance'. It was concluded that there was a food safety **benefit** and not a

⁵ page 2/3:

'The following information will be present at the slaughterhouse at least the day before slaughter:

On the plan list the following information will at least be present:

- The *Mycobacterium avium* Farm Risk Profile (FRP). Farms without FRP or farms with an FRP 'high' are not allowed to the system of supply chain meat inspection;
- Certified IKB farms, or equivalent quality assurance scheme; if not, these farms cannot participate in the system;
- The percentage affected lungs and/or pleuritis (calculated over the last 4 weeks, if less then 2 deliveries in these 4 weeks, then the last 2 deliveries of the farm (identified with farm identification number). If an additional sample is analysed as positive for the first screening of antibiotics, the next delivery of that farm, 1 pig of that delivery will be analysed again.

The following information will be present at the slaughterhouse at least before the physical slaughter of the pigs:

- Compliance to IKB standard of the individual pigs;
- Information about the origin of the animal feed;
- Information about the group treatments in the period of 2 months before slaughter until the slaughter date of the pigs.'

⁶ See also the procedure 'Food chain information (in regard to supply chain meat inspection)', page 2.

⁷ See also the procedure 'Food chain information (in regard to supply chain meat inspection)', page 2: 'When percentages of lung and liver inflammation and pleurisy are higher than twice the slaughterhouse average, additional checks for antibiotic residues will take place. A risk-based control is performed regarding a higher risk of group treatments.'

⁸ See: 'Detecting antibiotics in pork'

⁹ See: 'Salmonella monitoring'

¹⁰ See: 'Final report on the data analysis from the 'Visual inspection Pilot', appendix 3: 'The food safety implications of *Mycobacterium avium*'; Comparison of visual- and bacteriological examination of mandibular and mesenteric lymph nodes in pigs, experimentally infected with *Mycobacterium Avium* subsp. *Avium*, Wisselink H, e.a.

¹¹ See: 'Final report 'Pilot Pork Supply Chain Inspection VION', page 2

minimal loss of food safety as is stated in your question! These results are in line with the SCC "Opinion on Meat Inspection Procedures".

In this opinion it was concluded that hygienic conditions are of utmost importance during the slaughter and inspection process to reduce hazards to human health. From this point of view it was also concluded that the introduction of 'hands off' systems is preferable above maintaining the current inspection procedures which are an important source of cross contamination. A testing for *Salmonella* contamination confirmed this assumption.

In the pilot the possible loss of sensitivity for detecting *Mycobacterium avium* infections was compensated by serological testing. Based on current scientific insights this serological method does not only have a higher sensitivity but also a higher specificity.

Also additional food chain information, like results from prior slaughterings, to detect more precisely antibiotics residues, turned out to be a food safety benefit.

The conclusion was that these benefits led to an improved food safety as the loss of sensitivity caused by visual inspection compared to traditional inspection, was minimal and only in a certain percentage could be related to loss of food safety. More over, this loss of sensitivity could also largely have been explained by the 'human factor' in the starting phase of the pilot.

The VWA judged the pork supply chain inspection as a whole and come to the conclusion that:

- There was an improved food safety
- The conditions for visual inspection mentioned in Regulation (EC) 854/2004, Annex I, section IV, chapter IV, B Post-mortem inspection, paragraph 2, were fulfilled.

ANNEX

Salmonella

Salmonella can be present in the intestine, oral cavity and lymphatic tissue of market hogs delivered at slaughter plants.(1,2) Studies showed 21% of the market hogs are infected with salmonella in the lymphatic tissue around the oral cavity.(6,8)

In slaughter plants with a high degree of control of fecal contamination, salmonella contamination of carcasses is related to cross contamination in the slaughterhouse rather than to salmonella present in the intestine (2,3). An effective control of cross contamination is therefore crucial to decrease salmonella contamination of carcasses. To illustrate the performance of the slaughter plant figure 1 has been added to this report. It shows the percentage of salmonella positive analysis performed as a result of the standard food safety monitoring of carcasses.

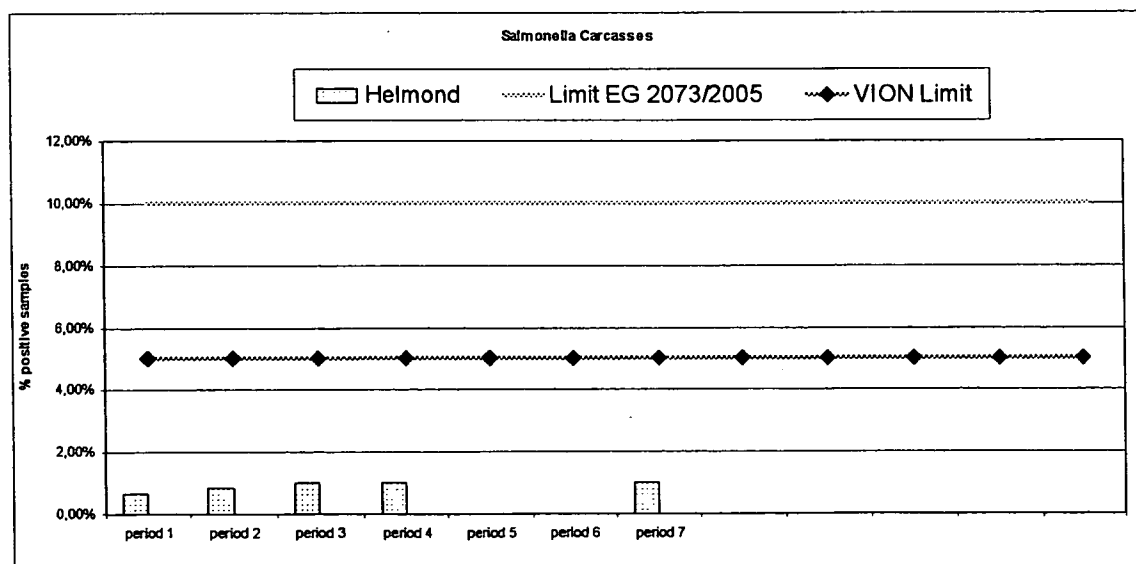
The incisions made during the traditional post mortem meat inspection are contributing to the cross contamination of salmonella (4). Omitting these incisions would therefore be an improvement in relation to the risk of cross contamination.

To visualize the effect of incision of the lymphnodes on cross contamination we conducted an experiment during the pilot in Helmond. Right before the incision of the lymphnodes the entire inner head area (which has been cut open during the process) was being swabbed with a sterile whirl-pack sponge. The procedure was being repeated right after the incisions in the head were made. Results showed an increase in salmonella present right after cutting (7) These results are illustrated in fig 2.

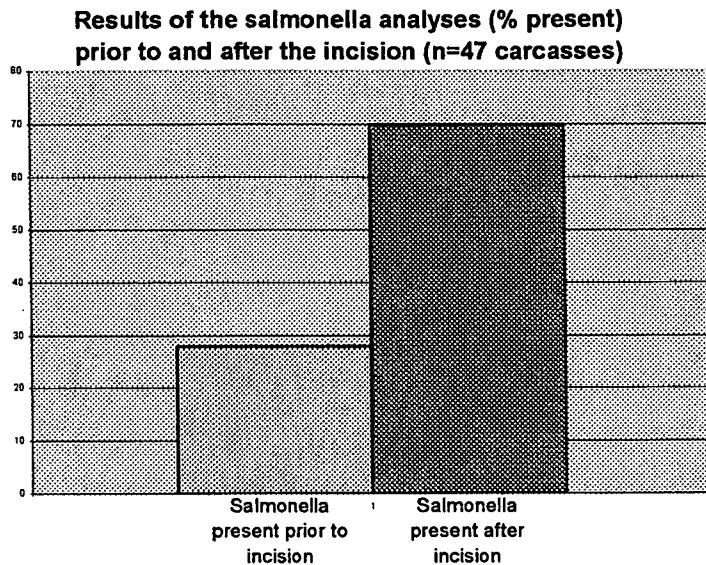
The increase can be explained by the opening of the lymphnodes containing salmonella in combination with manual handling of the head area by the inspection personnel.

These incisions are made to detect relevant hazards that pose a risk to food safety. The relevance of this instrument can be doubted in regard to many of the suspected risks. Many relevant risks are hardly detectable by visual inspection of the cut lymphnodes (1)

Other means of controlling these risks, like serological verification of *Mycobacterium avium*, are potentially more effective.



Graph 1 Average results in the standard food safety monitoring in the slaughter plant in Helmond. Each day 5 carcasses are being sampled and analyzed for the presence of salmonella. One "period" represents a period of 4 or 5 weeks. Period 1 represents weeks 1,2,3, and 4 in 2006 etc. Period 7 represents week 27,28,29 and 30 in 2006



Graph 2 Results of the salmonella analysis in the head-swabbing experiment during the pilot in Helmond.

Literature

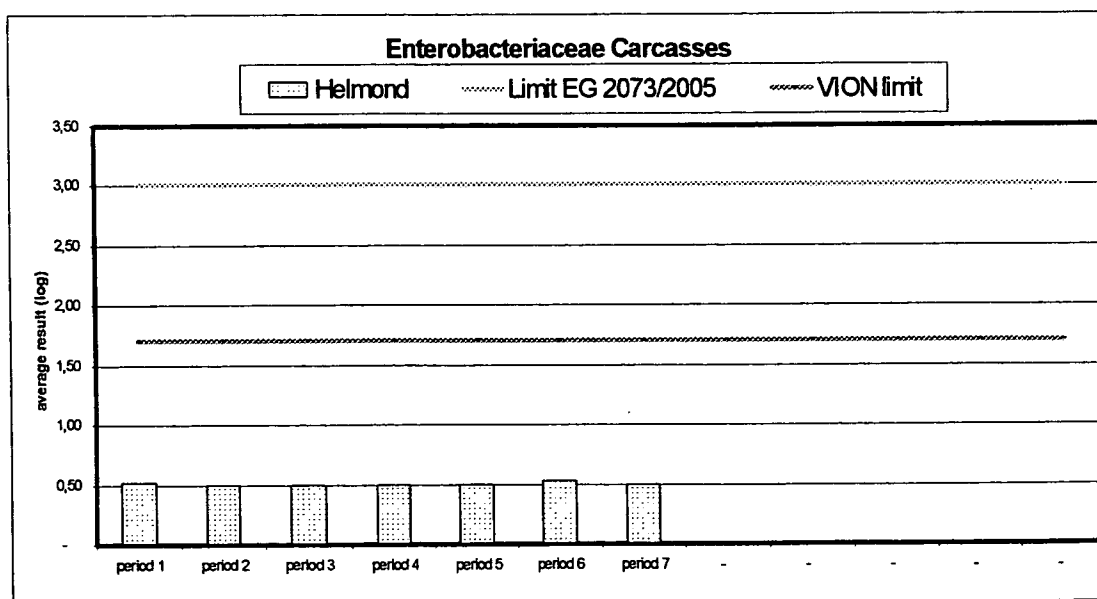
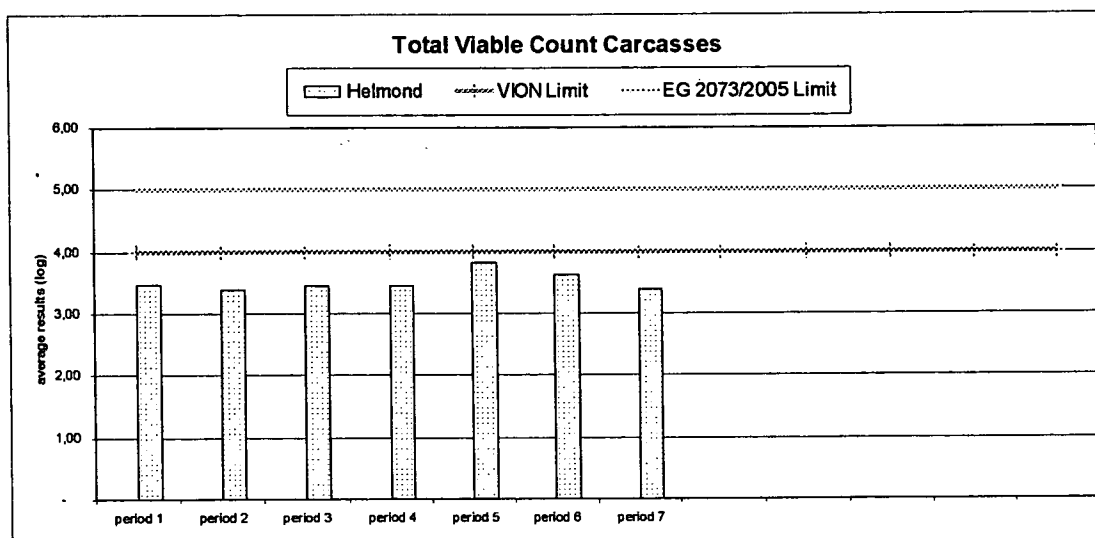
- 1.) Petersen JV, Andersen JK, Sorensen F, Knudsen H. Food safety on the slaughterline: inspection of pig heads. Vet Rec. 2002 Jun 22;150(25):782-4. Review.
- 2.) Swanenburg M, van der Wolf PJ, Urlings HA, Snijders JM, van Knapen F. Salmonella in slaughter pigs: the effect of logistic slaughter procedures of pigs on the prevalence of Salmonella in pork. Int J Food Microbiol. 2001 Nov 8;70(3):231-42.
- 3.) Swanenburg M, Berends BR, Urlings HA, Snijders JM, van Knapen F. Epidemiological investigations into the sources of Salmonella contamination of pork. Berl Munch Tierarztl Wochenschr. 2001 Sep-Oct;114(9-10):356-9.
- 4.) Berends BR, Van Knapen F, Snijders JM, Mossel DA. Identification and quantification of risk factors regarding Salmonella spp. on pork carcasses. Int J Food Microbiol. 1997 May 20;36(2-3):199-206.
- 5.) Swanenburg M, Urlings HA, Snijders JM, Keuzenkamp DA, van Knapen F. Salmonella in slaughter pigs: prevalence, serotypes and critical control points during slaughter in two slaughterhouses. Int J Food Microbiol. 2001 Nov 8;70(3):243-54.
- 6.) Swanenburg M, Urlings HA, Snijders JM, Keuzenkamp DA, van Knapen F. Salmonella in the lairage of pig slaughterhouses. J Food Prot. 2001 Jan;64(1):12-6.
- 7.) "salmonella monitoring" report made during the pilot "supply chain inspection" 2005-2006 in Helmond, the Netherlands
- 8.) Oosterom J, Dekker R, de Wilde GJ, van Kempen-de Troye F, Engels GB Prevalence of Campylobacter jejuni and Salmonella during pig slaughtering. Vet. Quarterly 7, 31-34.

Overall contribution of supply chain inspection to food safety.

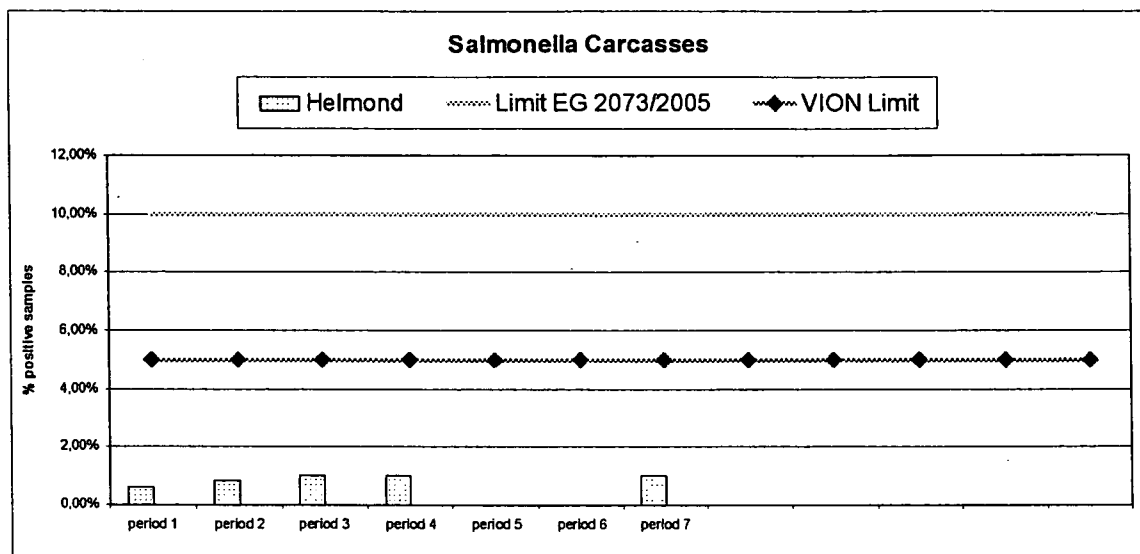
The program of supply chain inspection is based on the current EU legislation and combines control schemes at different parts of the supply chain in order to achieve a higher level of food safety in consumer products derived out of pork.

Current data of the newly implemented system of supply chain inspection system at the slaughterhouse in Helmond, show that:

1. The performance of the slaughterhouse Helmond with respect to hygiene is at a high level, according to the results of the official inspections and verifications as mentioned before in this document. Additional to that the results of the microbiological monitoring of the hygienically status of the carcasses confirms these observations



2. The contamination of carcasses with salmonella showed to be at a low level in the slaughterhouse Helmond. Samples for carcass monitoring of salmonella at the slaughterhouse are taken on a daily basis the next figure shows the performance of salmonella.



3. The results of the random screening on residues of antibiotics in market hogs in the Netherlands showed that the percentage of positive carcasses in Helmond is in the screening on kidney tissue and on meat samples both 1.3% (showing residues of antibiotics, not being above MRL) and in the general random sampling in the Netherlands for all market hogs these figures are 2,4% for kidney tissue and 2,0 for meat samples. The contribution of the supply chain inspection to control the use of antibiotics at farm level is obvious.

Summary of FSIS-Netherlands Bilateral Meeting on Visual Inspection of Market-Age Swine

Date: November 1, 2006

Country: Netherlands

FSIS Participants: Sally White, Director, IES, OIA, Steve McDermott, Deputy Director, IES, OIA, Ghias Mughal, Senior Staff Officer, IES, OIA, Nancy Goodwin, Senior Staff Officer, IES, OIA, David Smith, Staff Officer, IES, OIA, Scott Seebohm, Staff Officer, TSC, OPPED

Netherlands and EU Participants: Martijn Weijtens, DVM, PhD, Specialist Veterinary Public Health, Ate Jelsma, DVM, VWA, Inspection Systems, Henk Wisselink, PhD, Wageningen University and Research, Prof. Bert Urlings, DVM, PhD, Specialist Veterinary Public Health, Wolf Maier, DMV, DABT, Delegation of the European Commission, Wim Tacken, Agricultural Trade Counselor

The following items were discussed:

1. Presentation: "Project Visual P.M. Inspection in Pigs, in Relation to the Hygiene Package in the Netherlands," by Ate Jelsma
2. Presentation: "Serodiagnosis of *Mycobacterium avium* susp. *avium* infections in pigs," by Henk Wisselink.
3. Description of FSIS Market Swine HIMP pilot by Ghias Mughal.
4. Comparison Table: Swine Inspection Procedures
5. FSIS follow-up questions to Netherlands responses to FSIS questions: "Answers to Questions FSIS to the Netherlands" (See below)

FSIS asked these additional questions to follow-up on "Answers to Questions FSIS to the Netherlands":

- Q. 1. The U.S. legal definition of adulteration includes both food safety and non-food safety criteria. How does the Netherlands inspection system address the issue of adulteration for non-food safety conditions?

Response: The Netherlands inspection service verifies that the company implements programs to control pathological or hygiene defects through observation and review of records

- Q. 2. What are the provisions for government oversight of the IKB production scheme? When would the government get involved, and what actions could they take?

Response: There are both internal IKB audits, as well as audits by the government of Food Chain Information and on-farm conditions. Government audits occur on-farm approximately twice per year, or more frequently if needed.

The government is able to require additional steps in the IKB scheme, or exclude farms from participation when necessary.

- Q. 4. The response to Question 4 refers to several reference documents not previously provided to FSIS. We request copies of the additional documents that are relevant to the response (in English, if possible).

Response: Relevant references will be provided later.

- Q. 6. Please provide more specific explanation of how the Farm Risk Profile is calculated. How does it incorporate farm level information on *Salmonella* and *M. avium*? What specific criteria are used to determine whether a slaughter lot is eligible for visual inspection?

Response: The Farm Risk Profile is based on the history of *M. avium* serological testing. If a farm has 18 consecutive negative results (sampled from no more than 6 pigs in each of 3 deliveries), it is assigned to Neutral risk. When the farm has 18 additional negative samples (collected from 2 pigs in each of 9 deliveries), it is assigned to Low risk. To be eligible for visual inspection, swine must come from a farm with neutral or low Farm Risk Profile and must be accompanied by the Food Chain Information required under the IKB scheme.

- Q. 7. Please expand on the verification procedures. Explain how, where, and when the procedures are accomplished.

Response: Netherlands inspection personnel conduct audits in accordance with ISO 4511. Documented audit procedures will be provided to FSIS.

- Q. 7. During FSIS audits, where would we be able to find verification documents/records?

Response: Both company records and Inspection personnel records would be available for FSIS to verify performance and results of audit/verification activities.

- Q. 8. (Follow-up) How does the Farm Risk Profile consider *Salmonella* sample results and *M. avium* serology? What criteria for these samples would dictate traditional inspection?

Response: The Farm Risk Profile does not currently consider any organisms beside *M. avium*. *Salmonella* surveillance in live pigs is not considered to significantly improve food safety. *Salmonella* is controlled through hygienic slaughter procedures and prevention of fecal contamination. Documentation (thesis) to support these conclusions about *Salmonella* will be provided to FSIS later.

- Q. 9. When a group of pigs is sampled for antimicrobial residues, based on pathology levels (as described in response to Q6), please explain the sampling procedures. Will all animals in the lot be sampled? If not, what method will be used to select sampled animals?

Response: Because of the uniformity of intensively raised market swine, a single animal is sampled from any lot. The lots to be sampled are selected randomly under traditional inspection, but selected based on prevalence of pathological conditions in Food Chain Inspection. The results of these samples are then used to follow up with on-farm practices that resulted in violative residues.

- Q. 10. Response to a previous question to address this question. However, Please supply copies of the relevant references listed in the response to Q10 (in English, if possible).

Response: Relevant references will be provided.

- Q. 12 Response appears to address FSIS question. Please supply copies of the relevant references (in English, if possible).

Response: Relevant references will be provided.

Ghias Mughal
11-2-06

Mughal, Ghias

From: Seebohm, Scott
Sent: Monday, November 27, 2006 2:19 PM
To: Mughal, Ghias
Cc: Smith, David; Goodwin, Nancy
Subject: RE: visual inspection in the Netherlands: translated articles reg Q10 and ref for Q6 revised answer

Ghias,

I have read the documents you sent this morning. Here are my comments:

1. "System Audit from Start to End," Food and Consumer Product Safety Authority:
 This document describes more fully the Dutch government (VWA) approach to auditing a food establishment's food safety (HACCP) system. It appears to be analogous to FSIS Comprehensive Food Safety Assessment. The Netherlands approach uses an audit team which may include various subject matter experts as appropriate, while FSIS generally uses a single EIAO officer who may solicit technical assistance from other program areas when necessary. The general focus of the audit is the design and validation of the plant's HACCP program.
2. "From and For the Practice – Lesions in Slaughtered Animals."
 This paper is a brief summary of antemortem and postmortem findings in cattle and swine with endocarditis. The paper has little relevance to the current equivalence determination since FSIS does not routinely incise swine hearts.
3. W. Wouda, et. al. "Endocarditis and Meat Inspection in Pigs," (Parts 1 and 2).
 This paper presents a discussion of clinical and microbiological findings in market swine with endocarditis and a rough cost-benefit analysis of routine incision of hearts at postmortem inspection. The conclusion is that routine incision of swine hearts may not be economically beneficial. The paper has little relevance to the current equivalence determination, since FSIS does not require routine incision of swine hearts.

Regards.

Scott

Scott Seebohm, DVM
 Staff Officer
 FSIS Technical Service Center
 402-344-5000 / 800-233-3935

From: Mughal, Ghias
Sent: Monday, November 27, 2006 6:11 AM
To: White, Sally
Cc: Smith, David; Seebohm, Scott; Goodwin, Nancy; McDermott, Steve; Proudie, Robin
Subject: FW: visual inspection in the Netherlands: translated articles reg Q10 and ref for Q6 revised answer

The attached documents were sent to me by Dr. Hennecken last Thursday with a request to make them part of the NL responses previously sent to us.
 I have not read these yet.
 Ghias

M. Ghias Mughal, DVM; M.S.; Ph.D.
 Senior Equivalence Officer,
 Office of International Affairs
 USDA, Food Safety and Inspection Service

11/27/2006

1400 Independence Avenue, SW
 Washington, DC 20250
 Phone: 202 720-6400
 Email: ghias.mughal@fsis.usda.gov

-----Original Message-----

From: Hennecken, drs. M. (Martin) [mailto:m.hennecken@minInv.nl]

Sent: Thursday, November 23, 2006 8:50 AM

To: Mughal, Ghias

Cc: Jelsma, drs. A. (Ate); Weijtens, dr. M.J.B.M. (Martijn)

Subject: RE: visual inspection in the Netherlands: translated articles reg Q10 and ref for Q6 revised answer

Dear Dr. Mughal,

hereby you will receive the English translation of the last 4 reference documents that have to be included in the equivalence package for visual inspection in the Netherlands:

Q10,ref1: W. Wouda et. al., Endocarditis & Meat Inspection in pigs, part 1, Tijdschrift voor Diergeneeskunde, deel 112, afl. 21, 1987, p. 1226-1235

Q10, ref3: U. Narucka et. al., Lesions in slaughtered animals, Tijdschrift voor Diergeneeskunde, deel 110, afl. 19, 1985, p. 776-779

Q10, ref4: W. Wouda et. al. , Endocarditis & Meat Inspection in pigs, part 2, Tijdschrift voor diergeneeskunde, deel 112, afl. 21, 1987, p. 1236-1242.

Q6 revised answer, ref1: System Audit from Start to End

With these last documents the package is completed.

If you have further questions regarding this documentation please let me know.

Kind regards

Martin Hennecken

-----Oorspronkelijk bericht-----

Van: Hennecken, drs. M. (Martin)

Verzonden: dinsdag 14 november 2006 13:47

Aan: 'Mughal, Ghias'

CC: Jelsma, drs. A. (Ate); Weijtens, dr. M.J.B.M. (Martijn)

Onderwerp: FW: additional articles and revised answer Q6 reg. visual inspection

Dear Dr. Mughal,

hereby you will receive more additional documents/ articles as promised in my mail from 7 Nov.

1. question 4, ref 4 (Wallace JM, Hannah JB. Mycobacterium avium complex infection in patients with the acquired immunodeficiency syndrome. A clinicopathologic study. Chest. 1988 May;93(5):926-32.)

2. question 10, ref 5.(R. Fries und J. Leps, Die Incision des Herzens beim Schwein, Fleischwirtschaft, vol 10, 2005, p. 116-119.):

At the moment the authors of this article are preparing an English version of this article for publication in a journal, (most probably Veterinary Quarterly). We have agreed to wait for that publication and not to disturb this proces by translating ourselves. Meanwhile I have found the English summary of the dissertation of the authors on which the article had been based (**J. Leps, Incision of the heart during meat inspection of pigs - A risk analysis approach, dissertation FU Berlin, 2003**) I have attached the summary (English summary starts on page 5) and a document (index) with the abstract and further details. Most probably you will find this summary suitable enough for your purposes. Please let me know if you still need the English article; we will send it as soon as it is published.

11/27/2006

3. question 6, revised answer on verification procedures: as agreed during the last meeting.

This document refers to another VWA procedure document "**System Audit from Start 'til End**". This document is in the process of being translated and will be sent to you as soon as it is available.

Furthermore, as soon as Q10, ref 1,3 en 4 have been translated I will send them to you.

Kind regards

Martin Hennecken

-----Oorspronkelijk bericht-----

Van: Hennecken, drs. M. (Martin)

Verzonden: dinsdag 7 november 2006 15:40

Aan: 'Mughal, Ghias'

CC: Weijtens, dr. M.J.B.M. (Martijn); Jelsma, drs. A. (Ate); Hardenberg, I. (Inge) (VD)

Onderwerp: Expert meeting with FSIS and the Netherlands reg. visual inspection

Dear Dr. Mughal,

on behalf of Dr Weijtens I will send you herewith a "package" of additional articles, which have been mentioned in our report as a reference.

Most of these articles are in English, but 4 articles (question 10) have to be translated first. Unfortunately this will take some time, so you will receive them as soon as the translation has been completed. 2 other documents (q4ref1 and q4ref4) will be sent later.

Beneath you find a list of the articles which you will receive today (with several e-mails due to the size of the attachments) and 4 articles as soon as possible after translation has been completed.

If you miss any reference article in this list that had been agreed to send to you please let me know. I will arrange that asap.

Regards

Martin Hennecken

Drs. Martin Hennecken

Beleidsmedewerker vleeshygiëne

Directie Voedselkwaliteit en Diergezondheid

Ministerie van Landbouw, Natuur en Voedselkwaliteit

Adres: Bezuidenhoutseweg 73

Postbus: 20401, 2500 EK Den Haag

E-mail: m.hennecken@minlnv.nl

Telefoon: 070-3784289

Telefax: 070-3786389

Question 4:

Additional document: Justification for sampling of *Mycobacterium avium* in pork with regard to supply chain meat inspection (06-11-06)

References to additional document:

* New classification system for slaughter pig herds in the Danish surveillance- and-control program: L. Alban et.al., Prev.Vet. Med. 2002 (SDOC1268.pdf)

* Trichinae certification in the United States Pork industry: D.G. Pyburn et.al., Vet. Parasitology, 2005 (SDOC1267.pdf)

References Question 4:

1) Inderlied CB, Kemper CA, Bermudez LE. The *Mycobacterium avium* complex. Clin Microbiol Rev. 1993 Jul;6(3):266-310. Review. **(will be sent later)**

- 2) Komijn, RE., PEW de Haas, ME Schneider, T Eger, JHM Nieuwenhuis, RJ van den Hoek, D. Bakker, FG van Zijderveld and D van Soolingen. Prevalence of *Mycobacterium avium* in Slaughter Pigs in The Netherlands and Comparison of IS1245 Restriction Fragment Length Polymorphism Patterns of Porcine and Human Isolates. J of Clin Microb, 1999, 37, 1254-1259
- 3) Komijn, RE., HJ. Wisselink, VMC. Rijsman, N. Stockhofe-Zurwieden, D. Bakker, FG. van Zijderveld, T. Eger, JA. Wagenaar, FF. Putirulan and BAP. Urlings, Prevalence of *Mycobacterium avium* subsp. *avium* in lymphnodes of slaughter pigs in The Netherlands. Accepted for publication in Veterinary Microbiology (2007)
- 4) Wallace JM, Hannah JB. *Mycobacterium avium* complex infection in patients with the acquired immunodeficiency syndrome. A clinicopathologic study. Chest. 1988 May;93(5):926-32. (will be sent later)
- 5) Wisselink, HM, C van Solt-Smits, N Stockhofe-Zurwieden, H Bergen-Buys, P. Overduin, M van Prehn, D van Soolingen and J Thole. Comparison of visual and bacteriological examination of mandibular and mesenteric lymphnodes in pigs, experimentally infected with *Mycobacterium avium* subsp. *Avium*. IPVS Conference Copenhagen 2007.

References question 10:

1. W. Wouda et. al. , Endocarditis en vleeskeuring bij slachtvarkens, Tijdschrift voor Diergeneeskunde, deel 112, afl. 21, 1987, p. 1226-1235 (will be translated and sent later)
2. Masanori Katsumi et. al, Bacterial Isolation from slaughtered pigs associated with endocarditis, especially the isolation of *Streptococcus suis*, Journal of veterinary medical science, vol. 59, 1997, p. 75-78
3. U. Narucka et. al., Afwijkingen bij slachtdieren, Tijdschrift voor Diergeneeskunde, deel 110, afl. 19, 1985, p. 776-779 (will be translated and sent later)
4. W. Wouda et. al. , Endocarditis en vleeskeuring bij slachtvarkens, Tijdschrift voor diergeneeskunde, deel 112, afl. 21, 1987, p. 1236-1242. (will be translated and sent later)
5. R. Fries und J. Leps, Die Incision des Herzens beim Schwein, Fleischwirtschaft, vol 10, 2005, p. 116-119. (will be translated and sent later)
6. C. Tarrads et. al., Identification of *Streptococcus suis* Isolated from Swine: Proposal for Biochemical Parameters, journal of clinical microbiology, vol. 32, 1994, p. 578-580
7. J.J. Staats et. al., *Streptococcus Suis*: past and present, Veterinary research communications, vol. 21, 1997, p. 381-407.
8. Yu-Tsung Huang et. al., *Streptococcus suis* infection, Journal of Microbiol Immunol Infect, vol. 38, 2005, p. 306-313.

References reg. Annex salmonella:

1. Petersen JV, Andersen JK, Sorensen F, Knudsen H. Food safety on the slaughterline: inspection of pig heads. Vet Rec. 2002 Jun 22;150(25):782-4. Review.
2. Swanenburg M, van der Wolf PJ, Urlings HA, Snijders JM, van Knapen F. Salmonella in slaughter pigs: the effect of logistic slaughter procedures of pigs on the prevalence of Salmonella in pork. Int J Food Microbiol. 2001 Nov 8;70(3):231-42.
3. Swanenburg M, Berends BR, Urlings HA, Snijders JM, van Knapen F. Epidemiological investigations into the sources of Salmonella contamination of pork. Berl Munch Tierarztl Wochenschr. 2001 Sep-Oct;114(9-10):356-9.

4. Berends BR, Van Knapen F, Snijders JM, Mossel DA. Identification and quantification of risk factors regarding Salmonella spp. on pork carcasses. *Int J Food Microbiol.* 1997 May 20;36(2-3):199-206.
5. Swanenburg M, Urlings HA, Snijders JM, Keuzenkamp DA, van Knapen F. Salmonella in slaughter pigs: prevalence, serotypes and critical control points during slaughter in two slaughterhouses. *Int J Food Microbiol.* 2001 Nov 8;70(3):243-54.
6. Swanenburg M, Urlings HA, Snijders JM, Keuzenkamp DA, van Knapen F. Salmonella in the lairage of pig slaughterhouses. *J Food Prot.* 2001 Jan;64(1):12-6..
7. "salmonella monitoring" report made during the pilot "supply chain inspection" 2005-2006 in Helmond, the Netherlands
8. Oosterom J, Dekker R, de Wilde GJ, van Kempen-de Troye F, Engels GB Prevalence of Campylobacter jejuni and Salmonella during pig slaughtering. *Vet. Quarterly* 7, 31-34.

Dit bericht kan informatie bevatten die niet voor u is bestemd. Indien u niet de geadresseerde bent of dit bericht abusievelijk aan u is gezonden, wordt u verzocht dat aan de afzender te melden en het bericht te verwijderen. De Staat aanvaardt geen aansprakelijkheid voor schade, van welke aard ook, die verband houdt met risico's verbonden aan het elektronisch verzenden van berichten.

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NOTES FROM THE CONFERENCE CALL WITH DR. TERRY SUTTON
ON THE ELISA TEST USED BY NETHERLANDS' INSPECTION OFFICIALS

Date: March 5, 2007

Participants:

Dr. Terry Sutton, OPHS

Dr. David Smith, OIA

Dr. Ghias Mughal, OIA

This conference call took place as a follow up on Dr. Sutton's comments of March 3, 2007, relating to the Netherlands' ELISA testing of hog serum for the detection of *M. avium*.

Dr. Sutton concluded that:

- The ELISA test is sensitive enough to detect about 75% of the hogs infected with *M. avium subspecies avium* (MAA).
- The data submitted by the Netherlands did not address the specificity of this method. It did not show if there was a cross reactivity in sera of hogs infected with other strains of MAA, other non-TB group mycobacterium or organisms from the Mycobacterium-bovis group.
- Based on the Netherlands' data, the ELISA test, by itself, is not the most reliable test for the detection of MAA. However, the ELISA test, in combination with the following safeguards, can become a reliable test for the detection of MAA:
 - The production/slaughter of the market hogs is a vertically integrated operation,
 - There is a established frequency of follow-up testing for MAA,
 - No hogs, imported from any other country, are allowed in the program,
 - There is a TB testing program for the farm workers,
 - There is an environmental testing program for MAA, e.g., testing of bedding, house environment, etc., and
 - The participating companies have a control program for control of insects and other pests.

Dr. Sutton was further advised that in order for participating companies to be eligible for Visual Inspection, they must have a mandatory quality assurance (QA) program. The QA program is approved and verified by the Netherlands' inspection service on routine basis. The QA program must contain all six safeguards mentioned above.

MEMO: USE OF THE ELISA TEST BY NETHERLANDS' INSPECTION
OFFICIALS

Date: March 12, 2007

References: Following additional references from Netherlands and FSIS were reviewed:

1. with *Mycobacterium avium subsp. avium*. Henk Wisselink, Conny van Solt-Smits, Norbert Stockhofe-Zurweiden, Herma Bergen-Buys, Jelle Thole (Unpublished report, 2007)
2. . Compariso of Pathological and bacteriological examination of mandibulary and mesenteric lymph nodes in pigs, experimentally infected with mycobacterium avium subsp. avium . HJ Wisselink, CB Van Solt-Smits, N Stockofe-Zurwieden, H Bergen-Buijs, VMC Rijsman, P Overduin, M Van Prehn, D Van Soolingen and JE Thole. Proc. 19th IPVS Congress, Copenhagen, Denmark, 2006, vol. 1.
3. Prevalence of *Mycobacterium avium* in Slaughter Pigs in The Netherlands and Comparison of IS1245 Restriction Fragment Length Polymorphism Patterns of Porcine and Human Isolates. Komijn, RE., PEW de Haas, ME Schneider, T Eger, JHM Nieuwenhuis, RJ van den Hoek, D. Bakker, FG van Zijderveld and D van Soolingen. J of Clin Microb, 1999, 37, 1254-1259.
4. Evaluation of Five Antibody Detection Tests for Diagnosis of Bovine Paratuberculosis. Michael T. Collins, Scott J. Wells, Kristine R. Peterini, James E. Collins, Ronald Schultz, and Robert Whitlock. Clinical and Diagnostic Laboratory Immunology, June 2005, p. 685-692.

FSIS Documents:

1. Multi-species Disposition Basics with a Public Health Focus. Public Health Veterinarian Training – USDA FSIS Canter for Learning, April 2004.

Following conclusions were drawn from review of the above literature:

- FSIS does not appear to consider tuberculosis as a food borne disease of public health significance.
- FSIS' routine post mortem inspection procedures have an unknown level of detection for *M. avium*. Dispositions are based on visual inspection after palpation and observation of certain lymph nodes and organs and 100 per cent detection of lesions is not always possible.
- Presence of tuberculosis in the Netherlands not higher than the United States.
- ELISA test used by the Netherlands inspection service shows a high level of sensitivity at the slaughter age of 20-20 weeks, although results show a sensitivity of about 75 per cent in hogs infected and tested at earlier age.

- The data submitted by the Netherlands did not address the specificity of this method. They only used one strain of *M. avium*- MAA serotype 4, strain 17404 during the experiment. They did not show if there was a cross reactivity in sera of hogs infected with other strains of MAA, other non-TB group mycobacterium or organisms from the Mycobacterium-bovis group.
- Based on the Netherlands' data, the ELISA test, by itself, is not the most reliable test for the detection of MAA. However, the ELISA test, in combination with the following safeguards, can become a reliable test for the detection of MAA:
 - The production/slaughter of the market hogs is a vertically integrated operation,
 - There is a established frequency of follow-up testing for MAA,
 - No hogs, imported from any other country, are allowed in the program,
 - There is a TB testing program for the farm workers,
 - There is an environmental testing program for MAA, e.g., testing of bedding, house environment, etc., and
 - The participating companies have a control program for control of insects and other pests.

It was explained to Dr. Sutton that in order for participating companies to be eligible for Visual Inspection, they must have a mandatory quality assurance (QA) program. The QA program is approved and verified by the Netherlands' inspection service on routine basis. The QA program must contain all six safeguards mentioned above and she agreed that with all these safeguards the ELISA test is a step forward and provides added level of assurance for detection of TB in market hogs.

Participants:

Dr. Terry Sutton, OPHS

Dr. David Smith, OIA

Dr. Ghias Mughal, OIA

Dr. Raymond,

During our recent briefing to you regarding the Netherlands' equivalence request for post-mortem visual inspection of market hogs, you requested that we contact APHIS to determine whether visual inspection would fail to detect the swine diseases it had declared as being present in the Netherlands. We contacted APHIS and explained to them the difference between FSIS traditional post-mortem inspection and the Netherlands' visual inspection of the head, viscera, and carcass. APHIS advised us that visual inspection would have no impact on the ability to detect the four swine diseases of concern (Foot and Mouth Disease, Classical Swine Fever, African Swine Fever, and Swine Vesicular Disease) because the symptoms related to these diseases would be evident throughout the carcass and organs.

4/16/07

MEMO: USE OF THE ELISA TEST BY NETHERLANDS' INSPECTION
OFFICIALS

Date: March 12, 2007

References: Following additional references from Netherlands and FSIS were reviewed:

1. with *Mycobacterium avium subsp. avium*. Henk Wisselink, Conny van Solt-Smits, Norbert Stockhofe-Zurweiden, Herma Bergen-Buys, Jelle Thole (Unpublished report, 2007)
2. . Compariso of Pathological and bacteriological examination of mandibulary and mesenteric lymph nodes in pigs, experimentally infected with mycobacterium avium subsp. avium . HJ Wisselink, CB Van Solt-Smits, N Stockofe-Zurwieden, H Bergen-Buijs, VMC Rijsman, P Overduin, M Van Prehn, D Van Soolingen and JE Thole. Proc. 19th IPVS Congress, Copenhagen, Denmark, 2006, vol. 1.
3. Prevalence of *Mycobacterium avium* in Slaughter Pigs in The Netherlands and Comparison of IS1245 Restriction Fragment Length Polymorphism Patterns of Porcine and Human Isolates. Komijn, RE., PEW de Haas, ME Schneider, T Eger, JHM Nieuwenhuis, RJ van den Hoek, D. Bakker, FG van Zijderveld and D van Soolingen. J of Clin Microb, 1999, 37, 1254-1259.
4. Evaluation of Five Antibody Detection Tests for Diagnosis of Bovine Paratuberculosis. Michael T. Collins, Scott J. Wells, Kristine R. Peterini, James E. Collins, Ronald Schultz, and Robert Whitlock. Clinical and Diagnostic Laboratory Immunology, June 2005, p. 685-692.

FSIS Documents:

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Following conclusions were drawn from review of the above literature:

- FSIS does not appear to consider tuberculosis as a food borne disease of public health significance.
- FSIS' routine post mortem inspection procedures have an unknown level of detection for *M. avium*. Dispositions are based on visual inspection after palpation and observation of certain lymph nodes and organs and 100 per cent detection of lesions is not always possible.
- Presence of tuberculosis in the Netherlands not higher than the United States.
- ELISA test used by the Netherlands inspection service shows a high level of sensitivity at the slaughter age of 20-20 weeks, although results show a sensitivity of about 75 per cent in hogs infected and tested at earlier age.

April 19, 2007

Seller's

Dr. Peter W. de Leeuw
Chief Veterinary Officer
Ministry of Agriculture, Nature and Food Quality
PO Box 19506
2500 CM, The Hague
Netherlands

Dear Dr. de Leeuw:

This reaffirms my earlier notification to you on October 12, 2006, that meat products produced under visual inspection is not currently eligible for export to the United States. In that October 12 letter, I stated that the use of visual post-mortem inspection in establishments certified for export to the United States cannot commence until the Food Safety and Inspection Service (FSIS) completes the equivalence determination process.

It is our understanding that some of the swine slaughter establishments certified for export to the United States have been operating under visual inspection and is storing pork products with the expectancy to export to the United States following FSIS' equivalence approval of visual inspection. If this is occurring, it is important to understand that this product is not eligible for export to the United States now or following an acceptable equivalence determination by FSIS of the visual inspection. The date upon which FSIS notifies the Netherlands' government that it has determined the visual post-mortem inspection program to be equivalent will become the effective date that Netherlands' certified establishments can begin producing pork products for export to the United States under visual inspection.

If you have any questions regarding this matter, please contact me at telephone number (202) 720-3781, fax number (202) 690-4040, or electronic mail address: sally.white@fsis.usda.gov.

Sincerely,

Sally White
Director
International Equivalence Staff
Office of International Affairs

cc.

Roger Wentzel, Counselor, US Embassy, The Hague

Wim Tacken, Netherlands Embassy, Wash DC

Canice Nolan, Agric. / Consumer Affairs, EU Mission to the U.S., Wash DC

Bernard Van Goethem, Acting Director, Directorate E, European Commission, Brussels

Debra Henke, Minister-Counselor, US Mission to the EU in Brussels

Robert Macke, Assistant Deputy Administrator, OSTA, FAS

Dave Young, FAS Area Director

Marsha Singer, State Department

David Goldman, Acting Administrator, FSIS

Karen Stuck, Assistant Administrator, OIA, FSIS

William James, Deputy Assistant Administrator, OIA, FSIS

Donald Smart, Director, International Audit Staff, OIA, FSIS

Clark Danford, Director, IEPS, OIA, FSIS

Sally White, Director, IES, OIA, FSIS

Barbara McNiff, Director, FSIS CODEX

Mary Stanley, Director, IID, OIA, FSIS

Ghias Mughal, IES, OIA, FSIS

Country File

FSIS:OIA:IES:SMCDERMOTT:4-19-2007

Adams, Susan

From: White, Sally
Sent: Tuesday, May 06, 2008 12:14 PM
To: Adams, Susan
Cc: Smith, David
Subject: Fw: Supplementary information chain inspection

Attachments: Suppl info ketenkeuring 6-5-08.doc

Please print off and log

Sent from my BlackBerry Wireless Device

-----Original Message-----

From: Smith, David
To: White, Sally
Sent: Tue May 06 12:11:05 2008
Subject: FW: Supplementary information chain inspection



Suppl info
etenkeuring 6-5-08.

Frits in ended to send this to you as well, but he got the wrong Sally.

David Smith, DVM, MS, BS
Office of International Affairs
International Equivalence Staff
USDA, Food Safety and Inspection Service Room 3843 South Bldg.
1400 Independence Ave, SW
Washington DC 20250
Phone: (202) 720-3395
Email: david.smith@fsis.usda.gov

-----Original Message-----

From: Thissen, Frits [mailto:frits.thissen@minbuza.nl]
Sent: Tuesday, May 06, 2008 12:07 PM
To: sally.smith@fsis.usda.gov; Smith, David
Cc: Furey, Todd; Feitel, Caroline; Lammers, Sunny; Groeneveld, Am; i.hardenberg@minlnv.nl; m.j.b.m.weijs@minlnv.nl
Subject: Supplementary information chain inspection

Dear Sally and David,

I would like to forward to you a note with supplementary information on the system of chain inspection as promised. I would like you to handle this information with the utmost confidentiality, because there are issues of intellectual property rights as well as commercial interests involved.

IES
320
5/06/08
lea

I hope this information will satisfy your needs in terms of the scientific underpinning of the MAA testing method.

All in all I hope this information will help you overcome the last obstacles in providing Undersecretary Dr Richard Raymond with a positive briefing on the chain inspection system and addressing his specific concerns.

Kind regards,

Frits Thissen
Counselor for Agriculture,
Nature and Food Quality
Embassy of the Kingdom of the Netherlands

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Dit bericht kan informatie bevatten die niet voor u is bestemd. Indien u niet de geadresseerde bent of dit bericht abusievelijk aan u is toegezonden, wordt u verzocht dat aan de afzender te melden en het bericht te verwijderen. De Staat aanvaardt geen aansprakelijkheid voor schade, van welke aard ook, die verband houdt met risico's verbonden aan het elektronisch verzenden van berichten.

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ADDITIONAL INFORMATION ON PORK SUPPLY CHAIN INFORMATION

This document contains additional information on:

1. *Mycobacterium avium* spp *avium* (MAA) serological test characteristics;
2. Results of MAA control program within pork supply chain inspection, and
3. Summary of MAA control within pork supply chain inspection.

The scientific research laboratory wants to preserve its abilities to file intellectual property rights with respect to MAA serological testing. The data presented in this document are to be kept confidential.

Mycobacterium avium spp *avium* (MAA) serological test characteristics.

In order to demonstrate the presence of antibodies against MAA in pigs, an ELISA test has been developed. The antigen, cleared glycopeptide, used in this test is harvested from polar lipids of MAA bacteria. The bacterial MAA strain that is used originated from a slaughter pig in The Netherlands and is of the MAA hominissuis type. Glycopeptides are part of the polar lipids and originate from a genetically well-preserved area of MAA bacteria. Using a genetically well-preserved area of a bacterium provides the best ability to have cross-reactivity with different field strains of MAA.

When calculating the specifications of the MAA-Elisa, the bacteriological examination is used as the gold standard.

When an individual pig, or a pig herd, is suspected of an MAA infection at slaughter, there will be successive investigations in order to clear the case. Specific signs in these are: elevated serological results, specific liver abnormalities, and, or specific lymph node lesions. The examination of suspected herds consists of:

- Tuberculation of pigs at the herds of origin;
- When tuberculation reveals positive results, blood serum and lymph nodes of pigs at slaughter will be collected; and
- Serological, pathological and bacteriological examination of serum and lymph nodes at the veterinary research laboratory.

Additionally it needs to be noted that a Specialist Veterinary Pathologist carries out pathological examination.

Based on the above protocol, until 28 April, 2008, two pig farms confirmed positive on MAA have been detected in The Netherlands (since beginning 2006, the onset of supply chain inspection). A third suspected pig farm has been sampled extensively on 22 April, 2008, but the results are not yet available. Of the two confirmed positive pig farms, one farmer refused to cooperate with the scientific part of the research, so unfortunately only field data of one farm are available.

Table 1: Results validation MAA-ELISA. Numbers of pigs (%). Pathological examination was carried out on lnn of mandibular and mesenteric area. Serological result negative if PP% < 10, dubious if 10 < PP% > 20, positive if PP% > 20.

Experimental infection				
Examination	Negative	Positive	Dubious	Total (n)
Bacteriological	0 (0)	32 (100)		32
Pathological (lnn)	22 (69)	10 (31)		32
Serological	10 (31)	17 (53)	5 (16)	32
Field infection farm A				
Examination	Negative	Positive	Dubious	Total (n)
Bacteriological	90 (46)	104 (54)		186
Pathological	128 (68)	59 (32)		187
Serological	153 (78)	8 (4)	34 (18)	195

Table 2: Test characteristics MAA-ELISA, using bacteriology as the golden standard.

	Pathology		Serology	
	Specificity	Sensitivity	Specificity	Sensitivity
Experimental infection	100	31	100	69
Field infection farm A	73	35	79	22

According to Fisher's exact test the sensitivity of serology compared to pathology during the experimental infection is significantly different ($p=0.0003$). The sensitivity of serology compared to pathology at farm A is not significantly different ($p=0.132$). Specificity of the tests at farm A is not significantly different ($p=0.273$).

For tuberculosis and paratuberculosis it is concluded that the ELISA is a suitable test for herd diagnostics. Mycobacterial Elisa's are utilized with this purpose in a lot of countries.

Important for this conclusion is the fact that for MAA it is obvious that risks for introduction will apply to the whole farm of origin (for example bedding material), thus resulting in a population at risk.

The numbers of pigs to be tested to estimate the MAA status of a farm is based on epidemiological calculations. In these calculations the sensitivity, specificity and prevalence of MAA within the farm are taken into account. Given a number of tests, the probability of testing at least one animal positive can be calculated, as shown in the table 3. Even with a low sensitivity and high specificity (worst case calculation) the probability is over 95% to test a farm positive with 36 samples to estimate a definite MAA status. Based on literature, prevalence at farm within the herd could be expected to be over 40% when herds are infected by sawdust or peat.

Table 3: Statistical evaluation of the effect of the number of samples on the reliability of the herd risk estimation.

Number of samples tested	Prevalence MAA within farm	Specificity of serology	Sensitivity of serology	Probability of testing at least one positive
18	40%	100%	20%	0.999544
36	40%	100%	20%	1
18	20%	100%	20%	0.962439
36	20%	100%	20%	0.998589
18	10%	100%	20%	0.784079
36	10%	100%	20%	0.953378

According to Merchevsky et al. 1989, cited by Micheal Trustfield in: Veterinary Epidemiology, second ed. 1995. Blackwell Science Ltd.

Results of MAA control program within pork supply chain inspection.

In previous documents exchanged with the USDA/FSIS we have already elaborated about the ongoing research on MAA in The Netherlands. In a study in 1996 it was shown that a low prevalence of MAA was present in Dutch slaughter pigs (Komijn et al 1999). After the implementation of additional control measures at farm level within the farm code of practice (IKB), a study of 2004 showed that MAA could not be detected anymore in Dutch slaughter pigs (Komijn et al, 2007).

- Since the start of pork supply chain inspection more than 300,000 blood samples of pigs have been analyzed for the presence of antibodies against MAA.

Table 4: Classification of pig farms, August 2007.

	N	%
Low risk farms	3303	80,66
Neutral risk farms	744	18,17
High risk farms ¹	48	1,17
Total farms	4095	100

¹ Farms classified as high-risk are not allowed to deliver pigs for pork supply chain inspection and are part of the MAA specific control program.

- Until April 2008, 78 farms have been visited because of elevated levels of antibodies, or specific lesions observed during post-mortem inspection. These farms have strengthened their biosecurity control measures, especially with respect to the control of MAA.
- Several of the 78 farms visited have taken part in tuberculation testing at farm level. Until now only two farms showed positive results in tuberculation tests.

- Two farms have been observed to be bacteriologically positive for MAA. A third farm is still under investigation.
- The farms that showed bacteriologically positive results have taken effective measures to eliminate the MAA infection on the farm. Elimination of MAA at farm level is only practiced in pig farms that participate in the pork supply chain inspection program. Traditional inspection does not prescribe additional measures to control MAA at farm level.

Summary of MAA control within pork supply chain inspection.

Control of MAA in pork produced according to the supply chain inspection procedures consists of several control points within the pork supply chain.

1. All pig farms that supply pigs that are inspected according to the pork supply chain procedures need to produce according to the IKB code of practice at the farm level. On top of that the farm is not allowed to use wood shavings, peat or related MAA risk materials as bedding material. The IKB farm code of practice is audited and managed according to ISO 45011 rules.
2. A pig farm can only supply pigs that are to be inspected according to the pork supply chain procedures after at least 18 consecutive negative results of serological testing against MAA antigens. The procedure of calculating risk levels of individual farms with the respective sample sizes has already been reported to USDA/FSIS.
3. During the post-mortem inspection of carcasses and organs all pathological signs and morphological non-conformities are to be checked more in-depth at the re-assessment platform by the competent authorities. Specific pathological conditions, such as granulomatous lesions in lymph nodes and livers will be further evaluated.
4. Farms that show elevated serological test results, and, or specific pathological lesions will be visited. During the visit a re-assessment of the control points with respect to MAA will be carried out.
5. When the farm visit, or other slaughtering of pigs, shows increased risk of the presence of MAA, additional examination of the pigs and the farm of origin will occur. This examination consists of tuberculation of individual animals at the farm, and/or slaughtering and sampling of individual pigs for in-depth pathological, serological and bacteriological examination.

Based on the above information and the information that has been communicated before, it can be concluded that the control of MAA in pork supply chain inspection provides at least the same level of control as the procedures of the traditional post-mortem inspection. It is also obvious that none of the MAA control instruments alone provide a 100% control of MAA, nor does the traditional post-mortem inspection. The strength of the pork supply chain inspection is that it effectively combines MAA control measures at different parts of the supply chain. On top of that, refraining from cutting the lymph nodes in the mandibular area has demonstrated to reduce the level of cross-contamination with salmonella on pork substantially, thus resulting in safer pork.

Minutes of Meeting

COUNTRY: Netherlands

SUBJECT: Information regarding the public health significance of *Mycobacterium avium*.

DATE: May 29, 2008

FSIS REPRESENTATIVES:

Dr. William James, OIA

Sally White, OIA, IES

Dr. David Smith, IES, OIA

Dr. Robert Ragland, OPPD

Maritza Colon-Pullano, OPPD

SUMMARY: The meeting focused on the public health significance of *Mycobacterium avium* as it relates to food-borne transmission. In this meeting Dr. James discussed an email that was sent by Dr. Ragland. Dr. James described his understanding of Dr. Ragland's email as being that *Mycobacterium avium* is of minimal significance from the standpoint of public health as a zoonotic food-borne organism. Dr. Ragland agreed that was the message he was conveying in his email.

Smith, David

From: Ragland, Robert
Sent: Wednesday, June 04, 2008 7:24 AM
To: Smith, David
Cc: Derfler, Philip; Hicks, John; Linville, John; Bowman Blackwell, Quita
Subject: Comments on Netherlands/*M. avium*

Specific Responses to the two questions in Dr. Smith's Monday June 02 email are listed below after some comments.

It is not prudent for FSIS to state that there it does not have a "any real concerns regarding *Mycobacterium avium* as a food-borne public health concern" and definitely cannot make such a statement regarding some of the other Micobacteria.

The primary issue appears to be is whether visual inspection of market hogs is equivalent to traditional FSIS inspection. Testing designed to show error rates, sensitivity, and specificity of each system on the same population of market hogs can be conducted to demonstrate equivalence or non-equivalency. FSIS did this in the late 1980s to show that FSIS's traditional inspection was equivalent to EEC inspection. Did the Netherlands present such data? Did the results cause *M. avium* to become the "focal point?"

The *M. avium* issue appears to not be equivalence per say but whether the public health risk of a condition justifies or does not justify a certain inspection produce(s). Thus, the question is whether there is a difference or a significant difference in risk of infection of *M. avium* to humans when consuming pork inspected under visual inspection procedure or traditional FSIS inspection. Based on the current absence of a reported case of pork as the vehicle of *M. avium* infection in humans and other literature, it is my opinion, there is insignificant difference in the *M. avium* risk between the two systems of inspection. However, it is also my opinion that visual inspection will not remove swine tissue containing *M. avium* lesion as required by 9 CFR 311.2 as effectively as traditional inspection.

In addition, meat-born public health concerns regarding *M. avium* ranks at the bottom of FSIS current concerns. Also, some literature suggest that visual inspection reduces the public health risk of some other condition when compared to FSIS traditional inspection procedures.

Question1: Does FSIS have any real concerns regarding *Mycobacterium avium* or any of the Mycobacterium as a food-borne public health concern.

Response: The use of "real" suggests that there may be FSIS concerns that are not "real." "Real" should be defined is it an expression of a prejudgment or of quantifying scale for *M. avium* to be considered a food-borne public health concern.

I am not aware of a risk assessment related to *M. avium* in swine and human disease. However, FSIS/USDA in October 1986 publish *Mycobacterioses in Swine and Their Significance to Public Health*, Bibliographies and Literature of Agriculture, Number 46, National Agriculture Library, author Dey B. P. The conclusion in the paper was:

“All available evidence indicates that swine are not incidental host, but rather occasional host, and that MAIS [*M. avium*, *M. intracellulare*, *M. scrofulaceum*] complex infection of humans does not originate from swine. In a majority of cases, the organisms responsible for the lesions in swine are serotypically different from those encountered in human disease. Apparently, both swine and humans are constantly exposed to this group of organisms, abundantly present in the environment. In some people, with certain predisposition, organisms from this source may cause infection and disease.”

M. avium is the leading cause of tuberculosis in swine. The disease in swine is self-limiting with lesions usually found in the lymph nodes. Serotypes of *M. avium* isolated from humans are usually different from those isolated from chickens. In areas where the disease is common in chickens, the occurrence of avian tubercle bacillus infection is rare, indicating that humans are resistant to the disease.¹ Although, both man and animals can acquire the disease it does not appear to be transmissible from animal to man.²

1. Handbook of Zoonosis, Viral. Ed. George W. Beran. Boca Raton: CRC, 1994

2. Thoen, C.O. and Karlson, A.G. Avian Tuberculosis.

However, the importance of mycobacterial infections caused by strains of *Mycobacterium avium* complex (MAC) in animals and humans is continuously increasing (3, 4). In the human population, the condition is aggravated by the spread of human immunodeficiency virus (HIV) infection. In AIDS patients, the incidence of disseminated mycobacterial infection caused by MAC strains can reach up to 55% (5, 6)

Thus, it is not appropriate for FSIS to state that it does not have a real concern regarding *Mycobacterium avium* as a food-borne public health concern.

In addition, if *Mycobacterium tuberculosis* and *M. avium* subspecies *paratuberculosis* are considered, it is not appropriate for FSIS to state that it does not have a real concern regarding any of the *Mycobacterium* as a food-borne public health concern

The causative agent for Johne's disease in cattle is *Mycobacterium avium* subspecies *paratuberculosis* (MAP), and some clinical research reports that this bacterium may be associated with Crohn's disease in humans. Beef consumption may be a potential route of MAP transmission to humans

Question 2: Is FSIS PHV training manual statement “Tuberculosis is not a disease of public health concern.” consistent with current FSIS thinking. **Response:** The current PVH training manual 12/07/07 list tuberculosis in Section II Diseases and Condition not of Public Health Significance. This is not the same as stating the disease is not of public health concern.

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Email: robert.ragland@fsis.usda.gov

Smith, David

From: Thaler, Alice
Sent: Monday, June 02, 2008 2:41 PM
To: Smith, David
Subject: RE: FSIS position on Tuberculosis

The FSIS program addresses bovine TB to support APHIS in its eradication program. TB is primarily spread by aerosol (cow to cow) (or man to cow) or consumption of milk (cow to man) from infected animals. Extra-pulmonary TB is not considered a source of infection – hence occupational health issues for our inspectors is very low.

I am not sure if FSIS has looked recently at *Mycobacterium avium* and immunosuppressed people (AIDS)

Ref: Pan American Health Organization – Zoonoses and Communicable Diseases Common to Animals and Man.

Alice M. Thaler, DVM, DACVPM
Senior Director for Program Services
Office of Public Health Science
202-690-2687
Fax 202-720-8213
alice.thaler@fsis.usda.gov

From: Smith, David
Sent: Monday, June 02, 2008 1:31 PM
To: Thaler, Alice
Subject: FSIS position on Tuberculosis

Hi Dr. Thaler, this may sound a little strange but... I am trying to determine what the FSIS position on TB is, be it *M. bovis*, *M. avium*, whatever. I know about the condemnation of carcasses affected as described in the CFR, but as far as a *foodborne zoonotic public health concern* do you know what our position is? I have found a PHV training manual from 2004 (link below) that says TB is not considered of public health significance. Do you know if this is still the case? If you're not sure can you point me to someone who may know?

http://www.fsis.usda.gov/PDF/PHVt-Multi_Species_Disposition.pdf

Thanks,

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Phone: (202) 720-3395
Email: david.smith@fsis.usda.gov

Smith, David

From: Ragland, Robert
Sent: Friday, June 06, 2008 12:47 PM
To: Smith, David
Subject: RE: Comments on Netherlands/M. avium

To my knowledge, FSIS does not test serologically or type TB organism in any TB like lesions. There is a program for submitting all suspected TB lesions found in cattle to the APHIS lab not FSIS lab. There is not such a program for TB lesions found in swine. In the past APHIS did type for bovine and human TB organisms..

In addition, if a sample of cattle pathology submitted to a FSIS lab contains lesions or organisms suggestive of TB and a sample was not sent to the APHIS lab by the FSIS inspector the FSIS lab may sent some of the sample to the APHIS lab for testing for TB.

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Fax: 202-720-0582
Email: robert.ragland@fsis.usda.gov

From: Smith, David
Sent: Wednesday, June 04, 2008 4:24 PM
To: Ragland, Robert
Subject: RE: Comments on Netherlands/M. avium

Hi Bob thanks for the comments. I didn't mean to imply that any concerns on FSIS' behalf were not real.

Are you aware of any usage of serology testing for Mycobacteria spp. by FSIS?

Thanks,

David Smith, DVM, MS
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International Equivalence Staff
USDA, Food Safety and Inspection Service Room 3843 South Bldg.
1400 Independence Ave, SW
Washington DC 20250
Phone: (202) 720-3395
Email: david.smith@fsis.usda.gov

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Sent: Wednesday, June 04, 2008 7:24 AM
To: Smith, David
Cc: Derfler, Philip; Hicks, John; Linville, John; Bowman Blackwell, Quita

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TELECONFERENCE SUMMARY

COUNTRY: Netherlands

SUBJECT: Submission of information regarding visual inspection project of market hogs

DATE: June 25, 2008

FSIS REPRESENTATIVES:

Dr. David Smith, IES, OIA

Dr. Terrie Sutton, OPHS

Dr. Scott Hafner, OPHS

SUMMARY: The teleconference focused on further information provided by the government of Netherlands that was received on June 16, 2008.

- Review of the information provided by Netherlands showed that FSIS' questions and concerns from the previous review were addressed. Netherlands is working to further develop their serological testing.
- When viewed as a whole, the proposed program appears to provide adequate food safety control.

Answers on questions asked by USDA FSIS on June 5, 2008.

The questions are based on the additional information sent on May 6, 2008 concerning Supply Chain Inspection of Pork.

Question 1) In table 1 there is a comparison between an experimental infection study and a field infection farm A study. The conditions of the farm A study are not explained. Were the pigs infected or exposed to MAA?

Answer 1) On farm A, pigs had a natural MAA-infection.

Question 2) In the same table, there are columns labeled as negative, positive, and dubious. What is meant by dubious? It is unclear how the results in this column are to be interpreted without an understanding of what dubious means.

Answer 2) To discriminate in the MAA-ELISA between positive and negative serum samples, cut-off values were calculated (n=153). For this the ELISA results were used, obtained on sera of pigs bacteriologically negative for MAA. Cut-off values in percentage positivity (PP) were determined at specificities of 0.90, 0.95, 0.975 en 0.99. At a specificity of 0.95 the cut off value appeared to be 7.5 PP with a confidential interval of 5.1-14.4 PP. At a specificity of 0.99 the cut off value appeared to be 12.3 PP. Based on these results a cut-off of 10 PP was used. However, we decided to determine a transition range from negative to positive. Below 10 PP all serum samples were negative and above 20 PP the serum samples were positive. The range from 10-20 PP was classified as dubious, in other words, as intermediary between a negative and positive result.

Question 3) In the same table, for field examination farm A, on the row that gives results for bacteriological testing ? It is stated that 90 were negative, 104 were positive, but the total (n) is stated as being 186. How was this number calculated?

Answer 3) This is a failure in calculating. We are sorry for this. Indeed 90 were negative and 104 were positive, the total number of samples, examined bacteriologically was 194 and not 186.

Question 4) In table 2, the sensitivity of the serology for field infection A is stated as being 22. It appears as though this number was achieved by adding the positive percentage from field infection in table 1, which was 4, and the dubious results, which were 18. It's unclear what dubious means. If sensitivity is based on true positives then it appears that the sensitivity should be 4.

Answer 4) The calculation of the sensitivity is based on the sum of positive and dubious-positive results. As described in question 2, a value of 10 PP was calculated as cut-off between negative and positive.

Question 5) Is there any work on improving the sensitivity of this test?

Answer 5) Yes. We are working on an improved version of the serological test.

Firstly we need to find more MAA-positive herds. We identified two Dutch farms with an MAA-infection. The earlier to FSIS reported study of Komijn et al (2007), revealed already that the prevalence of MAA infected herds in The Netherlands is very low. This seems to be one of the reasons that we have such a low number of positive herds. However we have now a third farm (foreign farm) that is suspected of MAA and under further investigation. Three naturally infected farms are still a low number to base the test specifications on. We need positive farms to further prove that we are able to detect MAA infections under the field conditions. Secondly research goes on in order to improve the serological test. Identification of the antigens of MAA is part of that. We focus especially on purification of lipid antigens from the current preparation which we are using in the ELISA. We expect that purification leads to a higher sensitivity with at least the same or a higher specificity.

Question 6) If a carcass is determined to have granulomas that may be from tuberculosis, is the entire carcass condemned or is there any criteria for salvaging parts of a carcass? FSIS has regulations which address this situation and I am attaching them below.

Answer 6) If the inspection of the carcass and/or organs shows malformation of the product or any sign of a generalized (disseminated) process, the carcass and pluck (including spleen) are being taken off line to undergo further inspection, which includes additional palpation and incisions, and the intestines are condemned. Generalized lesions (multiple granulomas, different organs affected) will result in condemnation

of the entire carcass and all its organs. If the carcass or pluck is only locally affected and the infectious process is confined to one primary site of infection, this affected part is being removed and condemned. The unaffected parts can be passed for human consumption without restriction. This is the regime of the EU-legislation.

Literature

Ruud E. Komijn, Henk J. Wisselink, Vincent M.C. Rijsman, Norbert Stockhofe-Zurwieden, Douwe Bakker, Fred G. van Zijderveld, Tony Eger, Jaap A. Wagenaar, Frans F. Putirulan, Bert A.P. Urlings, 2007: Granulomatous lesions in lymph nodes of slaughter pigs bacteriologically negative for *Mycobacterium avium* subsp. *avium* and positive for *Rhodococcus equi*. *Veterinary Microbiology* 120 (2007) 352–357.

Smith, David

From: Feitel, Caroline [caroline.feitel@minbuza.nl]
Sent: Monday, June 16, 2008 2:51 PM
To: Smith, David
Cc: Thissen, Frits; Lammers, Sunny
Subject: Visual inspection -Q&A's
Importance: High
Attachments: 08-06-10-USDA-FSIS-PorkSupplyChain.doc

Hi David,

As discussed, please find attached the answers to your questions regarding the Netherlands chain inspection system. I know you had mentioned to have a telephone conference to discuss these Q&As, please let me know if you would still would like to have this to take place.

Thank you,

Caroline

Caroline Feitel
Agricultural Trade Officer
Netherlands Embassy
4200 Linnean Avenue, NW
Washington, D.C. 20008
Ph:202-274-2719
Fax: 202-244-3325

From: Smith, David [mailto:David.Smith@fsis.usda.gov]
Sent: maandag 16 juni 2008 14:05
To: Feitel, Caroline
Cc: Thissen, Frits; Lammers, Sunny
Subject: RE: Visual inspection

Hi Caroline,

Thanks for the help, I will try to get the call set up for one day the week of the 22nd. I will be in touch with you next week to refine the details.

Thanks,

David

Hi David,

Your questions have been forwarded to the Netherlands and our ministry is currently working on them. We anticipate that the written response will come soon. Due to travel commitments from the NL side, the first opportunity for a possible follow-up teleconference would be in the week

6/30/2008

of June 22. I hope you have good trip!

Best regards,

Caroline Feitel
Agricultural Trade Officer
Netherlands Embassy
4200 Linnean Avenue, NW
Washington, D.C. 20008
Ph:202-274-2719
Fax: 202-244-3325

From: Smith, David [<mailto:David.Smith@fsis.usda.gov>]
Sent: donderdag 5 juni 2008 13:43
To: Feitel, Caroline
Subject: FW: Visual inspection

Hi Caroline, I sent this earlier to Frits but I understand that he is out of the office until next week. Could you please follow up with the Ministry? Also, I sent an email to Frits proposing a teleconference with Netherlands to discuss the information below. We would like to try for one day during the week of June 16. Possibly Wednesday?

I am out of the office tomorrow, and next week, but I'll have my blackberry so I can respond to emails.

Thank you,

David Smith, DVM, MS, BS

Office of International Affairs

International Equivalence Staff

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Phone: (202) 720-3395

Email: david.smith@fsis.usda.gov
<<mailto:david.smith@fsis.usda.gov>>

From: Smith, David
Sent: Thursday, June 05, 2008 8:32 AM
To: 'frits.thissen@minbuza.nl'

6/30/2008

Subject: Visual inspection

Hi Fritz, after reviewing the most recent information that was provided to us with some of my colleagues we have the following questions:

<<Suppl info ketenkeuring 6-5-08.doc>>

1) In table 1 there is a comparison between an experimental infection study and a field infection farm A study. The conditions of the farm A study are not explained. Were the pigs infected or exposed to MAA?

2) In the same table, there are columns labeled as negative, positive, and dubious. What is meant by dubious? It is unclear how the results in this column are to be interpreted without an understanding of what dubious means.

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http://edocket.access.gpo.gov/cfr_2008/janqtr/pdf/9cfr311.2.pdf
<http://edocket.access.gpo.gov/cfr_2008/janqtr/pdf/9cfr311.2.pdf>

Thank you,

David Smith, DVM, MS, BS

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6/30/2008

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<<mailto:david.smith@fsis.usda.gov>>

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6/30/2008

van welke aard ook, die verband houdt met risico's verbonden aan het elektronisch verzenden van berichten.

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TELECONFERENCE SUMMARY

COUNTRY: Netherlands

SUBJECT: Submission of information regarding supply chain inspection project of market hogs

DATE: June 26, 2008

FSIS REPRESENTATIVES:

Dr. David Smith, IES, OIA

NETHERLANDS REPRESENTATIVES

Caroline Feitel, Embassy of Netherlands

Martin Weijtens, Deputy CVO

Bert Urlings, VION Food Group

Ate Jelsma, Senior Veterinary Officer, VWA

SUMMARY: The teleconference focused on further information requested of the Netherlands regarding supply chain inspection.

- Discussed briefly the upcoming trip by FSIS to the Netherlands.
- Discussed the questions which were asked of the Netherlands on June 23, 2008.
 - After a farm achieves a low risk categorization what is the ongoing sampling program to show that the farm is maintaining a low risk status? How many samples are collected per herd? Is it serology only, or is intra-dermal testing performed as well?
 - The low risk category of a farm is monitored by collecting 2 samples/herd when they arrive at the slaughter establishment. These samples are serological only. If 1 sample returns a positive result which exceeds the dubious positive cutoff then the status becomes neutral. If both exceed the cutoff then the status becomes high.
 - Why does Netherlands perform intra-dermal testing as well as pathological testing on top of serology?
 - Intradermal testing is performed on the farms by a veterinarian employed by VION. This testing is done as follow up testing for farms which are having their status re-evaluated. Also, intradermal testing has been used for collecting comparison data for the research on the serology test.
 - Is the IKB Pigs Scheme exclusive to supply chain inspection or does it apply to traditional as well?
 - The IKB Scheme is not exclusive to supply chain inspection, and not all pig farms participate in IKB. IKB is a program which makes allows access to a greater amount of information about the pig farms that do participate. There are farms whose pigs are subjected to traditional inspection which are participating in IKB, and there are farms whose pigs are subjected to traditional inspection which are not participating in IKB. However, all farms whose pigs go through supply chain inspection must participate in IKB.
 - How long does it take to receive the results of the serological testing?
 - Results are received in approximately 1 week.

Smith, David

From: Feitel, Caroline [caroline.feitel@minbuza.nl]
Sent: Monday, June 23, 2008 3:18 PM
To: Smith, David
Cc: Lammers, Sunny
Subject: RE: questions for Netherlands Inspection

Hi David,

Thank you! I will let you know tomorrow who will be at the teleconference on Thursday and the phone numbers.

Best,

Caroline

From: Smith, David [mailto:David.Smith@fsis.usda.gov]
Sent: maandag 23 juni 2008 14:23
To: Feitel, Caroline
Subject: questions for Netherlands Inspection

Hi Caroline, these are questions that we would like to discuss during the conference call Thursday.

1. After a farm achieves a low risk categorization what is the ongoing sampling program to show that the farm is maintaining a low risk status? How many samples are collected per herd? Is it serology only, or is intra-dermal testing performed as well?
2. Why does Netherlands perform intra-dermal testing as well as pathological testing on top of serology?
3. Is the IKB Pigs Scheme exclusive to visual inspection or does it apply to traditional as well?

Thank you,

David Smith, DVM, MS, BS

Office of International Affairs

International Equivalence Staff

USDA, Food Safety and Inspection Service Room 3843 South Bldg.

1400 Independence Ave, SW

Washington DC 20250

Phone: (202) 720-3395

Email: david.smith@fsis.usda.gov

6/30/2008



FSIS Documents

Comparison Table: Swine Inspection

FSIS Swine Inspection Procedures (traditional): <ul style="list-style-type: none"> • Authority: 21 USC 604 (FMIA), 9 CFR 310.1 • Procedures: Slaughter Inspection Training Materials (1/14/2005) 	FSIS Swine Inspection Procedures for Plants Operating Under HIMP: <ul style="list-style-type: none"> • Authority: 21 USC 604 (FMIA), 9 CFR 303.2 	Netherlands Swine Inspection Procedures for Plants Operating Under Visual Inspection: <ul style="list-style-type: none"> • Authority: EC 854/2004 • Procedures: "The New Organization of the Red Meat Inspection System in the Netherlands (2006)" 	EU Swine Inspection Procedures (traditional): <ul style="list-style-type: none"> • Authority: EC 854/2004 • Procedures: Annex I; Sec IV; Chap IV: Domestic Swine, B.—Post mortem Inspection
General: <ul style="list-style-type: none"> • For all swine 	<ul style="list-style-type: none"> • For market hogs slaughtered in plants operating under the HACCP-based Inspection Models Project (HIMP). • Carcasses must be presented for inspection with the mandibular lymph nodes incised. 	<ul style="list-style-type: none"> • For fattening pigs housed under controlled housing in integrated production systems since weaning. • At the discretion of the competent authority based on epidemiological or other data from the holding [farm]. • Data from the farm must include food chain information, results of testing for <i>M. avium</i>, and certain additional requirements to control hazards in the food supply chain. 	<ul style="list-style-type: none"> • For all swine except those identified under paragraph (2).

Head Inspection: <ul style="list-style-type: none"> • Observe head and cut surfaces – eyes, fat, cheek muscles, and other tissues for abnormalities. • Incise and observe mandibular lymph nodes. 	<ul style="list-style-type: none"> • Visual inspection of the head and throat. • Visual inspection of the incised mandibular lymph nodes. • Visual inspection of mouth, fauces, tongue. 	<ul style="list-style-type: none"> • Visual inspection of the head and throat, including the mandibular lymph nodes. • Visual inspection of mouth, fauces, tongue. 	<ul style="list-style-type: none"> • Visual inspection of the head and throat. • Incision and examination of the submaxillary lymph nodes (Lnn mandibulares). • Visual inspection of the mouth, fauces and tongue.
Viscera Inspection: <ul style="list-style-type: none"> • Observe eviscerated carcass, viscera and parietal (top) surface of spleen. • Observe and palpate mesenteric lymph nodes. • Palpate portal lymph nodes. • Observe dorsal (curved) surface of lungs. • Palpate bronchial lymph nodes. • Observe mediastinal lymph nodes. • Turn lungs over and observe ventral (flat) surfaces. • Observe heart. • Observe dorsal (curved) surface of liver. • Turn liver over and observe ventral (flat) surface. 	<ul style="list-style-type: none"> • Visual inspection of the lungs, trachea, and oesophagus. • Visual inspection of the pericardium and heart. • Visual inspection of the liver and hepatic and pancreatic (portal) lymph nodes. • Visual inspection of the gastro-intestinal tract, mesentery, gastric and mesenteric lymph nodes. • Visual inspection of the spleen. 	<ul style="list-style-type: none"> • Visual inspection of the lungs, trachea, and oesophagus. • Visual inspection of the pericardium and heart. • Visual inspection of the liver and hepatic and pancreatic (portal) lymph nodes. • Visual inspection of the gastro-intestinal tract, mesentery, gastric and mesenteric lymph nodes. • Visual inspection of the spleen. • Visual inspection of genital organs. 	<ul style="list-style-type: none"> • Visual inspection of the lungs, trachea and oesophagus. • Palpation of the lungs and the bronchial and mediastinal lymph nodes (Lnn. bifurcationes, eparteriales and mediastinales). • The trachea and the main branches of the bronchi must be opened lengthwise and the lungs must be incised in their posterior third, perpendicular to their main axes; these incisions are not necessary where the lungs are excluded from human consumption. • Visual inspection of the liver and the hepatic and pancreatic lymph nodes, (Lnn portales). • Palpation of the liver and its lymph nodes. • Visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (Lnn gastrici, mesenterici, craniales and caudales). • Palpation and, if necessary,

			incision of the gastric and mesenteric lymph nodes. <ul style="list-style-type: none"> • Visual inspection and, if necessary, palpation of the spleen.
Carcass Inspection:			
<ul style="list-style-type: none"> • Observe back of carcass (turn carcass or use mirror). • Observe front and inside of carcass, including <ul style="list-style-type: none"> ◦ Cut surfaces, ◦ All body cavities, ◦ Lumbar region, ◦ Neck region. • Grasp, turn, and observe the kidneys. 	<ul style="list-style-type: none"> • Visual inspection of the carcass. • Visual inspection of the pleura and peritoneum [lining of chest and abdominal cavities]. • Visual inspection of the kidneys. • Visual inspection of the diaphragm. • Visual inspection of the udder and its lymph nodes. • Visual inspection of the umbilical region and joints of young animals. 	<ul style="list-style-type: none"> • Visual inspection of the carcass. • Visual inspection of the pleura and peritoneum [lining of chest and abdominal cavities]. • Visual inspection of the kidneys. • Visual inspection of the diaphragm. • Visual inspection of the udder and its lymph nodes. • Visual inspection of the umbilical region and joints of young animals. 	<ul style="list-style-type: none"> • Visual inspection of the carcass. • Visual inspection of the pleura and peritoneum. • Visual inspection of the kidneys. • Incision, if necessary, of the kidneys and the renal lymph nodes (Lnn. renales). • Visual inspection of the diaphragm. • Visual inspection of the udder and its lymph nodes (Lnn. supramammarii). • Incision of the supramammary lymph nodes in sows. • Visual inspection and palpation of the umbilical region and joints of young animals. • In the event of doubt, the umbilical region must be incised and the joints opened.

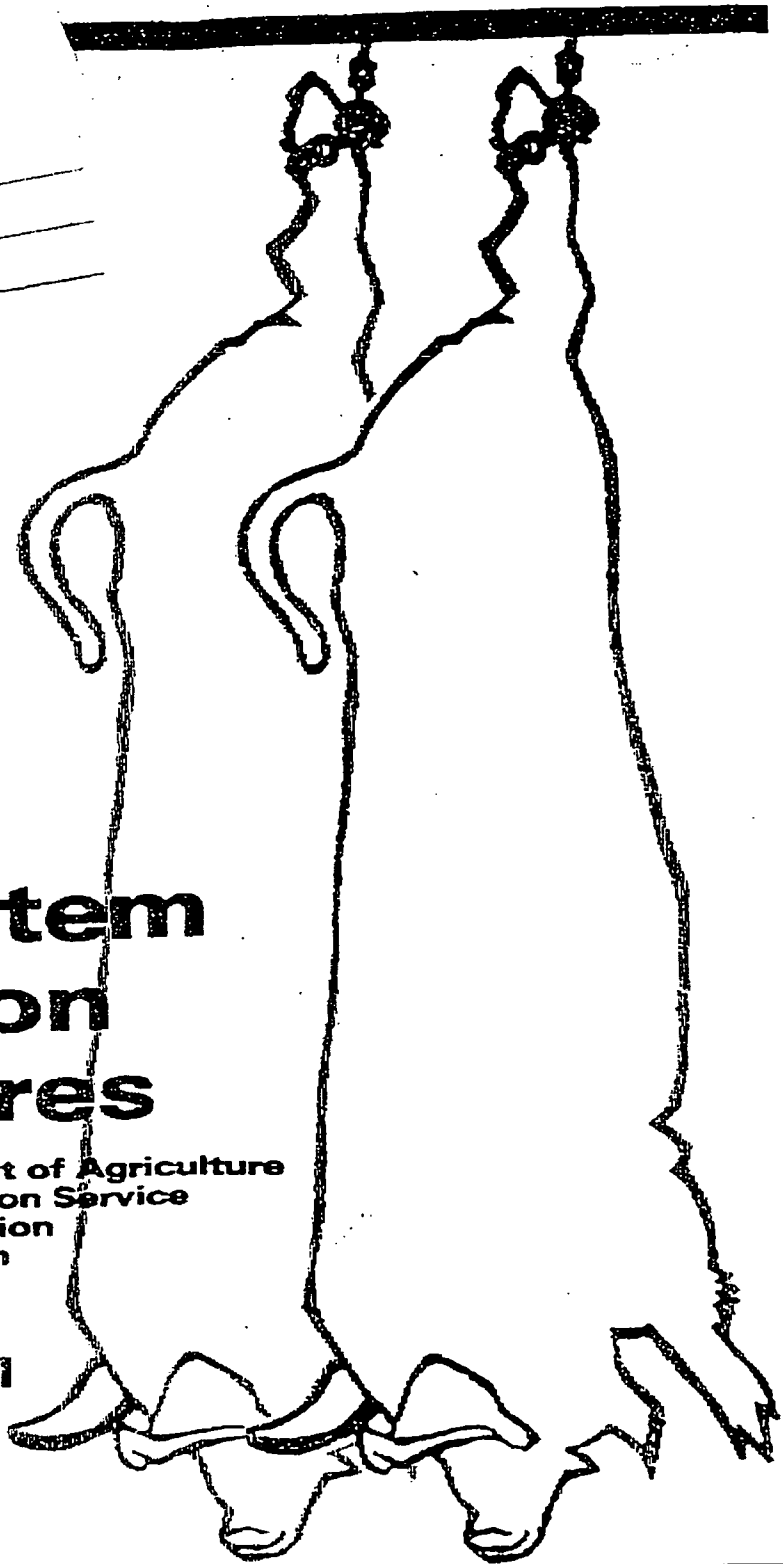


Revised Swine Postmortem Inspection Procedures

**United States Department of Agriculture
Food Safety and Inspection Service
Meat and Poultry Inspection
Program Training Division**

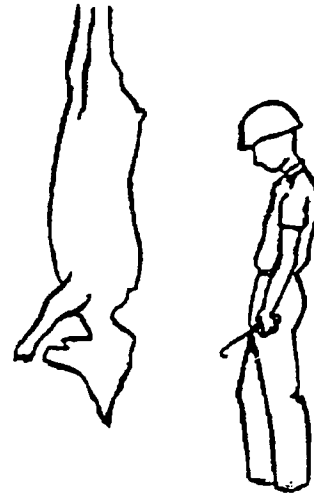


July 1981

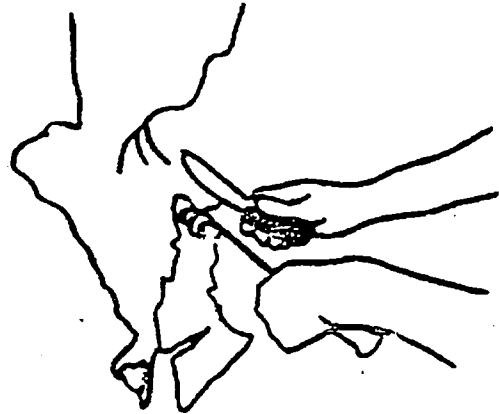


HEAD

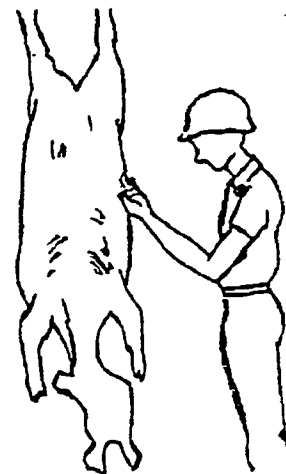
- STEP 1 OBSERVE HEAD AND CUT SURFACES. Observe the leading side of the head as the carcass approaches. The trailing side is observed after you have incised the mandibular nodes and observed the cut surfaces and as the carcass moves away from you.



- STEP 2 INCISE AND OBSERVE MANDIBULAR LYMPH NODES -- LEFT AND RIGHT. Use a wrist rolling motion to lay the slices open for greater exposure.

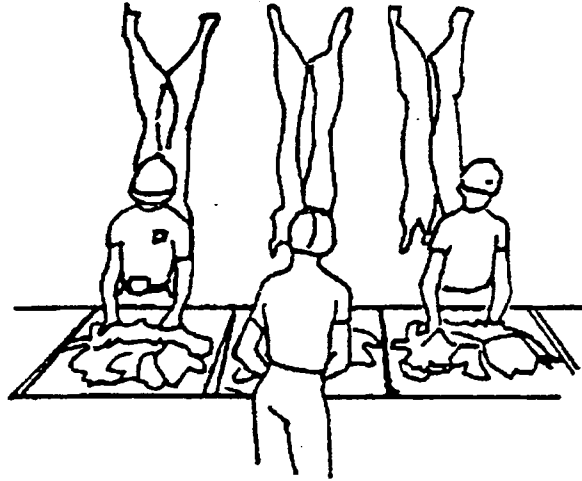


- STEP 3 OBSERVE/RETAIN CARCASS, WHEN REQUIRED. Normally it is not required to observe the carcass during head inspection. However while examining the head and cut surfaces you may see signs (such as abnormal color in the tissues) that may indicate a systemic condition. When this happens you should observe the carcass to determine if it should be retained for veterinary disposition.

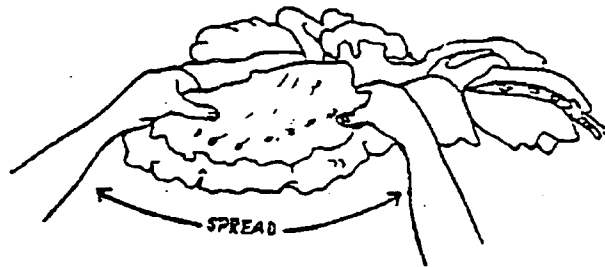


VISCERA

- 1 OBSERVE EVISCERATED CARCASS, VISCERA, AND PARIETAL (TOP) SURFACE OF SPLEEN. Viscera must be properly presented - mesentery toward you, spleen exposed, liver, and lungs dorsal surface up. The inspectors that face the carcasses should observe all of the eviscerated carcasses.

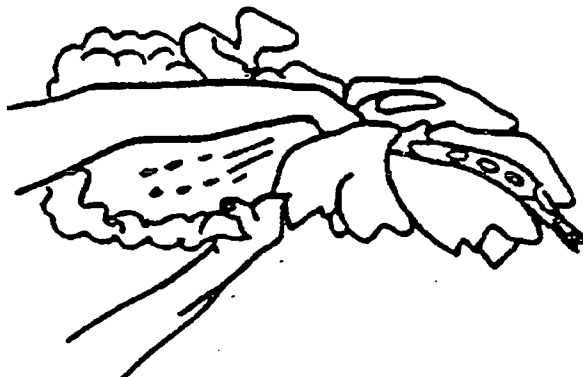


- 2 OBSERVE AND PALPATE MESENTERIC LYMPH NODES. Grasp and palpate the nodes in the center of the mesenteric lymph node chain with the thumb and fingers of both hands. Then palpate the remaining nodes in the chain by moving the hands away from the center toward the ends of chain. After this step is completed continue to grasp the end of the chain with your right hand. This will hold the viscera in place for the next step.



VISCERA (cont'd)

- STEP 3 PALPATE PORTAL LYMPH NODES. Grasp and palpate the portal nodes with the thumb and fingers of the left hand. Keep the left hand in this position to steady the viscera for the remaining steps.



- 4 OBSERVE DORSAL (CURVED) SURFACES OF LUNGS. Observe lungs while moving right hand into position over tracheobronchial (bronchial) nodes.



VISCERA (cont'd)PALPATE

~~THE~~ BRONCHIAL LYMPH NODES --
AND LEFT. Palpate the right ~~and~~
(left tracheobronchial nodes ~~USING~~
the thumb and first 3 fingers ~~OF~~
The right hand. (Use the ~~Thumb~~
and index finger to ~~PALPATE~~
~~the~~ the right node and the ~~MIDDLE~~
~~and~~ and ring fingers to palpate
left.)

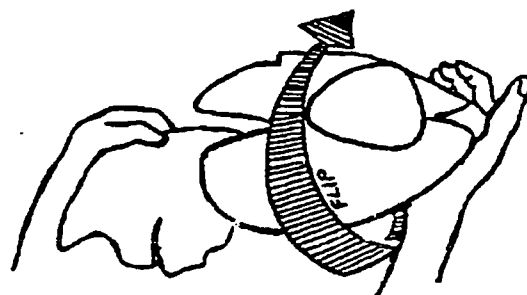
OBSERVE

~~THE~~ MEDIASTINAL LYMPH NODES.
ight amount of pressure
ted by the right hand will
e the mediastinal space
so the mediastinal nodes
be easily observed.

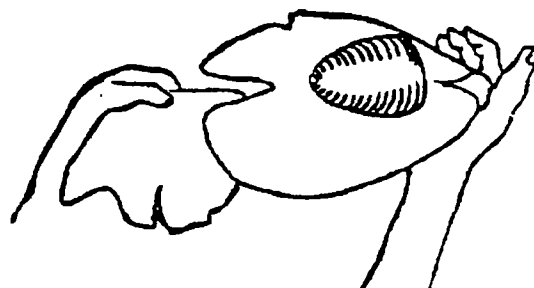


VISCERA (cont'd)

5.) 7 TURN LUNGS OVER AND OBSERVE VENTRAL (FLAT) SURFACES. With a turn of the wrist and forearm of the right hand turn the lungs over so the lung's ventral surfaces may be observed.



- STEP 8 OBSERVE HEART. While observing the heart release the hold you have with your right hand and begin moving the hand toward the liver.

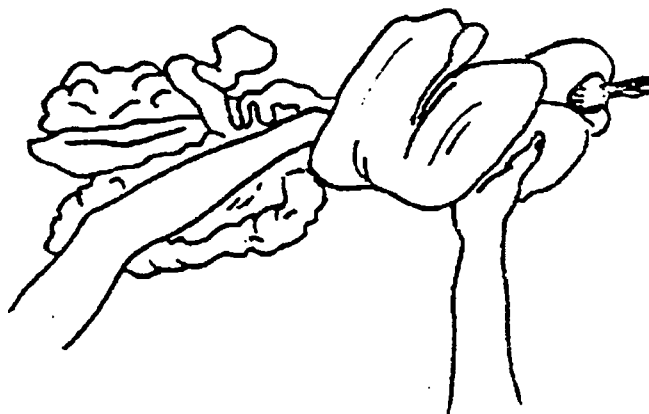


VISCERA (cont'd)

- EP 9 OBSERVE DORSAL (CURVED) SURFACE OF THE LIVER. As you observe the dorsal surface of the liver pass your right hand under the liver.

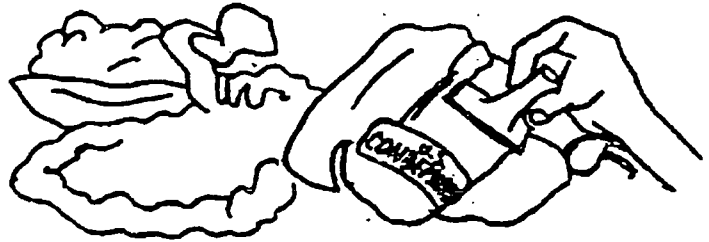


- EP 10 TURN LIVER OVER AND OBSERVE VENTRAL (FLAT) SURFACE. With a sweeping motion of the right hand lift the liver and turn it over allowing it to fall away from your grasp. Release your left hand from its hold on the portal nodes.

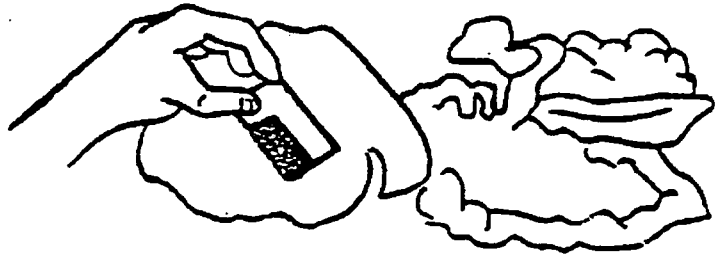


VISCERA (cont'd)

- EP 11 CONDEMN VISCERA OR PARTS WHEN REQUIRED. Identify as condemned those visceral organs or parts that require condemnation.



- EP 12 RETAIN CARCASS, VISCERA, AND PARTS WHEN REQUIRED. When veterinary disposition is required tag the viscera and retain the carcass and all parts, including the head.

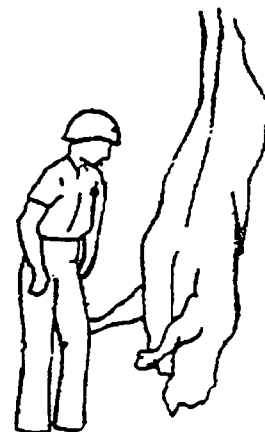


CARCASS

STEP 1 LOOK IN MIRROR AND OBSERVE BACK OF CARCASS. The establishment is required to install a mirror at the carcass station so the back (dorsal) surfaces of the carcass may be observed without turning the carcass. Look for melanosis, abscesses, injection lesions, etc.

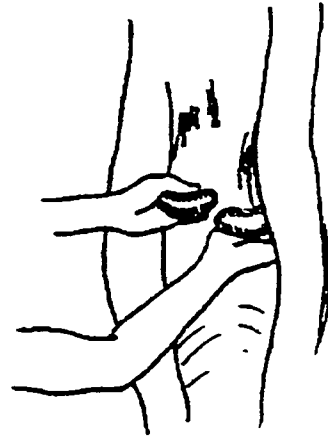


STEP 2 OBSERVE FRONT PARTS AND INSIDE OF CARCASS. This step includes observing those portions of the carcass not seen while looking at the carcass in the mirror. Such portions as the flank and neck regions of the carcass, the joints and axillary spaces, the entire front (ventral) surfaces of the carcass, as well as the cut surfaces and body cavities must be observed during this step.

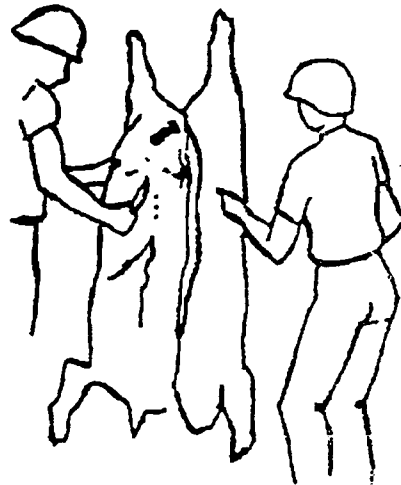


CARASSES (Cont.)

- 3 GRASP, TURN, AND OBSERVE KIDNEYS (BOTH SIDES). Turn the kidneys so that both sides may be observed.



- 4 DIRECT TRIM, REMOVE RETAIN TAGS, OR RETAIN CARCASS WHEN REQUIRED. When dressing defects or other abnormalities are observed take the required action.



SWINE POST-MORTEM INSPECTION 1/**HEAD****STEP**

- 1 Observe head and cut surfaces.
- 2 Incise and observe mandibular lymph nodes.
- 3 Observe/retain carcass, when required.

VISCERA**STEP**

- 1 Observe eviscerated carcass, viscera, and peritoneal (top) surface of spleen.
- 2 Observe and palpate mesenteric lymph nodes.
- 3 Palpate portal lymph nodes.
- 4 Observe dorsal surfaces of lungs.
- 5 Palpate bronchial lymph nodes.
- 6 Observe mediastinal lymph nodes.
- 7 Turn lungs over and observe ventral surfaces.
- 8 Observe heart.
- 9 Observe dorsal surface of liver.
- 10 Turn liver over and observe ventral surface.
- 11 Condemn viscera or parts when required.
- 12 Retain carcass, viscera, and parts when required.

CARCASS**STEP**

- 1 Look in mirror and observe back of carcass. 2/
- 2 Observe front parts and inside of carcass.
- 3 Grasp, turn, and observe kidneys (both sides).
- 4 Direct trim, remove retain tags, or retain carcass when required.

1/ Inspectors must examine carcasses, organs, and parts for ~~lesions, abnormalities, conditions~~

and remove back

SWINE POST-MORTEM INSPECTION 1/**HEAD****STEP**

- 1 Observe head and cut surfaces.
- 2 Inspect and observe mandibular lymph nodes.
- 3 Observe/retain carcass, when required.

VISCERA**STEP**

- 1 Observe eviscerated carcass, viscera, and parietal (top) surface of spleen.
- 2 Observe and palpate mesenteric lymph nodes.
- 3 Palpate portal lymph nodes.
- 4 Observe dorsal surfaces of lungs.
- 5 Palpate bronchial lymph nodes.
- 6 Observe mediastinal lymph nodes.
- 7 Turn lungs over and observe ventral surfaces.
- 8 Observe heart.
- 9 Observe dorsal surface of liver.
- 10 Turn liver over and observe ventral surface.
- 11 Condense viscera or parts when required.
- 12 Retain carcass, viscera, and parts when required.

CARCASS**STEP**

- 1 Look in mirror and observe back of carcass. 2/
- 2 Observe front parts and inside of carcass.
- 3 Grasp, turn, and observe kidneys (both sides).
- 4 Direct trim, remove retain tags, or retain carcass when required.

1/ Inspectors must examine carcasses, organs, and parts for
lesions, abnormalities, cleanliness.

2/ -same back

100

4261-256

10001

Part 310 Post Mortem Inspection

310.1 Extent and time of post-mortem inspection; post-mortem inspection staffing standards.

310.1(b)(1) The staffing standards on the basis of the number of carcasses to be inspected per hour are outlined in the following tables. Standards for multiple inspector lines are based on inspectors rotating through the different types of inspection stations during each shift to equalize the workload.

The inspector in charge shall have the authority to require the establishment to reduce slaughter line speeds where, in his judgment, the inspection procedure cannot be adequately performed at the current line speed because of particular deficiencies in carcass preparation and presentation by the plant at the higher speed, or because the health condition of the particular animals indicates a need for more extensive inspection.



Food Safety and Inspection Service
United States Department of Agriculture
 Washington, D.C. 20250-3700

Pathogen Reduction/HACCP & HACCP Implementation

October 4, 1999

Role of Inspectors under Traditional Inspection and HACCP-based Models Project

Traditional Inspection	Models Project
Every carcass receives inspection	Every carcass receives inspection
Inspector has authority to stop line, as appropriate	Inspector has authority to stop line, as appropriate
Inspector has authority to retain adulterated product	Inspector has authority to retain adulterated product
Inspector has authority to withhold marks of inspection	Inspector has authority to withhold marks of inspection
Inspector can take action on insanitary conditions	Inspector can take action on insanitary conditions
Inspector sorts carcasses and directs plant to remove animals and birds before slaughter, and carcasses and parts after slaughter, that are unsafe for human consumption or unwholesome	Plant removes animals and birds before slaughter, and carcasses and parts after slaughter, to meet FSIS standards. Inspector oversees and verifies this process
Inspector located at fixed point on slaughter line	Inspector <i>2013 Fixed location</i> Inspector is free to move—at assignment by inspector-in-charge (IIC)—to any point on slaughter line needing oversight
Inspector defines corrective actions	Inspector oversees and verifies plant's corrective actions
Inspector identifies and directs plant to remove defects	Inspector oversees and verifies plant's identification and removal of defects; verifies that products meets FSIS standards
Inspector solves production control problems	Inspector oversees plant's solutions to production

	control problems
Inspector takes samples of products for analysis, using scientific and technical methods as determined by statistical design and IIC	Inspector takes samples of products for analysis, using scientific and technical methods as determined by statistical design and IIC
	Inspector conducts in-depth reviews of selected plant records, as determined by statistical design and IIC



Food Safety and Inspection Service
United States Department of Agriculture
Washington, D.C. 20250-3700



Pathogen Reduction/HACCP & HACCP Implementation

July 22, 1998

HACCP-Based Inspection Models Project: Diseases and Conditions Observable in Meat and Poultry

Background

In a June 10, 1997, Federal Register notice, the Food Safety and Inspection Service (FSIS) requested public comments on the design and development of new inspection models for slaughter and processing in a Hazard Analysis and Critical Control Point (HACCP) environment (62 FR 31553). In a section discussing the need to reform the meat and poultry inspection program, the notice summarized recommendations by the National Academy of Sciences and the General Accounting Office that FSIS reduce its reliance on organoleptic inspection, shift to prevention-oriented inspection systems based on risk assessment, and redeploy its resources in a manner that better protects the public from foodborne diseases. FSIS will study how to bring about such inspection changes and resource redeployments during its HACCP-Based Inspection Models project. A June 24-25, 1997, public meeting, which the notice announced, provided a forum for dialogue between FSIS and all parties interested in the project. The project has been discussed in meetings of the National Advisory Committee on Meat and Poultry Inspection and in other forums.

Establishments volunteering to participate in the HACCP-Based Inspection Models project will carry out activities relating to food safety and other consumer-protection matters. FSIS will conduct activities aimed at improving inspection-system compatibility with the Pathogen Reduction/HACCP regulations. FSIS will develop inspection models in which slaughter process control is an industry responsibility under FSIS oversight and verification.

One step in the development of these inspection models is that of distinguishing, at post-mortem, animal diseases and conditions that are food-safety hazards from diseases and conditions that are objectionable for other reasons. This document reflects the current FSIS view of that distinction. In the course of the inspection models project, the volunteer establishments will decide how best to verify the removal from the food supply of carcasses or parts affected by these diseases and conditions and FSIS will decide how best to verify their removal. These decisions will depend partially on a consideration of this document.

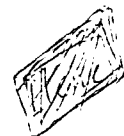
Please submit written comments on this document to Ms. Patricia Stolfa, Assistant Deputy Administrator, Office of Policy, Program Development and Evaluation, Room 402 Cotton Annex, 300 12th Street SW, Washington, DC 20250-3700. Comments may also be provided by facsimile (202-401-1760).

HACCP-Based Inspection Models Project: Food-Safety-Related and Other Diseases and Conditions Observable at Post-Mortem

Volunteer establishments will conduct a pathological and anatomical examination of each carcass while FSIS oversees and verifies the establishments' process controls. Livestock and poultry diseases and conditions identified at post-mortem are categorized according to their food-safety or other consumer-protection significance. Diseases and conditions likely to present a meat- or poultry-borne hazard to public health are considered food-safety hazards. Diseases and conditions having other consumer-protection significance are defects that rarely or never present a direct public health risk, but that are unacceptable components of meat and poultry products. Diseases and conditions in both categories are to be removed from the human food supply. Establishments will consider food-safety-related diseases and conditions for inclusion in their HACCP plans.

Handwritten notes:
2
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10 Carcasses, viscera / h
for FS Condition
10 Carcasses, viscera - Turkey
day shift for CCP



Part I -- Diseases and Conditions that Affect Food Safety**Food Safety Hazards**

FSIS has identified two general post-mortem food-safety categories: (1) Infectious Conditions and (2) Contamination. Food-safety-related infectious conditions and contamination are identified organoleptically, that is, by using the senses, and are presumed to contain infectious agents (bacteria, virus, rickettsia, fungus, protozoa or helminth organisms) that may cause a food to be unsafe for human consumption *and* that are likely to be transmitted through meat and poultry. Examples of diseases and conditions in each category are listed below.

(1) Infectious Conditions that Affect Food Safety

- (i) localized – remove lesion(s) and pass unaffected carcass portions
- (ii) generalized – condemn or treat to render non-infective

Examples:

- Abscess: A localized collection of pus.
- *Cysticercus bovis* * : The larval form of *Taenia saginata*. Any single cysticercus indicates generalized infection.
- *Cysticercus cellulosae* * : The larval form of *Taenia solium*. Any single cysticercus indicates generalized infection.
- *Mycobacterium bovis* (included to support eradication surveillance).
- Pyemia: Septicemia associated with multiple abscesses arising from vascular dissemination of pyogenic organisms.
- Septicemia: Systemic disease associated with the presence and persistence of pathogenic organisms in the bloodstream.
- Toxemia: Systemic disease associated with bacterial products (toxins) in the bloodstream.

(2) Contamination – prevent or remove in accordance with establishment HACCP plan

* Dependent on other elements in the HACCP plan. On-farm production records demonstrating no cysticercosis in a herd may obviate the need for cysticercosis in the slaughter component of the HACCP Plan.

Examples:

- Fecal material
- Milk (livestock)
- Ingesta (livestock)

Part II -- Diseases and Conditions with Consumer-Protection Implications Not Related to Food Safety

FSIS has identified four general categories of diseases and conditions that affect consumer protection because they adulterate products but that are not food-safety hazards. The categories and examples of diseases and conditions are listed below.

(1) Animal infectious conditions. Animal infectious conditions contain infectious agents that do not render foods unsafe to humans or are unlikely to be transmitted to humans.

- (i) localized – remove lesion(s) and pass unaffected carcass portions
- (ii) generalized – condemn or treat to render non-infective

Examples:

- Actinomycosis
- Actinobacillosis
- Airsacculitis
- Arthritis – infectious ✓
- Ascariasis
- Caseous lymphadenitis
- Coccidioidal granuloma
- *Cysticercus ovis*
- *Cysticercus tenuicollis*
- Erysipelas
- Fascioliasis
- Infectious process
- Mastitis
- Metritis
- *Mycobacterium avium*
- Nephritis, pyelitis
- Osteomyelitis
- Pericarditis
- Peritonitis
- Pleuritis
- Pneumonia
- Synovitis

(2) Neoplasia (tumors)

- (i) localized –remove localized lesion(s) and pass unaffected carcass portions
- (ii) metastatic – condemn

Examples:

- Carcinoma
- Epithelioma
- Lymphoma
- Sarcoma

(3) Pigmentary, metabolic, degenerative conditions

- (i) localized –remove localized lesion(s) and pass unaffected carcass portions
- (ii) generalized – condemn

Examples:

- Anasarca
- Anemia
- Arthritis – degenerative
- Ascites
- Emaciation
- Eosinophilic myositis
- Icterus
- Melanosis
- Sawdust liver
- Telangiectasia
- Uremia

- Xanthosis

(4) Miscellaneous

- (i) localized –remove localized lesion(s) and pass unaffected carcass portions
- (ii) generalized – condemn

Examples:

- Bruises
- Cadaver -- always considered generalized
- Fetus -- always condemned
- Fractures
- Overscald

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Food Safety and Inspection Service
United States Department of Agriculture
Washington, D.C. 20250-3700

Key Facts

December 1998

Slaughter Inspection Under the HACCP-Based Inspection Models Project- -Oversight and Verification

Introduction

FSIS is developing new models for slaughter inspection to be used in pilot plants that are extending their Hazard Analysis and Critical Control Point (HACCP) systems to cover additional parts of their slaughter operations. Only plants that slaughter young, healthy, uniform animals are being accepted as volunteers for this project.

The HACCP-Based Inspection Models Project is designed to test whether new government slaughter inspection procedures, applied in conjunction with extended plant HACCP controls, can improve food safety and increase consumer protection. Implementing HACCP alone does not fully accomplish this objective because FSIS continues to use its slaughter inspection workforce in traditional ways. This means that, during the slaughter process, FSIS inspectors have assumed responsibility for identifying and removing defects, defining corrective actions to prevent problems, and solving production control problems. This is in direct contrast with how FSIS inspection personnel now function with respect to other plant process control systems--HACCP and Standard Operating Procedures for sanitation. Here, plants assume their proper responsibilities for process control, and FSIS verifies that they are meeting regulatory requirements.

As part of the model development process, FSIS is further describing the procedures—oversight inspection and verification inspection—that inspectors will perform in slaughter plants participating in the project. FSIS will test different staffing arrangements in order to determine the most effective means of carrying out its inspection responsibilities. All existing statutory responsibilities will be met under the new inspection procedures.

Success of the new slaughter inspection models will permit FSIS to better use its resources and focus more aggressively on improving food safety and addressing public health concerns such as microbial pathogens. For example, FSIS already has set pathogen reduction performance standards for *Salmonella* and intends to set standards for *Campylobacter*. FSIS will also be able to move forward more quickly on implementation of its farm-to-table strategy by redeploying inspection resources made available through the models to carry out activities in-distribution.

Volunteer Plants

Baseline data collection has been completed in an initial group of volunteer plants that slaughter certain market classes of young, healthy, and uniform animals. These first five plants slaughter young poultry and market hogs. They are: Jennie-O Foods, Inc., Wilmar, MN, a turkey plant; Hatfield, Inc., Hatfield, PA, a swine plant; Rocco Farm Foods, Edinburg, VA, a poultry plant; Quality Pork Processors, Austin, MN, a swine plant; and Goldkist Inc., Guntersville, AL., a poultry plant. (Claxton Poultry Farms, Claxton, GA, a poultry plant, has deferred participation in the project until next year.) FSIS expects to expand the pilot project to involve more plants.

These plants will extend their HACCP plans to include food safety hazards that may occur beginning when live animals or birds enter the facility. In addition, the volunteer plants will design and implement process control plans that address other consumer protection matters, such as removing bruises and other quality defects. When volunteer plants take on these process control responsibilities, the FSIS inspection team will be able to implement and evaluate the new slaughter inspection procedures.

Oversight Inspection and Verification Inspection

In the pilot plants, slaughter inspection will consist of two types of procedures: oversight inspection and verification inspection. Only government inspectors will perform these procedures, and all government inspectors in the plant will be trained and expected to perform both types of procedures. The number of inspectors needed to perform these inspection procedures will vary according to factors such as plant size and complexity of its operations. The inspector-in-charge (IIC)--a veterinarian or other professional with a scientific background--will determine how to allocate inspection resources in the plant.

Oversight inspection

Under oversight inspection, FSIS inspectors make expert and informed observations of the company's HACCP and process control systems and immediately communicate process variations to the inspector-in-charge (IIC). HACCP systems address food safety concerns, and process control systems address other consumer protection concerns. *Every carcass will receive oversight inspection.* Whenever the plant is slaughtering, oversight inspection will occur.

Unlike the current system, where slaughter inspectors are assigned to fixed points along the slaughter line, under the models, inspectors may be assigned to perform oversight inspection at any point in the slaughter process. Inspectors may perform oversight inspection at places where plant employees are monitoring critical control points, at points where critical equipment such as poultry eviscerators are operating, or at the location where live animals and birds are arriving at the plant. In addition to performing oversight inspection at varied locations, inspectors will rotate through oversight inspection assignments. Under the current system, individual inspectors often spend long periods of time at one location, looking at carcasses that are highly uniform. Under the models, the IIC will determine where oversight inspection will be conducted and will assign a large portion of oversight inspection resources to sanitary dressing operations--removing inedible portions and making sure the edible portions are suitable for human consumption.

Inspectors conducting oversight inspection will be equipped with modern technology to immediately report to the IIC any observations of process variation beyond normal variation at their assigned locations. Food production processes are expected to vary throughout the day, and process control systems are designed to define normal variation and respond to it. At the time an oversight inspector observes a variation, he or she may not know if, down the line, the system catches and responds suitably to that variation. For example, the eviscerating equipment in a poultry plant may not be perfectly aligned for the size birds that have arrived that morning--as a result, an unusual portion of carcasses may be contaminated. The oversight inspector will immediately communicate this information to the IIC, who will decide how to respond.

Verification inspection

Verification is the other type of slaughter inspection under the new system. It consists of inspectors taking samples of products and plant records and carefully examining them. In examining these samples, verification inspectors will use a variety of scientific and technical methods to make sure that regulatory requirements have been met by the plant's control systems.

The frequency with which verification inspections will be conducted will be driven by two factors. There will be a routine or steady-state frequency designed to confirm successful performance. If successful, eventually this frequency will be incorporated into the agency's Performance Based Inspection System (PBIS)--the automated system through which inspection assignments are communicated and results reported. In addition, the IIC may choose to assign extra verification inspection procedures in response to oversight inspection findings reported to him or her. This strategic assignment of extra verification inspections will enhance the capacity of the regulatory system to hold establishments accountable for the continuous successful operation of their HACCP and other process control systems.

Verification inspection procedures will be carried out by inspectors after the company's process control systems have been completed. The slaughter process is generally considered to be complete after final washing and before carcasses enter the process for reducing temperatures. Thus, in poultry establishments, for example, samples taken after the final

wash but before carcasses enter the chiller will be carefully examined for a variety of food safety and other consumer protection defects that should be removed by this point.

Staffing Implications

The Agency has no plans to reduce its workforce. FSIS does, however, expect that its new slaughter inspection procedures will result in a need for fewer in-plant inspectors. Initially, in these five plants, FSIS will have one inspector per line for oversight, one or more inspectors per plant for verification, and one veterinarian per plant. Inspectors not needed in these plants will be used to cover existing vacancies as well as to perform in-distribution activities.

Regulatory Action by Inspection Personnel

Under the models, plants are required to take corrective action if their process control systems are not producing products meeting Federal standards. The authority of inspection personnel to take action in plants will be the same as in plants operating under traditional inspection. Inspectors have the authority to stop the line as appropriate, retain product that they believe is adulterated or misbranded, to withhold the marks of inspection, and to reject facilities, equipment, or any parts of the plant they determine are not in compliance with the regulations.

For Additional Information

General inquiries on the models project:

- Patricia Stolfa, leader, Steering Committee on the HACCP-based Inspection Models Project, (202) 205-0699
- Michael Grasso, special assistant, Office of Policy, Program Development, and Evaluation, (202) 205-0010

FSIS Steering committee on the HACCP-based Inspection Models Project:

- John McCutcheon, Office of Field Operations, (202) 720-5190
- William James, Office of Public Health and Science, (202) 501-7321
- Marlin Waller, Office of Management, (202) 720-4828
- Cheryl Hicks, Food Safety Executive Management and Coordination Staff, (202) 690-3881
- Danielle Schor, Congressional and Public Affairs Staff, (202) 690-0997.

Media Inquiries: (202) 720-9113

Congressional Inquiries: (202) 720-3897

Constituent Inquiries: (202) 720-8594

Consumer Inquiries: Call USDA's Meat and Poultry Hotline at 1-800-535-4555. In the Washington, DC, area, call (202) 720-3333. The TTY number is 1-800-256-7072.

FSIS Web site: <http://www.fsis.usda.gov>

For Further Information Contact:
FSIS Congressional and Public Affairs Staff
Phone: (202) 720-3897
Fax: (202) 720-5704

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United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

OCT - 2 2006

Dr. Peter W. de Leeuw
Chief Veterinary Officer
Ministry of Agriculture, Nature and Food Quality
PO Box 19506
2500 CM, the Hague
Netherlands

Dear Dr. de Leeuw:

This letter is in response to the July 14, 2006, letter from Dr. Martijn Weijtens, Deputy Chief Veterinary Officer, in which he provided results of the pilot project on visual post-mortem inspection of swine and provided information on the reorganization of the meat inspection system in the Netherlands, and requested a follow-up meeting to further discuss the following two issues:

1. Use of visual post-mortem inspection for swine carcasses in establishments certified to export to the United States. In the letter, Dr. Weijtens indicates that visual post-mortem inspection has become a normal inspection procedure in certain slaughter establishments that are certified for export to the United States.
2. Use of auxiliaries to conduct certain post-mortem inspection activities in establishments certified to export to the United States. The letter is not clear as to whether auxiliaries are currently being used to conduct these post-mortem activities. We understand that the use of auxiliaries is based on provisions contained in EC 852/2004 and EC 854/2004.

We would be pleased to discuss these issues further in a teleconference and are working to arrange such a call. However, we want to make it clear that when a Netherlands establishment is producing product destined for the United States, neither of these proposed changes can be used until FSIS completes an equivalence determination. If the changes have already been instituted in U.S.-certified establishments, and cannot be reversed, these establishments should suspend exports to the United States.

If you have questions regarding this matter, you may reach me by telephone at 202-720-3187, by facsimile at 202-690-4040 or electronic mail at sally.white@fsis.usda.gov.

Sincerely,

Sally White
Director
International Equivalence Staff
Office of International Affairs

Mughal, Ghias

From: Seebohm, Scott
Sent: Friday, November 17, 2006 9:30 AM
To: Mughal, Ghias
Cc: Smith, David
Subject: RE: additional articles and revised answer Q6 reg. visual inspection

Ghias,

Comments on the additional references:

1. Wallace and Hannah, "Mycobacterium avium Complex Infection in Patients with the Acquired Immunodeficiency Syndrome." This paper describes findings related to MAC infections in AIDS individuals. It has little relevance to the present equivalence determination.
2. "Summary of thesis: Incision of heart during meat inspection of pigs: a risk analysis approach." This paper finds that heart incision has little importance for public health. The issue is not relevant to the current equivalence determination since the US doesn't incise swine hearts at inspection.
3. "Audit and verification procedures regarding supply chain meat inspection." This is a written summary of the information provided during the meeting regarding verification activities, including slaughterhouse and on-farm verification activities.

Scott Seebohm, DVM
 Staff Officer
 FSIS Technical Service Center
 402-344-5000 / 800-233-3935

From: Mughal, Ghias
Sent: Wednesday, November 15, 2006 3:59 PM
To: Seebohm, Scott
Subject: FW: additional articles and revised answer Q6 reg. visual inspection

Scott, you were absolutely correct. I forgot to send you these and other set that came in this week. Here is one set. I will send the other set separately.
 Thanks

M. Ghias Mughal, DVM; M.S; Ph.D.
 Senior Equivalence Officer,
 Office of International Affairs
 USDA, Food Safety and Inspection Service
 1400 Independence Avenue, SW
 Washington, DC 20250
 Phone: 202 720-6400
 Email: ghias.mughal@fsis.usda.gov

-----Original Message-----

From: Mughal, Ghias
Sent: Tuesday, November 14, 2006 1:17 PM
To: Proudie, Robin
Cc: White, Sally; Smith, David; Goodwin, Nancy

11/17/2006

Subject: FW: additional articles and revised answer Q6 reg. visual inspect ion

Robin,
These documents just came in from NL. Please make copies and log these also.

David/Scott,
Please review these also and send me your comments ASAP.

M. Ghias Mughal, DVM;M.S; Ph.D.
Senior Equivalence Officer,
Office of International Affairs
USDA, Food Safety and Inspection Service
1400 Independence Avenue, SW
Washington, DC 20250
Phone: 202 720-6400
Email: ghias.mughal@fsis.usda.gov

-----Original Message-----

From: Hennecken, drs. M. (Martin) [mailto:m.hennecken@minlnv.nl]
Sent: Tuesday, November 14, 2006 7:47 AM
To: Mughal, Ghias
Cc: Jelsma, drs. A. (Ate); Weijtens, dr. M.J.B.M. (Martijn)
Subject: FW: additional articles and revised answer Q6 reg. visual inspect ion

Dear Dr. Mughal,

hereby you will receive more additional documents/ articles as promised in my mail from 7 Nov.

1. question 4, ref 4 (Wallace JM, Hannah JB. Mycobacterium avium complex infection in patients with the acquired immunodeficiency syndrome. A clinicopathologic study. Chest. 1988 May;93(5):926-32.)

2. question 10, ref 5.(R. Fries und J. Leps, Die Incision des Herzens beim Schwein, Fleischwirtschaft, vol 10, 2005, p. 116-119.):
At the moment the authors of this article are preparing an English version of this article for publication in a journal, (most probably Veterinary Quarterly). We have agreed to wait for that publication and not to disturb this proces by translating ourselves. Meanwhile I have found the English summary of the dissertation of the authors on which the article had been based (**J. Leps, Incision of the heart during meat inspection of pigs - A risk analysis approach, dissertation FU Berlin, 2003**) I have attached the summary (English summary starts on page 5) and a document (index) with the abstract and further details. Most propably you will find this summary suitable enough for your purposes. Please let me know if you still need the English article; we will send it as soon as it is published.

3. question 6, revised answer on verification procedures: as agreed during the last meeting.
This document refers to another VWA procedure document "**System Audit from Start 'til End**". This document is in the process of being translated and will be sent to you as soon as it is available.

Furthermore, as soon as Q10, ref 1,3 en 4 have been translated I will send them to you.

Kind regards

Martin Hennecken

-----Oorspronkelijk bericht-----

Van: Hennecken, drs. M. (Martin)
Verzonden: dinsdag 7 november 2006 15:40
Aan: 'Mughal, Ghias'

11/17/2006

CC: Weijtens, dr. M.J.B.M. (Martijn); Jelsma, drs. A. (Ate); Hardenberg, I. (Inge) (VD)

Onderwerp: Expert meeting with FSIS and the Netherlands reg. visual inspection

Dear Dr. Mughal,

on behalf of Dr Weijtens I will send you herewith a "package" of additional articles, which have been mentioned in our report as a reference.

Most of these articles are in English, but 4 articles (question 10) have to be translated first. Unfortunately this will take some time, so you will receive them as soon as the translation has been completed. 2 other documents (q4ref1 and q4ref4) will be sent later.

Beneath you find a list of the articles which you will receive today (with several e-mails due to the size of the attachments) and 4 articles as soon as possible after translation has been completed.

If you miss any reference article in this list that had been agreed to send to you please let me know. I will arrange that asap.

Regards

Martin Hennecken

Drs. Martin Hennecken

Beleidsmedewerker vleeshygiëne

Directie Voedselkwaliteit en Diergezondheid

Ministerie van Landbouw, Natuur en Voedselkwaliteit

Adres: Bezuidenhoutseweg 73

Postbus: 20401, 2500 EK Den Haag

E-mail: m.hennecken@minlnv.nl

Telefoon: 070-3784289

Telefax: 070-3786389

Question 4:

Additional document: Justification for sampling of *Mycobacterium avium* in pork with regard to supply chain meat inspection (06-11-06)

References to additional document:

* New classification system for slaughter pig herds in the Danish surveillance- and-control program: L. Alban et.al., Prev.Vet. Med. 2002 (SDOC1268.pdf)

* *Trichinae* certification in the United States Pork industry: D.G. Pyburn et.al., Vet. Parasitology, 2005 (SDOC1267.pdf)

References Question 4:

1) Inderlied CB, Kemper CA, Bermudez LE. The *Mycobacterium avium* complex. Clin Microbiol Rev. 1993 Jul;6(3):266-310. Review. **(will be sent later)**

2) Komijn, RE., PEW de Haas, ME Schneider, T Eger, JHM Nieuwenhuis, RJ van den Hoek, D. Bakker, FG van Zijderveld and D van Soelingen. Prevalence of *Mycobacterium avium* in Slaughter Pigs in The Netherlands and Comparison of IS1245 Restriction Fragment Length Polymorphism Patterns of Porcine and Human Isolates. J of Clin Microb, 1999, 37, 1254-1259

3) Komijn, RE., HJ. Wisselink, VMC. Rijsman, N. Stockhofe-Zurwieden, D. Bakker, FG. van Zijderveld, T. Eger, JA. Wagenaar, FF. Putirulan and BAP. Urlings, Prevalence of *Mycobacterium avium* subsp. *avium* in lymphnodes of slaughter pigs in The Netherlands. Accepted for publication in Veterinary Microbiology (2007)

4) Wallace JM, Hannah JB. *Mycobacterium avium* complex infection in patients with the acquired immunodeficiency syndrome. A clinicopathologic study. Chest. 1988 May;93 (5):926-32. **(will be sent later)**

5) Wisselink, HM, C van Solt-Smits, N Stockhofe-Zurwieden, H Bergen-Buys, P. Overduin, M van Prehn, D van Soelingen and J Thole. Comparison of visual and bacteriological examination of mandibular and mesenteric lymphnodes in pigs, experimentally infected with *Mycobacterium avium subsp. Avium*. IPVS Conference Copenhagen 2007.

References question 10:

1. W. Wouda et. al. , Endocarditis en vleeskeuring bij slachtvarkens, Tijdschrift voor Diergeneeskunde, deel 112, afl. 21, 1987, p. 1226-1235 **(will be translated and sent later)**
2. Masanori Katsumi et. al, Bacterial Isolation from slaughtered pigs associated with endocarditis, especially the isolation of *Streptococcus suis*, Journal of veterinary medical science, vol. 59, 1997, p. 75-78
3. U. Narucka et. al., Afwijkingen bij slachtdieren, Tijdschrift voor Diergeneeskunde, deel 110, afl. 19, 1985, p. 776-779 **(will be translated and sent later)**
4. W. Wouda et. al. , Endocarditis en vleeskeuring bij slachtvarkens, Tijdschrift voor diergeneeskunde, deel 112, afl. 21, 1987, p. 1236-1242. **(will be translated and sent later)**
5. R. Fries und J. Leps, Die Incision des Herzens beim Schwein, Fleischwirtschaft, vol 10, 2005, p. 116-119. **(will be translated and sent later)**
6. C. Tarrads et. al., Identification of *Streptococcus suis* Isolated from Swine: Proposal for Biochemical Parameters, journal of clinical microbiology, vol. 32, 1994, p. 578-580
7. J.J. Staats et. al., *Streptococcus Suis*: past and present, Veterinary research communications, vol. 21, 1997, p. 381-407.
8. Yu-Tsung Huang et. al., *Streptococcus suis* infection, Journal of Microbiol Immunol Infect, vol. 38, 2005, p. 306-313.

References reg. Annex salmonella:

1. Petersen JV, Andersen JK, Sorensen F, Knudsen H. Food safety on the slaughterline: inspection of pig heads. Vet Rec. 2002 Jun 22;150(25):782-4. Review.
2. Swanenburg M, van der Wolf PJ, Urlings HA, Snijders JM, van Knapen F. Salmonella in slaughter pigs: the effect of logistic slaughter procedures of pigs on the prevalence of Salmonella in pork. Int J Food Microbiol. 2001 Nov 8;70(3):231-42.
3. Swanenburg M, Berends BR, Urlings HA, Snijders JM, van Knapen F. Epidemiological investigations into the sources of Salmonella contamination of pork. Berl Munch Tierarztl Wochenschr. 2001 Sep-Oct;114(9-10):356-9.
4. Berends BR, Van Knapen F, Snijders JM, Mossel DA. Identification and quantification of risk factors regarding Salmonella spp. on pork carcasses. Int J Food Microbiol. 1997 May 20;36(2-3):199-206.
5. Swanenburg M, Urlings HA, Snijders JM, Keuzenkamp DA, van Knapen F. Salmonella in slaughter pigs: prevalence, serotypes and critical control points during slaughter in two slaughterhouses. Int J Food Microbiol. 2001 Nov 8;70(3):243-54.
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7. "salmonella monitoring" report made during the pilot "supply chain inspection" 2005-2006 in Helmond, the Netherlands
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Mughal, Ghias

From: Mughal, Ghias
Sent: Tuesday, February 20, 2007 2:07 PM
To: White, Sally
Cc: James, William; Smith, David
Subject: RE: Dr. Raymond's questions with answers on NL- Visual-

Sally,
I have forwarded this e-mail to David Smith also. Dr. Smith and I are getting together in next few minutes to go over Dr. Sutton's response and I will send you our comments shortly. Thanks. Ghias

M. Ghias Mughal, DVM;M.S; Ph.D.
Senior Equivalence Officer,
Office of International Affairs
USDA, Food Safety and Inspection Service
1400 Independence Avenue, SW
Washington, DC 20250
Phone: 202 720-6400
Email: ghias.mughal@fsis.usda.gov

-----Original Message-----

From: White, Sally
Sent: Tuesday, February 20, 2007 1:54 PM
To: Mughal, Ghias
Cc: James, William
Subject: Fw: Dr. Raymond's questions with answers on NL- Visual-

This is your top priority. Please cc me on your response...also Bill.

Sent from my BlackBerry Wireless Handheld

-----Original Message-----

From: Dey, Bhabani <Bhabani.Dey@fsis.usda.gov>
To: White, Sally <Sally.White@fsis.usda.gov>
CC: Thaler, Alice <Alice.Thaler@fsis.usda.gov>; Sutton, Mary <Mary.Sutton@fsis.usda.gov>
Sent: Tue Feb 20 13:49:32 2007
Subject: FW: Dr. Raymond's questions with answers on NL- Visual-

Mrs. White:

Here is the response from Dr. Sutton.
Bhabani

Alice, here is what I have in general terms. Whether the test is reliable or how specific and sensitive it is will rely on how well the ELISA has been designed for use in hogs. If you have any specifics on the serological test they are using or where I could look at their peer review on the study validating the test, please let me know.

<<Serological Testing of Hogs for Mycobacterium avium.doc>>

B.P.Dey, DVM, MS, MPH, PhD.
Room 341 Aerospace Bldg.
Washington, DC 20250
ph - 202-690-2676
fx - 202-720-8213
email: bhabani.dey@fsis.usda.gov

-----Original Message-----

From: Thaler, Alice
Sent: Friday, February 16, 2007 9:44 AM
To: White, Sally
Cc: Sutton, Mary; Dey, Bhabani
Subject: Dr. Raymond's questions with answers on NL- Visual-

Terri Sutton/pathologist FSIS Eastern Lab has agreed to handle this request for information. Incoming is attached.

<<Further clarification on Dr. Raymond's Q..doc>>

Alice M. Thaler, DVM, DACVPM
Senior Director for Program Services
Office of Public Health Science
202-690-2687
Fax 202-720-8213
alice.thaler@fsis.usda.gov

Tracking:

Recipient

White, Sally
James, William
Smith, David

Read

Read: 2/20/2007 2:24 PM

Mughal, Ghias

From: White, Sally
Sent: Tuesday, February 20, 2007 1:54 PM
To: Mughal, Ghias
Cc: James, William
Subject: Fw: Dr. Raymond's questions with answers on NL- Visual-

This is your top priority. Please cc me on your response...also Bill.

Sent from my BlackBerry Wireless Handheld

-----Original Message-----

From: Dey, Bhabani <Bhabani.Dey@fsis.usda.gov>
To: White, Sally <Sally.White@fsis.usda.gov>
CC: Thaler, Alice <Alice.Thaler@fsis.usda.gov>; Sutton, Mary <Mary.Sutton@fsis.usda.gov>
Sent: Tue Feb 20 13:49:32 2007
Subject: FW: Dr. Raymond's questions with answers on NL- Visual-

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Serological Testing
of Hogs fo...

<<Serological Test of Hogs for Mycobacterium avium.doc>>

B.P.Dey, DVM, MS, MPH, PhD.
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fx - 202-720-8213
email: bhabani.dey@fsis.usda.gov

Sutton

*Rec - info
① → what you need for
② →*

-----Original Message-----

From: Thaler, Alice
Sent: Friday, February 16, 2007 9:44 AM
To: White, Sally
Cc: Sutton, Mary; Dey, Bhabani
Subject: Dr. Raymond's questions with answers on NL- Visual-

Terri Sutton/pathologist FSIS Eastern Lab has agreed to handle this request for



Further clarification
on Dr. R...

information. In coming is attached.

<<Further clarification on Dr. Raymond's Q..doc>>

Alice M. Thaler, DVM, DACVPM

Senior Director for Program Services
Office of Public Health Science
202-690-2687
Fax 202-720-8213
alice.thaler@fsis.usda.gov

Serological Testing of Hogs for Mycobacterium avium

Alice, I am going to give you a preliminary response to the question posed by Drs. Raymond and Mann. In order to really give an accurate response, we would need to know what kind of serological test the Netherlands is using and find out what the sensitivity and specificity of the test in hogs from their data. I am assuming that the Netherlands is using an ELISA since their website indicates that, " - recently an ELISA assay for the serological detection of antibodies against MAA in pigs has become available. However, the test characteristics of this ELISA assay are not established yet. " I assume that the ELISA detects LAM-A (derived from Mycobacterium avium) or other cell wall component. I had read that the Pasteur Institute in Bucharest had developed an ELISA using LAM-A (derived from Mycobacterium avium spp. avium); although I have no evidence that this is the test that is being done in hogs in the Netherlands. I am still looking for a peer reviewed article about that method.

Many ELISAs used to detect Mycobacterium detect a component of the mycobacterial cell wall, like lipoarabinomannin (LAM). One of the hardest problems to correct with these analyses is that although they are fairly sensitive, there is a cross reaction problem with other mycobacterial organisms (lack of specificity). To correct this problem, many of the tests absorb their sera against other strains of mycobacteria (for example M. phlei). By doing this, and by using LAM derived from the strain of organisms that they wish to detect, they have reduced the cross reactivity due to other strains of Mycobacterium.

In general, the reliability of an ELISA to detect mycobacterium varies widely with the species of mycobacterium one is trying to detect and the species of animal that is being tested. For example, in detecting human TB, ELISA based tests are still of limited use, although the ELISA based tests are improving. One study I remember indicated that a specific ELISA test detected 76% of active tuberculosis infections in patients - where the time honored sputum test detection of active cases was lower, sometimes around 50%.

On the other hand, ELISA tests are the most sensitive and specific test for the detection of paratuberculosis (caused by Mycobacterium avium spp. paratuberculosis) in cattle. Sensitivity is comparable to complement fixation (CF) in clinical cases, but better than CF in subclinically infected carriers. Cross reactions with other strains of Mycobacterium (like M. avium) have been decreased by absorption of sera against M. phlei. In cattle, one kit was found to have sensitivity in clinical cases of 88.3% and a specificity of 99.8%; in sheep a sensitivity of 35-54% and specificity of 98.2-98.5% was reported. Although there are several commercially available ELISA tests for the detection of paratuberculosis in cattle, the sensitivity in ruminants (other than bovids) is generally much lower than in cattle.

If you have any information on the specific ELISA the Dutch are using please forward it to me. I will keep looking through available sources until I hear from you.

I did check with the TB group of APHIS (NVSL, Ames, IA) about the commercial availability of an ELISA for Mycobacterium avium in hogs. They indicated that they

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were unaware of any commercially available ELISA for use in hogs and that they didn't know of anyone in the US researching such a product.

Thank you.

Question 1 What other diseases were detected in the 2,116,536 swine study in the Netherlands? **(Dr. Raymond)**

ANS:

This study was done from Jan 2004 to August 2004 and focused only on the prevalence of granulomatous lesions found in the sub-maxillary (mandibular) lymph nodes.

- This study describes analysis of granulomatous lesions from mandibular lesions selected from farms with a high prevalence of mandibular lymph node lesions.
- It was a focused research study on the prevalence of *M. avium*. No data on prevalence on any other diseases was collected
- The researchers were unable to isolate *M. avium* from any lesions, but isolated *Rhodococcus equi* from many of the affected lymph nodes.
- The study was used as a support to show that incidence of *M. avium* was low in swine herds in the Netherlands..
- **Reference:** Wisselink HJ, Rijsman VMC, Stockhofe-Zurweiden N, Bakker D, van Zijderveld FG, Eger T, Wagenaar JA, Putirulan FF, Urlings B. Granulomatous lesions in lymph nodes of slaughter pigs bacteriologically negative for *Mycobacterium avium* subsp. *avium* and positive for *Rhodococcus equi*. Accepted for publication 2007).

Q. 2. What diseases were found in during the pilot study done on 174,250 swine in the Netherlands? **(Dr. Raymond and Dr. Mann)**

ANS:

- Focus of the study was diseases related to Food safety and public health. Lesions associated with the following three zoonotic diseases were observed on post-mortem examination during the pilot.
 1. Endocarditis in swine due to *E rhusiopathiae* (causes local dermatitis in humans)
 2. Infections due to *Rhodococcus equi*- granulomatous lesions in the lymph nodes of swine- (can cause pneumonia in HIV patients)
 3. *M. avium* infections- granulomatous lesion in the lymph nodes of swine (can cause respiratory tract infections in HIV patients)
- Inspectors who performed visual inspection missed lesions in nine carcasses. These carcasses were in rejected by the inspectors who performed traditional inspection. Following is detail of the lesions found:

1. infected legs/ abscesses in legs-----	3
2. Endocarditis-----	1
3. Jaundice---	1
4. Osteomyelitis -----	1
5. Tail abscesses-----	3

Total carcasses rejected during the traditional inspection: 9

Reference: Draft report of the pilot on Visual Inspection and the Netherlands answers to FSIS questions, 2006.

- Q. 3. a) Is the tuberculin testing a surveillance tools in these hog farms?
b) Is serological testing a reliable test (**Dr. Mann**)

ANS:

Both serological testing and Tuberculin testing was performed.

From each lot of pigs sent to slaughter house, 2 - 6 blood samples are taken for blood testing. A farm can only be qualified to participate in the visual inspection program only when 18 subsequent blood samples are found negative by ELISA test.

When lot from a farm repeated serologically tested positive for *M. avium*, these farms were visited by the VION group (Producer) and the accredited veterinarian for additional tests. These tests consist of tuberculin testing and further evaluation of the farm. Lymph nodes from the tested hogs are sent to lab and analyzed for the presence of *M. avium*.

Reference: Draft report of the pilot on Visual Inspection and the Netherlands answers to FSIS questions, 2006.

Notes:

OIA had a follow-up meeting (on 1-25-07)

Dr. James collecting further information on the following would help in clarifying answers:

1. Information on other zoonotic diseases found the Netherlands. I contacted Dr. Kristin Holt (FSIS liaison at the CDC). She responded to me on 2/5/07 that Netherlands participates in a surveillance system similar to CDC (European **Centre for Disease Prevention and Control**). – I have not had a chance to follow up on this lead thus far. I will do it immediately on return to the office.

2. I was asked to contact Dr. Alice Thaler to get more information on Dr. Mann's question relating to the reliability of serological test for *M. avium*. – I sent an E-mail to Dr. Thaler on 1-26-07 requesting name of a person I could contact to discuss the issue and I have not seen a response.

Mughal, Ghias

From: Sutton, Mary
Sent: Friday, March 02, 2007 6:22 PM
To: Mughal, Ghias
Subject: RE: Visual Inspection: Need more information

Dr. Mughal,

In this email, I have limited myself to evaluating the ELISA as a way reliable way to detect MAA infected hogs, not whether it is or could be equivalent to incision/ palpation of lymph nodes. The information in the article from the Netherlands has raised more questions than it has answered for me. The ELISA that they developed was able to detect about 70 - 75% of the Mycobacterium avium subspecies avium (MAA) experimentally infected hogs (32 hogs infected experimentally). This level of detection corresponds to some of the ELISA methods developed to detect M. tuberculosis - bovis infections in people (these detect about 3/4 of the people with active M. TB lesions). About 50% of the experimentally infected hogs had granulomatous lesions in the mandibular and/or mesenteric lymph nodes. From the data summarized in the article, I would say that the ELISA was sensitive enough to detect about 3/4 of the hogs infected with MAA serotype 4 strain 17404.

The data doesn't give me any real good grasp of the specificity of this ELISA method. The hogs were infected with the same strain of MAA that the ELISA antigen was isolated from. There is no data addressing whether there is cross reactivity in sera from hogs infected with other strains of MAA, other non-TB group mycobacterium or organisms from the Mycobacterium TB-bovis group. Nor is there any survey data comparing serological results using the experimental ELISA to the presence of granulomatous lesions in the mandibular and/or mesenteric lymph nodes and the culture results from slaughter hogs. Information from both of these types studies would be important to determine how this ELISA method compares to physical examination of mandibular and mesenteric lymph nodes to detect active infection with MAA.

The data presented about the MAA serotype 4 strain 17404 ELISA is an encouraging step forward, but doesn't give me the information needed to evaluate how good a test it will be to detect MAA infected herds.

Mary T. Sutton, DVM, MS
Chief, Pathology Branch
Eastern Laboratory, OPHS, FSIS, USDA
Russell Research Center
950 College Station Road
Athens, GA 0605
PH: 706-546-3556 FAX: 706-546-3589

-----Original Message-----

From: Mughal, Ghias
Sent: Thursday, March 01, 2007 3:40 PM
To: Sutton, Mary
Subject: RE: Visual Inspection: Need more information

That is great. You can let her read the material.

M. Ghias Mughal, DVM;M.S; Ph.D.
Senior Equivalence Officer,
Office of International Affairs
USDA, Food Safety and Inspection Service
1400 Independence Avenue, SW
Washington, DC 20250
Phone: 202 720-6400
Email: ghias.mughal@fsis.usda.gov

4/16/2007

- The data submitted by the Netherlands did not address the specificity of this method. They only used one strain of *M. avium*- MAA serotype 4, strain 17404 during the experiment. They did not show if there was a cross reactivity in sera of hogs infected with other strains of MAA, other non-TB group mycobacterium or organisms from the Mycobacterium-bovis group.
- Based on the Netherlands' data, the ELISA test, by itself, is not the most reliable test for the detection of MAA. However, the ELISA test, in combination with the following safeguards, can become a reliable test for the detection of MAA:
 - The production/slaughter of the market hogs is a vertically integrated operation,
 - There is a established frequency of follow-up testing ^{by} for MAA,
 - No hogs, imported from any other country, are allowed in the program,
 - There is a TB testing program for the farm workers,
 - There is an environmental testing program for MAA, e.g., testing of bedding, house environment, etc., and
 - The participating companies have a control program for control of insects and other pests.

It was explained to Dr. Sutton that in order for participating companies to be eligible for Visual Inspection, they must have a mandatory quality assurance (QA) program. The QA program is approved and verified by the Netherlands' inspection service on routine basis. The QA program must contain all six safeguards mentioned above and she agreed that with all these safeguards the ELISA test is a step forward and provides added level of assurance for detection of TB in market hogs.

Participants:

Dr. Terry Sutton, OPHS

Dr. David Smith, OIA

Dr. Ghias Mughal, OIA

Mughal, Ghias

From: Steven McDermott (b) (6) [REDACTED]@hotmail.com]
Sent: Sunday, April 15, 2007 2:37 PM
To: Mughal, Ghias
Cc: McDermott, Steve
Subject: Netherlands Serological Testing for Mycobacterium

Ghias

See if you agree with the following summary and we can discuss in the morning.

FSIS did receive information from the Netherlands regarding serological testing for Mycobacterium. This information was discussed with Dr. Terry Sutton, pathologist at FSIS Eastern Laboratory. Dr. Sutton had the following comments:

The ELISA (serological) test used by the Netherlands is sensitive enough to detect about 75% of the hogs infected with *M. avium* subspecies *avium* (MAA). The data submitted by the Netherlands did not address the specificity of the ELISA method. They only used one strain of *M. avium*, i.e., the MAA serotype 4, strain. The data did not show if there was a cross reactivity in sera of hogs infected with other strains of MAA, other non-TB group mycobacterium or organisms from the Mycobacterium-*bovis* group. Based on the Netherlands' data, the ELISA test, by itself, is not the most reliable test for the detection of MAA. However, the ELISA test can become a reliable test for the detection of MAA if it is combined with the following safeguards proposed by the Netherlands:

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- o The participating companies have a program for controlling insects and other pests.

It is also important to note that FSIS no longer considers TB as a food borne disease of public health significance caused by the consumption of meat. This is based on a decision made by FSIS in April 2004 with regard to changing the curriculum for its public health veterinarian training.

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http://im.live.com/messenger/im/home/?source=TAGHM_APR07

Brief of NL *Avian Report.*
Tues

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8-7-07

Steve,

Yesterday afternoon (8-6-07), I called APHIS- VS office in Maryland to check if APHIS would have any concerns about missing a disease(s) in market hogs of Netherlands going through visual post mortem inspection. I posed this question to Drs. Christopher Robinson and Lynette Williams after I explained to them FSIS traditional inspection procedures for market hogs and Netherlands visual inspection procedures and pointed out the differences between these procedures. I also inquired about list of the diseases of market hogs in Netherlands that APHIS considers to be important. They gave me the following list

- Food and Mouth Disease (FMD)
- Classical Swine Fever
- African Swine Fever
- Swine Vesicular Disease

Both of them said APHIS regulations refer to only one disease on Ante-mortem - FMD

Both stated that visual inspection would not impact on detection of any of the above diseases.

M. Ghias Mughal, DVM; M.S; Ph.D.

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Email: ghias.mughal@fsis.usda.gov

ISSUE ALERT: FSIS Determines Netherlands' Alternate Post-Mortem Inspection Procedure for Market Hogs is Equivalent

ISSUE: FSIS has conducted an equivalence review of the Netherlands' request to use an alternate post-mortem inspection procedure for market hogs slaughtered for export to the United States. The alternate procedure – visual inspection of the carcass and viscera – would occur in lieu of traditional post-mortem inspection procedures of incising the mandibular lymph nodes, palpating the mesenteric, portal and bronchial lymph nodes, turning the lungs and liver, and grasping and turning the kidneys.

BACKGROUND: A team of FSIS experts from OPPED and OIA reviewed the Netherlands' visual inspection procedures, scientific studies, and other supporting documents and information presented by Netherlands government officials during an FSIS-Netherlands bilateral meeting held November 1-2, 2006, in Washington, DC. The team evaluated the Netherlands' visual post-mortem inspection procedures against the two FSIS post-mortem inspection procedures [Traditional Inspection and HACCP-Based Inspection Models Project (HIMP)] currently conducted for market hogs slaughtered in the United States.

The basis of the Netherlands' alternative procedure is its use of pre-slaughter data collection and post-mortem inspection verification to ensure the identification and removal of sick animals and adulterated carcasses and parts from the food supply, and that the prevalence of *Mycobacterium avium*, the primary cause of Tuberculosis in swine, is very low. Pre-slaughter data collection is accomplished through a system called "Supply Chain Inspection," which is an integrated quality assurance program with comprehensive controls over the production chain requirements for feed, hygiene, the use of veterinary drugs, transport of animals, and animal welfare. The Netherlands' inspection system has legal jurisdiction over on-farm production. Market hogs processed under this program will continue to receive ante-mortem inspection, and visual post-mortem inspection will be conducted on the head, viscera, and carcass of all carcasses. If any abnormalities are discovered during visual inspection, the carcass will undergo traditional post-mortem inspection. In addition, all market hogs slaughtered for export to the United States must be born and raised in the Netherlands, and the farms must qualify as a neutral or low risk farm based on ongoing serological surveillance for *Mycobacterium avium*.

FSIS' traditional post-mortem inspection procedures for market hogs include incision, observation, and palpation, as applicable, of the head, viscera, and carcass. FSIS' HIMP post-mortem inspection procedures are very similar to the Netherlands' visual inspection procedure in that the FSIS inspector performs only a visual inspection, with no palpations or incisions. In both cases, the FSIS inspection procedures are intended to identify and remove unwholesome and adulterated carcasses and parts thereof from the food supply.

This equivalence decision is significant because other EU Member States are expected to request a similar equivalence determination for market hogs slaughtered for export to the United States.

TRADE IMPACT: The United States imported 7,762,202 pounds of pork products from the Netherlands from January 1 through November 30, 2006.

NEXT STEPS: FSIS will send a letter to the Netherlands informing meat inspection officials of its equivalence decision, and will observe the program in-practice during the next on-site audit of the Netherlands meat inspection system to verify implementation standards.

FSIS-OIA-Dec. 13, 2006

BRIEFING NOTES – NETHERLANDS

Equivalence Submission

- The Netherlands' Ministry of Agriculture, Nature and Food Quality submitted a request in 2006 to the Food Safety and Inspection Service (FSIS) to use an alternative inspection system in Netherlands' establishments slaughtering market hogs for export to the United States.
- The Netherlands' equivalence request is specific to using visual inspection procedures during post-mortem inspection of market hogs.
- Visual inspection is the examination of parts of the slaughtered hog (head, viscera, and carcass) without incising or palpating for identifying and removing adulterated carcasses and parts from the food supply chain.
- Vion Food Group, a supporter of post-mortem visual inspection, currently has six slaughter and processing establishments certified to export to the United States,
- FSIS is still in the evaluation process of the Netherlands' equivalence submission.
- Mr. Wim Tacke, Agricultural Counselor of the Netherlands' Embassy in Washington, DC, has met with FSIS on several occasions regarding this equivalence submission.

FSIS Audit of the Netherlands' Meat Inspection System

- FSIS recently completed an audit of the Netherlands' meat inspection system in March 2007.
- During this audit, the FSIS official identified that a slaughter establishment, a Vion slaughter facility, was operating under visual inspection. Since FSIS has not determined visual inspection to be equivalent to the U.S. inspection system, product produced in this establishment would not be eligible for export to the United States.

USDA-FSIS-OIA-April 12, 2007

Mughal, Ghias

From: White, Sally
Sent: Monday, April 16, 2007 7:28 PM
To: Stuck, Karen; James, William
Cc: Mughal, Ghias; McDermott, Steve
Subject: Fw: Netherlands data

Karen and Bill,
Please see attached a note drafted by Steve and Ghias from me to you. We hope this is helpful. Sally

Sent from my BlackBerry Wireless Handheld

-----Original Message-----

From: McDermott, Steve <Steve.McDermott@fsis.usda.gov>
To: White, Sally <Sally.White@fsis.usda.gov>
CC: Mughal, Ghias <Ghias.Mughal@fsis.usda.gov>
Sent: Mon Apr 16 15:58:28 2007
Subject: Netherlands data



Netherlands - MGM
-Brief on EI...

<<Netherland - MGM -Brief on EILSA Testi for TB in Hogs1.doc>>
I have reviewed Ghias' summary of information. See if you are ok with this. The attachment is written as a memo to Karen and Bill from you.

Steven A. McDermott
Deputy Director, International Equivalence Staff
Office of International Affairs
USDA, Food Safety and Inspection Service
Washington, DC
202-690-0297

Karen / Bill,

We did receive data from the Netherlands regarding serological testing for *Mycobacterium* and Ghias discussed this information with Dr. Terry Sutton, Chief of Pathology Section at FSIS Eastern Laboratory. Dr. Alice Thaler recommended that we discuss the Netherlands' data with Dr. Sutton.

Dr. Sutton had the following comments:

- The Netherlands' study indicates that for hogs infected with *M. avium* subspecies avium (MAA), the sensitivity of the ELISA (serological) test was 75% for hogs tested between 4 and 22 weeks of age.
- The data submitted by the Netherlands did not address the specificity of the ELISA method because only one strain of *M. avium* (MAA serotype 4) was used in the study.
- Based on the Netherlands' data, the ELISA test, by itself, is not the most reliable test for the detection of MAA. However, the ELISA test can become a dependable test for the detection of MAA if it is combined with the safeguards proposed by the Netherlands as part of its equivalence request. These safeguards are:
 - The production/slaughter of the market hogs is a vertically integrated operation,
 - There is an established frequency of follow-up testing for MAA,
 - Only hogs born and raised in Netherlands are allowed in the program,
 - There is a TB testing program for the farm workers,
 - There is an environmental testing program for MAA, e.g., testing of bedding, house environment, etc., and
 - The participating companies have a program for controlling insects and other pests.

It is also important to note the following:

- FSIS no longer considers TB as a food borne disease of public health significance caused by the consumption of meat. This is based on a the current FSIS' Training document (2004) used in the curriculum for its public health veterinarian training.
- FSIS' routine post-mortem inspection procedures have an unknown level of detection for *M. avium*. Dispositions are based on visual inspection after palpation and observation of certain lymph nodes and organs and 100% detection of lesions is not always possible.
- In regard to Dr. Sutton's comments about 75% sensitivity results, I understand that Bill and Ghias also reviewed the Netherlands' data and it showed that the sensitivity increased to about 90% in hogs tested between 20 and 22 weeks of age, which is the slaughter age of market hogs.
- Also, we believe we have found the research paper by J. F. T. Griffin of New Zealand that was mentioned by Dr. Mann. The article is entitled, "Immunoglobulin GI

Enzyme-Linked Immunosorbent Assay for the Diagnosis of Johne's Disease in Red Deer, by J. T. F. Griffin, Evelyn Spittle, Christie R. Rodgers, Simon Liggett, Marc Cooper, Douwe Bakker, and John P. Bannantine. Published in Clinical and Diagnostic Laboratory Immunology, December, 2005, pages 1401 – 1409.

This study was designed to develop a customized enzyme-linked immunosorbent assay (ELISA) for the serodiagnosis of Johne's disease in farm deer. Two antigens were selected on the basis of their superior diagnostic readouts. Sensitivity estimates and test parameters were established using 102 *Mycobacterium paratuberculosis*-infected animals from more than 10 deer herds and specificity estimates were determined using 508 unaffected animals from 5 known disease-free herds. There was 99.5% specificity and sensitivities of 84% and 88% between the two antigens.

The Netherlands also submitted a 2005 study conducted by the University of Wisconsin regarding an evaluation of five ELISA methods used for diagnosis of bovine TB caused by *Mycobacterium avium* subsp. *Paratuberculosis* in dairy cattle in support of their proposal. The results of this study show that the specificity of the three of the five ELISA methods was equal or above 99.8%. Specificity of the other two methods was 84.7% and 94.9%.

- The Netherlands' inspection service has implemented a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects. In the Netherlands, verification of visual inspection takes place on a daily basis (minimum once a day) and is carried out by the official veterinarian.

Definitions:

Sensitivity: An operating characteristic of a diagnostic test that measures the ability of a test to detect a disease (or condition) when it is truly present. Sensitivity is the proportion of all diseased patients for whom there is a positive test, determined as the number of true positives divided by the sum of true positives + false negatives. (Contrast with specificity.)

Specificity: An operating characteristic of a diagnostic test that measures the ability of a test to exclude the presence of a disease (or condition) when it is truly not present. Specificity is the proportion of nondiseased patients for whom there is a correctly negative test, expressed as the number of true negatives divided by the sum of true negatives + false positives. (Contrast with sensitivity.)

Mughal, Ghias

From: James, William
Sent: Sunday, April 15, 2007 1:32 PM
To: Stuck, Karen; McDermott, Steve; White, Sally; Mughal, Ghias
Subject: Re: Roger will call you about Dutch spareribs

IES has that. They can summarize it for Dr R on Monday.

Bill James
International Affairs

-----Original Message-----

From: Stuck, Karen <Karen.Stuck@fsis.usda.gov>
To: James, William <William.James@fsis.usda.gov>; McDermott, Steve <Steve.McDermott@fsis.usda.gov>
Sent: Sat Apr 14 17:11:16 2007
Subject: Fw: Roger will call you about Dutch spareribs

I thought we gave this to Dr. Raymond??

Karen Stuck
FSIS

-----Original Message-----

From: Dick.Raymond@usda.gov <Dick.Raymond@usda.gov>
To: Curt.Mann@usda.gov <Curt.Mann@usda.gov>; Garner, Arriell -USDA <Arriell.Garner@usda.gov>; Myers, Jean -USDA <jean.myers@usda.gov>; Stuck, Karen <Karen.Stuck@fsis.usda.gov>; Goldman, David <David.Goldman@fsis.usda.gov>; Quick, Bryce <Bryce.Quick@fsis.usda.gov>; Derfler, Philip <Philip.Derfler@fsis.usda.gov>; Mughal, Ghias <Ghias.Mughal@fsis.usda.gov>; McDermott, Steve <Steve.McDermott@fsis.usda.gov>; Goodwin, Nancy <Nancy.Goodwin@fsis.usda.gov>; White, Sally <Sally.White@fsis.usda.gov>; McNiff, Barbara <Barbara.McNiff@fsis.usda.gov>; James, William <William.James@fsis.usda.gov>; Danford, Clark <Clark.Danford@fsis.usda.gov>; Smart, Donald <Donald.Smart@fsis.usda.gov>; Stanley, Mary <Mary.Stanley@fsis.usda.gov>
Sent: Sat Apr 14 15:48:40 2007
Subject: RE: Roger will call you about Dutch spareribs

I had regeusted information from them regarding serological testing for Mycobacterium. Did we ever get that information from them?

-----Original Message-----

From: Stuck, Karen -FSISE2K3
To: Raymond, Dick; Mann, Curt; Garner, Arriell; Myers, Jean; Goldman, David -FSISE2K3; Quick, Bryce -FSISE2K3; Derfler, Philip -FSISE2K3; Mughal, Ghias -FSISE2K3; McDermott, Steve -FSISE2K3; Goodwin, Nancy -FSISE2K3; White, Sally -FSISE2K3; McNiff, Barbara -FSISE2K3; James, William -FSISE2K3; Danford, Clark -FSISE2K3; Smart, Donald -FSISE2K3; Stanley, Mary -FSISE2K3
Sent: 4/13/2007 2:45 PM
Subject: FW: Roger will call you about Dutch spareribs

Dr. Raymond: You may be getting a call from the U.S. Ambassador to the Netherlands on the request from the Dutch for equivalence of their visual inspection system for market hogs.

Karen Stuck
Assistant Administrator
Office of International Affairs
FSIS, U.S. Department of Agriculture
Phone 202-720-3473
Fax: 202-690-3856

-----Original Message-----

From: Mughal, Ghias
Sent: Friday, April 13, 2007 2:21 PM
To: James, William; Stuck, Karen
Cc: White, Sally; Goodwin, Nancy; McDermott, Steve
Subject: RE: Roger will call you about Dutch spareribs

Dr. James,
Attached is the revised Netherlands-Issue Brief which incorporates the requested statement. Thanks. Ghias

M. Ghias Mughal, DVM;M.S; Ph.D.
Senior Equivalence Officer,
Office of International Affairs
USDA, Food Safety and Inspection Service
1400 Independence Avenue, SW
Washington, DC 20250
Phone: 202 720-6400
Email: ghias.mughal@fsis.usda.gov

-----Original Message-----

From: James, William
Sent: Friday, April 13, 2007 12:48 PM
To: Mughal, Ghias; Stuck, Karen
Cc: White, Sally; Goodwin, Nancy; McDermott, Steve
Subject: RE: Roger will call you about Dutch spareribs

I think we need a sentence that says we have (or will) tell the Netherlands that product produced under the newly approved system (if approved) will be eligible only if produced after the approval date.

-----Original Message-----

From: Mughal, Ghias
Sent: Friday, April 13, 2007 12:45 PM
To: Stuck, Karen
Cc: White, Sally; Goodwin, Nancy; James, William; McDermott, Steve
Subject: RE: Roger will call you about Dutch spareribs

Karen, attached is a short brief focusing on the meeting with the US Ambassador as you requested.
Thank you,
Ghias

M. Ghias Mughal, DVM;M.S; Ph.D.
Senior Equivalence Officer,
Office of International Affairs
USDA, Food Safety and Inspection Service
1400 Independence Avenue, SW
Washington, DC 20250
Phone: 202 720-6400
Email: ghias.mughal@fsis.usda.gov

-----Original Message-----

From: Stuck, Karen
Sent: Friday, April 13, 2007 8:57 AM
To: McDermott, Steve
Cc: White, Sally; Mughal, Ghias; Goodwin, Nancy; James, William

Subject: Re: Roger will call you about Dutch spareribs

Steve: please prepare a short issue brief on this focusing on the meeting with the US ambassador and impending call to Dr. Raymond. Please get this to me today.

Karen Stuck
FSIS

-----Original Message-----

From: McDermott, Steve <Steve.McDermott@fsis.usda.gov>
To: Stuck, Karen <Karen.Stuck@fsis.usda.gov>
CC: White, Sally <Sally.White@fsis.usda.gov>; Mughal, Ghias <Ghias.Mughal@fsis.usda.gov>; Goodwin, Nancy <Nancy.Goodwin@fsis.usda.gov>
Sent: Fri Apr 13 07:50:17 2007
Subject: Fw: Roger will call you about Dutch spareribs

FYI

Sent from my BlackBerry Wireless Handheld

-----Original Message-----

From: Bob.Flach@USDA.GOV <Bob.Flach@USDA.GOV>
To: McDermott, Steve <Steve.McDermott@fsis.usda.gov>
CC: Roger.Wentzel@USDA.GOV <Roger.Wentzel@USDA.GOV>; (b) (6) @hotmail.com
(b) (6) @hotmail.com>; Marcel.Pinckaers@USDA.GOV <Marcel.Pinckaers@USDA.GOV>
Sent: Fri Apr 13 05:56:07 2007
Subject: Roger will call you about Dutch spareribs

Dear Steve,

It is a few years ago since we met during one of your audits in the Netherlands. I am writing you this mail because of the following:

The Director General of the Dutch MinAg, Mr Ate Oostra, contacted our office yesterday. He requested a meeting with our Ambassador, Mr Arnall, to discuss the Dutch system of visual inspection of slaughterhogs. This morning, Ate Oostra met with Mr Arnall. Because Roger is on holidays this week (he is back in the office on Monday) I was present at the meeting. To summarize the meeting:

Ate Oostra wanted to gently remind the U.S. Government how important a timely approval of the visual inspection of slaughterhogs is for the Dutch Vion Food Group. On the Ambassador's question on how long they could wait, he answered a month or so. At the moment, Vion reportedly stores the shipments destined for the U.S. market in a cold storage. Ate Oostra advocated the visual inspection system. I am sure FSIS has this information readily available, so I do need to summarize this for you.

At the moment we are preparing a memo for the Ambassador. This memo will contain the contact info of Richard Raymond as the person for the Ambassador to contact. So, Mr Arnall might call Mr Raymond regarding this matter. We will give this memo to the Ambassador on Monday.

Today Roger (he is in Paris right now) will try to contact you regarding this matter.

Kindest regards, bob

Bob Flach (Agricultural Specialist)
United States Department of Agriculture, Foreign Agricultural Service U.S. Embassy, Lange Voorhout 102, 2514 EJ The Hague, The Netherlands
Phone: ++31 (0)70 3102 303 Fax: ++31 (0)70 3657 681 <http://www.fas.usda.gov>

<<NETHERLANDS arnell-oostra mtg 4-13-07.doc>>

NETHERLANDS—Issue Brief

Meeting between US Ambassador Arnell and Mr. Ate Oostra, Director General, Ministry of Agriculture, Nature and Food Quality for the Netherlands

- On April 13, US Ambassador Arnell met with the Director General for the Ministry of Agriculture, Nature and Food Quality, Mr. Ate Oostra at the request of Mr. Oostra.
- The discussions centered on a pending equivalence determination from the Food Safety and Inspection Service regarding the Netherlands' request for the use of visual-only inspection of market age hogs.
- FAS, The Hague, reported that Mr. Oostra diplomatically reminded Ambassador Arnell that timely approval of the request is important for the Netherlands and that it was hoped that a decision could be reached and relayed to him within the next 30 days.
- FAS, The Hague, also reported that product produced under visual inspection is being stored in warehouses for eventual export to the United States.
- Ambassador Arnell was advised that Dr. Raymond is the contact point for further information. FAS reported that the Ambassador may call Dr. Raymond to discuss the situation.

BRIEFING NOTES

Meeting with Ate Oostra
(Director General Ministry of Agriculture, Nature and Food Quality)
Concerning Netherlands' Visual Meat Inspection
On April 13, 2007

Dear Ambassador Arnall,

Please find the answers on your questions regarding your meeting with Ate Oostra in this memo. The answers are based on my conversation with Martijn Weijtens, Deputy Chief Veterinary Officer of the Dutch Ministry of Agriculture, Nature and Food Quality.

When did the Vion Food Group started with the visual inspection procedures during post-mortem inspection of market hogs?

In September 2005, the Vion Food Group started a pilot project. In March 2006, they fully implemented the visual inspection procedures.

When did the European Commission (EC) approve the visual inspection of market hogs?

-The EC didn't approve the visual inspection procedures. The procedures don't need to be approved by the EC to be legally applied because they are conforming EC Regulation EC/854/2004. This Regulation is laying down specific rules for the organization of official controls on products of animal origin intended for human consumption.

-In February 2006, the European Food and Veterinary Office (FVO) inspected the Netherlands' meat inspection system. As part of their visit the FVO audited the execution of the visual inspection procedures in practice.

-The official report of the FVO regarding this visit is not yet public, and therefore not yet official. The content of the report is reportedly positive towards the implementation of the Dutch visual inspection procedures.

What is the percentage of hogs undergoing visual inspection on the total number of hogs slaughtered in the EU?

-Martijn Weijtens estimated the percentage at five percent. The Vion Food Group is the only company applying visual inspection. The Vion Food Group is the second largest hog slaughterer in Europe and owns slaughterhouses in the Netherlands and Germany.

Who is the best person in the USDA to contact?

Dr. Richard Raymond
Under Secretary for Food Safety
U.S. Department of Agriculture
227-E Jamie Whitten Building
Washington, DC 20250
Phone: (202) 720-0350
Fax: (202) 690-0820
Dick.Raymond@usda.gov

BRIEFING NOTES

For Meeting with Ate Oostra
(Director General Ministry of Agriculture, Nature and Food Quality)
Concerning Netherlands' Visual Meat Inspection
April 13, 2007

Equivalence Submission

- The Netherlands' Ministry of Agriculture, Nature and Food Quality submitted a request in 2006 to the Food Safety and Inspection Service (FSIS) to use an alternative inspection system in Netherlands' establishments slaughtering market hogs for export to the United States.
- The Netherlands' equivalence request is specific to using visual inspection procedures during post-mortem inspection of market hogs.
- Visual inspection is the examination of parts of the slaughtered hog (head, viscera, and carcass) without incising or palpating for identifying and removing adulterated carcasses and parts from the food supply chain.
- Vion Food Group, a supporter of post-mortem visual inspection, currently has six slaughter and processing establishments certified to export to the United States,
- FSIS is still in the evaluation process of the Netherlands' equivalence submission.
- Mr. Wim Tacken, Agricultural Counselor of the Netherlands' Embassy in Washington, DC, has met with FSIS on several occasions regarding this equivalence submission.

FSIS Audit of the Netherlands' Meat Inspection System

- FSIS recently completed an audit of the Netherlands' meat inspection system in March 2007.
- During this audit, the FSIS official identified that a slaughter establishment, a Vion slaughter facility, was operating under visual inspection. Since FSIS has not determined visual inspection to be equivalent to the U.S. inspection system, product produced in this establishment would not be eligible for export to the United States.

USDA-FSIS-OIA-April 12, 2007

Mughal, Ghias

From: McDermott, Steve
Sent: Tuesday, April 17, 2007 7:34 AM
To: Stuck, Karen; James, William
Cc: White, Sally; Mughal, Ghias
Subject: FW: Memo To Ambassador Arnall - Netherlands Visual Inspection

As the result of U.S. Ambassador Arnall's meeting with Director General's (Netherlands Agriculture Dept) last Friday, the Ambassador had a few follow-up questions, of which FAS provided the attached response.

Steven A. McDermott
Deputy Director, International Equivalence Staff
Office of International Affairs
USDA, Food Safety and Inspection Service
Washington, DC
202-690-0297

-----Original Message-----

From: Patricia.VanGeemen@USDA.GOV [mailto:Patricia.VanGeemen@USDA.GOV]
Sent: Tuesday, April 17, 2007 6:38 AM
To: McDermott, Steve
Cc: Bob.Flach@USDA.GOV; Roger.Wentzel@USDA.GOV
Subject: Memo To Ambassador Arnall

Dear Mr. McDermott,

Roger Wentzel asked me to forward the attached memo to you, delivered to our Ambassador this morning.

With regards,

Patricia van Geemen
Secretary FAS
Tel.: +31-(0)70-310-2299
Fax: +31-(0)70-365-7681
E-mail: patricia.vangeemen@usda.gov
agthehague@fas.usda.gov
vgeemenp@state.gov

4/17/2007

Memorandum

To: The Ambassador

Through: Roger Wentzel, Agricultural Counselor

From: Bob Flach, Agricultural Specialist

Subject: Follow-up To Your Meeting With Ate Oostra (Director General, Dutch Ministry of Agriculture) on April 13, 2007

You had a number of questions following your meeting with Ate Oostra, which are answered below. The answers are based on my telephone conversation with Martijn Weijtens, Deputy Chief Veterinary Officer of the Dutch Ministry of Agriculture.

When did the Vion Food Group begin using the visual inspection procedures during post-mortem inspection of market hogs?

In September 2005, the Vion Food Group started a pilot project. In March 2006, they fully implemented the visual inspection procedures.

When did the European Commission (EC) approve the visual inspection of market hogs?

-The EC didn't approve the visual inspection procedures. The procedures don't need to be approved by the EC to be legally applied because they are conforming EC Regulation EC/854/2004. This Regulation lays down specific rules for the organization of official controls on products of animal origin intended for human consumption.

-In February 2006, the European Food and Veterinary Office (FVO) inspected the Netherlands' meat inspection system. As part of their visit, the FVO audited the visual inspection procedures in practice.

-The official report of the FVO regarding this visit is not yet public, and therefore not yet official. The content of the report is reportedly positive towards the implementation of the Dutch visual inspection procedures.

What is the percentage of hogs slaughtered in the EU undergoing visual inspection ?

-Martijn Weijtens estimated the percentage at five percent. The Vion Food Group is the only company applying visual inspection. The Vion Food Group is the second largest hog slaughterer in Europe and owns slaughterhouses in the Netherlands and Germany.

Who is the best person in the USDA to contact?

Dr. Richard Raymond
Under Secretary for Food Safety
U.S. Department of Agriculture
227-E Jamie Whitten Building
Washington, DC 20250
Phone: (202) 720-0350
Fax: (202) 690-0820
Dick.Raymond@usda.gov

April 16, 2007

Memorandum

To: The Ambassador

Through: Roger Wentzel, Agricultural Counselor

From: Bob Flach, Agricultural Specialist

Subject: Follow-up To Your Meeting With Ate Oostra (Director General, Dutch Ministry of Agriculture) on April 13, 2007

You had a number of questions following your meeting with Ate Oostra, which are answered below. The answers are based on my telephone conversation with Martijn Weijtens, Deputy Chief Veterinary Officer of the Dutch Ministry of Agriculture.

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-The EC didn't approve the visual inspection procedures. The procedures don't need to be approved by the EC to be legally applied because they are conforming EC Regulation EC/854/2004. This Regulation lays down specific rules for the organization of official controls on products of animal origin intended for human consumption.

-In February 2006, the European Food and Veterinary Office (FVO) inspected the Netherlands' meat inspection system. As part of their visit, the FVO audited the visual inspection procedures in practice.

-The official report of the FVO regarding this visit is not yet public, and therefore not yet official. The content of the report is reportedly positive towards the implementation of the Dutch visual inspection procedures.

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Who is the best person in the USDA to contact?

Dr. Richard Raymond
Under Secretary for Food Safety
U.S. Department of Agriculture
227-E Jamie Whitten Building
Washington, DC 20250
Phone: (202) 720-0350
Fax: (202) 690-0820
Dick.Raymond@usda.gov

ISSUE ALERT: Equivalence Request for Netherlands' Visual Inspection

Issue: The government of Netherlands is requesting to use an alternative post-mortem inspection procedure for market hogs intended for export to the United States. The alternative procedure is visual inspection of the head, carcass and viscera, without incising or palpating, to identify and remove adulterated carcasses and parts.

Latest Development: July 2007: Dr. Ate Oostra, Director General for International Affairs of Netherlands Ministry of Agriculture, Nature and Food Quality, has requested a visit with the Office of the Under Secretary for Food Safety. The primary purpose of Dr. Oostra's visit is to ask about the status of FSIS' equivalence decision regarding Netherlands' visual inspection. Current FSIS import data show that U.S. imports of fresh and canned pork products from the Netherlands have decreased significantly from 2005 (10.3 million pounds) to 2007 (217,529 pounds – January through July). The Dutch Product Board states that this decrease is directly due to Netherlands' slaughter establishments owned by Vion Food Group producing under visual inspection and, therefore, ineligible to export to the United States directly (fresh product) or indirectly (supplier to canning establishments).

Background:

- In July 2006, FSIS received a request from the Netherlands to use an alternative post-mortem inspection procedure for market hogs—visual inspection of the head, carcass and viscera. The procedure does not require incising of the mandibular lymph nodes, palpation of the mesenteric, portal and bronchial lymph nodes, turning of lungs and liver, or grasping and turning of the kidneys, which are required under FSIS traditional post-mortem inspection procedures. The Netherlands' alternative post-mortem procedures under visual inspection are further explained in Attachment 1.

The basis of the Netherlands' provision for visual inspection is dependent on the implementation of an integrated quality control program by Netherlands' market hog producers coupled with a system of government verification for checking the accuracy of visually inspected carcasses and organs to ensure that passed carcasses and parts thereof are wholesome and not adulterated.

- On November 1 and 2, 2006, a team of Netherlands' inspection officials met with FSIS to provide further information regarding its request for visual inspection.
- During late 2006 and early 2007, Mr. Wim Tacken, Agricultural Counselor of the Netherlands' Embassy in Washington, DC, met with FSIS on several occasions regarding this equivalence submission. [*Mr. Tacken has since retired and has been replaced by Mr. Fritz Thissen.*]
- On January 22, 2007, FSIS/OIA briefed Drs. Raymond and Mann on the outcome of the equivalence review. At that time, Drs. Raymond and Mann requested additional information on the serological testing method used by the Netherlands for testing of *Mycobacterium avium* (*M. avium*) during the pilot phase of visual inspection. The purpose of the additional information was to determine the dependability of serological testing as an indicator for the detection of Tuberculosis (TB) in market hogs. FSIS/OIA received the additional information from the Netherlands' Chief Veterinary Officer and concluded that serological testing was a viable test under certain conditions. Further explanation is found in Attachment 2 and this information was sent to the Office of the Under Secretary for Food Safety on June 18, 2007.

- On April 13, 2007, Dr. Oostra met with the U.S. Ambassador to the Netherlands, Roland Arnall, concerning the status of FSIS' equivalence decision on visual inspection.
- On April 23, 2007, FSIS sent a letter to the Netherlands Ministry of Agriculture, Nature and Food Quality reaffirming FSIS' October 2006 communication that the Netherlands' establishments cannot produce pork products under visual inspection for export to the United States until FSIS determines that the alternative procedure is equivalent. The April letter was initiated after learning that Netherlands' slaughter establishments owned by Vion Food Group had implemented visual inspection. FSIS received a response dated May 29, 2007, from the Ministry of Agriculture, Nature and Food Quality stating that Netherlands' establishments are not producing for export to the United States while operating under visual inspection.

Other Interest in Visual Inspection

- Vion Food Group, the largest pork producer in the Netherlands and a supporter of post-mortem visual inspection, currently has six slaughter and processing establishments certified to export to the United States. However, since early 2007, the Vion slaughter establishments have been producing under visual inspection and thus, product has not been eligible for export to the United States. This has caused a significant decrease in the amount of pork imports into the United States from the Netherlands.
- Denmark has shown interest in requesting a similar equivalence determination for market hogs slaughtered for export to the United States although it has not submitted a formal equivalence request to FSIS. Other EU Member States are expected to request a similar equivalence determination.

FSIS/OIA Recommendation: FSIS/OIA has completed its equivalence review and determined that the Netherlands' alternative post-mortem inspection procedure of visual inspection is equivalent and, therefore, recommends granting the government of the Netherlands approval to implement this procedure for market hogs produced for export to the United States.

FSIS/OIA August 3, 2007

NETHERLANDS' VISUAL INSPECTION

Netherlands uses a combination of pre-slaughter data collection and post-mortem inspection verification to ensure the identification and removal of unhealthy animals, adulterated carcasses and parts and resulting products from the food supply. Pre-slaughter data collection is conducted through a system of "Supply Chain Inspection" called the IKB Varkens (IKB) program, which is an integrated quality assurance program with comprehensive controls over the production chain in addition to national and EU requirements for feed, hygiene, the use of veterinary drugs, transport of animals, and animal welfare. The IKB requires transfer of animal health records from the farm to both the establishment and inspection officials to provide greater assurance that only wholesome meat products are produced. All market hogs receive ante-mortem and post-mortem visual inspection of the head, viscera, and carcass. Only market hogs born and raised in the Netherlands and under the IKB program are eligible for visual inspection.

In addition, the Netherlands has implemented a government verification program to check the accuracy of the inspection tasks for the removal of both food safety and non-food safety defects (other consumer protection defects). The verification activities occur on a daily basis (minimum once a day), carried out by the official government veterinarian, and split into two basic standards: (1) standards for inspection procedures and (2) standards for inspection decisions. The government inspectors are required to perform inspection procedures correctly and completely. The government veterinarian verifies appropriate performance of inspection procedures by observing inspectors.

ANTE-MORTEM INSPECTION

Ante-mortem inspection on all market hogs is performed by the official government veterinarian using traditional inspection procedures, which are equivalent to FSIS' traditional inspection procedures.

POST-MORTEM INSPECTION

Visual post-mortem inspection of each head, viscera and carcass is performed by official government auxiliaries (contract inspectors) located at three fixed inspection stations. The procedures are as follows:

Head Inspection

- Visual inspection of the head and throat, including the mandibular lymph nodes
- Visual inspection of the mouth, fauces, and tongue

Viscera Inspection

- Visual inspection of the lungs, trachea, and esophagus
- Visual inspection of the pericardium and heart
- Visual inspection of the liver and hepatic and pancreatic (portal) lymph nodes
- Visual inspection of the gastro-intestinal tract, mesentery, gastric and mesenteric lymph nodes
- Visual inspection of the spleen
- Visual inspection of the genital organs

(Attachment 1 continue)

Carcass Inspection

- Visual inspection of the carcass
- Visual inspection of the pleura and peritoneum (linings of chest and abdominal cavities)
- Visual inspection of the kidneys
- Visual inspection of the diaphragm
- Visual inspection of the udder and its lymph nodes
- Visual inspection of the umbilical region and joints of young animals

**Additional Information Requested by Drs. Raymond and Mann
(Serological (ELISA) Testing for *M. avium*)**

- Sensitivity of ELISA (serological) test used by the Netherlands was about 75% of the hogs infected with *M. avium* subspecies *avium* (MAA) and tested at younger age. The data submitted by the Netherlands did not address the specificity of the ELISA method. They only used one strain of *M. avium*, i.e., the MAA serotype 4, strain. The data did not show if there was a cross reactivity in sera of hogs infected with other strains of MAA, other non-TB group mycobacterium or organisms from the Mycobacterium-bovis group. However, a 2006 study on the evaluation of five antibody detection tests for diagnosis of bovine tuberculosis caused by the *Mycobacterium avium* subsp. *paratuberculosis* shows that specificity of the three ELISA methods was equal or above 99.8 percent. Specificity of the other two methods was 84.7 percent and 94.9 percent. Four of the five tests produced similar sensitivity in detecting fecal culture positive cattle.
- Based on Netherlands' data, the ELISA test, by itself, is not the most reliable test for the detection of MAA. However, when the ELISA test is used as a component with the other on-farm measures listed below, the combined safeguards provide a dependable level of assurance that the market hogs slaughtered in Netherlands establishments undergoing visual inspection are free of TB.
 - The production/slaughter of the market hogs is a vertically integrated operation,
 - There is a established frequency of follow-up testing for MAA,
 - Only hogs born and raised in Netherlands are allowed in the program,
 - There is a TB testing program for the farm workers, and
 - There is an environmental testing program for MAA, e.g., testing of bedding, house environment, etc.
- During review of the proposal, FSIS technical experts also took note of the following:
 - FSIS no longer considers TB as a food borne disease of public health significance caused by the consumption of meat. This is based on the current FSIS' training document (2004) used in the curriculum for its public health veterinarian training.
 - A recent European Food Safety Authority publication on human Mycobacterium *bovis* states that transmission of tuberculosis to humans through the consumption of meat has not been documented as a public health risk during surveillance for TB in many countries over many decades. (Rua-Domenech, 2006). Additionally, the European Food Safety Authority's two most recent reports (2005, 2006) titled, "Trends and Sources of Zoonoses, Zoonotic Agents, Antimicrobial Resistance and Foodborne Outbreaks in the European Union" do not list any outbreaks of TB (from *M. bovis* or *M. avium*).
 - No reference could be found in the scientific literature specifically relating to *M. avium* transmission to humans from eating meat.

- During the past five years (August 1, 2002 to August 1, 2007), over 3.4 million market hogs were slaughtered in the United States and, of these, 2,566 were condemned for TB. The condemnation rate is 0.74 per 100,000 slaughtered.

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voedselkwaliteit

Your letter of	your reference	our reference	date
Feb. 24, 2006		VD 06.1018/IH	31-3-2006
re:		extension no.	enclosures
2006 audit preparation		+31-70-3785435	2

Dear Ms. White,

Your letter dated February 24, 2006, to the European Commission informing them of the dates of the upcoming annual audit of the Netherlands meat inspection system (April 19 through May 18, 2006) has been brought to my attention and I am happy to confirm these dates to you. The details of the audit and the itinerary to be followed are currently being worked out by our services.

As agreed during my visit of December 8, 2005, I take pleasure in providing you with additional information about recent changes in our meat inspection system, which I believe will be of benefit for your auditor in the preparation of his visit. These changes are in part resulting from the introduction of the new EU Hygiene Regulations on January 1, 2006, which cover the entire spectrum of food safety, including meat and meat products. This new legislation was discussed between FSIS and the European Commission at the recent Joint Management Committee meeting in October 2005. On January 12, 2006, the European Commission sent you a complete set of the acts and related implementing measures.

In our letter of February 14, 2006, we elaborated on the information provided by the Commission, by informing all CVO's in our foreign markets of the new and old legislation and certain other changes, which might have an effect on the text of our veterinary health certificates.

There are two aspects of our meat inspection system that I would like to specifically address in this letter, i.e. the option of visual post mortem inspection offered under the new legislation, and the delegation of certain elements of the post mortem meat inspection from the official veterinarian to official auxiliaries employed by an independent organization, which is permitted under both old and current EU legislation.

A. Visual post mortem inspection

During my visit on December 8, 2005, we discussed developments in the philosophy of meat inspection in the EU and certain comparable developments in the US (i.e. HIMP Market Hogs). We agreed that this topic was of mutual interest and that an exchange of

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information by U.S. and Dutch experts could take place during a conference call. Unfortunately, a mutually convenient date for this conference call has not been found yet, but we remain keenly interested in setting this up, preferably before the next audit.

The hygiene regulations EC 852/2004, EC 853/2004 and EC 854/2004 offer the possibility for fattening pigs, housed under controlled conditions in integrated production systems since weaning, to be subject to a visual inspection before and after slaughter. This visual inspection is part of a risk-based inspection system. Application of this inspection system requires the availability of food chain information and epidemiological data. Every enterprise has the option to either stick to the "old" system or to implement a visual inspection system. The legal basis of visual inspection is to be found in Appendix 1, Section IV, B post-mortem Inspection of EU Regulation 854/2004.

The VION Company, the major pork producer in the Netherlands, looked into the merits of this type of inspection and consulted with the competent authority, the Food and Consumer Product Safety Authority (VWA), on how to proceed. In order to get official approval for the new inspection system, VION had to demonstrate to VWA that the produced pork would at least meet the EU set levels of food safety and would fulfill the mandatory EU hygiene regulations provisions.

For your information I would like to refer you to the enclosed final evaluation of VION's pilot project, which was carried out in one of the slaughter plants of that company. As you will remember, a company report on this pilot project was submitted to you during our meeting on December 8, 2005.

VWA investigated the content of the chain management system in order to be convinced that the official requirements laid down in regulation (EC) 853/2004 have been met and that the submitted Food Chain Information was sufficient to realize - at least - a similar level of food safety by means of the applied visual inspection, in comparison to the current procedures for meat inspection. These two prerequisites constitute the basis for official certification. Based on their positive findings, VWA gave VION the green light to implement the visual inspection system. You will find the VWA final report 'Pilot Chain Management VION' enclosed.

In February 2006 the Food and Veterinary Office of the European Commission visited the pilot slaughterhouse during an inspection mission on the official controls related to food safety of animal products and took note of the applied visual inspection system. FVO found the slaughterhouse in compliance with EU legislation.

With both the VWA approval and the positive FVO report, VION intends to now fully implement this inspection system in their Helmond facility. This will enable your auditor to personally observe the way in which the system works, when he visits this establishment, which I believe is planned at the end of the program.

I would like to underline that it is a company's decision to apply for a food chain management and visual inspection system. Whether other Dutch pork producers will try to implement such a system is unknown. If they will, every implementation will be evaluated by VWA.

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B. New organization of the red meat inspection system

During our meeting on December 8, 2005, the delegation of certain aspects of the post mortem meat inspection from the VWA to an independent organization was also raised, and you indicated that this topic had been brought to your attention before. At your request, a formal document explaining the details of this delegation has been drawn up, and I take pleasure in sending you this report as an enclosure. The report focuses on meat slaughterhouses under permanent supervision of the VWA.

I hope that the above information on the new EU legislation and the modernization of meat inspection will provide a good basis for discussion during the upcoming audit. I am looking forward to your response with great interest, especially on my suggestion to hold a conference call on visual post mortem meat inspection on short notice.

Yours sincerely,

CHIEF VETERINARY OFFICER,



dr. P.W. de Leeuw

cc:

Ms. Karen Stuck, Assistant Administrator, USDA/FSIS
Mr. William James, Deputy Assistant Administrator, USDA/FSIS
Mr. Steven McDermott, Deputy Director International Equivalence Staff, USDA/FSIS
Mr. Ghias Mughal, Senior Equivalence Officer, USDA/FSIS
Ms. Anita Manka, Senior Food Technologist, USDA/FSIS
DG Sanco, Mr. Paul van Geldorp & Mr. Lorenzo Terzi
Food and Consumer Product Safety Authority (VWA)
Agricultural Counselor Washington, DC

The new organisation of the red meat inspection system in the Netherlands (2006)

Introduction

The Dutch government has decided to modernize the organisation of the red meat inspection system. The so-called post mortem inspection in red meat slaughter facilities was carried out so far by inspectors employed by the Food and Consumer Product Safety Authority (VWA). EU legislation allows the inspection to be carried out by official auxiliaries employed by an independent organisation. The VWA remains responsible for the official control and the verification of compliance. The official auxiliaries are independent of the slaughter facilities. On January 1, 2006, the official auxiliaries, who were up to then employed by the Dutch government, entered the service of an organisation based on civil law, the B.V. Kwaliteitskeuring Dierlijke Sector (KDS). For the purpose of this document, the independent organisation will be referred to as KDS.

Definitions

Competent authority

Competent authority means the central authority of a Member State competent to carry out veterinary checks or any authority to which it has delegated that competence.

Official veterinarian

Official veterinarian means a veterinarian qualified, in accordance with Regulation (EC) 854/2004, to act in such a capacity and appointed by the competent authority.

Official auxiliary

Official auxiliary means a person qualified, in accordance with Regulation (EC) 854/2004, to act in such a capacity, appointed by the competent authority and working under the authority and responsibility of an official veterinarian.

Red meat inspection

Inspection of meat from domestic bovine (including Bubalus and Bison species), porcine, ovine and caprine animals, and domestic solipeds

Inspection procedures

Inspection procedures as meant by Regulation (EC) 854/2004, Annex I, Section IV.

Protocol

Protocol as meant in section I, annex 27 of the Supervision Protocol which is drawn up by the official veterinarian of the VWA for each slaughter facility and which contains the arrangements which have been agreed upon between the VWA and the operator of the slaughter facility.

Philosophy

Practical experience and further analyses showed that if the way in which the official auxiliaries and the procedures concerning the red meat inspection (post mortem inspection) were structured, this could lead to certain advantages. These advantages were most visible if the official auxiliaries were placed in an organisational unit based on civil law independent of the slaughter facility concerned, of course with regard to the European Community legislation which states that the final responsibility for the inspection lies with the official veterinarian. These advantages can be found in aspects such as efficiency, lower labor cost and a reduction in overhead.

Legal basis

- Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (in force as of January 1, 2006, and in part replacing Directive 64/433/EEC). In this Regulation it has been decided that under certain conditions the official auxiliaries may assist the official veterinarian as regards certain inspection procedures.
- Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal

health and animal welfare rules (in force as of January 1, 2006, and in part replacing Directive 64/433/EEC).

- Agreement on the organisation of red meat inspection (post mortem) in the Netherlands dated June 6, 2004.
- Implementation contract between VWA and KDS dated November 29, 2005 (including the supervision protocol)

Parties involved

In order to safeguard animal and public health, the Dutch government is responsible for an adequate organisation of meat inspection, based on European Community legislation. An agreement between the government and the meat sector on the organisation of the red meat inspection (post mortem) in the Netherlands has been reached (the "Covenant"). The objective of this agreement is to make binding and enforceable commitments between the parties in the framework of the modernization of the meat inspection system, which should have as a result that effective January 1, 2006, the inspection procedures laid down in this agreement should transfer from the VWA to an independent organisation based on civil law, which is independent of the Dutch slaughter facilities. In the pilot phase which will run through the end of December 2007, the relevant meat inspection procedures will be assigned to the B.V. Kwaliteitskeuring Dierlijke Sector in a way which ensures that these activities are carried out independently of the slaughter facilities, but under the supervision and responsibility of the official veterinarians i.a., so that the requirements of the European legislation are met.

Parties involved:

- Ministry of Agriculture, Nature and Food Quality (LNV)
- Ministry of Public Health, Welfare and Sport (VWS)
- Food and Consumer Product Safety Authority (VWA)
- Commodity Board for Livestock and Meat (PVV)
- Central Organisation of the Meat Sector (COV)

B.V. Kwaliteitskeuring Dierlijke Sector (KDS)

KDS is an organisation based on civil law linked to the Foundation Central Bureau Services for Slaughter Animals (Stichting Centraal Bureau Diensten aan Slachtdieren). The government parties must be satisfied that this organisation operates independently from the slaughter facilities. As a minimum requirement, the organisation has to be accredited as an independent agency. KDS' independence is assured as follows:

- The majority of the board consists of independent persons, including the chairman.
- Accreditation by the Council on Accreditation according to the NEN EN 45004 (ISO/IEC 17020) norm.
- Requirements for training and education, and registration of the official auxiliaries.
- Requirements for bribery and conflict of interest situations included in the implementation contract (art. 31)

The transfer of inspection to KDS is a pilot for the duration of 2005, 2006 and 2007. KDS has been charged with the inspection of red meat until the end of 2007. Other organisations could in the future also be certified to perform these tasks.

Relationship between VWA and KDS

The relationship between the VWA and KDS has been laid down in an implementation contract, which has been drawn up between both parties. This contract includes the requirements for the inspection and the requirements for the official auxiliaries. It also describes the respective responsibilities of the VWA and KDS. Article 2 of the contract provides a basic outline of the content of the agreement:

1. The inspection procedures will be carried out by KDS effective January 1, 2006. KDS must assume an independent position vis-à-vis the Dutch slaughter facilities.
2. Official auxiliaries carry out the inspection procedures referred to under # 1.
3. The VWA supervises the implementation of the inspection procedures referred to under # 1 by KDS, in order to meet the requirements of relevant European legislation.
4. KDS guarantees that the inspection procedures carried out by her, or on her behalf, will meet the requirements laid down in the contract.
5. KDS guarantees that the inspection procedures carried out by her, or on her behalf, will be executed in a professional way.

Moreover, an application for meat inspection must be submitted by the operator of the slaughter facility to the VWA. The VWA issues written orders to KDS for each application of a slaughter facility. On these orders it is indicated when the inspection procedures have to be done.

Annexes to this implementation contract include the

- Quality Manual put together by KDS (Annex III to the implementation contract), which contains the policy of the organisation, its objectives, the relationships and the work procedures; and the
- Supervision Protocol (Annex II to the implementation contract), which contains a detailed description of the way in which the VWA supervises KDS per type of slaughter facility.

The final responsibility of the official veterinarian (VWA) is of great importance. The official veterinarian measures the quality level of the post mortem inspection and of the post mortem inspection procedures (outlined in enclosure 2) carried out by the official auxiliaries of KDS based on standards described in the Supervision Protocol (including standards for the quality of the red meat inspection, the number of staff required for supervision of the post mortem inspection, the number of official auxiliaries of KDS that should be present, the VWA staff requirements, a location (establishment level) protocol, auditing, and sanctions). These standards have been described in enclosure 1.

Financial structure

The VWA has to reimburse KDS for the time spent by the official auxiliaries for the inspection procedures (increments of 15 minutes). KDS needs to submit to VWA annually no later than July 1 an estimate of the cost and a proposal for a rate. The VWA converts these costs into tariffs, which are then officially fixed by the Ministry of Agriculture, Nature and Food Quality based on relevant legislation and rulemaking. VWA does the actual billing to the slaughter facility, while the Ministry of Agriculture, Nature and Food Quality has final responsibility for collection of payment.

Qualifications and education official auxiliaries

1. Education requirements laid down in Regulation EC/854/2004 (Annex I, Section III, Chapter IV)
2. VWA evaluates whether the training meets the requirements of the Regulation. VWA also determines the rules for examination for the training.
3. The official auxiliaries must be registered with VWA.
4. The official auxiliaries must maintain their knowledge through ongoing education and professional literature and need to keep informed of new developments. The content of the ongoing education is part of the Quality Manual of KDS.
5. VWA maintains a register of the official auxiliaries, checks annually whether they are still employed by KDS and whether they take part in the ongoing education.

Bibliography

1. Regulation (EC) 854/2004: Organisation of Official Controls on Products of Animal Origin Intended for Human Consumption
2. Agreement on the organisation of red meat inspection (post mortem) in the Netherlands
3. Implementation contract VWA-KDS
4. Supervision protocol (Annex II to the implementation contract)
5. Normstelling en normen roodvlees en *pluimveevlees* Slachthuizen, *uitsnijderijen* en koel- en vrieshuizen

Enclosure 1

Standards for meat slaughterhouses under permanent VWA supervision

Introduction

The standards and norms are divided into four elements:

1. Quality standards for meat inspection
2. Standard for the amount of staff required for supervision of the post mortem inspection and other supervisory tasks
3. Quality standards for auditing
4. Regulation of corrective measures

There is a division of responsibility between the official veterinarian and KDS. Both carry out their tasks following this division of responsibility as described in Regulation (EC) 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption. The official veterinarian is and remains ultimately responsible. Under the division of responsibility, the employees of KDS are qualified official auxiliaries, who carry out inspection procedures under full responsibility of the official veterinarian. The official veterinarian measures the quality level of the post mortem inspection and of the post mortem inspection procedures by the official auxiliaries of KDS based on the standards and norms described below.

1. Quality standards for meat inspection

In order to set criteria by which the official veterinarian can measure the post mortem inspection performance of KDS, several sources were consulted. One of these sources was the experience gained over the years in New Zealand with the implementation of meat inspection by an independent organisation and with clear standards for the quality of the meat inspection under the responsibility of the government. The New Zealand standards have been used as the main source in order to develop the standards in the Dutch system.

The standards can be distinguished into two basic elements, i.e. standards for inspection procedures and standards for inspection decisions:

1. Inspection procedures

The starting point is that inspection procedures have to be carried out in compliance with Regulation (EC) 854/2004. Verification of the execution of official controls has to be done on the inspection station. The standard for the number of procedures is fixed at 5% per inspection position. By this standard is meant the maximum number of deviations of the number of inspection procedures. The size of the random sample is determined at \sqrt{n} (n =number of animals in a one-day production cycle) over two batches. A summary of the inspection procedures can be found in enclosure 2.

2. Inspection decisions

The verification of the correct execution of the inspection decisions distinguishes two parts, i.e. pathological abnormalities and hygienic slaughtering. The verification of pathological abnormalities takes place on the inspection station, as long as the carcass and the organs are running synchronically. The verification of hygienic slaughtering takes place between the trimming station and the end of the slaughtering line.

Pathological abnormalities

Regulation (EC) 854/2004, annex 1, section II, chapter V describes which pathological abnormalities are reason to declare meat unfit for human and/or animal consumption. The standard for missed pathological abnormalities is determined at 6% cumulative and is in fact a check on wrongly approved material. This standard consists of a 2% standard for the carcass, 2% for the pluck, and 2% for the organs. This cumulative standard is based on the fact that this was found to be very realistic in New Zealand. New Zealand is the only country that has experience in this area with meat.

The size of the random sample per inspection position to test the standard of 6% cumulative is fixed at \sqrt{n} (n =number of animals in a one-day-production cycle) over two batches. If the result of \sqrt{n} exceeds 50, these batches will be traced to two batches of a minimum of 25 carcasses per inspection position. The cumulative standard of 6% for missed pathological abnormalities is a guidance standard for the assessment of the post mortem inspection quality. Together with the size of the random sample, a statistically justifiable picture of the post mortem inspection quality is created.

Hygienic slaughtering

In the first place it needs to be clear that faecal contamination has to be a Critical Control Point in the HACCP-system (EC Decision 2001/471). The slaughterhouse is responsible for the guaranteeing of this CCP.

In addition, slaughter animals with deviations as a result of errors in the slaughtering hygiene are offered for inspection, which require an inspection decision. The standard per carcass for contamination because of slaughtering errors is fixed at 2% total contamination and 0% faecal contamination. The faecal contamination will always have to be 0% at the end of the slaughtering line! The size of the random sample to test the standards of 2% and 0% is fixed at $2\sqrt{n}$ (n =number of animals in a one-day-production cycle) over four batches. If the result of \sqrt{n} exceeds 50, these batches will be traced to four batches of a minimum of 25 carcasses.

Assessment of other aspects in relation to the post mortem inspection

- Check on the synchronized running of the belts in relation to carcass and organs
- The official veterinarian will have to carry out the inspection of the carcasses which are to be examined further
- Supervision on the release of carcasses from the trimming station by KDS. The carcasses, which have to be transported to a trimming station, e.g. as a result of the implementation of the HACCP-system, will have to be cleaned up by employees of the slaughterhouse. Each slaughterhouse will have to arrange its processes this way. The release from the trimming station takes place under responsibility of KDS. KDS in turn operates under the responsibility of the official veterinarian.

2. Standard for the amount of staff required for supervision of the post mortem inspection and other supervisory tasks

The supervision on the execution of the post mortem inspection (belt inspection) consists of the following elements:

- a) The Food and Consumer Product Safety Authority (VWA), Implementation Division, regularly audits externally for the compliance of the execution of the Quality Manual of KDS. The frequency of the audit varies between 1 to 4 times a year and will be based on a bonus/malus system.
- b) The official veterinarian verifies in each participating slaughterhouse the execution and compliance of the Quality Manual of KDS. This verification is aimed at veterinary procedures/training/refresher courses in the Quality Manual. The frequency of this verification will be based on a bonus/malus system.
- c) KDS will have to take care of sufficient availability of official auxiliaries. The VWA will not fill in "empty spots" for the post mortem inspection at the belt. No execution of the inspection means no slaughtering. The official veterinarian supervises the execution of the post mortem inspection carried out by official auxiliaries of KDS.
- d) The quality of the execution of the post mortem inspection will have to be verified regularly by the official veterinarian (in principle daily, but for small-sized meat slaughterhouses a different frequency can be used). The set standards and checklists will be used.

The other supervisory activities in a meat plant are contained in the hygiene regulations ((EC) 852/2004, 853/2004, 854/2004 and 882/2004) and other European regulations, and consists of the following elements:

- a) Supervision/execution ante mortem inspection (live inspection)
- b) Verification of hygiene plan on the basis of HACCP/hygiene codes/microbiological controls
- c) Verification of technical construction and equipment of the establishment; verification of various managerial aspects in an establishment, such as water management, pest control, health attestations of employees, register of incoming and outgoing material and general tracking and tracing, verification of the removal of animal by-products (category 1-, 2- and 3-material as meant in Regulation (EC) 1774/2002).
- d) Daily verification of hygiene, both before the start of the slaughtering and during the slaughtering
- e) Periodic sampling for residues, such as the National Plan and in case of suspected prohibited materials and in case of a suspicion of a contagious animal disease.
- f) With the implementation of Regulation (EC) 854/2004 on January 1, 2006, supervision will be directed more towards process control based on a complete HACCP integration and the evaluation of food chain information prior to slaughter.

The standard for the number of VWA staff required for the supervisory tasks listed above will be dependent on the situation of the slaughterhouse. This means that the number of official veterinarians and the number of assistants to supervisory veterinarians have to be determined.

3. Quality standards for auditing

The official veterinarian has to have auditing qualifications in line with Regulation (EC) 854/2004.

4. Regulation of corrective measures

KDS has to set up a system of guarantees and corrective measures based on the quality standards for post mortem inspection. This system will be part of the Quality Manual of KDS and will be tested by the VWA.

In case of insufficient performance of KDS, the official veterinarian may have to decide to withdraw inspection or to adapt the speed of the belt. Before taking such a measure, KDS will be offered the opportunity to take steps to guarantee the quality of the post mortem inspection procedures. If the steps taken by KDS do not guarantee the post mortem inspection quality, then it is up to the official veterinarian to take corrective measures.

5. Standard for the number of KDS official auxiliaries that need to be present

Regulation (EC) 854/2004, Article 5, Part 4 states the following. Official auxiliaries may assist the official veterinarian with the official controls carried out in accordance with Sections I and II of Annex I with the frequency specified in Section III, Chapter I. In line with the implementation contract between VWA and KDS, the standard for the number of KDS official auxiliaries is determined as follows:

- a) VWA determines the number of official auxiliaries that perform inspection tasks and need to be present at the slaughter line of a slaughtering facility. This is in line with article 5, paragraph 5, part a of Regulation (EC) 854/2004 and based on a risk-based approach. The number of official auxiliaries is dependent on the type of slaughter facility and is fixed in the protocol in such a way that all requirement of Regulation (EC) 854/2004 are met.
- b) KDS may submit a proposal to change this number of official auxiliaries per slaughter line and slaughter facility. This proposal based on a risk-based approach per slaughter line and per slaughter facility, where the inspection takes place. KDS may request information from the official veterinarian about this risk-based approach.
- c) KDS will clarify this approach and will in consultation with the official veterinarian of the slaughter facility concerned submit a proposal to VWA on how the determined number of official auxiliaries should be changed.
- d) VWA will evaluate the KDS proposal and will proceed to determine the number of official auxiliaries that perform inspection tasks per slaughter line and per slaughter facility. VWA will then confirm this new number in the protocol of the slaughter facility concerned.
- e) VWA has the authority to change the number of official auxiliaries mentioned under a) and d), if the risk-based approach mentioned under a) and b) calls for it. If the number of determined official auxiliaries needs to be changed, VWA and KDS will consult together in order to guarantee the quality of the inspection procedures. In case of a change, the procedure listed under d) will be followed.
- f) KDS has to ensure that the number of required official auxiliaries determined under a) and d) is present at the slaughter line and in the slaughter facility concerned during the planned activities. KDS needs to take measures if the determined amount of official auxiliaries is not present to perform the inspection tasks. These measures are listed in the Quality Manual.

6. Standards for VWA staff

For the supervision in a EU approved meat slaughter facility, the daily supervision consists of:

- Verification of control before the slaughtering begins
- Control on the hygienic procedures of the establishment
- A verification of the post mortem inspection
- Sampling of animals to be tested/National Plan
- Conclude extensive testing
- General supervision, such as BSE/Trichinella and category 1-, 2-, 3- material as meant under Regulation (EC) 1774/2002
- Administrative tasks

To carry out these supervisory duties, it was concluded that at least one official veterinarian would be required, together with a maximum of one assistant supervisory veterinarian in meat slaughter facilities under permanent VWA supervision.

Under this standard, the additional supervisory tasks that have to be carried out have not been taken into account. These are tasks such as:

- UBA/ISI¹ reporting, for which there is a separate frequency, depending on the degree in which the establishment meets the approval requirements
- HACCP-audit twice a year and a weekly verification of an effective implementation of the HACCP-system. The audit of the HACCP-system has to be done by an official veterinarian, because this is prescribed in Regulation (EC) 854/2004. A system auditor may assist.
- Audit for USA approval or other obligations of the establishment resulting from exports to a third country
- Assessment of protocols for BSE/TSE/third country canalisation requirements
- Export certification for third countries

The ante mortem inspection will also have to be done by the official veterinarian. For this the presence of at least one official veterinarian in a large meat slaughter facility is necessary. The policy to make use of official veterinarians for the ante mortem inspection, which was started a number of years ago, will thus remain unchanged.

7. Protocol

For each slaughter facility a protocol needs to be set up, in which the number of official auxiliaries at the belt will be determined on an individual slaughterhouse level (see 5). Also the standard for the VWA activities need to be incorporated. This will result in a customized belt staffing and supervision. The protocol also needs to contain the agreements made, for instance for the processing of BSE, TSE, Trichinella results, permanent VWA supervision, and ritual slaughtering.

¹ UBA and ISI are data registration systems

Enclosure 2

Post mortem inspection procedures of the official auxiliaries for domestic porcines

- 1) Carcasses and offal of pigs other than those referred to in paragraph 2 are to undergo the following post mortem inspection procedures:
 - a) Visual inspection of the head and throat; incision and examination of the submaxillary lymph nodes (Lnn. mandibulares); visual inspection of the mouth, fauces and tongue;
 - b) Visual inspection of the lungs, trachea and oesophagus; palpation of the lungs and the bronchial and mediastinal lymph nodes (Lnn. bifurcationes, eparteriales and mediastinales). The trachea and the main branches of the bronchi must be opened lengthwise and the lungs must be incised in their posterior third, perpendicular to their main axes; these incisions are not necessary where the lungs are excluded from human consumption;
 - c) Visual inspection of the pericardium and heart, the latter being incised lengthwise so as to open the ventricles and cut through the interventricular septum;
 - d) Visual inspection of the diaphragm;
 - e) Visual inspection of the liver and the hepatic and pancreatic lymph nodes (Lnn. Portales); palpation of the liver and its lymph nodes;
 - f) Visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (Lnn. gastrici, mesenterici, craniales and caudales); palpation and, if necessary, incision of the gastric and mesenteric lymph nodes;
 - g) Visual inspection and, if necessary, palpation of the spleen;
 - h) Visual inspection of the kidneys; incision, if necessary, of the kidneys and the renal lymph nodes (Lnn. renales);
 - i) Visual inspection of the pleura and the peritoneum;
 - j) Visual inspection of the genital organs (except for the penis, if already discarded);
 - k) Visual inspection of the udder and its lymph nodes (Lnn. supramammarii); incision of the supramammary lymph nodes in sows;
 - l) Visual inspection and palpation of the umbilical region and joints of young animals; in the event of doubt, the umbilical region must be incised and the joints opened.
- 2) The competent authority may decide, on the basis of epidemiological or other data from the holding, that fattening pigs housed under controlled housing conditions in integrated production systems since weaning need, in some or all of the cases referred to in paragraph 1, only undergo visual inspection).

Apart from the inspection procedures mentioned above, the VWA may indicate that other inspection procedures need to be done by the official auxiliaries. These may differ between slaughter facilities, but they are in all cases related to the post mortem inspection of red meat. Examples are sampling under the National Plan and for Trichinella testing.

Mughal, Ghias

From: Feitel, Caroline [caroline.feitel@minbuza.nl]
Sent: Thursday, May 18, 2006 12:29 PM
To: McDermott, Steve
Cc: Mughal, Ghias; WAS-LNV; White, Sally; Tacken, Wim
Subject: Visitor from the Netherlands-May 26th-risk assessment

Dear Steve,

A representative of the Netherlands Food and Consumer product Safety Authority (VWA), Dr. Benno ter Kuile will give a presentation on risk management in the Netherlands, the interaction with the European Food Safety Authority and consequences for international trade, during the 106th General Meeting of the American Society for Microbiology. After this meeting, which will take place May 21-25 in Orlando Florida, Dr. Ter Kuile will be visiting Washington, DC on Friday May 26th. Dr. Ter Kuile would be very interested to discuss risk management with FSIS representatives and could give his powerpoint presentation on risk assessment, which he gave in Florida, to interested FSIS parties on the (morning of) the 26th. Afterwards there could be an informative exchange of views between professionals in the field of risk assessment. Would you be able to find out if there is interest within FSIS for a presentation by Dr. Ter Kuile? I would accompany him to FSIS. To make his presentation valuable he would prefer to give his actual powerpoint presentation.

Alternatively, FSIS is also invited to come to our Embassy, where Dr. Ter Kuile could also give his presentation that morning. Whatever would work best.

Thank you very much for your help. I very much look forward to hearing from you.

Yours truly,

Caroline Feitel

Caroline Feitel
Agricultural Trade Officer
Royal Netherlands Embassy
4200 Linnean Avenue, NW
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Fax: 202-244-3325

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memo

To
Steering group visual inspection

Subject
Final Report 'Pilot Chain Management VION'

Deleted:

datum
24 januari 2006
ons kenmerk

Introduction

With the implementation of the hygiene regulations EC 852/2004, EC 853/2004 & EC 854/2004 the possibility was created for the application under certain conditions of a differentiated inspection regime for fattening pigs by which one or more incisions can be omitted (henceforward to be referred to as "visual inspection"). The verbatim text is as follows:

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behandeld door
R. Lesuis
telefoon (0575) 58 81 00
rene.lesuis@vwa.nl

*'The competent authority may decide, on the basis of epidemiological or other data from the holding, that fattening pigs housed under controlled housing conditions in integrated production systems since weaning need, in some or all of the cases referred to in paragraph 1, only undergo visual inspection.'*¹

The condition 'epidemiological or other data' included above will be in addition to the providing of food chain information, which has also become mandatory on January 1, 2006.²

Based on this new legislation, the Food and Consumer Safety Authority (VWA) together with VION Food Group started a pilot in 2005 where a regime of visual inspection was applied in one slaughtering facility (Helmond). Under 2005 legislation (EC directive 64/433) incisions were still mandatory. Therefore, the pilot was a combination of visual inspection and traditional inspection.

The objective of the pilot was to gain answers to three questions, i.e.:

- Does the system of visual inspection guarantee that the right food chain information is provided in the right manner? If not, which adaptations are necessary.

¹ EC regulation 854/2004, Annex I, section IV, chapter IV, B Post-mortem inspection, paragraph

2

² Meanwhile, a phased implementation within the EU has been agreed on.

- Does the system safeguard that at least the same level of food safety is guaranteed.
- Is the selected supervision arrangement adequate, both in a quantitative sense as in the qualitative sense.

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24 januari 2006
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In order to translate these questions into verifiable working procedures, three procedures were draughted in the initial phase, i.e.

- Procedure Control of Mycobacterium Avium in pork
- Procedure Food chain information
- Procedure Visual inspection

This report will describe the answers to the first two questions. The third question will not be answered in this report but will be dealt with in a different context.

Material and methods

Both the VION Food Group and the VWA did research and collected data to provide answers to the questions that were formulated. The following types of data were collected:

By the VWA:

- A numeric comparison of historical VWA-inspection data with those of the pilot
- Results of checks performed by the official veterinarian during the pilot
- Results of risk-based research into antibiotics residues where food chain information played a role
- Specific rejection data (particularly endocarditis and results of bacteriological research)
- Supplementary literature data in relation to the categories mentioned above. In addition, literature data were collected in relation to:
 - The potential food safety risk of *Rhodococcus equi* in fattening pigs.
 - The potential food safety risk of *Mycobacterium Avium* in fattening pigs.
- Results of VWA-audits on the correct implementation of the three procedures mentioned above.

By Vion Food:

- A serological testing method for Mycobacterium avium was developed and tested
- A system for the supplying of food chain information was developed and tested

Procedural results

As mentioned in the introduction, specific procedures were developed for the pilot. In order to evaluate the content of the collected data on the pilot it is important to establish whether these procedures were followed. For this purpose the following information sources can be used:

- Audit reports: the audits did not show any serious shortcomings. The main findings were some necessary text adaptations in the procedures.
- Checks by the official veterinarian. During these checks it was found:
 - That the drawing of blood during slaughter took place lege artis and that the traceability of the samples was safeguarded.
 - That with the exception of the information on the *M. avium* status in the initial phase, the described food chain information has been correctly supplied in a minimum of 90 % of the cases.
- VION's own checks on the completeness of the supplied food chain information (see *Results Food Chain Information (FCI) in the pilot 'Visual inspection'*): in the vast majority of the cases the FCI had been supplied in conformity with the procedure. At the start of the pilot the lack of information on group treatments was the main quantitative shortcoming. In the second phase it concerned mainly the information about the origin of the feed.

Evaluation food safety balance

The project team determined in advance that visual inspection couldn't be introduced until at least the same level of food safety can be guaranteed as in the case of traditional inspection. Based on the collected data the following semi-quantitative balance can be provided per defined data source:

1. A numeric comparison of historical VWA-inspection data with those of the pilot (see also the Preliminary final report of the data analysis "pilot visual inspection", 5.1)

Initially a comparison was made between the inspection data from the historical summary and the inspection data during the pilot. It turned out that the total number of rejections with the historical data differed significantly in comparison with the data of the pilot. Because a traditional inspection also always took place during the pilot, which in principle did not differ from the inspection during the historical summary, this difference was unexpected. This difference could be explained by the fact that the supply of fattening pigs from the historical data did not match with the supply during the pilot. On the basis of possible bias, no further comparison of these two types of data was done.

During the pilot it turned out that a number of deviations, which were reason for rejection, and which were detected during the traditional inspection, were not detected

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Significant
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Supply & Rugs

during visual inspection. This happened in nine cases out of a total of 174250. In one case the testing for antibiotics was positive, in a number of cases the bacteriological testing was positive.

It should be mentioned, however, that there were also logistical factors, which could partly explain the difference between visual inspection and traditional inspection.³

The meaning of the pathogen agents which lead to a positive bacteriological testing will be explained later.

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Based on the data mentioned above it can be concluded that there is minimal loss of food safety.

2. Results of risk-based research into antibiotics residues where food chain information played a role (see also Preliminary final report of the data analysis " pilot visual inspection", 5.3 & VION Food Group contribution Detecting antibiotic residues in pork)

Based on earlier slaughtering data (increased number of lung-pleura deviations in four previous weeks), targeted testing for antibiotics was done. During the first screening a significant number of animals tested positive for antibiotics⁴. In two cases the MRL was exceeded which was a reason for rejection.

The conclusion that a – limited – gain in food safety was reached seems justified.

3. Specific rejection data (particularly endocarditis and results of bacteriological research) (see also Preliminary final report of the data analysis " pilot visual inspection", enclosure 2)

It was expected that the elimination of incisions in the heart muscle could result in the missing of a number of cases of endocarditis. It should be noted however that the prevalence of endocarditis is very low. (During the pilot 0,0034 %; range comparable historical data 0,005%⁵ - 0,036%⁶).

Of the total number of six cases of endocarditis, two were detected during visual inspection. Only one of the six found endocardites turned out to be positive at bacteriological testing. This is lower than the percentage of positive endocarditides in

³ The comparison with the historical data showed, however, that the total number of rejections (the sum of visual inspection and traditional inspection) was significantly lower. This strongly suggests that the findings from historical data was not 100% comparable to the findings during the pilot.

⁴ Reference: results of samples taken under the National Residues Plan at the slaughter facility in Helmond

⁵ Slaughter establishment Meppel, 2004

⁶ W.Wouda et al. Endocarditis and meat inspection of slaughter pigs. Journal of Animal Medicine, part 112, edition 21, 1987, p. 1226-1235. The percentage mentioned concerns data of 1982.

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2004 at slaughter facility Meppel, but in view of the low numbers it is difficult to draw hard conclusions from this.

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From VWA's own data, but also from literature data, it turns out that in a number of cases (10,5-16,7%) a pathogen agent (*A. pyogenes*) is concerned of which the significance for public health is considered negligible. In a number of other cases it is not always possible to make a direct connection with food safety.

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The conclusion is that the possible missing of endocarditides could mean a limited to very limited loss of food safety, especially if the pathogenicity of the pathogen agents found is incorporated.

4. Data surface contamination *Salmonella* spp. Head area before and after incision of the mandibular lymph nodes (see *Vion Food -contribution Salmonella monitoring*)

It has turned out that the incision of the mandibular lymph nodes greatly increases the chance for surface contamination with *Salmonella*. From a pathophysiological point of view, this is explainable because the mandibular lymph nodes are a predilection location for the presence of *Salmonella*. In a small number of cases there is a reversed effect, namely that is no longer possible to demonstrate the presence of *Salmonella* after the incision. This could be explained by values that are close to the detection limit of the analysis.

Based on these data, the demonstrated over-all positive effect of no incision and other literature data, the VION Group contribution shows that the omission of the incision can play a clear role in the prevention of *Salmonella* caused food infections originating from contaminated pork..

The conclusion is that omitting the incision of the mandibular lymph nodes in relation to the risk of *Salmonella*-contamination leads to considerable gains in food safety.

5. Literature data collected in relation to the potential food safety risk of *Rhodococcus equi* in the mandibular lymph nodes of fattening pigs. (See also Preliminary final report of the data analysis "pilot visual inspection", enclosure 1)

The reason for including this pathogen agent in the research was the fact that this pathogen agent has been found fairly regularly in lymph nodes with purulent lesions of pigs. The lesion is comparable to the lesion that can be caused by *M. Avium*. In humans with immunodeficiencies (HIV/AIDS patients) the pathogen agent can a.o. cause pneumonia, with fatal results. A clear etiological connection has not been demonstrated, however. Moreover, it can be argued that the incision of the lymph nodes could have a

contraproductive effect. In addition, it is known from literature that the macroscopic detection of *Rhodococcus equi* infections using purulent infection focuses has its limitations.

An important difference with *M. avium* (see below) is that the presence of *Rhodococcus equi* in fattening pigs is almost always limited to the head lymph nodes. *M. avium* can also systemically spread in pigs.

The conclusion is that there are, for the time being, not enough data available to determine either a gain or a loss in food safety.

6. Literature data in relation to the potential food safety risk of *Mycobacterium Avium* in fattening pigs. (See also the Preliminary final report of the data analysis "pilot visual inspection", enclosure 3)

It has turned out that that presence of purulent lesions in lymph nodes is not always an indication of the presence of *M. Avium*. Inversely *M. Avium* can also be found in lymph nodes without such lesions. No distinct conclusion can be drawn over the zoonotic character. Just like in the case of *Rhodococcus equi* this pathogen agent especially plays a role in immunodeficient humans and in children. As mentioned above, this pathogen agent could spread systemically in fattening pigs. In the analysis *Risk Assessment System Meat Production Chain – phase 1* a panel of experts has concluded that with respect to the significance of *M. avium* for food safety there are gaps in knowledge, but that there could be an element of priority.⁷

The conclusion is that :

- The significance of *M. Avium* in fattening pigs for food safety is largely unknown, but should not be considered a negligible risk either
- The incision of lymph nodes as a means of detection has limited significance

7. The results of serological monitoring for *M. Avium* (see *Results monitoring Mycobacterium avium*⁸ and *A serological approach of the control of Mycobacterium avium spp avium in the fattening pigs production chain: a descriptive analysis of the pilot data of the Vion Food Group and Animal Sciences Group*⁹)

In the course of the pilot, a considerable number of samples have been taken (22461). Because new pigs farms joined in the course of the pilot, it was not possible to determine the *Mycobacterium avium* status for all farms conform the procedure for the minimum number of samples. Nevertheless, it was possible to take more than 10

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⁷ Risk Assessment System Meat Production Chain– Report phase 1, Final draft 11 August 2004.

⁸ Draft version

⁹ Concept version

U.S. Department of Agriculture
Food Safety and Inspection Service
International Equivalence Staff
Ms Sally White
Director
South Building, room 4434
Washington, D.C. 20250



landbouw, natuur en
voedselkwaliteit

U.S.A.

Your letter of	your reference	our reference	date
Feb. 24, 2006		VD 06.1018/IH	31-3-2006
re:		extension no.	enclosures
2006 audit preparation		+31-70-3785435	2

_____ Dear Ms. White,

|

Your letter dated February 24, 2006, to the European Commission informing them of the dates of the upcoming annual audit of the Netherlands meat inspection system (April 19 through May 18, 2006) has been brought to my attention and I am happy to confirm these dates to you. The details of the audit and the itinerary to be followed are currently being worked out by our services.

As agreed during my visit of December 8, 2005, I take pleasure in providing you with additional information about recent changes in our meat inspection system, which I believe will be of benefit for your auditor in the preparation of his visit. These changes are in part resulting from the introduction of the new EU Hygiene Regulations on January 1, 2006, which cover the entire spectrum of food safety, including meat and meat products. This new legislation was discussed between FSIS and the European Commission at the

Ministry of Agriculture,
Nature and Food Quality
Food Quality and Animal
Health
Cluster International
Bezuidenhoutseweg 73
Postal Address: P.O. Box

recent Joint Management Committee meeting in October 2005. On January 12, 2006, the European Commission sent you a complete set of the acts and related implementing measures.

In our letter of February 14, 2006, we elaborated on the information provided by the Commission, by informing all CVO's in our foreign markets of the new and old legislation and certain other changes, which might have an effect on the text of our veterinary health certificates.

2500 EK The Hague
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There are two aspects of our meat inspection system that I would like to specifically address in this letter, i.e. the option of visual post mortem inspection offered under the new legislation, and the delegation of certain elements of the post mortem meat inspection from the official veterinarian to official auxiliaries employed by an independent organization, which is permitted under both old and current EU legislation.

A. Visual post mortem inspection

During my visit on December 8, 2005, we discussed developments in the philosophy of meat inspection in the EU and certain comparable developments in the US (i.e. HIMP Market Hogs). We agreed that this topic was of mutual interest and that an exchange of

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information by U.S. and Dutch experts could take place during a conference call. Unfortunately, a mutually convenient date for this conference call has not been found yet, but we remain keenly interested in setting this up, preferably before the next audit. The hygiene regulations EC 852/2004, EC 853/2004 and EC 854/2004 offer the possibility for fattening pigs, housed under controlled conditions in integrated production systems since weaning, to be subject to a visual inspection before and after slaughter. This visual inspection is part of a risk-based inspection system. Application of this inspection system requires the availability of food chain information and epidemiological data. Every enterprise has the option to either stick to the "old" system or to implement a visual inspection system. The legal basis of visual inspection is to be found in Appendix 1, Section IV, B post-mortem inspection of EU Regulation 854/2004. The VION Company, the major pork producer in the Netherlands, looked into the merits of this type of inspection and consulted with the competent authority, the Food and Consumer Product Safety Authority (VWA), on how to proceed. In order to get official approval for the new inspection system, VION had to demonstrate to VWA that the produced pork would at least meet the EU set levels of food safety and would fulfill the

mandatory EU hygiene regulations provisions.

For your information I would like to refer you to the enclosed final evaluation of VION's pilot project, which was carried out in one of the slaughter plants of that company. As you will remember, a company report on this pilot project was submitted to you during our meeting on December 8, 2005.

VWA investigated the content of the chain management system in order to be convinced that the official requirements laid down in regulation (EC) 853/2004 have been met and that the submitted Food Chain Information was sufficient to realize - at least - a similar level of food safety by means of the applied visual inspection, in comparison to the current procedures for meat inspection. These two prerequisites constitute the basis for official certification. Based on their positive findings, VWA gave VION the green light to

implement the visual inspection system. You will find the VWA final report 'Pilot Chain Management VION' enclosed.

In February 2006 the Food and Veterinary Office of the European Commission visited the pilot slaughterhouse during an inspection mission on the official controls related to food safety of animal products and took note of the applied visual inspection system. FVO found the slaughterhouse in compliance with EU legislation.

With both the VWA approval and the positive FVO report, VION intends to now fully implement this inspection system in their Helmond facility. This will enable your auditor to personally observe the way in which the system works, when he visits this establishment, which I believe is planned at the end of the program.

I would like to underline that it is a company's decision to apply for a food chain management and visual inspection system. Whether other Dutch pork producers will try to implement such a system is unknown. If they will, every implementation will be evaluated by VWA.

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31-3-2006

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B. New organization of the red meat inspection system

During our meeting on December 8, 2005, the delegation of certain aspects of the post mortem meat inspection from the VWA to an independent organization was also raised, and you indicated that this topic had been brought to your attention before. At your request, a formal document explaining the details of this delegation has been drawn up, and I take pleasure in sending you this report as an enclosure. The report focuses on meat slaughterhouses under permanent supervision of the VWA.

I hope that the above information on the new EU legislation and the modernization of meat inspection will provide a good basis for discussion during the upcoming audit. I am looking forward to your response with great interest, especially on my suggestion to hold a conference call on visual post mortem meat inspection on short notice.

Yours sincerely,
CHIEF VETERINARY OFFICER,



dr. P.W. de Leeuw

cc:

Ms. Karen Stuck, Assistant Administrator, USDA/FSIS
Mr. William James, Deputy Assistant Administrator, USDA/FSIS
Mr. Steven McDermott, Deputy Director International Equivalence Staff, USDA/FSIS
Mr. Ghias Mughal, Senior Equivalence Officer, USDA/FSIS
Ms. Anita Manka, Senior Food Technologist, USDA/FSIS
DG Sanco, Mr. Paul van Geldorp & Mr. Lorenzo Terzi
Food and Consumer Product Safety Authority (VWA)
Agricultural Counselor Washington, DC

(Draft)

Results Food Chain Information (FCI) in the pilot 'Visual Inspection'

Summary

During the pilot, Food Chain Information (FCI) is made available by the supply chain for the visual inspection of slaughter pigs. On average, 98% of the delivered herds arrived at the slaughter plant with the correct FCI. While on average for 99% of the delivered herds the information is available just before slaughtering the pigs. Lack of information about the origin of feed is the main reason for not being accepted to 'visual inspection'. The FCI is also used to decide whether a farm is part of the residue monitoring program. This program is risk based and resulted in average on 14% of the farms that were selected for residue monitoring. The serological results of MA monitoring is not yet part of the Food Chain Information, while the monitoring started during the pilot.

Methods

During the pilot, FCI is provided through the supply chain for the visual inspection of slaughter pigs. All groups of pigs presented for inspection must comply with the following information:

- Pigs from farms meeting the requirements laid down in the Code of Practice of the IKB-scheme or equivalent quality assurance schemes;
- Individual pigs of IKB status;
- Pigs from farms providing data on origin of feed;
- Pigs from farms providing data on group treatment of pigs covering a minimum period of two months prior to slaughter.
- Pigs from farms with a neutral to low Farm Risk Profile (FRP) with respect to *Mycobacterium avium* (This was not yet implemented in the pilot).
- When percentages of lung lesion and pleurisy in the previous 4 weeks, are higher than twice the slaughterhouse average, additional checks for antibiotic residues will occur. A risk-based monitoring is performed regarding a higher risk of group treatments.

The farmer supplies the information on group treatment and IKB status of the pigs, the other information is supplied through Vion Farming. The slaughterhouse checks the IKB status of every batch of pigs presented for slaughter (verification with the aid of Verin's database and IKB-2004). IKB audits verify the delivery of GMP+ approved feed. Data on delivery forms are checked against data on feed supply documents. When in doubt, calculations can be made on the basis of the stated quantity of feed and the number of pigs presented for slaughter.

In the future, the official veterinarian decides on basis of this information, whether the carcasses of pigs will be subjected to a visual or a traditional post mortem inspection. In the pilot, all the carcasses are is subjected to visual and traditional post mortem inspection.

An employee at the slaughterhouse checks if all the required Food Chain Information is available. The employee checks the IKB status, group medicine information, percentage of lung lesions and/or pleurisy and origin of feed. Incomplete information for one of these items is recorded per farm.

Pigs not complying with IKB are separated by means of canalisation. From each herd with lung lesions and/or pleurisy higher than twice the slaughterhouse average an additional check on antibiotic residues is carried out.

Results

Figure 1 and 2 show the % farms which are accepted for 'visual inspection' at respectively arrival at the slaughterhouse and just before the actual slaughtering, in the period of 15 September 2005 till 5 January 2006.

The information needed for the visual inspection of slaughter pigs is not always complete at arrival at the slaughterhouse. On average, 98% of the delivered herds provide the correct information at arrival at the slaughter plant, while for 99% of the delivered herds the information is available just before slaughtering the pigs.

Figure 1 % Farms accepted to 'visual inspection' at arrival slaughterhouse (except for *M. avium*)

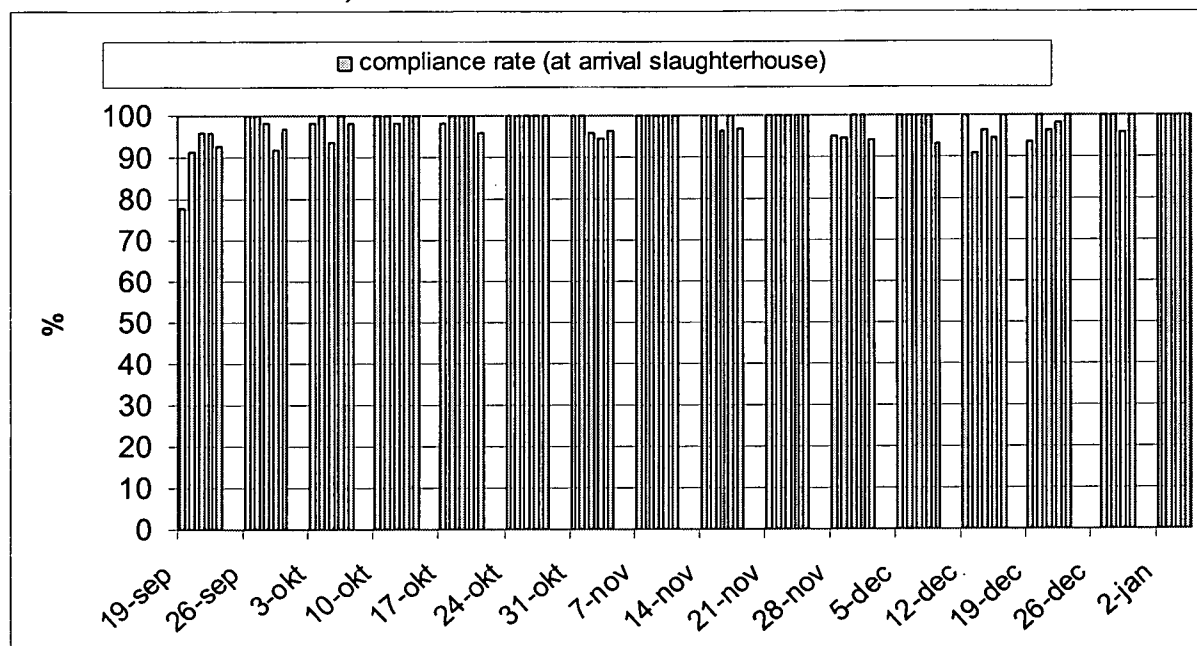


Figure 2 % Farms accepted to 'visual inspection' at start slaughtering pigs (except for *M. avium*)

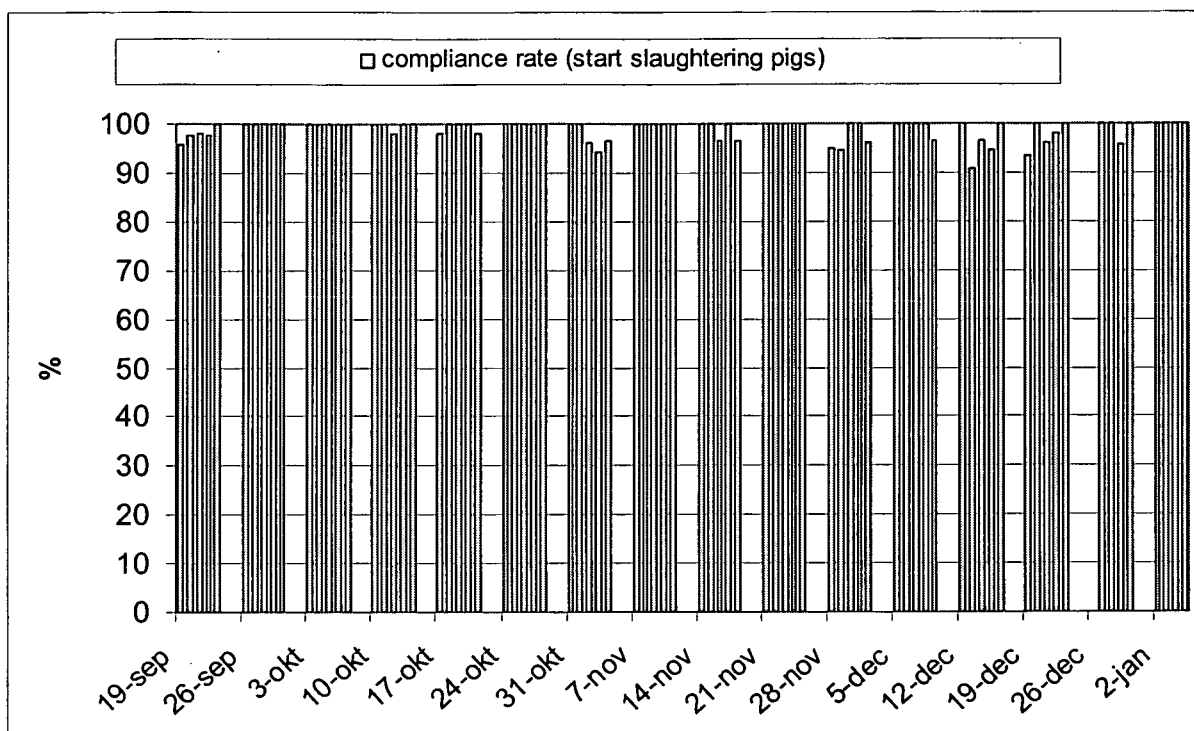
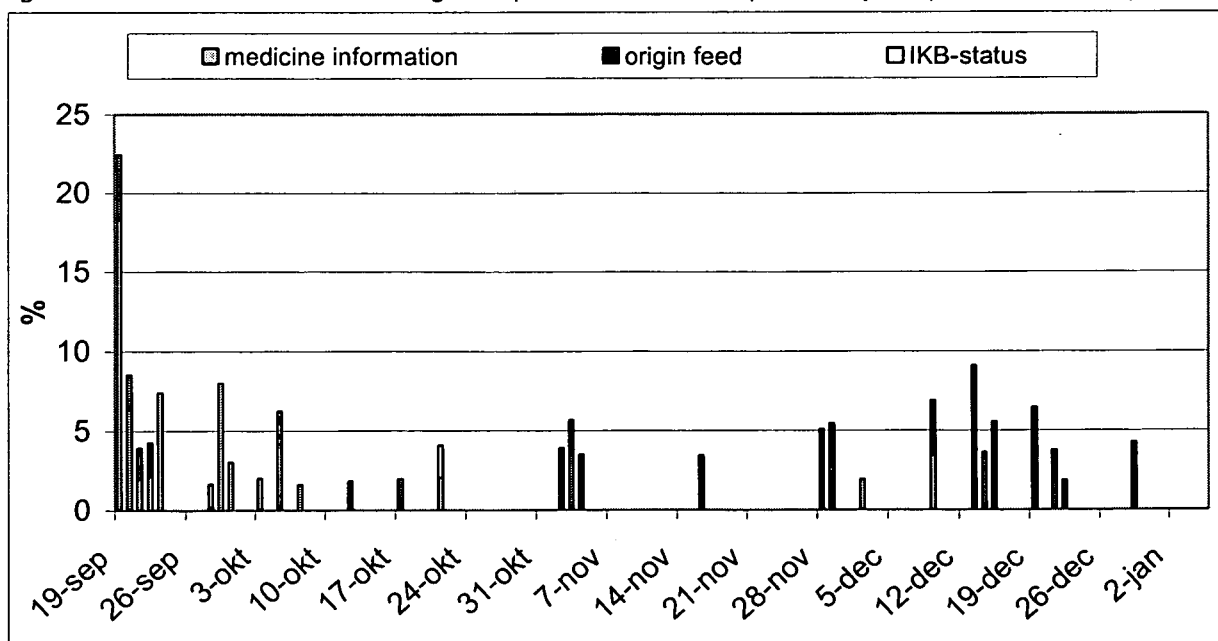


Figure 3 shows the reasons for not being accepted for 'visual inspection'. The Farm Risk Profile for M. Avium is not yet included in this figure. In the beginning of the pilot the absence of the information concerning group treatment was the main reason for a herd of pigs not being accepted for 'visual inspection' (see figure 3). The farmers had to adjust to the new procedure to provide this information on the transport document. VION Farming records the origin of feed per farm. Figure 3 shows that this record is not 100% complete yet and is during the pilot the main reason for not being accepted to 'visual inspection'.

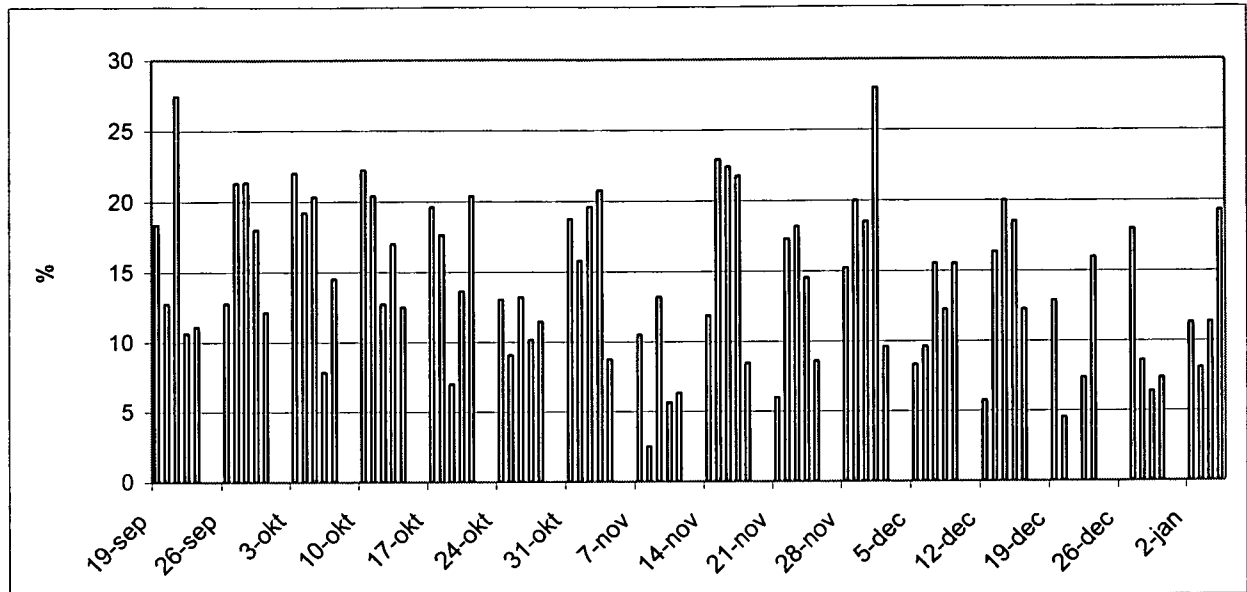
Figure 3 Reason for not being accepted for 'visual inspection' (except for M. Avium)



When percentages of lung and liver lesion and pleurisy in the previous 4 weeks, are

higher than twice the slaughterhouse average, additional checks for antibiotic residues will occur. A risk-based control is performed regarding a higher risk of group treatments.

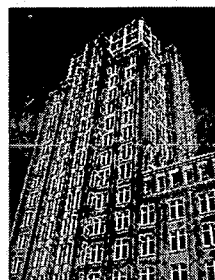
Figure 4 % farms with % lung lesion and/or pleurisy more than twice the average of the slaughterhouse



On average 14% of all farms, had in the previous 4 weeks an average percentage of lung and/or pleurisy lesions, higher than twice the slaughterhouse average. From each farm of that group, an additional check for antibiotic residues was required.

Pork Supply Chain Meat Inspection

Ate Jelsma
Food and Consumer Product Safety Authority (VWA)
Directorate of Inspection and Communication
The Netherlands



Subjects:

- (small) overview relevant EU legislation
- project visual inspection pigs and results in NL 2005/2006
- continuation project and results until 2008

EU-Food safety legislation

- General Food law – Regulation 178/2002
- H 1 - hygiene of foodstuffs – Regulation 852/2004
- H 2 - hygiene rules for food of animal origin – Regulation 853/2004
- H 3 - official controls (meat inspection) – Regulation 854/2004
- H 4 – 2002/99/EC (animal health)
- H 5 - repealing 17 directives
- Official Feed & Food Controls – Regulation 882/2004

Pilot project pork supply chain meat inspection in the Netherlands

Hygiene Package, Regulation 854/2004, ANNEX I, section IV, Chapter IV, point B 2:

"the competent authority may decide, on the basis of epidemiological or other data from the holding, that fattening pigs housed under controlled housing conditions in integrated production systems since weaning need, in some or all of the cases referred to in paragraph 1, only undergo visual inspection"

Pilot project

Procedures:

- Procedure Food Chain Information (FCI)
- Procedure control of *Mycobacterium avium*
- Procedure visual p.m. inspection
- Inspection arrangement VWA
- Investigation on Salmonella in throat area before and after incision of lymph nodes of the head

FCI

Based on the IKB system of the industry:

- FCI: items of Regulation 853/2004, Annex II, Section III, point 3, a) till h)
- Water, pest control
- Animal health and animal movements
- Additional on top of IKB:
- Feed origin
- Outdoor management
- Control on compost (not used)
- History of treatment with antibiotics last two months before slaughtering
- Historical data of previous pathological findings at slaughter (pleurisy, pneumonia, liver and skin disorders).

Procedure FCI

Allowed to visual p.m. inspection:

- IKB status/FCI format + additional requirements
- Selection of pigs from farmers with more than the average of deviations of lungs/pleura for further investigation on antibiotics (VWA)
- Only fattening pigs
- Comply with *M. Avium* procedure

Procedure *M. Avium*

Procedure *M. Avium* :

- Blood sera for verification on *M. avium*
- Registration of all the results gives a Risk Profile at farm level (BRP)
- Three categories BRP:
 - Neutral, low and high with different decisions
- Supervision of control is based on:
 - Samples are taken under supervision of competent authority
 - Audit by the competent authority of the procedures

Procedure visual p.m. inspection pigs

Visual inspection based on:

- FCI information available in the slaughterhouse, 24 hours before slaughtering
- BRP *M. Avium* is neutral or low
- Visual inspection, and for all non-conformities followed by "traditional" inspection with incisions of heart, lung and lymph nodes of the head

Procedure inspection arrangement

VWA audits and verification

- Audit on procedures FCI and *M. Avium*
 - Audit on delivering FCI at slaughterhouse level
 - Audit on implementation of FCI
- Verification at slaughterhouse level: FCI, *M. Avium* and visual inspection (see next slide)
- Verification at farm level

Procedure inspection arrangement

Verification by official veterinarian of the VWA at slaughterhouse level

- Check on FCI
- Check on *M. Avium* status with Risk Profile level (BRP)
- Check on program of blood-sera and traceability of samples
- Check on decisions made by visual p.m. inspectors

Supervision on p.m. in Pork Supply Chain Meat Inspection

Supervision based on two pillars:

1. Regular supervision by the OV of the work of the OA
 - Inspection tasks
 - Inspection decisions (pathological defects and hygienic slaughtering)
 2. Monitoring of the plant operators on slaughter defects and pathological observations just before cooling:
 - 4 times a day 40 carcasses
 - 2 times a day 40 plucks
- This performance of the whole process of pm inspection and rework should be below 2% defects.
- The OV verifies 2x /day also 40 carcasses to check the quality of the monitoring of the plant.

Literature aspects

Three aspects in literature

- Hazard analysis for food safety of *Rhodococcus equi*
- Risk assessment for food safety of endocarditis
- Hazard analysis for food safety of *M. avium*

Testing during pilot

During pilot tests have been done for:

- Comparison inspection results visual and traditional p.m. inspection
- Selection of pigs from farmers with more than the average of deviations of lungs/pleura for further investigation on antibiotics
- Literature
- Serological verification system for *M. avium*
- Investigation on Salmonella in throat area

Result Comparison inspection results

Comparison inspection results visual p.m. inspection with historical results:

- Report with analysis of the data from pilot and historical data
- During the pilot 174,250 pigs were inspected

Result Comparison inspection results

- 174,250 were inspected
- 9 carcasses were not detected by visual inspectors and were condemned by traditional inspection
 - 1 positive for antibiotic examination
 - 4 positive by bacteriological examination (3 *A. pyogenes*)
 - 4 other reasons

Result Comparison inspection results

- Low amount of not detected carcasses
- Maybe logistic reasons for not detecting some carcasses
- Literature of *A. pyogenes*: low risk for food safety

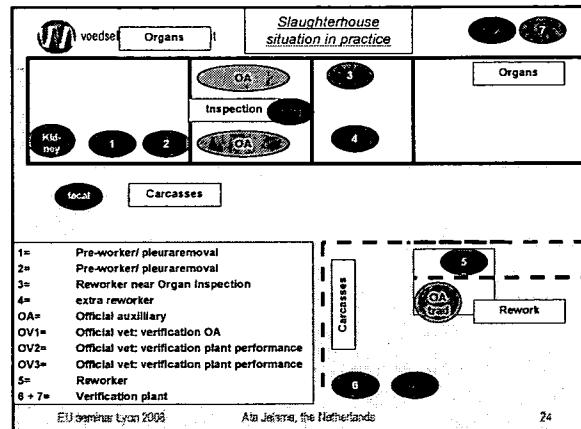
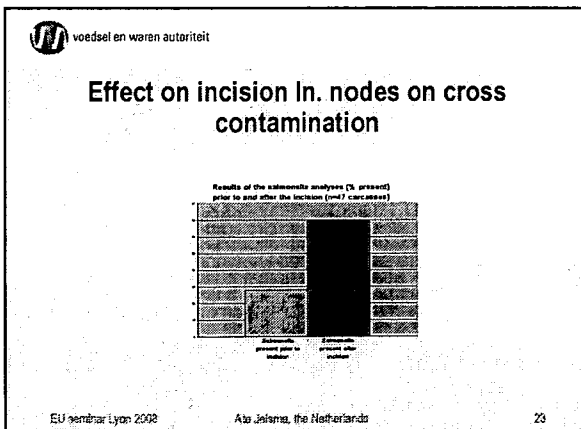
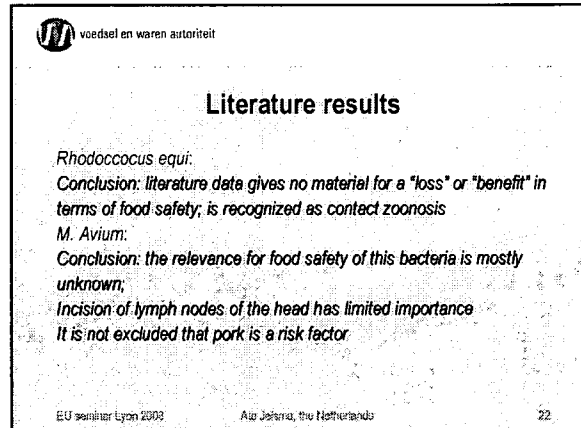
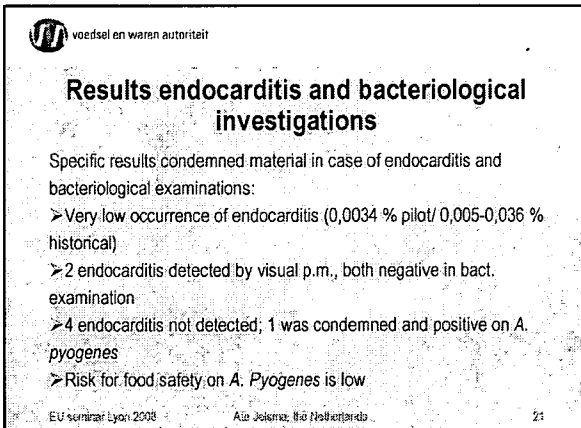
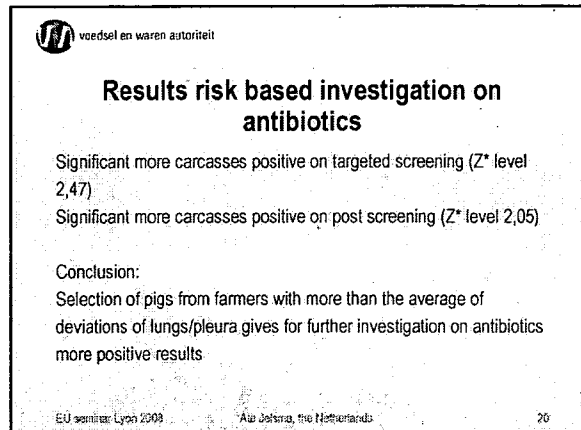
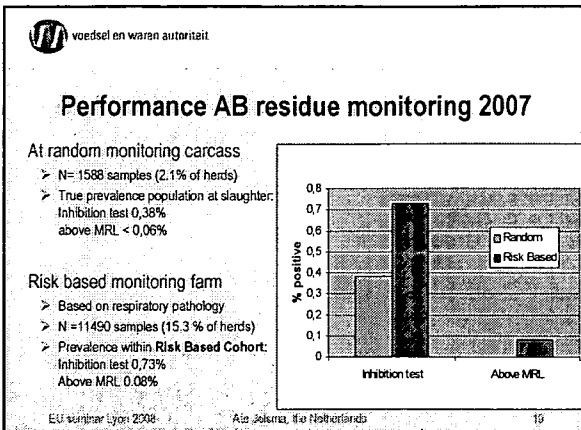
Results audits and controls of official veterinarian

Audits:

- no major remarks

Verification by Official Veterinarian:

- Verification on program of blood-sera and traceability of samples: no remarks
- After "start" problems: delivering FCI correct for > 90 %



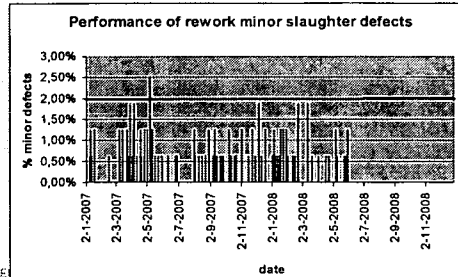
Standard visual inspection

- > Same standard as used for traditional inspection
 - > Inspection tasks
 - > Inspection decisions (pathological defects and hygienic slaughtering)

Results of check on performing the p.m inspection in traditional and visual inspection (pork supply chain meat inspection) during and after pilot: no difference in results and both systems fulfil the standard (inspection task: 5% and path. defects and hyg. slaughtering: both below 2%)

Reporting process performance 2007-2008

Target level is below 2% daily. Non conformance with this target is followed by increased inspection by the competent authority.



Risk profiling farms for MAA

- High risk farms
- >> traditional inspection
 - >> control program at farm
 - >> access to supply chain inspection after repeated negative testing

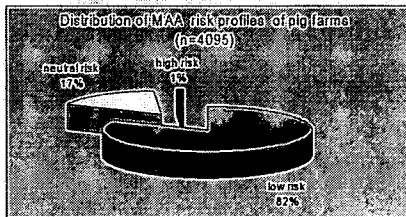


Figure: Distribution of MAA risk profiles of pig farms (n=4095), August 2007.

Does the system safeguard that at least the same level of food safety is guaranteed?

Level of food safety

- > Number of condemnations
 - > Pilot: visual + traditional: 0,0247 %
 - > Pilot: visual: 0,0195 %
 - > Pilot: visual not detected and condemned by traditional: 0.0052 %;
- > Endocarditis: two out of six cases detected with visual inspection;
- > Risk-based testing against residues of antibiotics: significant more carcasses positive on (post) screening;
- > Omitting of incision of the mandibular lymphnodes showed a substantial reduction in the cross contamination of salmonella in that region;
- > Implementation of *M. Avium* farm control system with the monitoring of antibodies as a verification procedure and defining a herd status

Level of food safety

The introduction of a hands off system by visual inspection during the pilot has shown that this system has an advantage in terms of food safety!



Key terms

- FCI from farmer level to the slaughterhouse is basic
- Serological monitoring system: Risk profil farmer (M. Avium)
- Information on slaughterhouse level used for testing residues related to farmer level
- OV in charge for auditing the system



memo

To
Steering group visual inspection

Subject
Final Report 'Pilot Chain Management VION'

Deleted:

datum
24 januari 2006
ons kenmerk

Introduction

With the implementation of the hygiene regulations EC 852/2004, EC 853/2004 & EC 854/2004 the possibility was created for the application under certain conditions of a differentiated inspection regime for fattening pigs by which one or more incisions can be omitted (henceforward to be referred to as "visual inspection"). The verbatim text is as follows:

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behandeld door
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telefoon (0575) 58 81 00
rene.lesuis@vwa.nl

*'The competent authority may decide, on the basis of epidemiological or other data from the holding, that fattening pigs housed under controlled housing conditions in integrated production systems since weaning need, in some or all of the cases referred to in paragraph 1, only undergo visual inspection.'*¹

The condition 'epidemiological or other data' included above will be in addition to the providing of food chain information, which has also become mandatory on January 1, 2006.²

Based on this new legislation, the Food and Consumer Safety Authority (VWA) together with VION Food Group started a pilot in 2005 where a regime of visual inspection was applied in one slaughtering facility (Helmond). Under 2005 legislation (EC directive 64/433) incisions were still mandatory. Therefore, the pilot was a combination of visual inspection and traditional inspection.

The objective of the pilot was to gain answers to three questions, i.e.:

- Does the system of visual inspection guarantee that the right food chain information is provided in the right manner? If not, which adaptations are necessary.

¹ EC regulation 854/2004, Annex I, section IV, chapter IV, B Post-mortem inspection, paragraph 2

² Meanwhile, a phased implementation within the EU has been agreed on.

- Does the system safeguard that at least the same level of food safety is guaranteed.
- Is the selected supervision arrangement adequate, both in a quantitative sense as in the qualitative sense.

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In order to translate these questions into verifiable working procedures, three procedures were draughted in the initial phase, i.e.

- Procedure Control of Mycobacterium Avium in pork
- Procedure Food chain information
- Procedure Visual inspection

This report will describe the answers to the first two questions. The third question will not be answered in this report but will be dealt with in a different context.

Material and methods

Both the VION Food Group and the VWA did research and collected data to provide answers to the questions that were formulated. The following types of data were collected:

By the VWA:

- A numeric comparison of historical VWA-inspection data with those of the pilot
- Results of checks performed by the official veterinarian during the pilot
- Results of risk-based research into antibiotics residues where food chain information played a role
- Specific rejection data (particularly endocarditis and results of bacteriological research)
- Supplementary literature data in relation to the categories mentioned above. In addition, literature data were collected in relation to:
 - The potential food safety risk of *Rhodococcus equi* in fattening pigs.
 - The potential food safety risk of *Mycobacterium Avium* in fattening pigs.
- Results of VWA-audits on the correct implementation of the three procedures mentioned above.

By Vion Food:

- A serological testing method for Mycobacterium avium was developed and tested
- A system for the supplying of food chain information was developed and tested

Procedural results

As mentioned in the introduction, specific procedures were developed for the pilot. In order to evaluate the content of the collected data on the pilot it is important to establish whether these procedures were followed. For this purpose the following information sources can be used:

- Audit reports: the audits did not show any serious shortcomings. The main findings were some necessary text adaptations in the procedures.
- Checks by the official veterinarian. During these checks it was found:
 - That the drawing of blood during slaughter took place lege artis and that the traceability of the samples was safeguarded.
 - That with the exception of the information on the *M. avium* status in the initial phase, the described food chain information has been correctly supplied in a minimum of 90 % of the cases.
- VION's own checks on the completeness of the supplied food chain information (see *Results Food Chain Information (FCI) in the pilot 'Visual inspection'*): in the vast majority of the cases the FCI had been supplied in conformity with the procedure. At the start of the pilot the lack of information on group treatments was the main quantitative shortcoming. In the second phase it concerned mainly the information about the origin of the feed.

Evaluation food safety balance

The project team determined in advance that visual inspection couldn't be introduced until at least the same level of food safety can be guaranteed as in the case of traditional inspection. Based on the collected data the following semi-quantitative balance can be provided per defined data source:

1. A numeric comparison of historical VWA-inspection data with those of the pilot (see also the Preliminary final report of the data analysis "pilot visual inspection", 5.1)

Initially a comparison was made between the inspection data from the historical summary and the inspection data during the pilot. It turned out that the total number of rejections with the historical data differed significantly in comparison with the data of the pilot. Because a traditional inspection also always took place during the pilot, which in principle did not differ from the inspection during the historical summary, this difference was unexpected. This difference could be explained by the fact that the supply of fattening pigs from the historical data did not match with the supply during the pilot. On the basis of possible bias, no further comparison of these two types of data was done.

During the pilot it turned out that a number of deviations, which were reason for rejection, and which were detected during the traditional inspection, were not detected

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during visual inspection. This happened in nine cases out of a total of 174250. In one case the testing for antibiotics was positive, in a number of cases the bacteriological testing was positive.

It should be mentioned, however, that there were also logistical factors, which could partly explain the difference between visual inspection and traditional inspection.³

The meaning of the pathogen agents which lead to a positive bacteriological testing will be explained later.

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Based on the data mentioned above it can be concluded that there is minimal loss of food safety.

2. Results of risk-based research into antibiotics residues where food chain information played a role (see also Preliminary final report of the data analysis " pilot visual inspection", 5.3 & VION Food Group contribution Detecting antibiotic residues in pork)

Based on earlier slaughtering data (increased number of lung-pleura deviations in four previous weeks), targeted testing for antibiotics was done. During the first screening a significant number of animals tested positive for antibiotics⁴. In two cases the MRL was exceeded which was a reason for rejection.

The conclusion that a – limited – gain in food safety was reached seems justified.

3. Specific rejection data (particularly endocarditis and results of bacteriological research) (see also Preliminary final report of the data analysis " pilot visual inspection", enclosure 2)

It was expected that the elimination of incisions in the heart muscle could result in the missing of a number of cases of endocarditis. It should be noted however that the prevalence of endocarditis is very low. (During the pilot 0,0034 %; range comparable historical data 0,005%⁵ - 0,036%⁶).

Of the total number of six cases of endocarditis, two were detected during visual inspection. Only one of the six found endocardites turned out to be positive at bacteriological testing. This is lower than the percentage of positive endocarditides in

³ The comparison with the historical data showed, however, that the total number of rejections (the sum of visual inspection and traditional inspection) was significantly lower. This strongly suggests that the findings from historical data was not 100% comparable to the findings during the pilot.

⁴ Reference: results of samples taken under the National Residues Plan at the slaughter facility in Helmond

⁵ Slaughter establishment Meppel, 2004

⁶ W.Wouda et al. Endocarditis and meat inspection of slaughter pigs. Journal of Animal Medicine, part 112, edition 21, 1987, p. 1226-1235. The percentage mentioned concerns data of 1982.

2004 at slaughter facility Meppel, but in view of the low numbers it is difficult to draw hard conclusions from this.

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From VWA's own data, but also from literature data, it turns out that in a number of cases (10,5-16,7%) a pathogen agent (*A. pyogenes*) is concerned of which the significance for public health is considered negligible. In a number of other cases it is not always possible to make a direct connection with food safety.

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The conclusion is that the possible missing of endocarditides could mean a limited to very limited loss of food safety, especially if the pathogenicity of the pathogen agents found is incorporated.

4. Data surface contamination *Salmonella* spp. Head area before and after incision of the mandibular lymph nodes (see *Vion Food -contribution Salmonella monitoring*)

It has turned out that the incision of the mandibular lymph nodes greatly increases the chance for surface contamination with *Salmonella*. From a pathophysiological point of view, this is explainable because the mandibular lymph nodes are a predilection location for the presence of *Salmonella*. In a small number of cases there is a reversed effect, namely that is no longer possible to demonstrate the presence of *Salmonella* after the incision. This could be explained by values that are close to the detection limit of the analysis.

Based on these data, the demonstrated over-all positive effect of no incision and other literature data, the VION Group contribution shows that the omission of the incision can play a clear role in the prevention of *Salmonella* caused food infections originating from contaminated pork..

The conclusion is that omitting the incision of the mandibular lymph nodes in relation to the risk of *Salmonella*-contamination leads to considerable gains in food safety.

5. Literature data collected in relation to the potential food safety risk of *Rhodococcus equi* in the mandibular lymph nodes of fattening pigs. (See also Preliminary final report of the data analysis "pilot visual inspection", enclosure 1)

The reason for including this pathogen agent in the research was the fact that this pathogen agent has been found fairly regularly in lymph nodes with purulent lesions of pigs. The lesion is comparable to the lesion that can be caused by *M. Avium*. In humans with immunodeficiencies (HIV/AIDS patients) the pathogen agent can a.o. cause pneumonia, with fatal results. A clear etiological connection has not been demonstrated, however. Moreover, it can be argued that the incision of the lymph nodes could have a

contraproductive effect. In addition, it is known from literature that the macroscopic detection of *Rhodococcus equi* infections using purulent infection focuses has its limitations.

An important difference with *M. avium* (see below) is that the presence of *Rhodococcus equi* in fattening pigs is almost always limited to the head lymph nodes. *M. avium* can also systemically spread in pigs.

The conclusion is that there are, for the time being, not enough data available to determine either a gain or a loss in food safety.

6. Literature data in relation to the potential food safety risk of *Mycobacterium Avium* in fattening pigs. (See also the Preliminary final report of the data analysis "pilot visual inspection", enclosure 3)

It has turned out that the presence of purulent lesions in lymph nodes is not always an indication of the presence of *M. Avium*. Inversely *M. Avium* can also be found in lymph nodes without such lesions. No distinct conclusion can be drawn over the zoonotic character. Just like in the case of *Rhodococcus equi* this pathogen agent especially plays a role in immunodeficient humans and in children. As mentioned above, this pathogen agent could spread systemically in fattening pigs. In the analysis *Risk Assessment System Meat Production Chain – phase 1* a panel of experts has concluded that with respect to the significance of *M. avium* for food safety there are gaps in knowledge, but that there could be an element of priority.⁷

The conclusion is that :

- The significance of *M. Avium* in fattening pigs for food safety is largely unknown, but should not be considered a negligible risk either
- The incision of lymph nodes as a means of detection has limited significance

7. The results of serological monitoring for *M. Avium* (see *Results monitoring Mycobacterium avium*⁸ and *A serological approach of the control of Mycobacterium avium spp avium in the fattening pigs production chain: a descriptive analysis of the pilot data of the Vion Food Group and Animal Sciences Group*⁹)

In the course of the pilot, a considerable number of samples have been taken (22461). Because new pigs farms joined in the course of the pilot, it was not possible to determine the *Mycobacterium avium* status for all farms conform the procedure for the minimum number of samples. Nevertheless, it was possible to take more than 10

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⁷ Risk Assessment System Meat Production Chain– Report phase 1, Final draft 11 August 2004.

⁸ Draft version

⁹ Concept version

NETHERLANDS—**VISUAL INSPECTION OF SWINE****Questions and Concerns on the Draft Final Report titled “Pilot Pork Supply Chain Inspection VION”**

1. The pilot study concludes that visual inspection failed to reject 9 of 174,250 (.0052%) carcasses that were inspected. However, this also represents 9 of 43 (20.9%) carcasses rejected during the pilot study. Therefore visual inspection failed to detect a significant portion (21%) of carcasses affected with pathological conditions that warranted rejection. It appears that the Netherlands considers it acceptable to pass one fifth of all carcasses that should be condemned for pathology. Is this correct? Can human factors of visual-only inspection be an aggravating factor?
2. The paper mentions that pigs from farms meeting requirements laid down in the Code of Practice of the IKB Scheme or an equivalent quality assurance scheme were used. Further information on the scheme is needed. For example, what records are available related to ongoing disease surveillance, treatment records, production methods to reduce exposure to specific pathogens, etc?
3. The paper did not provide adequate historical data to support that there are enhancements of visual-only inspection over traditional inspection. It was stated that total number of condemnations during the previous year differed significantly in comparison with data of the pilot. It was concluded that this difference could be explained by the fact that the supply of fattening pigs during the previous year did not match the supply during the pilot. This suggests and does support that source has a significant impact on “risk.” More information is needed to support if such decisions can be maintained regularly and predictably in the future. It is difficult to make a comparison of inspection methods if the source animals are not from the same source.
4. The report indicates that decision making was made primarily on farm data and history. A serological test would need to be reliable as a predictor for evaluating the TB herd status. It was not clear if reliability and value of an antibody test for *M. avium* had been established. The report indicates that antibody testing should be, for the time being, be considered as the most sensible diagnostic tool. However, no specific data was presented supporting serological testing as an effective or practical herd monitoring tool for TB.
5. It is not clear if visual inspection would be used for non-market weight hogs, such as sows and boars. Since the basis for deciding not to incise lymph nodes is based on epidemiological data of pigs raised since weaning, and TB, if present, is more or less likely to be seen in older animals, detection in sows might be more important in evaluating the risk of TB. Are incisions to be performed in older animals (non-market hogs)?
6. It is not clear if/how the Farm Risk Profile considers previous slaughter results? What criteria will be used to determine whether a particular slaughter lot requires more intensive inspection procedures? How rapidly will those criteria be re-evaluated based on information from previous slaughter lots (or even the current slaughter lot)? Is the data real time?
7. How will scheduling of verification procedures occur to ensure that visual inspection continues to protect food safety? Verification procedures should be initiated based on random and biased factors. Verification lots of market hogs where abscess/granulomas

are observed in the mesenteric lymph nodes would be an excellent way to rule out *M. avium* lesions that might have been missed by not incising the mandibular lymph nodes.

8. How does the Farm Risk Profile factor impact *M. avium*, *Salmonella*, etc. without validated blood testing or historical slaughter data under traditional inspection? It is reasonable to factor seasonal changes in calculating risk of disease (pneumonia) and need for additional residue testing.
9. Will verification testing for residues be based on history of treatment? It is not clear what value the history of "group treatments" has on supporting visual-only inspection to rule out whether non-TB abscesses or drug residues are likely to be present.
10. A discussion on the impact of visual inspection on detection of endocarditis lesions and some of the causative agents has been provided in the draft report. Results indicate that inspectors will not be able to identify as many lesions as during traditional inspection. Although some possible reasons have been mentioned, further information and discussion on this issue are needed, especially discussion on *Strep. suis* and other microorganisms of zoonotic concern.
11. It is not clear if farm workers are subject to health testing. This may be of concern in cases where there is a high turnover rate and there are migrant workers from other EU countries and non EU countries that work on farms. What is the normal turnover rate for the work force at the farms. There could be a potential risk of farm or abattoir workers introducing TB, especially drug-resistant TB, to livestock or food products.
12. The report indicated that the supply of food chain information was at a high rate of compliance, but it did not indicate what information was provided. The report also indicated that visual inspection resulted in a minimal loss of food safety. Food safety improvements were based on increased risk based testing for residues (regardless of the new scheme). The claim that, omitting incision of mandibular lymph nodes reduced the spread of *Salmonella*, was not supported. The claim that the incision of mandibular lymph nodes to detect *M. avium* is "not very meaningful" is without support. Further information is needed.

U.S. Department of Agriculture
Food Safety and Inspection Service
International Equivalence Staff
Director
Ms. Sally White
South Building, room 4434
Washington, D.C. 20250
U.S.A.



landbouw, natuur en
voedselkwaliteit

Your letter of	your reference	our reference	date
		VD 06.1985/IH	14-07-2006
re:		extension no.	enclosures
Pork Supply Chain Inspection System		+31-70-3785435	6

Dear Ms. White,

I should like to make reference to the conference call of June 19, 2006, with Mr. Steve McDermott and associates, during which we had an interesting exchange of information on new developments in meat inspection systems in both our countries. As a general remark, I feel that a further exploration of these issues would be useful and I would, therefore, like to repeat my suggestion for a follow-up scientific meeting, either in the Netherlands, or in the U.S.

In our letter of April 3, 2006, we provided information on the pilot on visual post-mortem inspection, which was conducted in one of the VION-slaughter facilities, and we included the final report of the Food and Consumer Product Safety Authority (VWA) on this pilot. This report included a positive recommendation for the implementation of this type of inspection, if the industry chooses to do so. As I stated during the conference call, the supply chain inspection system has since then become the normal way of operation in the VION-Helmond slaughter facility. I promised to send an update of the VWA Final Report including supplemental information on data analysis, the results of Food Chain Information, monitoring for Mycobacterium avium, detecting antibiotic residues in pork and Salmonella monitoring. This information has been enclosed with this letter. Although these papers are indicated as "drafts", they can be considered as final. The "draft" label merely indicates that the papers are pending publication in scientific journals.

On the topic of the reorganization of the meat inspection system, whereby certain post mortem inspection activities are carried out by official auxiliaries under the supervision and responsibility of the official veterinarian who is permanently present during the operating hours of the slaughter facility, I should like to draw your attention to the paper "The new organization of the red meat inspection system in the Netherlands (2006)", which was included with our letter of April 3, 2006. If you should need any further clarification on this paper, I would be most willing to provide that, possibly during a follow-up conference call at your convenience.

The issue of palpation of mesenteric lymph nodes was briefly discussed. I intend to send you updated information on this in the near future.

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165-252

Date
14-07-2006

Reference
VD 06.1985/IH

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On a final note, I have requested our Agricultural Counselor in Washington, D.C. to send you a copy of the Guidance Document on the implementation of procedures based on the HACCP principles, and facilitation of the implementation of the HACCP principles in certain food businesses, which was published by the European Commission to elaborate on the HACCP principles laid down in Regulation (EC) 852/2004 and which includes guidance particularly to small food businesses. This document might be helpful in the further development of the FSIS Strategic Implementation Plan for Strengthening Small and Very Small Plant Outreach, which we also discussed during the conference call. I trust that you have received this document in the meantime.

I have very much appreciated the opportunity for a useful exchange during the conference call and I am looking forward to your reaction with great interest.

Sincerely yours,

DEPUTY CHIEF VETERINARY OFFICER,



dr. M.J.B.M. Weijtens

Cc: Mr. Steven McDermott, OIA, FSIA; Mr. Ghias Mughal, OIA, FSIS; Mr. Rober Wentzel, FAS, The Hague; Dr. P.W. de Leeuw, CVO; Mr. Wim Tacken, Agricultural Counselor Washington, D.C.

Mughal, Ghias

From: Hennecken, drs. M. (Martin) [m.hennecken@minlnv.nl]
Sent: Thursday, October 05, 2006 6:05 AM
To: Mughal, Ghias
Cc: Valk, drs. F.J. van der (Frank Jan); Jelsma, drs. A. (Ate); Berenschot-Feitel, drs. A.C. (Caroline); Weijters, dr. M.J.B.M. (Martijn); Leeuw, dr. P.W. de (Peter); Ham, mr.drs. J.W. van der (Jan Willem)
Subject: RE: Netherlands request for visual inspection of mesenteric Lymph Nodes of young hogs

Dear Mr. Mughal,

I received your request for information and I hereby will try to answer your question below. If you need further detail information on specific points please do not hesitate to ask.

1. Regarding your specific question on verification of visual inspection of mesenteric Lymph Nodes I can inform you that we do not sample Lymph Nodes at random after visual inspection. Instead we have serological sampling at the slaughter line on batch/farm level on M.avium as a precondition to perform visual inspection. Only hogs from a farm that has minimal 18 consecutive negative results are allowed to be visually inspected. This will be verified before admission to slaughter.

2. Furthermore if visual inspection of mesenteric Lymph Nodes results in suspicion of pathological conditions both, organs and carcass will be railed out and inspected by the traditional way. Cutting of Lymph Nodes and focused sampling are possible actions. In protocols and instructions special attention is paid to good communication between (visual) inspectors of the intestines and inspectors of the carcass.

3. Please note that beside "systematic serological sampling on M.avium" as a precondition for visual inspection also specific rules at farm level have to be obeyed and specific food chain information (batch-specific) has to be available before slaughter can start. Based on this food chain information (e.g. disease history) the official vet can decide about focused surplus testing at the slaughter line.

The effectivity of this system had been tested with good results in a pilot that had been performed end of 2005/beginning 2006 (I presume you have received the report of that pilot). A system of verification of the performance/ accuracy of both, inspectors and the preconditions for visual inspection by the competent authority is in place.

As you can conclude from the above the risk of pathological conditions that cannot be found at visual inspection is secured by preconditions for visual inspection at farm level (food chain information) and a system of serological monitoring for M.avium at slaughter. Focused sampling and cutting of Lymph Nodes of suspected carcasses is always possible and laid down in protocols/ instructions. We think that our system secures the above mentioned risk in a different, but equivalent way.

Best regards

Drs. Martin Hennecken
Directie Voedselkwaliteit en Diergezondheid
Ministerie van Landbouw, Natuur en Voedselkwaliteit
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Postbus: 20401, 2500 EK Den Haag
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-----Original Message-----

From: Mughal, Ghias [mailto:Ghias.Mughal@fsis.usda.gov]
Sent: woensdag 27 september 2006 14:19
To: Feitel, Caroline
Cc: White, Sally
Subject: RE: Netherlands request for visual inspection of mesenteric Lymph Nodes of young hogs

Good afternoon Caroline,

I am in process of preparing final draft of FSIS' response to the Netherlands request for equivalence on the visual inspection of mesenteric lymph nodes of young swine. I need your help in getting one more piece of information, from Dr. de Leeuw's office, as explained below.

Under HACCP-Based Inspection Model Project (HIMP), FSIS periodically verifies the accuracy of visual inspection by taking samples of the viscera and carcasses passed (by the on-line inspector performing visual inspection) at some point below his/her inspection station. This is done to ensure that no diseased carcass or parts are passed for human consumption. In reviewing the documents sent to us along with the request, I could not discern if any such of verification is done by your inspection service.

I would appreciate, if you could contact Dr. de Leeuw to get a clarification on the type of a carcass and parts verification system in place in swine establishments undergoing visual inspection of mesenteric lymph nodes.

Thank you very much,

Best Regards,
Ghias Mughal

M. Ghias Mughal, DVM;M.S; Ph.D.
Senior Equivalence Officer,
Office of International Affairs
USDA, Food Safety and Inspection Service
1400 Independence Avenue, SW
Washington, DC 20250
Phone: 202 720-6400
Email: ghias.mughal@fsis.usda.gov

-----Original Message-----

From: Feitel, Caroline [mailto:caroline.feitel@minbuza.nl]
Sent: Wednesday, July 26, 2006 2:20 PM
To: White, Sally
Cc: McDermott, Steve; Mughal, Ghias; WAS-LNV; Tacken, Wim
Subject: NL data on health status hogs-palpation

Dear Sally:

During the telephone conference between FSIS and the Netherlands on June 19th, 2006, the topic of equivalence determination for palpation of lymphnodes was discussed. During this discussing the Netherlands promised FSIS that additional information on this issue would be provided. With reference to the conference, please find attached a letter of Dr. Weijtens, the Netherlands Deputy CVO and updated information on the health status of hogs presented for slaughter in the Netherlands.

Once I receive the original hard copy version of Dr. Weijtens letter and the document I will deliver it to your office.

This report, the DG Sanco paper sent on the 30th of June, and the information I sent to you earlier by email on July 17th are all the documents the Netherlands had promised to provide to FSIS during the teleconference on the 19th of June. Please let me know if you need additional information or if there are any questions.

Best regards,

Caroline Feitel
Agricultural Trade Officer
Royal Netherlands Embassy
4200 Linnean Avenue, NW

Ministry of Agriculture, Nature and Food Quality

United States Department of Agriculture
Food Safety and Inspection Service
International Equivalence Staff
Office of International Affairs
Attn. Mrs. S. White
Director
US Department of Agriculture
Room 2137, South Building
Washington, DC 20250

landbouw, natuur
voedselkwaliteit

Your letter
October 2, 2006

your reference

our reference
VD.06.2687.PL

Date
October 6, 2006

Re:
US certified establishments

extension no.
+3170-3785037

enclosures

Dear Mrs. White,

Herewith I acknowledge the receipt of your email preceding an official letter regarding U.S. certified establishments in the Netherlands implementing visual post-mortem inspection and employing auxiliaries for the inspection. The mail was forwarded to me by Mr. Roger Wentzel, Agricultural Counselor of the U.S. Embassy, The Hague, on October 3, 2006.

The email did surprise us, as we felt that we had been trying to be fully transparent, unfortunately additional clarification seems to be necessary. I would highly appreciate if you would be willing to receive a mission from the Netherlands, headed by my Deputy Dr. Martijn Weijtens, at your earliest convenience. I consulted the European Commission and they like Dr. Wolf Maier from the EU representation in the US to take part in the discussion as well, in particular on the question of equivalence. Our Agricultural Counselor in Washington, Mr. Wim Tacken, will also be involved in the mission and will be the contact point with respect to the organization of the mission.

*Need
to
Plan*
In the meantime we took your message seriously and we discussed it with our Food and Consumer Products Authority and the Vion Company that owns the establishments involved. The company decided to wait for the outcome of the discussions that we are trying to arrange and for the time being not to ask for certification for the U.S., effective of Monday next.

I hope that this information suffices for now and that we can have the meeting as suggested already next week.

Our Agricultural Counselor in Washington informed me on your health. May I wish you a full and quick recovery.

If you have any questions regarding this letter, you can reach me by email: p.w.de.leeuw@minlnv.nl or even better on my mobile (011) 31-6-53707842.

Sincerely,
CHIEF VETERINARY OFFICER

Dr. P.W. de Leeuw

Proudie, Robin

From: White, Sally
Sent: Wednesday, November 08, 2006 7:19 AM
To: Proudie, Robin
Subject: Fw: additional articles reg. visual inspection: q4ref1 Part a

Please log

Sent from my BlackBerry Wireless Handheld

-----Original Message-----

From: Mughal, Ghias <Ghias.Mughal@fsis.usda.gov>
To: White, Sally <Sally.White@fsis.usda.gov>
CC: Seebohm, Scott <Scott.Seebohm@fsis.usda.gov>; Smith, David
<David.Smith@fsis.usda.gov>; Goodwin, Nancy <Nancy.Goodwin@fsis.usda.gov>; McDermott,
Steve <Steve.McDermott@fsis.usda.gov>
Sent: Wed Nov 08 07:16:17 2006
Subject: FW: additional articles reg. visual inspection: q4ref1 Part a



Q4Ref1a
Inderlied.pdf (2 MB)

This is part one of an article on Mycobacterium avium complex that came in this morning.

M. Ghias Mughal, DVM;M.S; Ph.D.

Senior Equivalence Officer,

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-----Original Message-----

From: Hennecken, drs. M. (Martin) [mailto:m.hennecken@minlnv.nl]
Sent: Wednesday, November 08, 2006 3:00 AM
To: Mughal, Ghias
Cc: Weijters, dr. M.J.B.M. (Martijn)
Subject: RE: additional articles reg. visual inspection: q4ref1 Part a

dear Dr. Mughal,

IES-#416
RP 2/1/07

herewith I send you ref 1 of question 4 (1) Inderlied CB, Kemper CA, Bermudez LE. The Mycobacterium avium complex. Clin Microbiol Rev. 1993 Jul;6(3):266-310. Review.). Due to the big size of the article we had to split it into two parts (a en b sent by two mails).

best regards

Martin Hennecken.

-----Oorspronkelijk bericht-----

Van: Hennecken, drs. M. (Martin)

Verzonden: dinsdag 7 november 2006 15:40

Aan: 'Mughal, Ghias'

CC: Weijtens, dr. M.J.B.M. (Martijn); Jelsma, drs. A. (Ate); Hardenberg, I. (Inge)

(VD)

Onderwerp: Expert meeting with FSIS and the Netherlands reg. visual inspection

Dear Dr. Mughal,

on behalf of Dr Weijtens I will send you herewith a "package" of additional articles, which have been mentioned in our report as a reference.

Most of these articles are in English, but 4 articles (question 10) have to be translated first. Unfortunately this will take some time, so you will receive them as soon as the translation has been completed. 2 other documents (q4ref1 and q4ref4) will be sent later.

Beneath you find a list of the articles which you will receive today (with several e-mails due to the size of the attachments) and 4 articles as soon as possible after translation has been completed.

If you miss any reference article in this list that had been agreed to send to you please let me know. I will arrange that asap.

Regards

Martin Hennecken

Drs. Martin Hennecken

Beleidsmedewerker vleeshygiëne

Directie Voedselkwaliteit en Diergezondheid

Ministerie van Landbouw, Natuur en Voedselkwaliteit

Adres: Bezuidenhoutseweg 73

Postbus: 20401, 2500 EK Den Haag

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Telefoon: 070-3784289

Telefax: 070-3786389

Question 4:

Additional document: Justification for sampling of Mycobacterium avium in pork with regard to supply chain meat inspection (06-11-06)

References to additional document:

* New classification system for slaughter pig herds in the Danish surveillance- and-control program: L. Alban et.al., Prev.Vet. Med. 2002 (SDOC1268.pdf)

* Trichinae certification in the United States Pork industry: D.G. Pyburn

References Question 4:

- 1) Inderlied CB, Kemper CA, Bermudez LE. The Mycobacterium avium complex. Clin Microbiol Rev. 1993 Jul;6(3):266-310. Review. (will be sent later)
- 2) Komijn, RE., PEW de Haas, ME Schneider, T Eger, JHM Nieuwenhuis, RJ van den Hoek, D. Bakker, FG van Zijderveld and D van Soolingen. Prevalence of Mycobacterium avium in Slaughter Pigs in The Netherlands and Comparison of IS1245 Restriction Fragment Length Polymorphism Patterns of Porcine and Human Isolates. J of Clin Microb, 1999, 37, 1254-1259
- 3) Komijn, RE., HJ. Wisselink, VMC. Rijsman, N. Stockhofe-Zurwieden, D. Bakker, FG. van Zijderveld, T. Eger, JA. Wagenaar, FF. Putirulan and BAP. Urlings, Prevalence of Mycobacterium avium subsp. avium in lymphnodes of slaughter pigs in The Netherlands. Accepted for publication in Veterinary Microbiology (2007)
- 4) Wallace JM, Hannah JB. Mycobacterium avium complex infection in patients with the acquired immunodeficiency syndrome. A clinicopathologic study. Chest. 1988 May;93(5):926-32. (will be sent later)
- 5) Wisselink, HM, C van Solt-Smits, N Stockhofe-Zurwieden, H Bergen-Buys, P. Overduin, M van Prehn, D van Soolingen and J Thole. Comparison of visual and bacteriological examination of mandibular and mesenteric lymphnodes in pigs, experimentally infected with Mycobacterium avium subsp. Avium. IPVS Conference Copenhagen 2007.

References question 10:

1. W. Wouda et. al. , Endocarditis en vleeskeuring bij slachtvarkens, Tijdschrift voor Diergeneeskunde, deel 112, afl. 21, 1987, p. 1226-1235 (will be translated and sent later)
2. Masanori Katsumi et. al, Bacterial Isolation from slaughtered pigs associated with endocarditis, especially the isolation of Streptococcus suis, Journal of veterinary medical science, vol. 59, 1997, p. 75-78
3. U. Narucka et. al., Afwijkingen bij slachtdieren, Tijdschrift voor Diergeneeskunde, deel 110, afl. 19, 1985, p. 776-779 (will be translated and sent later)
4. W. Wouda et. al. , Endocarditis en vleeskeuring bij slachtvarkens, Tijdschrift voor diergeneeskunde, deel 112, afl. 21, 1987, p. 1236-1242. (will be translated and sent later)
5. R. Fries und J. Leps, Die Incision des Herzens beim Schwein, Fleischwirtschaft, vol 10, 2005, p. 116-119. (will be translated and sent later)
6. C. Tarrads et. al., Identification of Streptococcus suis Isolated from Swine: Proposal for Biochemical Parameters, journal of clinical microbiology, vol. 32, 1994, p. 578-580
7. J.J. Staats et. al., Streptococcus Suis: past and present,

Veterinary research communications, vol. 21, 1997, p. 381-407.

8. Yu-Tsung Huang et. al., Streptococcus suis infection, Journal of Microbiol Immunol Infect, vol. 38, 2005, p. 306-313.

References reg. Annex salmonella:

1. Petersen JV, Andersen JK, Sorensen F, Knudsen H. Food safety on the slaughterline: inspection of pig heads. Vet Rec. 2002 Jun 22;150(25):782-4. Review.
2. Swanenburg M, van der Wolf PJ, Urlings HA, Snijders JM, van Knapen F. Salmonella in slaughter pigs: the effect of logistic slaughter procedures of pigs on the prevalence of Salmonella in pork. Int J Food Microbiol. 2001 Nov 8;70(3):231-42.
3. Swanenburg M, Berends BR, Urlings HA, Snijders JM, van Knapen F. Epidemiological investigations into the sources of Salmonella contamination of pork. Berl Munch Tierarztl Wochenschr. 2001 Sep-Oct;114(9-10):356-9.
4. Berends BR, Van Knapen F, Snijders JM, Mossel DA. Identification and quantification of risk factors regarding Salmonella spp. on pork carcasses. Int J Food Microbiol. 1997 May 20;36(2-3):199-206.
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7. "salmonella monitoring" report made during the pilot "supply chain inspection" 2005-2006 in Helmond, the Netherlands
8. Oosterom J, Dekker R, de Wilde GJ, van Kempen-de Troye F, Engels GB. Prevalence of Campylobacter jejuni and Salmonella during pig slaughtering. Vet. Quarterly 7, 31-34.

Dit bericht kan informatie bevatten die niet voor u is bestemd. Indien u niet de geadresseerde bent of dit bericht abusievelijk aan u is gezonden, wordt u verzocht dat aan de afzender te melden en het bericht te verwijderen. De Staat aanvaardt geen aansprakelijkheid voor schade, van welke aard ook, die verband houdt met risico's verbonden aan het elektronisch verzenden van berichten.

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The *Mycobacterium avium* Complex

CLARK B. INDERLIED,^{1*} CAROL A. KEMPER,^{2,3} AND LUIZ E. M. BERMUDEZ⁴

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* Corresponding author.

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CLASSIFICATION

Conventional Criteria.

Mycobacteria have been conventionally classified into four or five broad taxonomic groups on the basis of the following general criteria: pathogenicity for humans and animals, rate of growth at optimum temperatures, and effect of visible light on pigment production. These criteria have proven useful for the classification of mycobacteria since first developed by Runyon and others in the early 1950s (179, 408, 451); recent evidence from comparative 16S rRNA sequencing studies (437) has corroborated their taxonomic validity. Accordingly, mycobacteria included in the *Mycobacterium avium* complex (MAC) are classified as acid-fast, slowly growing bacilli that may produce a yellow pigment in the absence of light (exposure to light often intensifies pigment production). The MAC is composed of opportunistic pathogens capable of causing disease in both animals (448) and humans (253, 504). Tuberculosis, caused by mycobacteria in the *M. tuberculosis* complex, has been traditionally viewed as the "typical" mycobacterial disease; thus, other species of mycobacteria (with the exception of *M. leprae*) have been viewed by contrast as "atypical." Consequently, mycobacteria other than *M. tuberculosis* and *M. leprae* have been commonly referred to by the imprecise and taxonomically inappropriate term atypical mycobacteria. Other terms commonly applied to these mycobacteria are mycobacteria other than tuberculosis, or MOTT, and nontuberculous mycobacteria (NTM). Wayne and Sramek (474) recently reviewed the systematics of the mycobacteria and pointed out that the distinction among *M. tuberculosis*, *M. leprae*, and the other species of mycobacteria is not the ability to cause serious disease in humans but rather differences in natural habitats and contagiousness. Thus, they proposed the term potentially pathogenic environmental mycobacteria, or PPEM, a term which emphasizes the importance of environmental exposure to these mycobacteria since there is little or no contagiousness between humans associated with these microorganisms.

Serotypes

The MAC is a serological complex of 28 serovars of two species, *M. avium* and *M. intracellulare*, which sometimes has been extended to include three additional serovars of a third species, *M. scrofulaceum*. Therefore, the mycobacteriology literature may include references to the complex as the *M. avium-M. intracellulare* complex or the *M. avium-M. intracellulare-M. scrofulaceum* intermediate complex. However, the inclusion of *M. scrofulaceum* is no longer appropriate given our current understanding of mycobacterial systematics (474). The distinction between *M. avium* and *M. intracellulare* is now well established, and Thorel et al. (450) have proposed three subspecies of *M. avium* on the basis of phenotypic properties and nucleic acid studies: *M. avium* subsp. *avium*, *M. avium* subsp. *paratuberculosis*, and *M. avium* subsp. *silvaticum*. The International Working Group on Mycobacterial Taxonomy has suggested, however, that there is taxonomic evidence for a third genospecies within the MAC (473).

Serovar distinctions within the MAC are based on a seroagglutination procedure originally described by Schaefer (419). Later, Brennan and coworkers (65-67) showed that the serovar antigens of the MAC have a common lipopeptidyl-*O*-methyl rhamnose linked to an oligosaccharide; i.e., serologic specificity was conferred by the specific oligosaccharide residues of the C-mycoside glycopeptidolipids (GPLs), which are integral constituents of the cell wall and envelope. On the basis of this more complete knowledge of the chemistry of the serovar antigens, strains now are serotyped by thin-layer chromatography (68, 454) and enzyme-linked immunosorbent assay (ELISA) analysis (498) of species- and type-specific glycolipids as well as by the conventional seroagglutination procedure. More recently, Rivoire et al. (399) described an ELISA system that used murine monoclonal antibodies to specific sugar epitopes of the MAC derived with either purified GPL antigens or synthetic neoantigens. The focus of the latter study was to generate monoclonal antibodies that were absolutely specific for each of the major serovars of the MAC. In achieving this objective, the oligosaccharide haptens were defined for the

most common serovars of the MAC isolated from patients with AIDS in the United States, i.e., serovars 1, 4, and 8 (399). Serovar and DNA relatedness studies have led to a consensus that serovars 1 through 6 and 8 through 11 are assigned to *M. avium* while serovars 7, 12 through 17, and 19, 20, and 25 are assigned to *M. intracellulare* (413).

Multilocus Enzyme Electrophoresis Types

Recently, Wasem et al. (470) examined 35 strains of the MAC and an additional 12 species or strains of other mycobacteria by multilocus enzyme electrophoretic typing, using 20 different enzymes. A total of 33 electrophoretic types (ETs) were identified, of which 24 types included the 35 MAC strains. Two distinct clusters were apparent in the resulting dendrogram of the 24 ETs: an *M. intracellulare* cluster and an *M. avium* cluster. The clustering agreed entirely with the species identity as determined by the GenProbe nucleic acid hybridization system. When the analysis was extended to include all 33 ETs, again two distinct clusters were observed, but with an *M. scrofulaceum* strain joined to the *M. intracellulare* cluster and an *M. paratuberculosis* strain joined to the *M. avium* cluster. All but one of the serovars separated into the *M. intracellulare* and *M. avium* clusters when ET types were compared with serovar classification. The common serovars, serovars 1, 4, 8 to 10, 14, and 16, could be subdivided into two to four ETs. Although the authors pointed out that serovar and ET designations are not interchangeable, it was of interest that serovars 1 to 4 and 8 to 10 appeared in the *M. avium* ET cluster and serovars 12, 14, 16, and 19 appeared in the *M. intracellulare* cluster. These results are in virtually complete agreement with earlier DNA-DNA relatedness studies or GenProbe DNA-rRNA hybridization and serovar studies. There are two DNA relatedness groups that make up the *M. avium-M. intracellulare* complex (a third group includes *M. scrofulaceum*) (400), and DNA relatedness studies first performed by Baess (13) and later confirmed by Yoshimura and Graham (500) showed that serovars 1 to 6 and 8 to 11 were *M. avium* whereas serovar 7 and serovars 13 to 28 were *M. intracellulare*. More recently, Saito et al. (413) used the GenProbe DNA-rRNA hybridization system to analyze the species distribution of serovars and concluded that serovar 21 is most likely *M. avium* and serovars 7, 12 to 20, and 25 are *M. intracellulare*; serovars 22 to 24 and 26 to 28 were too disordered to assign a species epithet.

Phage Types

Although phage typing has proven to be a useful tool for discriminating between strains of *M. tuberculosis* (434), there has been only a limited application of phage typing to the epidemiology of the MAC. Crawford et al. (111) described a technique of phage typing for the *M. avium-M. intracellulare-M. scrofulaceum* complex and applied the technique in a study of several hundred *M. avium-M. intracellulare-M. scrofulaceum* complex strains isolated from the environment, animals, and clinical specimens from geographically disperse humans (107). Only approximately one-third of the isolates and none of the environmental isolates were susceptible to the mycobacteriophages tested. Nevertheless, for susceptible strains, the phage-typing system appeared to be a reliable epidemiological tool, but the lack of phage susceptibility of the majority of strains is an important limitation. Crawford and Bates (107) pointed out that several factors can influence the susceptibility of myco-

bacteria to phage infection, including a requirement for accessible cell surface receptors, lysogenic immunity, the presence of a restriction-modification system, and plasmid interference. It is conceivable that all or any combination of these factors might influence the phage susceptibility of the MAC. Restriction-modification systems have been described in the MAC (110), and many MAC isolates carry plasmids (332). The lack of phage susceptibility may be an important complication to the otherwise exciting potential application of luciferase-phagemid systems to the direct detection and identification of the MAC in clinical specimens as well as susceptibility testing (15).

Plasmid Types

Plasmid typing may be similarly limited for epidemiology studies in that only 50% of clinical isolates and only 20% of environmental isolates carry plasmids (332); however, there is evidence that there may be an epidemiologically significant uneven distribution of MAC strains, both clinical and environmental, which carry plasmids. In a study of 26 MAC isolates from AIDS patients, Crawford and Bates (108) described three types of plasmids that were present in various configurations in all strains. Indeed, all strains carried plasmids that hybridized to recombinant molecules carrying fragments of a small plasmid (pLR7) derived from a serotype 4 strain of the MAC. However, this observation is somewhat at odds with other more recent studies that showed that only 5 of 16 MAC isolates from AIDS patients in Denmark carried plasmids (260) and that there was no difference in the rate of plasmid carriage in 128 strains from AIDS and non-AIDS patients in the United Kingdom (215). Morris et al. (344) determined the plasmid profiles of 12 separate *M. avium* isolates and identified multiple plasmids of <100 kb in 9 of 12 isolates. Although the pLR7 plasmid probe hybridized to DNA extracts from all plasmid-bearing strains, restriction analysis suggested that the plasmids were not identical. Morris et al. (344) concluded that plasmids may not be required for the development of disseminated MAC disease and the role of plasmids can be determined only by virulence transformation experiments. Meissner and Falkinham (332) showed that although on average only 19% of environmental isolates carried plasmids, 75% of isolates from aerosols carried plasmids. Also, the study by Hellyer et al. (215) concluded that plasmids were common in serovar 4 and 8 strains of the MAC and corroborated the observation of Crawford et al. (108) that these plasmids had DNA sequences homologous to that of the pLR7 plasmid. The role of plasmids in the biology and pathogenicity of the MAC may be important because of the association of plasmids with virulence factors (162, 382) and, in two studies, with antibiotic resistance (155, 339).

Large RFLP Types

Distinctions between MAC strains have been achieved by restriction fragment length polymorphism (RFLP) analysis of genomic DNA, using endonucleases with both frequent and infrequent restriction sites and separation of large DNA fragments. The application of the latter technique to mycobacteria takes into consideration that mycobacterial DNA contains a high percentage of guanine plus cytosine (62 to 70 mol%); therefore, restriction endonucleases with 6-base recognition sites that are rich in adenine and thymine are likely to cleave mycobacterial DNA into 30 or fewer fragments. The number of fragments can be predicted by a

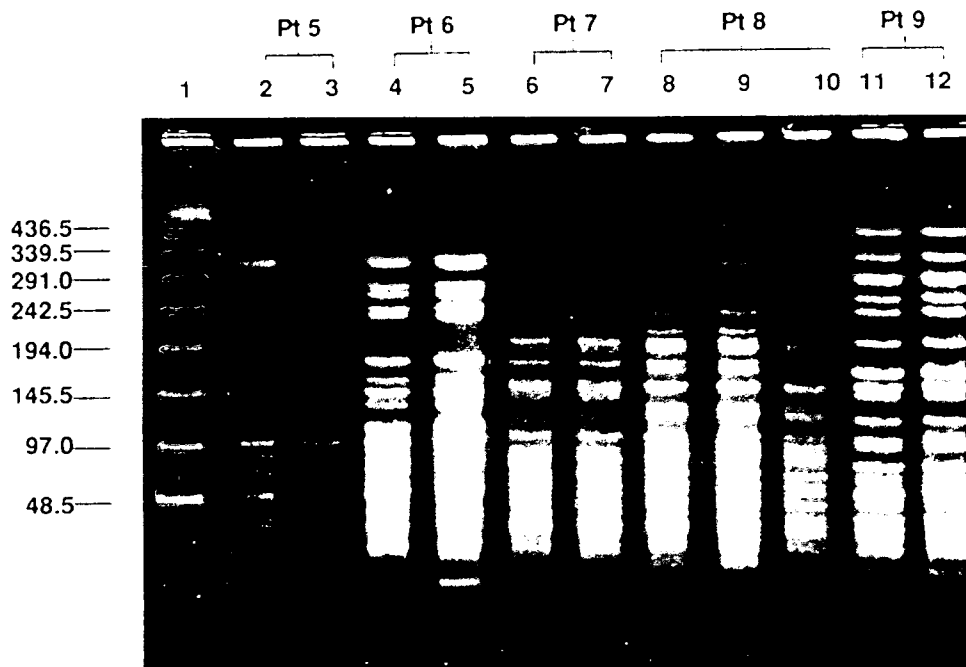


FIG. 1. Large RFLPs of two separate isolates of MAC from each of five patients, taken from Mazurek et al. (320). Mycobacterial DNA was restricted with *Xba*I, and fragments were separated by pulsed-field gel electrophoresis. For patients 6, 7, and 9, both isolates were from sputum, while for patients 5 and 8, the isolates were from different body sites. Reprinted with permission of the publisher.

nearest-neighbor analysis; however, as with other bacteria, in the few studies of the MAC that have been published, fewer fragments are generated than are predicted by such an analysis. Nevertheless, the number and size of fragments often approximate the total DNA content of the cell, and the resulting RFLP patterns most likely reflect the distribution of restriction sites within nearly the entire genome. Two endonucleases (with the corresponding restriction sites) that have proven useful in generating RFLP patterns with mycobacterial DNA are *Dra*I (AAATTT) and *Ssp*I (AATATT). These enzymes generate large restriction fragments that can be resolved only by field inversion gel electrophoresis or pulsed-field gel electrophoresis into fragments that range from 45 to >400 kb. Levy-Frebault et al. (299) examined various strains of mycobacteria by RFLP analysis by using *Dra*I and pulsed-field gel electrophoresis and showed that strains of *M. paratuberculosis* were identical to strains of mycobacteria isolated from patients with Crohn's disease, confirming the earlier observations of McFadden et al. (327). Furthermore, Levy-Frebault et al. (299) showed that wood pigeon mycobacteria could be distinguished from *M. paratuberculosis* and that *M. avium* isolates were readily distinguished from *M. intracellulare*. Coffin et al. (93) used *Ssp*I and pulsed-field gel electrophoresis to identify five RFLP groups in a study of 13 MAC strains. Their results showed that RFLP analysis allows one to readily distinguish between strains of *M. paratuberculosis* isolated from cattle. An *M. paratuberculosis* strain grouped with a serovar 8 MAC strain (the authors apparently mistakenly identified this serovar as *M. intracellulare*), which is consistent with the aforementioned conclusion that *M. paratuberculosis* is most likely a subspecies of *M. avium*. In a large recent study, Mazurek et al. (320, 321) analyzed 72 MAC isolates from 44 patients, including 16 patients with two to five isolates. RFLP patterns

generated with *Dra*I were unique for different patients, while multiple isolates from individual patients, including isolates from a variety of body sites, were identical; patterns of multiple isolates were identical over as long as 6 months between isolations (Fig. 1). Arbeit et al. (9) recently reported a similar study of 69 MAC isolates from 14 patients, using the restriction enzyme *Ase*I, but discovered 2 patients who were infected with more than one strain of MAC, suggesting that mixed infections may be common in certain patients or patient populations.

Colony Variant Types

Perhaps one of the most important, yet incompletely understood, features of the MAC is the occurrence of colony type variations. Three colony variants have been described: (i) a smooth, opaque, and domed type; (ii) a smooth, transparent, and flat type; and (iii) a rough type. Clinical isolates of the MAC usually appear as smooth transparent or smooth opaque types or as a mixture of the two. In our experience, MAC isolates from AIDS patients with disseminated disease are frequently exclusively of the smooth transparent type. Barrow and Brennan (16) showed that the rough colony type can be selected by promoting the growth of a pellicle in a broth medium, but once isolated, rough colony types are stable even when repeatedly subcultured on 7H11 agar. They showed that rough colony types lacked both polar and apolar GPLs, and when examined by electron microscopy, rough colony types lacked the sheath (capsule) of fibrillar filaments seen with smooth opaque colony-type cells. Although rough colony variants may occur naturally as an inapparent subpopulation of smooth-type cells, rough forms do not appear to be found in primary isolations from

clinical specimens, and their clinical significance is unknown.

In contrast, the translucent colony variants are reported to be more resistant to antimicrobial agents (391, 411, 486), and there is evidence based on both macrophage and animal studies that this variant is more virulent (116, 335, 407, 420). Stormer and Falkinham (442) isolated nonpigmented colony variants from both environmental sources and clinical material from AIDS patients and showed that these variants were significantly more resistant to antimicrobial agents than pigmented segregants of the same strains. Furthermore, pigmented segregants grew faster on agar media, leading to a concern that the less obvious nonpigmented variants could be overlooked when colonies were being selected for susceptibility testing. Thorel and David (449) showed that there are significant differences in the expression of cell surface antigens between transparent and opaque colony variants; however, such specific differences have not been related to functional differences such as antimicrobial resistance or pathogenicity.

Despite the apparent relationship between colony type and antimicrobial resistance, very little is known about the genetics and regulation of colony type variation. Woodley and David (486) showed that the rate of the transparent-to-opaque transition was dependent on temperature and thus is not a consequence of mutation. The same investigators also indicated that colony type transition was not linked to mutator effects (MAC is not unusually susceptible to UV-induced mutations) or the presence or absence of extra-chromosomal genetic elements (124). The rate of transparent-to-opaque transition was 4.6×10^{-4} , while the rate of opaque-to-transparent transition was about 10^{-6} per bacterium per generation (486).

CELL WALL AND ENVELOPE

Structure

One of the best-studied aspects of mycobacteria is the structure and function of the mycobacterial cell wall and envelope which confers upon these unusual bacteria their distinctive feature of acid fastness. The envelope is composed of a variety of soluble proteins, carbohydrates, and lipids and basically three insoluble macromolecular components: arabinogalactan, peptidoglycan, and mycolic acid (329). Together, the insoluble macromolecules constitute the mycoylarabinogalactanpeptidoglycan core of the cell wall, one of two lipopolysaccharides (LPS) common to all mycobacteria. The mycoylarabinogalactanpeptidoglycan appears as electron-dense and electron-transparent zones in thin sections of mycobacteria viewed by negative staining. However, the core is frequently surrounded by additional electron-dense layers at the surface of the cell. This electron-dense layer is made up, in part, of unique GPLs that are specific for the MAC. In addition, all mycobacteria possess a second LPS as a component of the cell envelope, more specifically, a lipoarabinomannan. The lipoarabinomannan is not covalently linked to the mycoylarabinogalactanpeptidoglycan core but most likely is anchored in the plasma membrane of the mycobacterial cell, with the polysaccharide extending to the exterior of the cell. The mycoylarabinogalactanpeptidoglycan, lipoarabinomannan, and GPLs of the MAC are strongly immunogenic, with properties similar to those of the LPS of other bacteria. In addition, certain

components of these complex macromolecules have proven to have diagnostic utility; e.g., tuberculostearic acid (10-methyloctadecanoate), which is a useful diagnostic marker for *M. tuberculosis*, occurs as a fatty acid in the lipoarabinomannan of this species. A cartoon of the cell wall structure of mycobacteria that displays the orientations and relationships between the various components of this complex structure is shown in Fig. 2.

McNeil and Brennan (329) discussed the possible relationships between the cell envelope structural features and the noted resistance of the MAC to antimicrobial agents. Clearly, the complex array of parallel hydrocarbon chains is the most likely source of the impermeability of mycobacteria. Camphausen et al. (75) also suggested that these unusual structures were consistent with the long-held conclusion of Rastogi et al. (391, 393) that the antimicrobial resistance of the MAC can be attributed to a lack of drug penetration. Although intrinsic drug resistance is likely to reflect the complex cell wall structure, at the same time these unique structures, amide-linked fatty acids, D-amino acids, and methylated 6-deoxyhexoses, and the corresponding biosynthetic enzymes are excellent potential targets for highly selective and nontoxic antimycobacterial agents.

The impermeability of the MAC cell wall and membrane has been the focus of attempts to potentiate the effect of antimicrobial agents by combining agents with a cell wall-active agent such as ethambutol or a detergent such as Tween 80. Rastogi et al. (392) showed that both ethambutol and an inhibitor of C-mycoside biosynthesis (*m*-fluorophenylalanine) enhanced the activity of other drugs, and Yamori and Tsukamura (496) demonstrated that the activities of rifampin and streptomycin increased in the presence of Tween 80; paradoxically, Tween 80 diminished the activities of ethambutol and sulfadimethoxine.

As mentioned previously, the MAC is a collection of serovars that are distinguished from one another on the basis of antigenic differences in the GPL oligosaccharides. The MAC GPLs, referred to previously as C-mycosides or Shaefer antigens, are alkali-stable molecules, a feature that has been exploited in their analysis, since alkali treatment reduces nonspecific serologic reactions and permits the analysis of whole lipid preparations by ELISAs. In addition, the antigens of other atypical mycobacteria such as *M. kansasii*, *M. xenopi*, and *M. szulgai* are lipo-oligosaccharides that are readily destroyed by alkali (498). *M. simiae* and *M. fortuitum* complex also have alkali-stable GPLs, but there is only limited cross-reaction between these GPLs and those of the MAC. In general, there is good agreement among seroagglutination, thin-layer chromatography, and ELISA; however, some strains remain intractable to analysis by any of these methods, including the monoclonal antibody-based assays. In addition, cross-reactions in the ELISAs are not uncommon and thin-layer chromatography patterns can be indistinct. The type-specific antigens for many of the *M. avium* serovars have been fully described; for example, the structures for serovars 2 and 4 are 2,3-di-O-methyl-fucopyranosyl-($\alpha 1 \rightarrow 3$)-L-rhamnopyranosyl-($\alpha 1 \rightarrow 2$)-6-deoxytalose and 4-O-methyl-L-rhamnopyranosyl-($\alpha 1 \rightarrow 4$)-2,3-di-O-methyl-fucopyranosyl-6-deoxytalose, respectively (66).

Synthesis

Although McNeil and Brennan (329) have proposed a hypothetical biosynthetic pathway for the assembly of the

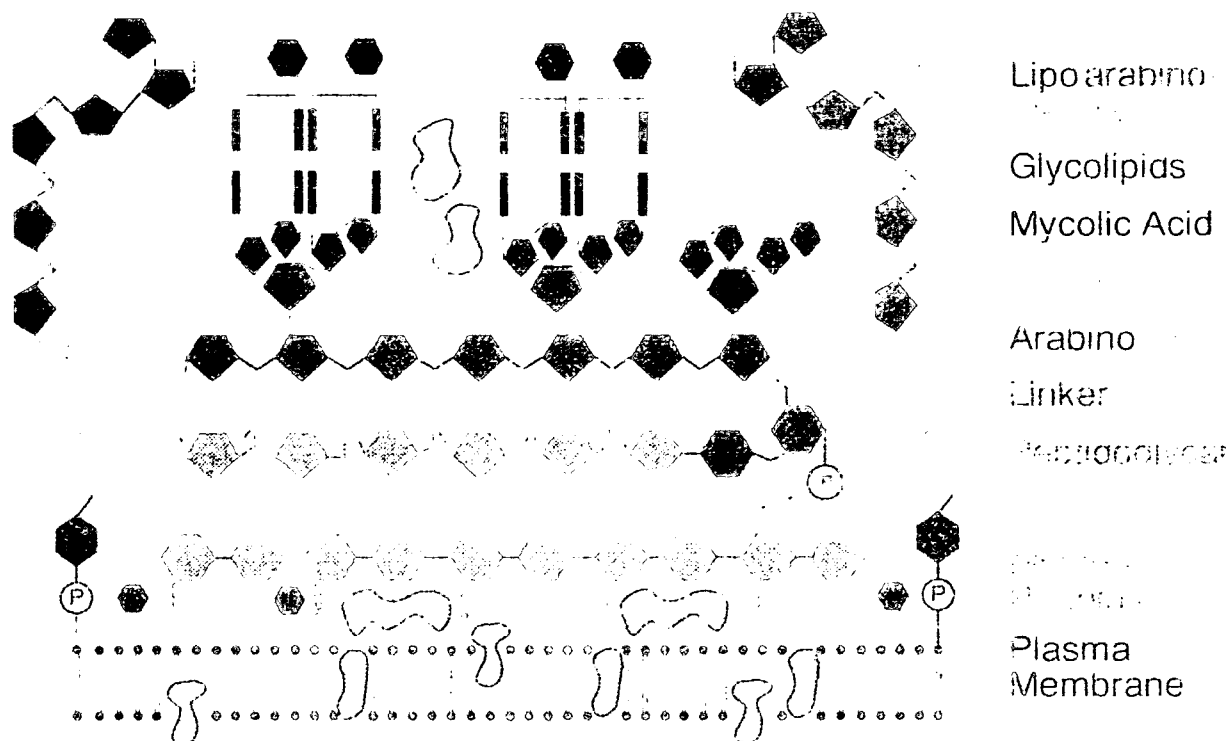


FIG. 2. Schematic representation of the mycobacterial cell wall, taken from McNeil and Brennan (329). MAC serovars are distinguished on the basis of differences in the oligosaccharide component of the glycolipid component. Tuberculostearic acid is a component of the lipoarabinomannan of *M. tuberculosis*. Reprinted with permission of the publisher.

arabinogalactan, including attachment to the peptidoglycan and mycolylation, there is no direct evidence for the biosynthetic enzymes and only a few of the intermediates have been isolated and identified from mycobacteria. Therefore, the recent publication of Belisle et al. (18) on the cloning of genes responsible for the synthesis of GPL antigens must be viewed as a landmark study in the efforts to understand the synthesis of the mycobacterial cell wall and envelope. By using a genomic library prepared from a serovar 2 strain of MAC, the gene cluster responsible for the synthesis of the serovar 2-specific GPL was cloned into *M. smegmatis* mc²155 with the pYUB18 shuttle cosmid (256). Clones were screened for expression of the serovar 2-specific GPL (antigen) by using a monoclonal antibody directed against this GPL (399). A cluster of genes, designated *ser2*, within a 22- to 27-kb continuous segment of genomic DNA was identified as responsible for the expression of the specific oligosaccharide; chemical analysis revealed that only the oligosaccharide segment arose from the cloned genes. Belisle et al. (18) pointed out that the cloned fragment was larger than necessary to encode the two or three transferases needed to synthesize the oligoglycosyl unit; thus, the fragment may contain multiple operons or other genes. Recently, the same group (130) identified the isomerase that converts ribulose-5-phosphate to arabinose-5-phosphate, which is incorporated into arabinofuranose; this may lead to a better understanding of the mechanism of action of ethambutol since ethambutol is known to disrupt the incorporation of arabinose-5-phosphate into cell wall arabinan.

MICROBIAL PHYSIOLOGY AND GENETICS

Physiology

Considerable basic information about the metabolism and physiology of the MAC is lacking; e.g., there is little or no information about anabolic or catabolic enzymatic pathways, energy metabolism, or carbon and nitrogen cycles. Furthermore, there have been no studies directed at understanding the regulation of macromolecular synthesis or gene expression in this increasingly important group of mycobacteria. As discussed earlier, although there is considerable information about the chemistry of important cell wall constituents, especially antigenic components, there is limited or no information about the biosynthetic pathways. Fundamental work on the growth and nutrition of the MAC, largely from Charlotte McCarthy's laboratory, revealed that the growth of these microorganisms is complex. By studying partially synchronized cultures, McCarthy and Ashbaugh (326) were able to show that the growth of MAC isolates, either transparent or opaque colony variants, occurs in three stages. During the first stage, cells elongate and there is a rapid uptake of fatty acids and an increase in protein and DNA, but without cell division. Binary fission occurs during the second stage of growth, with a generation time as short as 6 h. Protein synthesis continues during the second stage of growth, but at a diminished rate, and the uptake of fatty acids decreases and intracellular pools of triglycerides are catabolized to supply carbon and energy. At the end of the second stage, most cells are in the form of coccobacilli.

During the third stage of growth, which is most analogous to the conventional stationary phase, the morphology of the cells becomes quite heterogeneous, leading to a mixture of filaments, rods, and coccobacilli. McCarthy and her colleagues concluded that the opaque colony cells will increase during the third stage of growth since these cells are nutritionally less demanding than the cells of the transparent type. These observations have clear and compelling implications for antimicrobial resistance and possibly virulence, but to understand these relationships, additional information is needed about the regulation of the growth cycle and, perhaps especially, the mechanisms of differentiation.

Palmitic and oleic acids are important sources of carbon and energy for the MAC. McCarthy (322) showed that during the first stage of growth there was a rapid uptake of ^{14}C -palmitic acid which ceased with the initiation of cell division or fragmentation. Cells of both the transparent and the opaque colony types exhibited similar responses to palmitic acid. Other carbon sources, such as glycerol and glucose, failed to support cell division. During the first part of the growth cycle, exogenous fatty acids are initially incorporated into the triglyceride fraction and then redistributed into other components. By the end of the fission stage of growth, exogenous fatty acid is incorporated into the polar fraction, primarily glycolipids. The triglyceride fraction is metabolized during the cell division phase as the uptake of exogenous fatty acids ceases. Curiously, smooth transparent-type cells produce large numbers of nonviable particles during all phases of growth, and these particles consist in large part of sulfolipids (323). McCarthy also showed that nitrogen metabolism varies depending on the stage of growth within the cell cycle. During elongation, cells were unable to use organic forms of nitrogen such as glutamic acid or glutamine, but they used these amino acids as well as sulfur during periods of rapid cell fission (324). More recently, McCarthy (325) showed that the MAC, including several clinical isolates, preferentially uses ammonia and nitrite and, with the exception of glutamine, does not use amino acids as a source of nitrogen.

Genetics

In those mycobacteria that have been studied in detail, the genome has been found to consist of a single length of DNA in the form of a closed loop. The genome is not contained by a nuclear membrane, although the tightly packed DNA is recognizable on electron microscopy as a nuclear body. Genome size determinations revealed that mycobacteria, compared with most other prokaryotes, have large genomes, in the range of 2.8×10^9 to 4.5×10^9 bp (91). The DNAs of most mycobacteria have between 64 and 70 mol% guanine plus cytosine, and DNA from the *M. tuberculosis* complex exhibited 4 to 25% homology with DNA from members of the fast-growing mycobacterial groups. Extrachromosomal DNA in the form of self-replicating plasmids is common in the MAC (106, 108, 109), but attempts to clearly define the biologic significance of plasmids in *M. avium* strains have been unsuccessful so far. A recent study described an insertion sequence (IS901) found in pathogenic strains of *M. avium* but absent in *M. avium* isolates from patients with AIDS (291). The IS901 insertion element has a nucleotide sequence of 1,422 bp with one open reading frame (ORF1), which encodes a protein of 401 amino acids. It was also determined that the terminal ends and target sites of IS901 were similar to those of the IS900 insertion element of *M. paratuberculosis*, while the DNA sequence of both elements

exhibited only 60% homology. *M. avium* strains containing IS901 were found to be more virulent in mice than closely related strains lacking IS901. RFLP analyses suggest that *M. avium* A/I (which contains a single copy of IS901) and *M. paratuberculosis* (which contains multiple copies of IS900), both of which cause enteritis and disseminated infection in birds and ruminants, have evolved from an ancestral *M. avium* type A which lacks both insertion sequences (328). Interestingly, *M. avium* RFLP type A is the predominant strain isolated from AIDS patients with disseminated infection as well as from non-AIDS patients with focal disease, while *M. avium* type A/I is rarely isolated from either group.

Genetics of Antimicrobial Resistance

The MAC is considered inherently resistant to most, if not all, traditional antimycobacterial agents (179, 341). As mentioned previously, the basis for this resistance has been largely ascribed to the complex structure of the cell wall and the resulting impermeability (391, 392). There is no evidence that the MAC produces aminoglycoside- and peptide-inactivating enzymes (341), but there is evidence of the production of β -lactamases (340). The role of the cell wall architecture in antimicrobial resistance is underscored by a variety of observations. (i) Targets of certain antimicrobial agents, such as the ribosomes, bind the respective agents, and their function is inhibited despite the fact that intact organisms are resistant to these agents (341). (ii) Reagents such as Tween 80 potentiate the effect of antimicrobial agents most likely as a result of the surfactant effect on the cell wall structure (316, 496). (iii) There is growing evidence that ethambutol potentiates the activity of other agents (220, 394, 494), and this influence is a consequence of an ethambutol effect on cell wall permeability as evidenced, for example, by microcalorimetric measurements (221).

The colony type has a strong relationship with antimicrobial susceptibility (329, 341, 391), and because colony type transition is not a mutational event, the conversion of antimicrobial resistance phenotypes that is linked to the colony type transition occurs at a relatively high frequency, i.e., 10^{-4} (transparent-resistant to opaque-susceptible) to 10^{-6} (opaque-susceptible to transparent-resistant). Superimposed on this phenomenon is the mutation rate for resistance to specific drugs or heavy metals, which is in the range of 10^{-5} to 10^{-9} per bacterium per generation. The resistance associated with colony type may be considered a type of phenotypic or adaptive resistance and, as such, may be expressed to varying degrees. However, it has been difficult to assess the influence of colony type transitions on some of these measurements. In general, the nontuberculous mycobacteria and MAC, in particular, should be considered heterogeneous, with subpopulations of resistant microorganisms which may range in frequency from 10^{-4} to 1 (125).

EPIDEMIOLOGY

General

Human disease caused by the MAC reportedly occurs worldwide but is predominantly endemic in certain Northern temperate geographic areas, including the United States (180), Canada (170, 250), Great Britain (240), Europe (127, 331), The Netherlands (144), and Japan (338); disease also occurs in Australia (126) and South Africa (356).

Infections with NTM are not reportable in the United States; as a result, the true prevalence of NTM disease is not

known. While *M. gordonae* is the most frequent NTM species isolated from human specimens, MAC is most frequently associated with human disease (38.2 to 73.3% of all pathogenic isolates) (127, 180, 250). The incidence of laboratory isolation of MAC in the United States, based on a 1979 survey of 44 state public health laboratories, is estimated to be 3.2 cases per 100,000 population and was greatest for Hawaii (10.8 cases), Connecticut (8.9 cases), Florida (8.4 cases), Kansas (6.8 cases), North Carolina, Maryland, Rhode Island, and Arizona (180). Several authors have noted an apparent increase in the incidence of NTM infections in the United States and Europe, even when cases in patients with AIDS are excluded (7, 21, 103, 127, 136, 365). In at least two locations, however, the incidence of MAC in non-AIDS patients remained stable or decreased. The rate of isolation of MAC from respiratory specimens at the San Francisco General Hospital steadily increased from 1977 to 1989, but the rate of increase paralleled the increasing incidence of AIDS cases in that city, while the prevalence of MAC isolated in respiratory specimens from non-AIDS patients remained stable (approximately 0.3%) (354). Clinical and laboratory diagnoses of NTM infections actually declined in British Columbia from 1972 to 1981 (250).

Serovar analyses indicate that there are differences in the patterns of human disease-related strains between geographic areas. In the United States, 40 to 50% of the clinical MAC infections in non-AIDS patients are caused by *M. intracellulare*, whereas in western Germany, 81% of the human infections are due to *M. avium* and only 19% are due to *M. intracellulare* (331). In addition, serovar analyses suggest a shift in the proportion of human disease caused by *M. avium* relative to that caused by *M. intracellulare* in certain geographic areas. Meissner and Anz noted that while disease due to intermediate *M. avium* serovars (4 to 6 and 8 to 11) increased from 26 to 71%, the frequency of disease due to *M. intracellulare* decreased from 22 to 5% from 1965 to 1975 in western Germany (331). In Japan, of 661 isolates that caused pulmonary disease, biotype studies indicate a similar significant shift from *M. intracellulare* to *M. avium* in the period 1976 to 1986 (338).

MAC organisms are ubiquitous in nature and can be isolated from natural sources of water, pools, soil, plants and bedding material, and even house dust (158, 243, 396, 467). Surveys of skin test reactivity to antigens prepared from *M. intracellulare* (PPD-B) indicate that the frequency of exposure to this organism is high, particularly in the coastal regions of the southeastern United States and the Gulf, especially in rural areas (>70% in some counties) (140). Data suggest that environmental sources of water constitute the greatest risk of exposure for humans (77, 85, 137, 148, 184, 331, 376, 435, 477), but there are significant gaps in our understanding of the mode of acquisition and pathogenesis of this disease. Indeed, NTM have been isolated from the water supplies of some of the largest metropolitan areas in the United States, including the water supplies of hospitals (85, 138). Drinking water contaminated with MAC was found in 32 of 141 rainwater tanks in Queensland, Australia, but there was no relationship to human disease (458).

Organisms of the MAC may be isolated from both fresh- and saltwater sources (17 to 61% of samples), but recovery is more frequent from waters of moderate salinity (≤ 2 g% NaCl) and from the Southeast (33%) compared with the Northeast (20%) (148, 190). Studies of soil samples taken from the flood plains of four major eastern rivers demonstrated higher rates of recovery from soil and water samples of relatively high acidity (pH 4.6 to 6.8) and at lower

altitudes (69). MAC, but not *M. scrofulaceum*, is found in aerosols in droplet sizes of 0.7 to 3.3 mm above fresh water which is sufficiently small to reach the alveolar spaces after inhalation (477). These studies led the authors to estimate that as many as 18 organisms may be inspired by a human during a 1-h period of exposure. Although isolation from seawater is slightly less frequent than that from fresh water, *M. intracellulare* is highly concentrated within jet droplets released from the air-seawater interface (190). These findings may explain the greater frequency of isolation of *M. intracellulare* from respiratory specimens in some geographic areas.

Plasmids are more commonly found in isolates from surface layer aerosols (75%) compared with isolates identified in soil (5%), dust (7%), and water samples (25%), and the plasmid DNA profiles of aerosolized isolates closely resemble those most commonly isolated from humans (332). A comparison of clinical and environmental MAC isolates revealed that clinical isolates were better able to grow at 43°C without oleic acid-albumin-dextrose-catalase enrichment and more frequently expressed resistance to cadmium compared with environmental isolates, features that closely correlated with the presence of plasmids (158). Only environmental isolates identified in droplets above bodies of water shared those unique characteristics.

M. avium is an important cause of disease in poultry and swine and is commonly excreted in the feces of birds (but not cattle or swine), after which the bacilli can persist in the soil for long periods of time. Although the direct transmission of *M. avium* from animals to humans is thought to be exceedingly rare, epidemiologic analyses of infecting strains suggests that the avian-associated serovars 1 to 3 cause infections in areas where humans and fowl are in close proximity; swine and cattle are even less frequently implicated as the source of infection for humans (331). Additional studies indicate disparity between the serovars that commonly infect humans, poultry, and swine (92, 356). The results of skin test surveys of relatives and housemates of infected persons do not support human-to-human transmission as a significant risk factor (140).

Vaccination with *M. bovis* BCG results in some cross-protection from *M. avium* infection in animals and, possibly, humans. The rate of recovery of viable organisms is lower in BCG-vaccinated mice than in nonvaccinated mice aerogenically challenged with *M. avium* or *M. kansasii*, but not *M. intracellulare* (99, 371). This moderate degree of protection may explain an increase in NTM infections in children following the cessation of community-wide BCG vaccination programs (403).

Patients with AIDS

Since the advent of the AIDS epidemic, immune deficiency due to human immunodeficiency virus (HIV) infection has become the single most significant risk factor for MAC disease. On the basis of AIDS case reporting to the Centers for Disease Control through 1987, the incidence of disseminated MAC as the AIDS-defining illness was 5.5% (233). By December 1990, there were more than 12,000 cases of disseminated NTM infection among the 161,073 patients with AIDS reported to the Centers for Disease Control; of these, the vast majority (96 to 98%) were due to MAC (191, 225, 233). Progressive immunodeficiency due to HIV infection appears to be the single most significant risk factor for disseminated MAC disease (81, 199, 234, 358). The incidences of disseminated disease 1 and 2 years after a diagno-

sis of AIDS, as defined by at least one blood culture positive for MAC, were 21 and 43%, respectively (358). The incidence of disseminated MAC at 1 year was 39% for patients with CD4 counts of <10 per mm³, but it was only 3% for patients with CD4 counts of 100 to 200 per mm³ (234). These data correspond to histopathologic evidence of MAC infection in 47 to 50% of patients at autopsy (10, 466). At any given level of immunity, however, the incidence of MAC disease is greater for patients with AIDS compared with those HIV-infected patients without AIDS and is linear over time, suggesting that disseminated MAC may be an inevitable outcome in all HIV-infected patients who do not die of other causes (83, 358).

While there is no apparent age discrimination, disseminated MAC infection is more frequent in Caucasians compared with Hispanic, Haitian, and African-Americans (58, 226, 233, 342, 385). In addition, in patients with HIV infection, disseminated NTM disease is somewhat more frequent in men than in women (9.4 versus 7.0%), in homosexual and bisexual men compared with persons in other HIV risk categories (9.5 versus 6.2%), and in adults compared with children (8.3 versus 5.7%) (226). In contrast, infection due to *M. tuberculosis* is more common in Hispanic, Haitian, and African-Americans compared with Caucasians (58, 226). Inner-city intravenous drug users and women are also more likely to be infected with tuberculosis compared with their homosexual, white male counterparts (151). For example, in a sample of HIV-infected patients with mycobacterial disease, 27 of 45 (60%) Haitian patients were infected with *M. tuberculosis* compared with only 1 of 37 non-Haitians (385).

Despite its emergence as an increasingly common infection in the United States and other developed countries (233), disseminated MAC infection is uncommon in AIDS patients in countries of Africa and other developing nations (58, 345). Serial blood cultures failed to reveal a significant incidence of disease in Ugandan patients with AIDS, even though *M. avium* can frequently be recovered from soil and water specimens in that country (345). This finding may be, in part, due to the significantly higher incidence of tuberculosis and toxoplasmosis in patients with AIDS from developing countries compared with those from developed countries (58). Whereas tuberculosis can occur at any level of immunity, disseminated MAC infection predominantly occurs in patients with profoundly compromised immunity (<50 CD4 cells per mm³). In geographic areas with inadequate health care and a high incidence of tuberculosis and tuberculosis-associated mortality, patients may not survive long enough to develop disseminated MAC infection.

Environmental strain-related differences also may account for different prevalence rates in various geographic areas. MAC strains isolated from patients with AIDS in the United States and Australia are predominantly serovars 1, 4, and 8 (108, 126, 282, 495). In Sweden, however, while the incidence of disseminated MAC disease is relatively low in patients with AIDS, serovar 6 is most commonly isolated from clinical specimens in that country (219). In Africa, the predominant human and environmental isolate, RFLP type H, does not correlate with any known strain isolated from Western or European AIDS patients (328).

Also, environmental exposure may differ between populations; whereas 98% of MAC infections in AIDS patients are due to *M. avium*, approximately 40% of MAC isolates recovered from patients without AIDS are *M. intracellulare* (191). In addition, *M. intracellulare* made up 13% of respiratory isolates in one large survey of patients with AIDS but

only 1.3% of blood isolates and none of the stool isolates (495). Based on RFLP analyses, 73% of the MAC strains recovered from individual patients with AIDS were found to be genetically indistinguishable (194). These intriguing observations suggest that the source of environmental exposure, the route of infection, and other complex host factors, independent of the nature of the infecting strain, may differ in patients with and without HIV infection.

In addition, certain strains of MAC may possess virulence factors that more readily lead to infection and dissemination in patients with HIV infection. In one small study, all 26 strains isolated from persons with AIDS carried plasmids (11 carried one small plasmid and 15 carried two), suggesting that plasmids may play a pathogenetic role in patients with AIDS (108). No data to confirm a role for plasmids in the pathogenicity of MAC are available. The predominant strains isolated from patients with AIDS are, however, serovars 4 and 8, which frequently contain small plasmids or portions of plasmids (215, 265, 344). These plasmids are similar to those identified in serovars 4 and 8 isolated from environmental specimens (265), suggesting that these plasmids may confer specific virulence.

Although MAC organisms can occasionally be isolated from the stools of healthy humans, most are not associated with disease. Furthermore, strains that are more frequently isolated from AIDS patients with disseminated disease are not commonly found in the stools of healthy individuals (194). This observation led investigators to suggest that MAC isolates that cause disease in AIDS patients are not simply gratuitous opportunists but possess specific genetic determinants that confer an ability to penetrate and multiply within macrophages and host cells and contribute to the existing immunodeficiency (194). Implicit in this postulate is the assumption that there are host immune defects, possibly unrelated to the underlying HIV infection, which predispose patients to disseminated infection (39, 54, 114, 115, 224, 352, 446, 457).

PATHOGENESIS

Pathogenesis and the Host

Despite the fact that disease caused by mycobacteria has been known since the time of Koch and that satisfactory therapy exists for most mycobacterial infections, very little is known about the mechanisms of pathogenesis of the most common mycobacteria that cause disease, including *M. tuberculosis*, *M. leprae*, the MAC, and *M. kansasii*.

While humans are highly susceptible to *M. tuberculosis* and *M. leprae* infection, most people who are exposed to these bacteria never develop clinical disease, indicating that the normal immune system can control these microorganisms (86, 483). This observation is even more applicable to exposure to MAC organisms because, despite evidence of exposure rates as high as 70%, the incidence of clinical disease is remarkably low (<10 cases per 100,000 population). Before the AIDS epidemic, pulmonary infection was the principal, albeit infrequent, manifestation of disease. Dissemination of infection was unusual and, with rare exception, occurred in persons with defects in cellular immunity. However, even in severely immunocompromised individuals, such as those with hairy cell leukemia who seem to be predisposed to MAC infection (21, 64, 318, 397, 440, 476, 481), the incidence of MAC infection is only 5%. In contrast, *M. avium* appears to have a particular predilection for infecting and disseminating within HIV-infected patients.

Routes of Infection

The most likely route of penetration of opportunistic mycobacteria into tissue is across the bronchial or intestinal mucosa. Current evidence points to the intestinal tract as the primary route of *M. avium* infection in AIDS patients (186, 287, 342, 436, 466) and the respiratory tract as a secondary and significantly less frequent portal of entry (4, 231, 257, 388). Disseminated disease in AIDS patients is frequently preceded by gastrointestinal tract colonization (22, 87, 231, 388) as evidenced by the relatively high frequency of positive stool cultures (22, 120, 202, 231, 342, 436) and the high frequency of gastrointestinal involvement, with large numbers of mycobacteria infiltrating the intestinal mucosa and submucosa (120, 186, 287, 406). A study of AIDS patients by Damsker and Bottone (120) was one of the first to suggest that colonization of the intestinal tract preceded the development of bacteremia. Other work supports this concept and, indeed, colonization of the intestinal tract with *M. avium* in patients with AIDS was shown to precede the appearance of bacteremia and disseminated disease by 4 to 5 months (53). Massive Peyer's patch and mesenteric lymph node involvement is a common histopathologic finding in these patients, along with intestinal erosion and chronic diarrhea (120, 287, 405, 406, 484).

Although there is little direct evidence that *M. avium* disseminates from the lung, one study showed that sputum cultures were twice as likely to be positive as stool cultures (66 versus 33%) (231). Progression to dissemination occurred with equal frequency (33%) in patients with positive respiratory or stool isolates during a mean observation period of 5 months. Recent data presented by Chin et al. (87) indicated that nearly 75% of patients develop mycobacteremia within 1 year (median duration time of 6 months) after the isolation of MAC organisms from respiratory secretions or stool. Nevertheless, of those patients who developed MAC bacteremia, only 25 and 36% had a preceding positive respiratory or stool culture, respectively. These data suggest that the methods available to screen for gastrointestinal tract colonization lack sufficient sensitivity, resulting in a poor negative predictive value.

Asymptomatic respiratory and intestinal colonization with *M. avium* can be seen in healthy individuals, but the development of focal or disseminated disease in them is rare. Ingestion of mycobacteria in water or food appears to lead to colonization of the intestinal tract (100, 309). Our studies with a beige (C57BL/6 *bg+/bg+*) mouse model of oral infection demonstrated that oral exposure of *M. avium* strains isolated from AIDS patients leads to intestinal colonization and subsequent dissemination of infection. Detailed studies of bacterial localization along the gastrointestinal tract showed that the great majority of the organisms are found in the terminal ileum and ascending colon (34). Concomitant ingestion of a mucosal irritant, such as ethanol, led to an increased colonization of the upper gastrointestinal tract, with a large number of bacteria being cultured from the stomach and mucosa and submucosa of the proximal intestines. Once in the intestinal lumen, the bacteria bind to enterocytes and probably M cells and quickly penetrate the intestinal epithelial cells before translocating into the lamina propria. The bacteria can colonize Peyer's patches and are eventually found localized in the liver and spleen as well as circulating in the blood.

It is possible that factors such as gastric achlorhydria and the use of oral antibiotics facilitate the colonization by *M. avium*. Studies in animals support this hypothesis, although

even closely related mycobacterial species can exhibit wide variations in mouse virulence when introduced by the oral route (34).

Invasion of Mucosal Cells

We showed that AIDS-related *M. avium* strains can bind and invade HT-29 cells, a well-differentiated human intestinal epithelial cell line, in a manner that is likely to mimic the attachment and invasion of mycobacteria to the gastrointestinal tract of humans (41). Non-AIDS-related *M. avium* strains also bind and invade but are less efficient than AIDS-related strains. In addition, *M. avium* can bind and invade both human oropharyngeal cells and the HEp-2 oropharyngeal cell line (41). In more recent studies, we injected mycobacteria into the intestinal lumen of an isolated segment of the terminal ileum of C57BL *bg+/bg+* mice being kept alive under anesthesia. Following different periods of exposure, we performed quantitative cultures on a 2-in. (ca. 5-cm) segment of the terminal ileum to measure the number of bacilli associated with mucosa and submucosa. In these experiments, we found that *M. avium* rapidly bound to and invaded the intestinal mucosa; however, this feature was strain specific. Strain MAC 101 colonized and invaded more rapidly than another AIDS-related strain (MAC 107, a serovar 8 strain) (236). Histopathological studies, in which hundreds to thousands of mycobacteria were observed in intestinal macrophages, clearly confirm that disease-associated strains of *M. avium* readily invade the intestinal mucosa and submucosa (236). Less virulent serovars of *M. avium* also possess the necessary cell wall adhesion but probably lack accessory virulence factors and do not survive within tissue macrophages.

Recent studies of *M. tuberculosis* demonstrated that the ability of tubercle bacilli to invade HeLa cells is encoded in a 3-kb genomic DNA fragment (11). In a parallel series of experiments, we used an *M. avium* library of chromosomal DNA to transform *Escherichia coli* K-12, which cannot invade cultured mammalian cells. *E. coli* transformants that had acquired a 2.7-kb fragment of chromosomal DNA and the ability to bind and invade human HT-29 and HEp-2 cells were isolated. Thus far, we have evidence for the presence of at least one adhesion protein in virulent strains of *M. avium*. Specific antibody generated with a purified preparation of a 27-kDa putative adhesion protein blocked the binding of *M. avium* strains to both intestinal and oropharyngeal mucosal cells (236). However, it seems clear from our studies and studies of *Yersinia enterocolitica*, *Yersinia pseudotuberculosis*, and *Salmonella cholerae-suis* that the ability to penetrate epithelial mucosal cells can proceed by a number of pathways (154, 251). In the case of *Salmonella* sp., Finlay and Falkow (154) showed that a cluster of proteins is synthesized in response to contact with MDCK cells. A mutation that blocks the synthesis of these proteins interferes with the ability of salmonellae to bind and enter mammalian cells; by extrapolation, intestinal cells may play an active role in taking up *M. avium*. Indeed, a 47- to 50-kDa glycoprotein present on HT-29 cells and oropharyngeal cells binds to the putative 27-kDa *M. avium* adhesion protein and appears to be involved in the binding of several different *M. avium* strains. However, it must be emphasized that in AIDS patients a number of factors probably facilitate *M. avium* infection and invasion of the intestinal mucosa, including coinfections with cytomegalovirus and HIV type 1.

Infection of Nonprofessional Phagocytes

Virulent MAC strains can invade and survive within cells other than mononuclear phagocytes and epithelial cells. This ability to infect a variety of cell types may be related to the persistence of infection in the immunocompromised host; e.g., Bermudez (26) demonstrated that MAC organisms can infect and grow within fibroblasts and, once inside the fibroblast, the mycobacteria are protected against nonspecific mechanisms of killing. Once the bacilli are intracellular, major histocompatibility class I-mediated or NK cell-mediated cytotoxicity is necessary to release the bacilli from the cells. Although it is difficult to assess the overall importance of the ability of MAC to infect "nonprofessional" phagocytes, it is plausible that in a setting of profoundly impaired cytotoxic response the ability to invade fibroblasts, endothelial cells, and other nonprofessional phagocytes contributes to persistence and dissemination.

Interaction with Mononuclear Phagocytes

Intracellular pathogens typically reside within a niche of the host where the pathogen can multiply or survive the onslaughts of cellular and humoral defense mechanisms. Thus, the armamentarium of pathogens includes mechanisms that counteract both nonspecific and specific host defenses. Studies with *M. tuberculosis* (421) and *M. leprae* (422) demonstrated the importance of complement receptors (CR1 and CR3) for the binding and phagocytosis of mycobacteria. In addition, it is now clear that several species of mycobacteria including *M. leprae*, *M. tuberculosis*, and *M. bovis* bind to serum fibronectin by way of a 30-kDa receptor (1). Phagocytosis of the MAC by monocytes and macrophages occurs mainly via the CR3 receptors in both the presence and the absence of serum (47, 401). In addition, MAC organisms bind to serum fibronectin and the bacilli are internalized by macrophages by using the integrin fibronectin receptor. The use of an Fc receptor-independent pathway for uptake may offer significant advantages for the invading microorganism. For instance, a study by Wright and Silverstein (488) showed that phagocytosis with Fc receptors, but not complement receptors, is associated with superoxide anion production by phagocytic cells, and invasion by other mechanisms may influence the structure and function of the intracellular vacuole. Although the ability to multiply inside mononuclear phagocytes is not uniform among *M. avium* strains, AIDS-associated strains remain viable within human and murine macrophages (39, 116) and resist the respiratory burst-associated bactericidal mechanisms (42, 166). MAC as well as *M. tuberculosis* synthesize a 23-kDa superoxide dismutase that can inactivate macrophage-derived superoxide anion (319) and other proteins, such as the 65-kDa heat shock protein, which are powerful inhibitors of superoxide anion production (30). The origin of this activity is unknown, but the 65-kDa protein is released in large quantities in response to stress conditions such as high temperature, change in pH, and phagocytosis (30). The survival of pathogenic strains of *M. avium* within macrophages also is related in part to their capacity to inhibit fusion of the phagosome and lysosome, thus preventing contact with proteolytic enzymes (54, 115). In the absence of phagolysosome fusion, the intracellular environment of the macrophage remains neutral or alkaline, which may directly influence pathogen survival and the effectiveness of certain antimicrobial therapies. Studies by Frechel and colleagues (156) suggested a role for cell surface components, other than the C-myo-

sidis, in this phenomenon. Walker and Lowrie (465), using *M. microti*, proposed a role for cyclic AMP and prostaglandin E₂ in phagolysosome fusion.

IMMUNE RESPONSE

Cellular Immunity

Mycobacteria are considered the archetypical intracellular pathogens because of the capacity of these bacilli to invade and multiply within macrophages (39, 116); thus, the cellular immune response to mycobacterial infection has been a subject of considerable study. Phagocytosis and processing of antigens by macrophages or B lymphocytes trigger a specific cellular immune response, including the activation of T-helper cells, macrophages, T-cytotoxic cells, and NK cells. Antigen processing occurs after infection with mycobacteria and leads to a complex host response involving multiple arms of the immune system (427, 428). Although there is evidence that CD4⁺ T cells, CD8⁺ T cells, NK cells, and $\gamma\delta$ T cells (197, 237, 348) are important factors in this response, there is surprisingly little information about the cellular immune response to NTM. For example, some strains of the MAC induce a chronic, lifelong lung infection in normal mice (102), while more virulent MAC strains cause a disseminated disease associated with high mortality (163). Most strains of *M. intracellulare* are less virulent and tend to induce chronic pulmonary infections in C57BL/6 or beige mice (370), but infection with these strains is exacerbated by the absence of T cells such as in congenitally athymic *nu/nu* mice (101). In mice, resistance to early growth of *M. bovis*, *M. lepraemurium*, *M. intracellulare*, and *M. avium* may be controlled by a single dominant autosomal gene, *Bcg* (424). Furthermore, phagocytosis- or ligand-induced respiratory burst activity is significantly greater in macrophages from resistant animals than in macrophages from susceptible mice (372), and the transfer of immune cells (T or NK cells) from resistant to susceptible mice is associated with an increased ability of the latter animals to control *M. avium* infection (31). However, these observations contradict the observation that peritoneal macrophages from MAC-resistant and MAC-susceptible mice have equal capacities to ingest and inhibit or kill MAC in vitro (31).

Role of Cytokines

Both cultured mouse and human macrophages can be stimulated by cytokines to inhibit or kill intracellular *M. avium*. Bermudez and coworkers (45, 51) and Denis and Gregg (132) showed that recombinant tumor necrosis factor (TNF) and granulocyte-macrophage colony-stimulating factor (GM-CSF) induce mycobacteriostatic and/or mycobactericidal activity and that macrophages stimulated with TNF or GM-CSF respond differently than unstimulated macrophages. In stimulated macrophages, there is an increased release of superoxide anion and phagolysosome fusion occurs more frequently following uptake of mycobacteria (54). Although the mechanisms of inhibition and killing of intracellular MAC are not completely understood, the nonoxidative mechanisms of defense have an important role (27, 42). Bactericidal proteins purified from human macrophages increase the permeability of the mycobacterial cell, and this effect is ultimately bactericidal (40). Although the nitric oxide-dependent pathway of intracellular killing is associated with the nonoxidative killing of a number of intracellular pathogens such as *Toxoplasma gondii* (3) and *Leishmania*

major (187), there is controversy about the role of this pathway in the killing or inhibition of mycobacteria. Some studies suggest that this pathway is important in the killing of the MAC (131), *M. leprae* (2), and *M. tuberculosis* (84), while other studies show that this pathway is not important for the killing or inhibition of MAC growth (27).

The ability of cytokines to stimulate macrophages and inhibit growth of the MAC depends on the strain; e.g., gamma interferon (IFN- γ) stimulates inhibition or killing of certain non-AIDS strains of MAC (44), but not that of AIDS-related MAC strains (51). Paradoxically, the administration of recombinant TNF or GM-CSF was associated with increased killing of mycobacteria in the beige mouse model of disseminated MAC infection (32, 35), but macrophage monolayers infected with MAC organisms for longer than 48 h failed to respond to these cytokines even when the cytokines were administered 7 days after infection (44). The conclusion was that response to cytokine stimulation reflects the influence of MAC infection on the ability of macrophages to respond to cytokines. In addition, the MAC can interfere with other cytokine pathways by stimulating the production and release of suppressor molecules such as interleukin-6 (IL-6) and transforming growth factor β (TGF- β) or by directly influencing the mechanism of signal transduction within macrophages (28, 38). The release of inhibitory cytokines by MAC-infected macrophages occurs within a few days of infection, and infection with AIDS-related strains of the MAC stimulates the release of IL-6 and a suppression of macrophage function by down-regulating the expression of TNF receptors and decreasing TNF production (35, 57, 132). There is some evidence that IL-6 stimulates growth of the MAC (426); however, IL-6 binds not only to virulent MAC strains, but also to nonvirulent strains, *M. smegmatis*, *E. coli*, and *Pseudomonas aeruginosa*, raising the possibility that the influence of IL-6 binding is nonspecific (35).

M. avium-infected macrophages release TGF- β soon after infection (28), and the 61- and 33-kDa cell surface proteins of MAC stimulate macrophages to release TGF- β in culture (28). Furthermore, much of the TGF- β released from infected macrophages is in the active form, whereas TGF- β released from control macrophages is in the inactive form. Since TGF- β is known to impair the ability of macrophages to respond to cytokines, the release of TGF- β is likely to be responsible for the lack of response to IFN- γ by MAC-infected macrophages. A specific amino acid sequence within the 33-kDa protein interferes with the regulation of transcription in macrophages, which in turn influences the response of macrophages to stimulation with TNF- α (29). Interference with cytokine-related signal transduction and transcription is probably an important mechanism of pathogenesis and contributes to the persistence of MAC within macrophages.

Thus far, the results of various studies directed at understanding the nature of the interaction between HIV type 1 and *M. avium* within macrophages are inconclusive. In some studies of coinfecting macrophages, HIV type 1 did not affect the *M. avium* infection, while others claim that *M. avium* grew significantly faster in HIV-infected macrophages (262, 267). Peripheral blood mononuclear phagocytes obtained from AIDS patients are not functionally impaired (334), since these phagocytes respond to stimulation with cytokines several days after being harvested from blood; however, phagocytic cells obtained from the peripheral blood may be significantly less impaired than heavily infected tissue macrophages.

Finally, a number of cofactors could contribute to the

impairment of macrophage function in AIDS patients. Alcohol ingestion is common in some at-risk population groups (315). Because of the relationship between alcohol consumption and pulmonary tuberculosis (70, 238), it is plausible that there is an association between alcohol consumption and *M. avium* infection in AIDS patients. Human macrophages exposed to serum-achievable concentrations of ethanol are more permissive to intracellular growth of *M. avium* than macrophages not treated with ethanol (46), and ethanol both impairs the ability of macrophages to respond to stimulation with TNF and GM-CSF (37) and may act as a mycobacterial stress factor (43). Other drugs of abuse impair macrophage function. Peterson et al. (381) demonstrated that treatment of macrophage monolayers with cocaine was associated with increased replication of HIV type 1; however, the relationship between this observation and infection of macrophages with MAC organisms is unknown.

Role of Lymphocytes

Several studies have shown that T lymphocytes are important in the immune response to mycobacterial infections including the generation of a positive skin hypersensitivity response to intradermal administration of PPD. In the infected host, expression of class II molecules by infected macrophages results in the presentation of mycobacterial antigens to class II-restricted CD4⁺ T lymphocytes of the helper/inducer type. Mice inoculated with a crude lysate of *M. tuberculosis* or *M. avium* will respond with a proliferation of T cells specific for mycobacterial antigens. In a limiting-dilution analysis, approximately 20% of the CD4⁺ T lymphocytes that were reactive to mycobacterial antigens recognized the mycobacterial 60-kDa heat shock protein (272).

Little is known about the role of T cells in preventing the growth of *M. avium* in the tissues of immunocompetent hosts. While T-cell depletion enhances the severity of infections with some MAC strains, T-cell depletion does not affect the severity of infection with other strains (101). Depletion of the L3T4⁺ or Lyt-2⁺ T-cell subpopulation does not have any significant effect on the immune response to *M. avium* in mice, but depletion of both subsets ablates the immune response (237). However, it appears that the interaction of activated CD4⁺ T cells with macrophages does not have the same effect with *M. avium* as with *M. tuberculosis* (271).

The antibody response of humans and mice to MAC infection, as judged by Western blots (immunoblots), is heterogeneous (36, 343), and blot profiles from different patients show distinct individual patterns with a few predominant common bands. Like *M. tuberculosis*, *M. avium* releases a 65-kDa protein in response to the stress of increased temperature or exposure to acid pH (39). The release of proteins in response to stress has been demonstrated in nonmycobacterial systems, and Young and Garbe (501) speculated that the 65-kDa protein of *M. tuberculosis* is an analog of the GroEL protein in *E. coli*. Other mycobacterial antigens, including the 71-, 65-, 38-, 33-, 30-, and 10-kDa proteins, can be released and recognized by CD4⁺ and CD8⁺ T lymphocytes. In addition, mycobacterial glycolipids can have an immunomodulatory effect (447) and certain GPLs from *M. avium* can interfere with the lymphoproliferative response (72). T cells bearing the $\gamma\delta$ T-cell receptor appear to have a special role in the immune defense system and there is a strong correlation between infection with an intracellular pathogen and the accumulation of $\gamma\delta$ T cells at

the sites of infection, including the skin and lung epithelium. The relationship between $\gamma\delta$ T cells and invading microorganisms is central to the hypothesis of immunosurveillance and suggests that a primitive subset of T cells provides an initial line of immune defense by recognizing highly conserved molecules produced during environmental stress; i.e., $\gamma\delta$ T cells with a severely restricted receptor repertoire react to the release of highly conserved mycobacterial 60- and 70-kDa heat shock proteins. O'Brien et al. showed that $\gamma\delta$ T cells proliferate in response to PPD and to a recombinant 65-kDa protein of *M. tuberculosis* (368), and our preliminary studies confirmed these findings and extended the observation to *M. avium*; i.e., $\gamma\delta$ T cells from four different donors lysed infected target cells in a major histocompatibility complex-independent manner after stimulation with *M. avium* (33).

The role of human $\gamma\delta$ T cells in the first line of immune defense to mycobacterial infections also is strongly suggested by the accumulation of $\gamma\delta$ T cells at the site of granulomatous responses to *M. leprae* (462) and in tuberculous lymphadenitis (258). Among the $\gamma\delta$ T-cell subpopulations there is evidence that the response to pathogenic *M. tuberculosis*, *M. avium*-*M. intracellulare*, and *M. scrofulaceum* is mainly confined to the V δ 9 V δ 2 TCR-positive cells, and the selective triggering of these T cells may reflect a super-antigen-like effect of mycobacterial antigens or antigen-specific stimulation, possibly in response to the heat shock protein 60 (196, 367).

Role of NK Cells

The role of NK cells in the immune response to *M. tuberculosis* and *M. avium* has been well established in a variety of studies (50, 55, 270). More recent findings indicated that NK cells are cytotoxic in a nonrestricted manner and stimulate mycobacteriostatic and mycobactericidal activities in infected macrophages (50, 55, 270). The cytotoxicity of NK cells for infected macrophages appears to depend on binding via the LFA-1 glycoprotein receptor (56); however, the validity of this observation could be questioned since other recent studies showed that NK cells do not efficiently bind or lyse target cells expressing the class I major histocompatibility complex. It is of interest to note that Blanchard and colleagues (57) showed that NK cells exposed to *M. avium* release large amounts of IL-6, which may have an important influence on the host immune response.

The mechanism by which NK cells stimulate macrophages appears to be mediated by the release of cytokines. Gomez et al. (176) and Pohjda et al. (387) demonstrated the ability of activated NK cells to produce cytokines that activate macrophages, and studies of the role of NK cells in the inhibition and killing of MAC organisms are in agreement with these previous studies (50). TNF, IFN- γ , and GM-CSF are secreted by activated NK cells and, theoretically, can influence macrophage activity. Anti-TNF antibody, but not anti-GM-CSF antibody, partially blocks the stimulatory effect of the supernatant fraction of activated NK cells but cannot block the effect of purified NK cells. This observation suggests that the effect of NK cells on macrophages occurs through direct cell-to-cell contact (50). Numerical and functional deficiencies of NK cells in patients with AIDS (61) may account for the ability of *M. avium* to invade and establish infection in tissues. This hypothesis is supported by a recent study that showed that C57BL/6 mice treated

with antibody to deplete NK cells developed a more severe form of disseminated disease than untreated mice (197).

CLINICAL DISEASE IN PATIENTS WITHOUT AIDS

Pulmonary Disease

The first case of human disease due to *M. avium* was reported in 1943 in a middle-aged underground miner from the Mesabi Iron Range of Minnesota in what became a classic description of pulmonary disease due to this organism (152). During the next two decades, a number of cases of MAC pulmonary disease were reported (113, 300, 451), and until the emergence of AIDS, lung infection alone was the most common presentation of disease due to this organism.

Pulmonary disease due to *M. avium* predominantly involves white males 45 to 65 years of age with preexisting pulmonary disease (144, 145, 404, 468), but there is tremendous variation in the sex, age, and race of these patients. Predisposing conditions such as chronic obstructive pulmonary disease, bronchiectasis, chronic aspiration or recurrent pneumonia, inactive or active tuberculosis, pneumoconiosis, and bronchogenic carcinoma are present in 54 to 77% of patients with pulmonary MAC disease (144, 145). Also, MAC organisms are frequently recovered from adults with cystic fibrosis, particularly in the southeastern United States (283). Differentiation of infection from the coexistent pulmonary disease may be difficult, and the clinical and radiographic presentation may be indistinguishable from tuberculosis (373). A positive tuberculin skin test may be helpful in differentiating the two processes; however, coinfection with *M. tuberculosis* and *M. avium* has been demonstrated (456).

The symptoms are varied and nonspecific, commonly including chronic productive cough, dyspnea, sweats, malaise, fatigue, and, less commonly, hemoptysis. Fever and weight loss are not common but may occur. Approximately 75% of patients have evidence of cavitory infiltrate on chest roentgenograms, typically involving the apical and anterior segments of the upper lobes, but dense unilobular or multilobular infiltrates, diffuse interstitial or reticulonodular infiltrates, or a solitary pulmonary nodule may occur (89, 188, 310, 389). Cavities or infected bullae tend to be thin walled with less surrounding infiltrate than that associated with tuberculosis. Bilateral involvement is common and there may be a dense pleural reaction, but pleural effusions are unusual. The radiograph of a patient without AIDS and one of a patient with AIDS, both with pulmonary disease, are shown in Fig. 3 and Fig. 4 and may be compared.

MAC organisms may be isolated from the sputum in the absence of apparent disease, particularly in patients with chronic respiratory disorders; such low-grade infection or colonization is more common than true disease. These patients may have episodic excretion of organisms which frequently clears with good pulmonary toilet. Also, isolation of the organism may simply represent contamination of the specimen, and care must be exercised in interpreting the results of these cultures.

Guidelines have been suggested for distinguishing patients with NTM lung disease from patients who are simply colonized. NTM disease in patients with noncavitory infiltrates can be assumed to be present when (i) two or more sputum or bronchoalveolar wash specimens are smear positive and/or result in moderate to heavy growth in culture; (ii) sputum cultures fail to revert despite good pulmonary toilet or 2 weeks of antimycobacterial therapy; and (iii) reasonable attempts fail to identify other underlying causes of disease

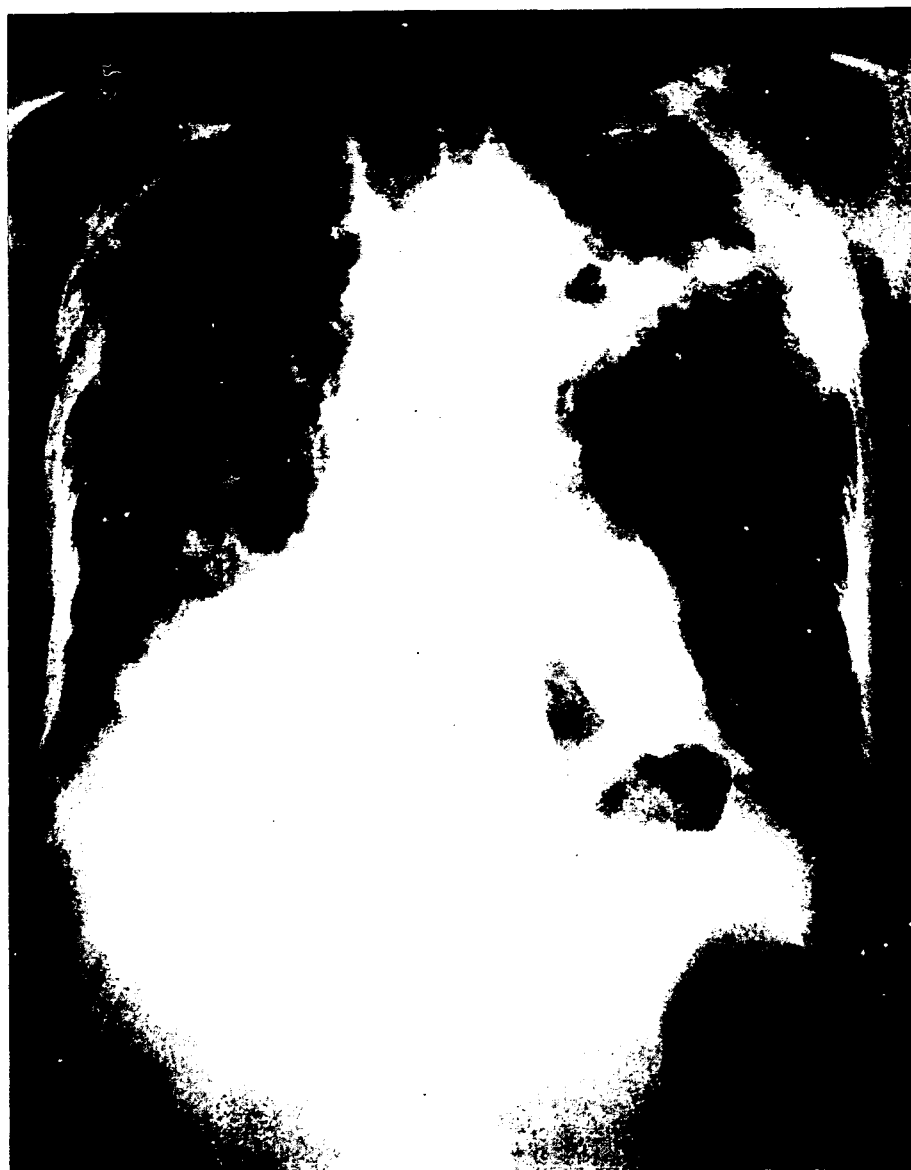


FIG. 3. Posterior-apical chest roentgenogram of a 48-year-old immunocompetent woman with severe bullous emphysema and extensive pulmonary disease due to MAC. Scattered infiltrates and a diffuse irregular pleural thickening are noted bilaterally.

(468). It is important to note that these guidelines may not apply to immunodeficient patients.

More individuals, especially women, in previously good health and without the usual predisposing conditions are being recognized with pulmonary MAC disease (252, 389, 395). Many of these patients were older women with indolent symptoms and atypical radiographic features (e.g., a solitary nodule), which frequently resulted in a delayed diagnosis. Six of 29 patients, all female, with *M. avium* pulmonary infection had isolated middle lobe or lingular involvement (395). The authors termed this the Lady Windermere's Syndrome, after Oscar Wilde's Victorian character, because many patients had a fastidious habit of cough suppression that the authors considered a potential predisposing factor. In another series, 4 of 21 patients died from progressive pulmonary MAC infection, and none of these patients had an

underlying immunodeficiency or other contributing disease (389). The prognosis of *M. avium* pulmonary disease may be worse than that of *M. intracellulare* disease. In one survey, 3 of 28 patients with *M. avium* died and 1 was cured, while none of 27 patients with *M. intracellulare* died and 6 were cured of disease (497).

Patients with an underlying immunodeficiency are at risk for pulmonary MAC disease, including those compromised by cytotoxic chemotherapy, corticosteroids, or allogeneic bone marrow, renal, or cardiac transplantation. Such patients commonly present with atypical radiographic features (292), and attempts at establishing a diagnosis may be difficult and complicated by the presence of multiple pathogens. Also, the administration of steroids may mask the clinical symptoms. Pulmonary MAC disease in children is rare and is usually a component of disseminated infection in



FIG. 4. Posterior-apical chest roentgenogram of a 39-year-old, HIV-infected male with isolated pulmonary MAC infection of the superior posterior portion of the left lower lobe. Note the absence of a pleural effusion or scarring, cavitation, or hilar lymphadenopathy.

the presence of an underlying immunodeficiency (216, 305). The role of MAC in one special pediatric population, cystic fibrosis patients, is unclear; however, the isolation of MAC organisms from respiratory secretions of older cystic fibrosis patients is not uncommon (283).

In most cases, the diagnosis of MAC pulmonary disease can be established without lung biopsy, but in patients with low numbers of organisms or an unexplained or atypical radiographic presentation, percutaneous, transbronchial, or open lung biopsy may be necessary. A recent study identified MAC organisms in the sputum of 11 of 97 patients with active tuberculosis (cultures were first incubated at 42°C for 3 weeks to suppress the growth of *M. tuberculosis*) (456); however, the clinical significance of *M. avium* in these patients was not entirely clear. Antibodies to *M. avium* detected in serum or pleural fluid are not specific, and antibodies in the pleural fluid most likely reflect passive diffusion from sera and not localized production (298).

Histopathologic presentations are varied; both caseating and noncaseating granulomatous necroses are common and may be associated with a granulomatous bronchitis. Ill-formed granulomata with histiocytic reaction are more commonly reported in immunodeficient patients but also are seen in immunocompetent hosts. A granulomatous vasculitis (histologically similar to Wegener's granulomatosis) or a non-specific interstitial pneumonitis with organizing pneumonia may be the only finding (310). A survey of 20 resected

solitary pulmonary nodules with histologic evidence of granulomata and acid-fast bacilli indicated that 12 (60%) were due to MAC, 1 was due to *M. tuberculosis*, and 5 were culture negative (188).

Subacute Lymphadenitis

Granulomatous inflammation accounts for approximately 20% of cases of upper anterior cervical, submandibular, submaxillary, and pre-auricular lymphadenopathy in children 1 to 5 years of age. Most of these cases are the result of infection due to the MAC, *M. scrofulaceum*, or the etiologic agent of cat scratch disease. Mycobacterial lymphadenitis usually presents as an insidious, painless, unilateral process involving one or more nodes in a regional distribution (20, 170, 264, 293, 417, 468); axillary and inguinal nodes are occasionally involved (98). Spontaneous sinus tract formation occurs in approximately 6% (264). Children above the age of 12 years are rarely infected except in circumstances of immunodeficiency or disseminated disease (293).

Of the mycobacteria isolated from the nodes of children which can be characterized, 63 to 80% are MAC, 10 to 20% are *M. scrofulaceum*, and approximately 10% are *M. tuberculosis* (20, 170, 264, 293, 468). These findings are in distinct contrast to mycobacterial lymphadenitis in persons older than 12 years, 95% of which is due to infection with *M.*

tuberculosis and only 3% of which is due to infection with MAC organisms (293).

While more than 90% of children with mycobacterial lymphadenitis have a positive skin test reaction to PPD-B (264), safe, standardized, antigenic material is not available for routine diagnostic purposes. Such patients would, however, have a negative tuberculin skin test, unless they were coinfectd with *M. tuberculosis*. Fine-needle aspiration may yield the diagnosis with a positive culture in less than 50% of cases (8, 438). Histopathologic presentations of lymphadenitis are varied but generally demonstrate caseating granulomatous inflammation and necrosis, epithelioid histiocytes, and occasional giant cells. Rarely, histiocytic inflammation and a lack of granulomatous inflammation occur, chiefly in children with selective immunodeficiency (347).

Disseminated Infection

An excellent review of disseminated MAC infection in non-AIDS patients is provided by Horsburgh et al. (230), and several comprehensive reviews of the spectrum of clinical disease have been provided elsewhere (253, 305, 468, 482, 487); the following presents a brief overview of disseminated disease and of unusual sites of involvement.

Disseminated infection with the MAC was extremely unusual prior to the AIDS epidemic. Typically, the disease occurred in individuals with underlying malignancy or inherited or therapeutic immunodeficiency, especially children and young adults with hematogenous malignancy or severe combined immunodeficiency syndrome, transplant recipients, and patients receiving cytotoxic chemotherapy or corticosteroids (230, 361, 468, 482). A specific immune defect may predispose patients with hairy cell leukemia to disseminated disease (64, 318, 397, 440, 476, 481). In one large series, 5% of patients with hairy cell leukemia were diagnosed with NTM infections (21), and other data indicate an association of disseminated NTM infections in cardiac transplant recipients with prior nocardiosis (430). Holland (223) recently described a possible X-linked deficiency of CD45RO cell IFN- γ production in a child with disseminated MAC infection; two maternal uncles of the child had chronic disseminated MAC infection and abnormally low levels of IFN- γ .

The most frequent presentation of disseminated infection in the immunocompromised host is fever of undetermined etiology. Dissemination may involve any organ system but, most commonly, the lungs and large airways, the mononuclear phagocyte system including the liver, spleen, and retroperitoneal nodes, the gastrointestinal tract, the skeletal system, and the skin (76, 157, 230, 305, 415, 482). Rarely, the brain, cerebrospinal fluid, and orbit are involved (147, 282, 305, 459). Mycobacteremia was seldom reported previously, but with the improvement in isolation techniques, bacteremia may be identified in more than 90% of non-AIDS patients with disseminated infection (282).

Massive histiocytic infiltration with innumerable acid-fast bacilli, resembling the "foamy" histiocytes of lepromatous leprosy, occurs in some patients and may immediately suggest the diagnosis. However, the histopathologic changes in severely immunocompromised hosts are often nonspecific with necrotizing acute and chronic inflammation, histiocytosis, and a lack of granulomatous inflammation or apparent acid-fast bacilli (150). Chronic ulceration of duodenal and colonic mucosa with histiocytic infiltration, which was ultimately fatal due to gastrointestinal hemorrhage, has been reported (337). Despite administration of multiple antimycobacterial

bacterial agents, most cases of disseminated disease have been fatal (55 to 100%), particularly in children and immunocompromised hosts (230, 305, 482).

Stone et al. (441) recently presented two cases of disseminated MAC disease in children without HIV infection and reviewed an additional 30 cases of serious MAC disease in children involving visceral dissemination, localized pulmonary disease, disseminated osteomyelitis, mastoiditis, otomastoiditis, meningitis, and mediastinal mass. The overall mortality for all of the patients included in this study was 41%; however, for children with visceral dissemination, the mortality was 82% (approximately one-third of the patients had visceral disseminated disease). In contrast, patients with localized disease or osteomyelitis had a favorable outcome.

Unusual Sites of Infection

The MAC has been implicated in numerous articular and periarticular infections, causing granulomatous inflammation of any joint, bursa, or tendon sheath, but with the joint spaces of the hands and wrist most commonly involved (141, 217, 445, 499). Extension to adjacent bone and soft tissue occasionally occurs. Trauma, puncture wounds, and needle injection are common inciting risk factors, but hematogenous dissemination, particularly in patients with underlying disease, is likely. The disease is typically indolent and delays in diagnosis are common; at least 40% of the cases of NTM in one series had received intra-articular steroids for non-specific tenosynovitis or arthritis prior to recognition of the infection (217). In only 15% of the cases can the diagnosis be made on culture of joint aspirate and surgical biopsy, and culture of synovial material is necessary for diagnosis in most cases. The majority of cases respond, with preservation of joint function, to a combination of surgical excision of infected material and antituberculous chemotherapy (141). A single case of reactive arthritis in a patient with *M. avium* pulmonary infection has been described (313).

Osteomyelitis, usually with multiple bony lesions, skeletal destruction, contiguous abscess formation, and draining sinuses, is rare (305, 482). It most commonly occurs in children who have hematologic malignancy, but rarely in apparently healthy individuals (19, 97, 259).

NTM infection of the urinary tract, which may be clinically indistinguishable from tuberculosis, is uncommon (90, 377) but can involve any structure in the genitourinary system including granulomatous prostatitis in a recently reported unusual case in an immunocompetent elderly male (336). The presence of MAC in the urine does not necessarily imply tissue infection, however.

Numerous cases of cutaneous abscesses, ulcerations, or nodules due to infection with MAC organisms have been reported, and these have been a result of either direct inoculation, trauma, or surgery or, more often, a consequence of hematogenous dissemination in an immunosuppressed patient (96, 157, 189, 307). Frank cellulitis is rare (415). Localized infection of breast tissue after breast augmentation and silicone injection due to *M. avium* has been reported (379), but *M. fortuitum* and *M. chelonae* are more commonly the cause of these mycobacterial infections.

Acute otolaryngeal, mastoid, and mediastinal infections have been described, probably as a result of extension of infection from the adjacent pharyngeal spaces (274, 285, 469). Also, there are reports of mycotic aneurysmal infection (135, 149), peritonitis associated with ambulatory peritoneal dialysis (390), and corneal ulceration (288).

CLINICAL DISEASE IN PATIENTS WITH AIDS

Focal Disease

Patients with AIDS may present with infection of the respiratory tree or gastrointestinal tract; such infection may be symptomatic or asymptomatic. Distinction between colonization and infection is often difficult, particularly in asymptomatic patients. The MAC is not uncommonly isolated from sputum or stool culture specimens in patients with AIDS (22, 202, 214, 231, 257, 388, 436), and patients may have a single positive culture of either sputum or stool or episodic excretion of organisms without apparent disease. While isolation of MAC organisms in stool is common in the absence of apparent clinical disease in HIV-infected patients without AIDS, 20 to 45% of patients with AIDS and positive stool cultures will have evidence of disseminated disease (120, 186, 388, 436). The presence of the MAC in cultures of either sputum or stool is a risk factor for disseminated disease, but approximately 64 to 75% of patients who develop bacteremia have no previous evidence of colonization (87). The detection of MAC organisms in cultures of stool or respiratory secretions in patients at risk for disseminated disease should therefore prompt a thorough search for evidence of focal or disseminated disease should therefore prompt a thorough search for evidence of focal or disseminated disease, but the routine screening of stool and sputum specimens is not advocated.

Some patients with AIDS may present with focal pulmonary infection due to *M. avium* without evidence of dissemination (342, 468). The clinical presentation is similar to that of immunocompromised hosts but is generally milder than tuberculosis (342). Patients may complain of persistent productive cough, dyspnea, fever, sweats, malaise, and weakness; hemoptysis rarely occurs. The pattern of radiographic involvement is varied. Diffuse interstitial or reticulonodular infiltrates occur in approximately 50%, alveolar infiltrates occur in 20%, and apical scarring or upper lobe involvement occurs in <10% of patients. In contrast to non-AIDS patients with pulmonary MAC infection, cavitory disease is unusual (<5%). The thick pleural reaction often seen in normal hosts with chronic pulmonary disease is not seen, and pleural effusions are rare (Fig. 3 and 4).

MAC pulmonary disease may be clinically and radiographically indistinguishable from bacterial pneumonia or pulmonary disease due to pneumocystosis, tuberculosis, aspergillosis, cryptococcosis, or coccidioidomycosis. Determination of the etiologic agent may be difficult, and more than one pathogen may be present. Despite the isolation of *M. avium* or *M. intracellulare* from cultures of sputum or bronchoalveolar lavage fluid, a careful search for other potential pathogens should be made. In a patient who has a single sputum or bronchoalveolar lavage culture positive for MAC, radiographic evidence of pulmonary infiltrative disease more likely signals the presence of a pathogen other than MAC organisms (314). Transbronchial biopsy or percutaneous needle biopsy may be necessary, but open lung biopsy should be considered in those patients in whom other measures have failed to reveal the diagnosis and in whom assessment suggests that the benefits outweigh the risks.

In the absence of data specific for patients with HIV infection, HIV-positive patients with sputum repeatedly culture positive for MAC and with persistent symptoms and/or evidence of radiographic disease, not attributable to another pathogen, may be considered candidates to receive antimycobacterial therapy. However, any HIV-positive patient with isolation of acid-fast bacilli in the sputum which

has not yet been identified, particularly those with CD4 counts of >100 per mm³ or abnormalities on chest radiographs, regardless of the results of PPD skin testing, should receive empiric therapy active against *M. tuberculosis* until the identity of the organism can be established.

Peripheral lymphadenitis due to *M. avium*-*M. intracellulare* occasionally occurs in patients with HIV infection without evidence of disseminated disease, sometimes associated with overlying cutaneous lesions (14). In patients with fever of undetermined etiology and negative mycobacterial blood cultures, gallium scanning may identify infected lymph nodes accessible for biopsy (12a, 308). Using the modified Diff-Quik methods, smears of fine-needle aspirate material may reveal histiocytes with negatively stained linear cytoplasmic inclusions, termed pseudogaulcher cells (438). On histopathologic examination, poorly defined granulomas with histiocytes filled with mycobacteria are common; well-formed granulomas with fibrosis, necrosis, epithelioid histiocytes, lymphocyte infiltration, and Langhans' giant cells are present in less than one-third of cases (287). While lymphadenitis may occur in patients who have disseminated MAC infection, isolated peripheral node involvement is more likely due to *M. tuberculosis* (342). Patients with histopathologic evidence of granulomatous inflammation or acid-fast bacilli that have not yet been identified or do not grow in culture should probably receive empiric antituberculous therapy. It is important to point out that some cases of culture-negative disease could be caused by one of the recently recognized species of mycobacteria, *Mycobacterium haemophilum* and *Mycobacterium genavense*, which grow only under certain culture conditions (62, 105, 402).

Disseminated Infection

Disseminated infection due to the MAC in patients with AIDS commonly causes a progressive illness characterized by intermittent fever, sweats, weakness, anorexia, and weight loss; it is believed to be a major cause of wasting syndrome in patients with AIDS. Most patients, by the time they present for evaluation, will complain of 2 to 6 weeks of recurrent fever and unexplained weight loss. Approximately 40% will have nausea or diarrhea, 20% will complain of vomiting, and a few may complain of intractable, crampy abdominal pain (278, 342). On examination, hepatic and splenic enlargement is common, but significant peripheral lymphadenopathy (>1.0 cm) is unusual (<9% of cases). Possible clues to the presence of disseminated disease in a patient at risk and who has unexplained fever may be either worsening anemia or a markedly elevated alkaline phosphatase, not necessarily associated with comparable elevations in hepatic transaminases (266, 275, 279).

While the mononuclear phagocyte system is the predominant site of infection, almost any organ system can be involved, including the skin (14, 359), bone and joints (59), eyes (94, 202), thyroid (202), large airways (330, 374), adrenals (202), testis (133), and brain. Isolation of *M. avium* from the cerebrospinal fluid has been reported in patients with disseminated disease (255), but the significance of this finding is not known. Although the adrenals are commonly infected, adrenal insufficiency or a blunted response to adrenocorticotropin stimulation is more likely due to concomitant infection with cytomegalovirus (174).

Although the gastrointestinal tract may be an initial site of infection (22, 120, 231, 257, 388), patients with histologic evidence of gastrointestinal involvement invariably have disseminated disease (120, 186, 388, 436). Duodenal or rectal

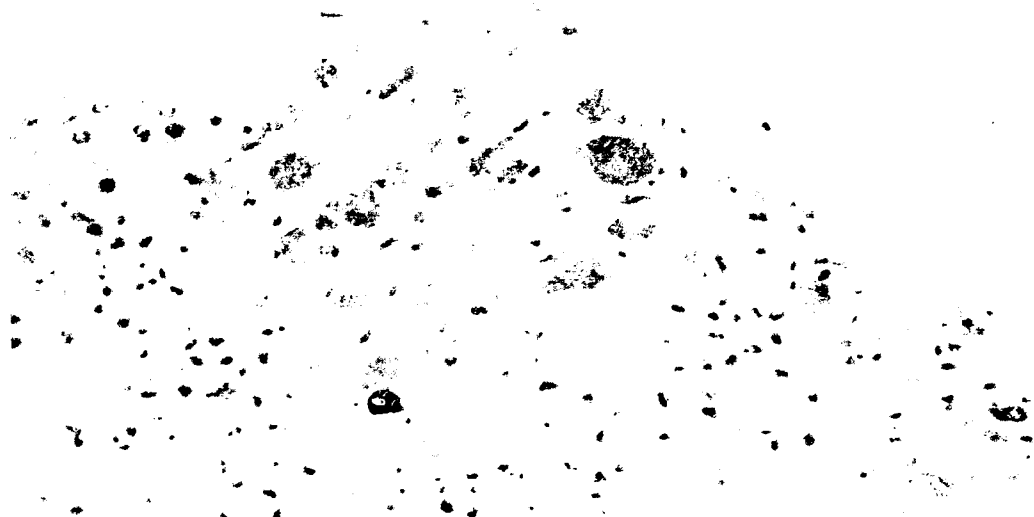


FIG. 5. Intracellular replication of MAC within fixed-tissue macrophages in a bone marrow biopsy specimen obtained from a patient with AIDS. The tissue was fixed and stained with a mixed polyclonal rabbit antimycobacterial antibody immunoperoxidase stain (478). Photomicrograph is courtesy of Stephen D. Nightingale and Elizabeth L. Wiley.

biopsies may be diagnostic. In one series, fine white mucosal nodules believed to be characteristic of MAC infection were visualized in the duodenum on endoscopy in 88% of patients with documented gastrointestinal involvement; associated malabsorption, as determined by the D-xylose test, was common (186). Colonic, sigmoid, and rectal involvement is also common, and esophageal, colonic, and rectal erosions and ulcerations due to MAC organisms may occur (120, 186, 405, 484). Upper gastrointestinal studies may reveal dilatation and thickening of the mucosal folds of the small bowel which may be clinically indistinguishable from lymphoma (463). Multiple large retroperitoneal and mesenteric lymph nodes are often demonstrated on abdominal computed tomographic scans (363). Patients may have marked histiocytic and mycobacterial infiltration on histopathologic specimens which, when visualized in the small intestine, resembles bovine paratuberculosis (Johne's disease) or Whipple's disease (185a, 287, 405, 463).

Bacteremia, with the organism found almost exclusively in circulating monocytes, occurs in 86 to 98% of patients with disseminated disease. Most patients have colony counts in the range of 10^1 to 10^3 CFU/ml of whole blood (200), but high levels of mycobacteremia, with up to 10^6 CFU/ml, are not uncommon (202, 342, 466, 485). The tissue load of infection may be 10^2 to 10^5 times greater than that in the blood. While a few patients have continuous low levels of mycobacteria in their bone marrow and bloodstream, suggesting that they have, to a limited degree, control of the infection, intracellular replication within macrophages is unchecked in many patients (Fig. 5). The large numbers of organisms within circulating monocytes and fixed-tissue macrophages, even after prolonged treatment, are evidence of an immune deficiency that

profoundly impairs the ability of the host immune system to restrict the intracellular growth of these mycobacteria.

While it is not known to what degree the level of mycobacteremia correlates with the level of infection in tissues, the assessment of changes in the numbers of circulating mycobacteria has evolved as a surrogate marker of therapeutic efficacy (88, 123, 202, 278). The use of quantitative bacteremia as an endpoint in clinical trials is based on the presumption that mycobacteremia will not decrease or disappear spontaneously. While limited data suggest that the level of bacteremia progressively increases in patients who do not receive treatment (123, 257), a preliminary study suggests that the correlation between the level of infection in tissues and that in the bloodstream may be poor (479). Recent data indicate that patients who have disseminated MAC infection may have fluctuating low levels of mycobacteremia and intermittently negative blood cultures.

We identified 9 patients, including 7 of 60 patients (12%) enrolled in a prospective randomized clinical trial of MAC bacteremia (276, 277), in whom bacteremia became undetectable in the absence of antimycobacterial therapy (275). All patients had at least two negative blood cultures by both lysis-centrifugation and BACTEC methods 1 to 57 days after their first positive blood culture. Such patients reported fewer and less severe symptoms and survived longer than patients with sustained bacteremia (59 versus 31 weeks, respectively). Although the data were not statistically significant, the mean alkaline phosphatase level was lower in patients with transient bacteremia than in patients with sustained bacteremia (0.96 versus 1.68 times the upper limit of normal, respectively), and there was no apparent difference in the duration of AIDS, leukocyte count, hematocrit,

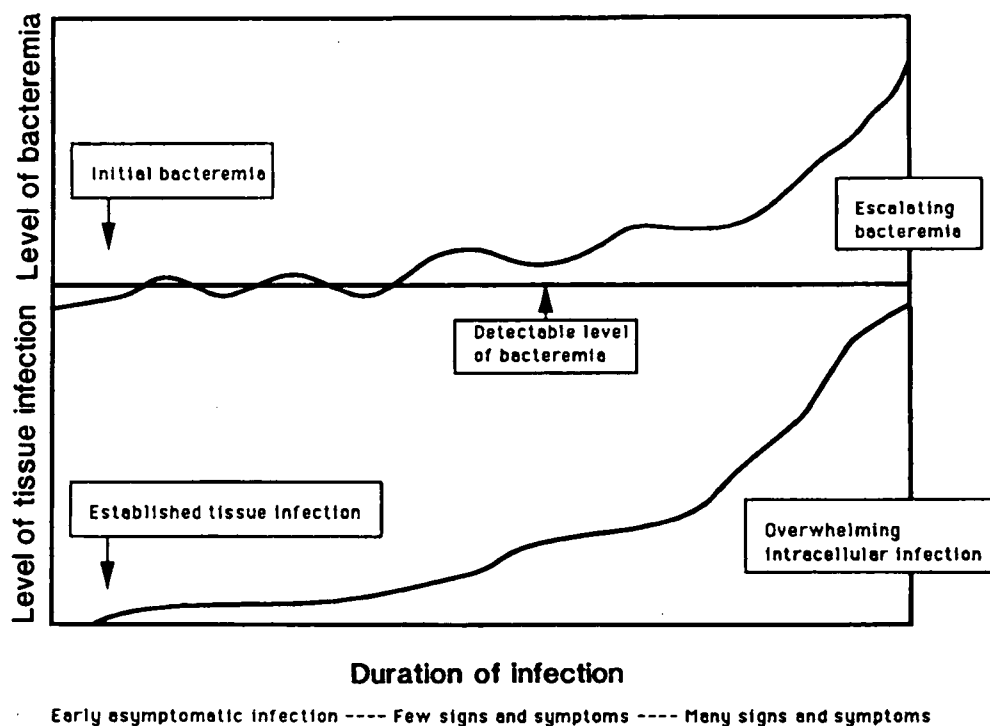


FIG. 6. Schematic representation of the course of disseminated MAC disease characterized by initial fluctuations in both mycobacteremia and clinical symptomatology but inexorably leading to a sustained and substantial mycobacteremia, most likely reflecting the underlying and often overwhelming infection of tissue.

CD4⁺ cell count, or body weight between the two groups. Whether patients with transient bacteremia were diagnosed at an earlier stage of disease or whether they had inherently better immunity to combat infection is not known, but it is likely that these patients had less total body load of organisms than patients with sustained bacteremia. Despite the administration of one or more antimycobacterial agents for varied periods of time, six of the nine patients had subsequent recurrence of bacteremia 4 to 45 weeks after their negative pretreatment cultures, four of which occurred after treatment had been discontinued. These data suggest that these patients had established tissue sites of infection in which microorganisms were suppressed for varied periods of time but were released in transient "showers," just above the level of detection of bacteremia (Fig. 6).

Of interest, data obtained during the large rifabutin MAC prophylaxis trials (74, 181) suggest that at the time the first positive blood culture was obtained only approximately 36% of patients had self-reported fever or sweats. Approximately 30% of persons who first developed MAC bacteremia had no apparent signs or symptoms, although most became symptomatic within 1 to 2 months. Many had only one or two signs or symptoms suggestive of MAC infection, including a 5% weight loss, a decrease in hemoglobin of >1.0 g/dl, or an increase in alkaline phosphatase of >300 U/liter. Less than 30% of patients had fever (or sweats) and a 5% weight loss, and only 7% of the patients had the classic constellation of fever (or sweats), weight loss, and anemia at the time bacteremia was first detected. These data suggest that it may be difficult to recognize the presence of early infection in patients receiving prophylaxis.

Delayed Confirmation of Clinical Diagnosis

Delay in identification of acid-fast bacilli visualized by smear from respiratory secretions, tissue specimens, or stool smears is particularly problematic in the management of AIDS patients. While several clues may facilitate the management of a patient with an infection due to an unidentified mycobacterium, because of the fulminant nature of tuberculosis in patients with AIDS, the availability of effective therapies, and the public health implications of an untreated infection, the possibility of *M. tuberculosis* infection requires a guarded and conservative approach (Table 1). Empiric antituberculous therapy is probably warranted for those patients who have isolated peripheral lymphadenitis or clinical and radiographic pulmonary disease and culture or smear evidence of infection due to an unidentified mycobacterium. The presence of a positive blood culture for mycobacteria in these circumstances, however, makes the diagnosis of tuberculosis somewhat less likely. Blood cultures are positive in 86 to 98% of patients with disseminated MAC, often within 14 days (reflecting the high level of bacteremia), but are rarely positive in patients with tuberculosis (202, 342, 466, 485). While sputum smears are much more likely to be positive in patients with tuberculosis than in those with MAC infection (83 versus 16%), both organisms are isolated with fairly equal frequency from lymph node, bone marrow, and stool specimens (342). The frequency of tuberculosis also depends, to some degree, on the patient's sex, ethnicity, and HIV risk group.

TABLE 1. Features which may distinguish between MAC and *M. tuberculosis* (MTB) infection in HIV-infected patients also infected with an unidentified mycobacterium*

Feature	MAC patients	MTB patients
Sex, ethnicity, HIV risk group	More likely non-Hispanic, white homosexual male	More likely African-American, Hispanic, Haitian, female, or intravenous drug user
AIDS status	>90% have preexisting AIDS	70% do not have AIDS
CD4 counts	Rarely >100/mm ³	Any level of immunity
Chest radiograph	Usually normal (75%)	Frequently abnormal (83%)
Pulmonary disease	Unusual, 4–10%	Occurs in 70%
Pulmonary findings	Unusual to have hilar lymphadenopathy, cavitary disease, or pleural effusions	25% with hilar lymphadenopathy; cavitary disease and pleural effusions may occur
Sputum	16% of smears positive; 25% of cultures positive	60% of smears positive; 70% of cultures positive
Extrapulmonary disease	Common	Common
Bacteremia	>85% of patients	2–12% of patients
Blood cultures	Positive in 1–4 wk	Positive in 4–8 wk
Stool	40–50% of smears and cultures positive	40–50% of smears and cultures positive

* Compiled, in part, from several sources (233, 245, 342, 468).

In addition to these findings, the onset of mycobacterial disease relative to the onset of AIDS may be helpful in distinguishing between tuberculosis and MAC disease. Tuberculosis occurs at any level of immunity, characteristically precedes the diagnosis of AIDS in 40 to 67% of cases, and occurs as the AIDS-defining illness or concurrent with AIDS in 26% of cases (342, 433). In contrast, only 3 to 13% of MAC infections represent the AIDS-defining illness, frequently concurrent with another opportunistic infection, and the majority of cases usually occur late in the course of AIDS (199, 234, 358). Differentiation between the two infections may be more difficult in patients with severely depressed immunity. While the presentation of tuberculosis in patients with HIV infection and relatively intact immunity is similar to that of non-HIV-infected patients, patients with severely depressed CD4⁺ cell counts often present with atypical radiographic features, a lack of cavitary disease or lymphadenopathy, and a greater incidence of extrapulmonary disease (95). Despite a high incidence of anergy, skin test reactivity should be determined and, when negative, repeated in 1 to 4 weeks. Credence should not be given to a negative skin test with PPD in a patient strongly suspected of having tuberculosis.

THERAPEUTIC AGENTS AND TREATMENT

Licensed Therapeutic Agents

The agents most commonly used in the treatment of infection due to MAC include parenterally administered amikacin and orally administered clofazimine, ciprofloxacin, ethambutol, isoniazid, rifampin, and rifabutin. In clinical trials in patients with AIDS, two recently introduced macrolides, clarithromycin and azithromycin, demonstrated remarkably impressive bacteriologic activity. The therapeutic dosages and adverse side effects of these agents are addressed in Table 2.

Amikacin. Amikacin, a semisynthetic aminoglycoside antibiotic derived from kanamycin, remains one of the most bactericidal agents against MAC both in vitro and in the beige mouse model (49, 161, 165, 246). Analysis of in vitro susceptibilities of clinical isolates indicates that 9% of MAC isolates are susceptible to 12 µg of amikacin per ml, but 75% are susceptible to 30 µg/ml (317). In the beige mouse model, administration of amikacin resulted in 1.2- and 2.6-log₁₀

reductions in splenic and pulmonary CFU per milliliter, respectively, by 2 weeks (165). The addition of clofazimine to amikacin also was effective, resulting in a more than 4-log₁₀ reduction in colony counts in spleen tissue, but the addition of rifabutin did not appear to enhance the microbiologic activity of the two-drug combination. Unfortunately, amikacin is not absorbed from the gastrointestinal tract and requires parenteral administration, usually in a single or divided dose of 7.5 to 15 mg/kg of body weight per day. The most significant adverse effects are ototoxicity and nephrotoxicity, and ototoxicity may develop in up to 13% of patients with AIDS (23, 278). Some of these dose-related toxicities may be ameliorated by lower dosages and a shorter total course of administration.

Azithromycin and clarithromycin. The macrolide antibiotics azithromycin and clarithromycin are similar in structure to erythromycin (384) and concentrate to high levels in tissues and macrophages with little toxicity. Clarithromycin differs by a single substitution of a methyl group for a 6-hydroxyl group in the 14-membered ring of erythromycin. This substitution increases its bioavailability, decreases metabolism of the drug, and enhances the microbiologic activity. Clarithromycin is resistant to the intramolecular cyclization at acidic pH; thus it lacks much of the gastrointestinal side effects commonly observed with erythromycin. Clarithromycin is metabolized in the liver to 14-OH-clarithromycin, which is biologically active against many microorganisms and partially active against MAC. Clarithromycin is rapidly absorbed, with a bioavailability of approximately 55%; peak blood levels of 2 to 3 µg/ml are seen 2 h after a 500-mg dose. The serum half-life after a 500-mg dose is 5 to 6 h, while that of 14-OH-clarithromycin is 7 h.

Clarithromycin inhibited more than 90% of MAC strains at concentrations that are therapeutically achievable in humans (153, 350). The MICs, as determined by broth microdilution at neutral to slightly alkaline pH, were 0.25 to 0.5 µg/ml for most strains (212, 378). Administration of clarithromycin to beige mice resulted in a significant reduction in the number of mycobacteria in tissue and blood (153). The intracellular activity of clarithromycin in J774 cells and in alveolar macrophages from HIV-infected patients was enhanced by the addition of ethambutol and rifampin, but the addition of ciprofloxacin did not improve intracellular killing (493). The activity of this three-drug regimen (clarithromycin, etham-

TABLE 2. Antimycobacterial agents commonly used in the treatment of MAC infection^a

Agent	Adult dose	Pediatric dose ^b	Adverse effects
Common agents			
Amikacin	7.5–15 mg/kg QD ^c	10–15 mg/kg QD i.v. ^c	Ototoxicity, nephrotoxicity
Azithromycin	500 mg/day ^d	10–20 mg/kg/day ^e	Diarrhea, nausea, vomiting, abdominal pain, headache, dizziness, elevations in hepatic enzymes
Ciprofloxacin	750 mg BID	20–30 mg/kg/day, divided, Q12h ^f	Anorexia, nausea, vomiting, abdominal pain, diarrhea, rash, (rarely) mental status changes
Clarithromycin	500–1,000 mg BID ^g	30 mg/kg/day, divided, Q12h ^e	Diarrhea, nausea, vomiting, elevations in hepatic enzymes, abdominal pain, renal insufficiency
Clofazimine	100–200 mg/day ^h	1–2 mg/kg/day ⁱ	Skin discoloration, ichthyosis, anorexia, nausea, vomiting, abdominal pain, peripheral neuropathy, (rarely) ocular changes
Ethambutol	15 mg/kg/day ^j	15–25 mg/kg/day ^k	Anorexia, nausea, vomiting, diarrhea, rash, mental status changes, retrobulbar neuritis
Rifampin	10 mg/kg/day ^j	10–20 mg/kg/day ^m	Anorexia, nausea, vomiting, diarrhea, rash, elevations in hepatic enzymes
Rifabutin	300 mg/day ⁿ	No recommendation ⁿ	Anorexia, nausea, vomiting, diarrhea, rash, myalgias, arthralgias, headache
Alternative agents			
Cycloserine	10–20 mg/kg/day	10–20 mg/kg/day	Somnolence, headache, tremor, vertigo, mental status changes, visual changes, seizures
Ethionamide	15–20 mg/kg/day	15–20 mg/kg/day	Anorexia, nausea, vomiting, diarrhea, rash, elevations in hepatic enzymes, mental status changes, seizures, neuropathy

^a QD, once a day; i.v., intravenously; BID, twice a day; Q12h, every 12 h.^b Pediatric dosages are not to exceed maximum adult dosages.^c Or equivalent dose twice a day.^d Dosages of 600 to 1,200 mg/day in a lactose-free formulation are being studied in a dose-ranging fashion.^e Pediatric suspension formulations are available for both azithromycin and clarithromycin; azithromycin maximum dose, 40 mg/kg.^f Ciprofloxacin is not recommended for children under 18 years of age; however, ciprofloxacin and other quinolones have been, when necessary, administered to children with few serious adverse effects (418).^g Dosages of up to 2,000 mg orally twice a day have been used in the treatment of MAC infection but are associated with higher rates of toxicity and should probably be reserved for those patients failing to respond to lower dosages.^h Dosages of up to 300 mg/day have been used in the treatment of other diseases and can be administered to patients with AIDS and MAC bacteremia but are associated with a higher incidence of skin discoloration and gastrointestinal toxicity.ⁱ Dosages of up to 50 mg/day have been given to children less than 4 years of age (approximately 4 mg/kg/day) (297), but a pediatric formulation is not available.^j Dosages of up to 25 mg/kg/day can be given for short durations (<1 month); dose should not exceed 600 to 1,000 mg/day.^k Caution is recommended in children under 12 years of age; monthly vision checks should be performed on pediatric patients receiving ethambutol or adults receiving >15 mg/kg/day for more than 1 month. The maximum dose is 2.5 g.^l Dosages of 150 to 600 mg/day have been used in both AIDS and non-AIDS patients with MAC infection, but the relative efficacies of these various dosages are not known.^m The maximum rifampin dose is 600 mg/day.ⁿ Dosages of 75 mg/day have been given to children less than 4 years of age (approximately 6 mg/kg/day) (297), but a pediatric formulation is not available. Higher dosages up to 150 mg/day (6 to 25 mg/kg/day) have been used (301).

butol, and rifampin) has been confirmed in other in vitro analyses (439). In one small trial, the combination of clofazimine and clarithromycin resulted in clearance of bacteremia in all 11 patients after only 1 week of therapy (409). In another recent clinical trial in patients with AIDS, 75% of patients developed negative blood cultures after 1 to 2 months of single-agent therapy (123). After administration for more than 10 to 22 weeks, however, drug resistance and rebound bacteremia were seen in some patients. Clarithromycin administered in a dose of 500 to 1,000 mg twice daily is moderately well tolerated. While adverse effects are reported in approximately 4% of patients (384), gastrointestinal side effects are apparently more common in patients with AIDS.

Azithromycin, an azalide, has an additional nitrogen in the erythromycin ring structure, resulting in a 15-member derivative. The drug is well absorbed and has a terminal half-life of 68 h. Peak serum concentrations after single or multiple 500-mg doses range from 0.40 to 0.62 µg/ml, but the drug concentrates within macrophages and in tissues to remarkably high concentrations, as high as 2,000 µg/g (49, 172, 173). The in vitro activity of azithromycin appears modest, with a broad range of MICs from 32- to 64-fold above the peak serum concentration in humans. Nevertheless, in beige mice, azithromycin had significant activity against the MAC, resulting in a 95% survival and a significant decrease in the number of mycobacteria in blood, liver, and spleen (247). The therapeutic efficacy most likely reflects the high tissue

concentrations of the drug. A recent uncontrolled pilot trial showed that, when patients with AIDS and MAC bacteremia received 20 to 30 days of azithromycin alone (500 mg/day), colony counts in the bloodstream were reduced from 2×10^3 to 1.4×10^2 CFU/ml; fever resolved in 71% of patients who were febrile at entry to the study and sweats resolved in 83% (505). Long-term administration of azithromycin resulted in recrudescence of bacteremia and high-level resistance. Thus, the administration of azithromycin or clarithromycin as a single agent is not recommended. Adverse reactions reportedly occur in less than 12% of patients and include diarrhea (3.6%), nausea (2.6%), and abdominal pain (2.5%), as well as headaches and dizziness (1.3%) (384), but gastrointestinal complaints appear more common in patients with AIDS. Deafness has been reported in a small number of patients during long-term administration but is apparently reversible upon discontinuation of the drug.

Clofazimine. Clofazimine is an iminophenazine red dye with a long elimination half-life; the elimination half-life from fatty tissues and the mononuclear phagocyte system is approximately 70 days (167); the drug is highly concentrated in tissues. Clofazimine has been a mainstay of leprosy therapy. The drug is very active (on a weight basis) in vitro against most MAC isolates; the MIC for 90% of *M. avium* isolates (MIC₉₀) is approximately 3 µg/ml and that for *M. intracellulare* isolates is approximately 2 µg/ml (306, 452). In the beige mouse model, clofazimine is extremely effective in combination with amikacin (165); however, in patients with AIDS and MAC bacteremia, clofazimine, administered as a single agent (200 mg/day), resulted in a median reduction of only 0.20 log₁₀ CFU/ml in the bloodstream (18% reduction in baseline colony counts) by 4 weeks (277). These data suggest that effective clofazimine therapy may require longer periods of treatment to saturate the tissues; e.g., in patients with leprosy, it may take up to 4 months to achieve a 99% reduction in tissue colony counts. Clofazimine is administered in a 100- to 200-mg daily dose (up to 300-mg daily doses have been used in the treatment of other diseases), and the drug is fairly well tolerated, with skin discoloration as the most frequent side effect. Dose-limiting intolerance occurs in approximately 2.5% of patients with AIDS (278), but the skin discoloration is more common at dosages of ≥ 200 mg/day. Clofazimine crystals may be deposited in organs and cause intractable abdominal pain, a symptom often confused with MAC infection (167, 239, 416). While clofazimine crystals are found in the tears of 32% of leprosy patients receiving long-term therapy (273), ocular effects, such as corneal-conjunctival pigmentation and a "bull's-eye" retinopathy, are unusual (112, 273, 429). Clofazimine treatment also has been associated with peripheral neuropathy.

Ciprofloxacin. Ciprofloxacin and the other fluoroquinolones (e.g., ofloxacin, levofloxacin, lomefloxacin, sparfloxacin, and WIN 57273) have varied in vitro activities against the MAC (211, 246, 303, 503). MIC₅₀ and MIC₉₀ values of ciprofloxacin against *M. avium*, as determined by broth dilution susceptibility tests on large numbers of isolates, are 4 and 16 µg/ml, and those against *M. intracellulare* are 1 and 8 µg/ml, respectively (303). Only 30% of MAC isolates were susceptible to 2 mg of ciprofloxacin per ml. Values for ofloxacin were similar. Quinolone resistance is common and related, in part, to the mechanism of action (inhibition of DNA synthesis). Ciprofloxacin is administered in a dosage of 750 mg twice daily and is moderately well tolerated. Dose-limiting side effects, primarily gastrointestinal, occur in up to 15% of patients with AIDS (278); rash, headaches, and mental status changes may occur. Ciprofloxacin should not

be administered in conjunction with magnesium- or aluminum-containing antacids or sucralfate. Absorption of ciprofloxacin is effectively negligible after ingestion of 2.0 g of sucralfate. Ciprofloxacin inhibits the metabolism of methylxanthines, including theophylline, and there is an intriguing, but preliminary, observation that quinolones may induce IL-2 production and decrease IL-2 receptor expression, resulting in prolonged IL-2 kinetics (398).

Ethambutol. Ethambutol is a dextro-2,2'-(ethylenedimino)-di-1-butanol-dihydrochloride with a high degree of antituberculous activity. A recent analysis demonstrated that only 7% of MAC isolates tested were susceptible to 5 µg of ethambutol per ml, but 76% of isolates were susceptible to 10 µg/ml (317). Although these susceptibility tests suggest that ethambutol should not be a very effective agent, ethambutol may potentiate the action of combined therapies as a result of the effect of this drug on cell wall permeability (220, 268, 490). Nevertheless, recent animal and human studies indicate that ethambutol alone has significant anti-MAC activity. In one study, ethambutol reduced colony counts in beige mice in a dose-response fashion; at 6 mg/kg per day, mycobacteria were reduced by approximately 1.0 log₁₀ by 9 weeks (183). Furthermore, ethambutol (15 mg/kg/day), administered as a single agent, significantly reduced mycobacteremia by a median 0.6 log₁₀ CFU/ml after 4 weeks in patients with AIDS and MAC bacteremia (276). Ethambutol is commonly administered in a dose of 15 mg/kg of body weight per day, usually as a single dose, and is fairly well tolerated in the treatment of MAC disease. Dose-limiting side effects, primarily gastrointestinal, may occur in 5 to 10% of patients with AIDS, but severe toxicity is unusual (278, 433). Higher doses (25 mg/kg of body weight) have been used, but may be associated with retrobulbar neuritis and loss of color vision. These side effects are uncommon, typically associated with long-term use (longer than 1 month), and in most cases, reversible if the drug is promptly discontinued.

Rifampin. Rifampin is a 3,4-(methylpiperazinyl-iminomethylidene)-rifamycin SV and is in the rifamycin group of antimicrobial agents. Rifampin is a broad-spectrum antimicrobial agent with antituberculosis activity but only modest anti-MAC activity. The concentration of rifampin in tissues is significantly higher than that in serum, and rifampin is concentrated fourfold above serum levels in mouse macrophages and fivefold above serum levels in human monocytes (410). The in vitro activity of rifampin is heterogeneous, with significant differences between the various MAC serovars (452), but most MAC isolates are resistant in vitro, with rifampin MICs of > 100 µg/ml (317). The activity of rifampin in combination with other agents is not known, but in vitro data indicate that some combinations are synergistic (490). In patients with AIDS and MAC bacteremia, logarithmic colony counts in the bloodstream actually increased 17% after 4 weeks of rifampin alone (276). The commonly administered dose for the treatment of MAC disease is 600 mg/day as a single or divided dose for patients weighing 50 kg or more (typically 10 mg/kg of body weight). It is well absorbed when taken without food (patients should be advised to take rifampin at least 2 h before or after any meal), and a peak serum concentration of approximately 10 mg/ml occurs within 2 h of oral administration. Rifampin is moderately well tolerated, but approximately 12% of patients with AIDS will have adverse effects, usually gastrointestinal, necessitating discontinuation of the drug (278, 433).

Rifabutin. Rifabutin, an ansamycin derived from rifamycin-S, has significantly better in vitro activity against the

Adams, Susan

From: White, Sally
Sent: Friday, March 28, 2008 12:47 PM
To: Adams, Susan
Subject: FW: Letter to Under Secretary Raymond
Attachments: Ubrief OVD08.643 van DGH aan Raymond.pdf; Ubrief 08.0490.IH TB testing.doc.pdf; Presentatie serodiagnosis Mycobacterium avium 02.11.06.pdf

Please print off and fill out sheet for logging.

From: Thissen, Frits [mailto:frits.thissen@minbuza.nl]
Sent: Friday, March 28, 2008 12:44 PM
To: Caughey, Savonne -USDA
Cc: White, Sally; Smith, David; Goodwin, Nancy; Feitel, Caroline; Lammers, Sunny; i.hardenberg@minlnv.nl; m.j.b.m.weijs@minlnv.nl
Subject: Letter to Under Secretary Raymond

Dear Savonne,

I would like to forward to you this letter (with annexes) from Director-General Hans Hoogeveen of the Netherlands Ministry of Agriculture, Nature and Food Quality to Under Secretary Dr Richard Raymond with a further clarification of the question on chain inspection of hogs Dr Raymond asked during the conversation with Mr Oostra on August 6th, 2007. For your clarification, Mr Hans Hoogeveen is the successor of Mr Oostra, who has retired.

Mr Hoogeveen invites Under Secretary Raymond to come to the Netherlands to see for himself how the system works. We would be very happy to combine this particular subject of his possible visit with other subjects in which he would be interested. For instance, I understood Dr Raymond was also very much interested in methods for humane slaughtering of animals.

This letter and its annexes are an electronic copy. The hard copy is now on its way to the US and will be sent to you as soon as possible after arrival.

Best wishes,

Frits Thissen
Counselor for Agriculture,
Nature and Food Quality
Embassy of the Kingdom of the Netherlands

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U.S. Department of Agriculture
Food Safety and Inspection Service
Under Secretary for Food Safety
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1400 Independence Avenue, S.W.
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UNITED STATES OF AMERICA



landbouw, natuur en
voedselkwaliteit

your letter of	your reference	our reference	date
		VD 08.643/IH	March 27, 2008
re:		extension no.	enclosures
Supply chain inspection of pork		+31(0)70-3784385	2

Dear Dr. Raymond,

On 6 August 2007 you discussed pork supply chain inspection with my predecessor Ate Oostra. The Dutch veterinary authorities had submitted the dossier to USDA/FSIS in October 2006 to assess whether inspection methods were equivalent. The issue of equivalence had been discussed in November 2006 and discussions were concluded successfully. Early in 2007, an FSIS inspector visited The Netherlands to assess our supply chain inspection system. This visit too was a success.

When Mr. Oostra visited you on 6 August, 2007, you asked him about tuberculation and our CVO sent you a written reply on 5 March, 2008 (enclosed). During discussions with Ms. Sally White and Dr. David Smith, Mr. Weijters, deputy CVO, gave further details on 13 March, 2008. Following this, I am now sending you additional information. I hope you have received sufficient information now and expect this will conclude matters, so that we can come to an equivalence determination for supply chain inspection in the very short term. I would also like to invite you to The Netherlands to come and see our inspection procedures in practice.

Before answering your question in detail, allow me to sketch the context within which my answer is to be understood. In classic meat inspection lymph node incisions are made to detect macroscopic irregularities. In many cases these concern *Arcanobacterium pyogenes* or *Rhodococcus equi* which are not so relevant for public health. Lymph node incision is not the best method for the detection of *M. avium*, as cases may be overlooked (bacteriological positive results but no visible signs). Lymph node incision is not a very specific or a very sensitive detection method (see publications sent to you earlier).

Bacteriological tests of lymph nodes for *M. avium* are both specific and sensitive, but these tests take 3 to 6 months and are therefore not very practical for slaughterhouse use. For the same reason such tests are not suitable for the classification and monitoring of farms.

Tuberculation of pigs by means of an intradermal test is a possibility. The tuberculin must be administered directly behind the pig's ear. A positive reaction produces redness

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and swelling of the skin. Research (see appendix) shows this is a very sensitive diagnostic test. The drawback however is that pigs need to be fixed twice, which may produce a great deal of stress in the animals. Distinguishing tested from non-tested animals may also give rise to problems.

How then do we guarantee the absence of *M. avium* contamination in pork? In my earlier letter of 5 March I said that *M. avium* incidence rates in The Netherlands are very low. However, we do want to rule out *M. avium* contaminations. To this end The Netherlands has decided to use a preventive approach, which involves classifying farms and introducing specific preventive measures that can be taken into account at meat inspections in slaughterhouses. In other words, a preventive approach is used rather than identifying individual pigs.

Farms are classified as follows. From every three consecutive batches presented for slaughter (in The Netherlands, the average batch consists of 100 pigs) 6 blood samples per batch are taken for serological tests. If all samples test negative the farm is given a neutral status. In this case supply chain inspection will be possible. Monitoring the farm is continued (which means two blood samples are taken from every batch). After 36 negative results in a row the farm is given the status low while monitoring continues. If a positive sample is found in the first 18 samples, chain inspection is not allowed and the farm will be visited and subjected to a risk analysis. Hygiene must be improved. When later samples test positive the farm is visited again to be subjected to specific inspections.

Blood tests are a sensitive detection method. Our research results show that pigs infected at an early age (at 2.5 weeks, for instance) or at different subsequent intervals (at 2.5, 4.5 and 18 weeks) test 100% positive. The same is true for pork pigs that are infected at 4.5 weeks of age (with 5 out of 8 pigs testing positive). Pigs infected later in life (18 weeks) show 2 out of 8 with positive results.

In view of the fact that on infected farms pigs are generally infected at an early age and a minimum of 18 samples are taken for the initial categorisation of farms after which they continue to be monitored, it can fairly be concluded that the use of serological tests is a very suitable detection method.

It should also be noted that serological tests show cross-reactivity with other forms of tuberculosis like *M. bovis* and *M. tuberculosis*. Not much has yet been published about this test, which has to do with intellectual property, but details will appear in scientific magazines.

This is, therefore, a preventive approach with farms classified on the basis of measurable data. Farms that cannot be classified or whose test results are worsening are not allowed to be included in supply chain inspection until they have improved their performance. In short, supply chain inspection is only feasible for farms with a good track record. This kind of inspection is a more effective approach to the detection of *M. avium* than the classic meat inspection procedures. In this case serological testing is more effective than tuberculation.

Date

March 27, 2008

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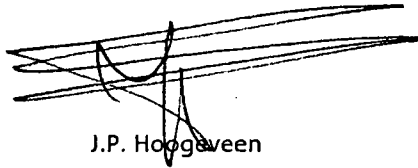
Following page

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———— I would suggest that you contact the Agricultural Counsellor of the Kingdom of The Netherlands in Washington so that a date for your visit can be arranged.

Yours sincerely,

DIRECTOR-GENERAL
FOR THE MINISTER OF AGRICULTURE, NATURE AND
FOOD QUALITY,

A handwritten signature in black ink, consisting of several overlapping loops and strokes, positioned above the printed name.

J.P. Hoogaveen

U.S. Department of Agriculture
Ms. Savonne Caughey, Confidential Assistant
Office of the Under Secretary for Food Safety
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your letter of	your reference	our reference	date
		VD 08.490/IH	March 5, 2008
re:		extension no.	enclosures
PM inspection procedures market hogs; tuberculosis testing		+31(0)70-3785435	2

Dear Ms. Caughey,

During a meeting between the Under Secretary for Food Safety, Dr. Richard A. Raymond, and Director General Ate Oostra of The Netherlands Ministry of Agriculture, Nature and Food Quality, which took place in August of last year, the access to the U.S. market of Dutch pork processed by the VION slaughterhouses in The Netherlands was discussed. Pigs slaughtered in these slaughterhouses are monitored for *Mycobacterium avium* subsp. *avium* (MAA) infections via a new chain inspection system in which blood tests were used for the detection of MAA infections. During the meeting between the Under Secretary and the Director General a technical question arose about the reliability of blood tests for the detection of tuberculosis infections.

In order to answer this question I will first provide some background information about tuberculosis infections in humans and animals. Subsequently I will discuss the post mortem procedures for the detection of MAA infections in pigs and the new chain inspection system.

Human Tuberculosis

Human Tuberculosis (TB) is an acute or chronic infection, mainly caused by the tubercle bacillus *Mycobacterium tuberculosis*. Humans are the primary reservoir, diseased cattle rarely act as reservoirs. TB in man is diagnosed by a consideration of the clinical presentation, tuberculin skin test using the Mantoux procedure, radiographic examination, sometimes including CT scans and culture for the *M. tuberculosis*.

Bovine Tuberculosis

Bovine Tuberculosis is an infectious disease sustained by *Mycobacterium bovis*, which poses major problems of animal health and a substantial zoonotic risk. Bovine Tuberculosis has therefore been targeted by extensive control and eradication programs for a long time. The Netherlands is officially free of Bovine Tuberculosis. In 1951 The Netherlands started an extermination program, which included tuberculation of individual cows. Animals found positive for the presence of bovine tuberculosis were disposed of. This approach led to a rapid decline of the prevalence of Bovine Tuberculosis and as a result of this the Bovine Tuberculosis free status was granted to The Netherlands. For monitoring Bovine Tuberculosis since 1993 the compulsory tuberculation test has been substituted by a monitoring system in slaughter plants. During ante mortem and post mortem examination of cows during the meat inspection attention is being paid to

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the results of 1996 (Komijn et al 2007). However, in contrast to the results of the study in 1996, in 2004 targeting herds at risk, no MAA bacteria could be detected in these lymph nodes after bacteriological examination. Apparently, the prevalence of MAA infections in The Netherlands in 2004 was considerably less when compared with the prevalence in 1996. This significant decrease in prevalence can be explained by additional management measures within the IKB system for production chain control of the Dutch Product Boards for Livestock, Meat and Eggs, which came into effect in 2001, tightening biosecurity on the farm even further.

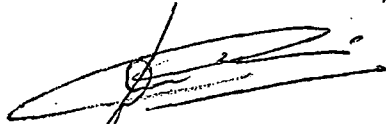
Conclusion

The prevalence of MAA infections of pigs in The Netherlands is very low. Results of scientific research showed that incision of the mandibular lymph nodes during post mortem inspection for diagnosis of MAA infections has a low sensitivity and specificity. The blood testing for anti MAA antibodies offers an attractive alternative. This procedure combined with additional measures on the farm results in safer pork.

I trust that I have answered Dr. Raymond's question adequately and that this will complete the information necessary to make an equivalence determination of the chain inspection system for market hogs.

Sincerely yours,

THE CHIEF VETERINARY OFFICER,



Dr. P.W. de Leeuw

Enclosures:

1. Ruud E. Komijn, Petra E.W. de Haas, Margriet M.E. Schneider, Tony Eger, Jan H.M. Nieuwenhuijs, Remco J. van den Hoek, Douwe Bakker, Fred G. van Zijderveld, Dick van Soolingen.
Prevalence of *Mycobacterium avium* in Slaughter Pigs in The Netherlands and Comparison of IS1245 Restriction Fragment Length Polymorphism Patterns of Porcine and Human Isolates.
Journal of Clinical Microbiology, May 1999; Vol. 37, No. 5: P. 1254-1259
2. Ruud E. Komijn, Henk J. Wisselink, Vincent M.C. Rijsman, Norbert Stockhofe-Zurwieden, Douwe Bakker, Fred G. van Zijderveld, Tony Eger, Jaap A. Wagenaar, Frans F. Putirulan, Bert A.P. Urlings.
Granulomatous lesions in lymph nodes of slaughter pigs bacteriologically negative for *Mycobacterium avium* subsp. *avium* and positive for *Rhodococcus equi*.
Veterinary Microbiology 120 (2007); p. 352-357; Elsevier publishing 2006 Nov 28.

Prevalence of *Mycobacterium avium* in Slaughter Pigs in The Netherlands and Comparison of IS1245 Restriction Fragment Length Polymorphism Patterns of Porcine and Human Isolates

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A significant increase in the incidence of caseous lesions in the lymph nodes of slaughter pigs prompted a large-scale investigation in five slaughterhouses in The Netherlands. In total, 158,763 pigs from 2,899 groups underwent gross examination. At least one pig with caseous lesions in the submaxillary and/or mesenteric lymph nodes was observed in each of 154 of the 2,899 groups examined (5%). In total, 856 pigs (0.5%) were affected. As many as five pigs in each of 141 of the 154 positive groups (91.5%) had lymph node lesions. Greater numbers of pigs with affected lymph nodes were found in 13 groups (8.5%). Four pigs had lesions in the kidneys, liver, or spleen. Acid-fast bacteria were detected by microscopic examination of 121 of 292 Ziehl-Neelsen-stained smears of caseous lesions (41%). In a follow-up study, *Mycobacterium avium* complex (MAC) bacteria were isolated from 219 of 402 affected lymph nodes (54.2%). Ninety-one of the isolated strains were analyzed by restriction fragment length polymorphism (RFLP) typing with insertion sequence IS1245 as a probe. All but 1 of these 91 strains contained IS1245 DNA, indicating that pigs in The Netherlands carried almost exclusively *M. avium* bacteria and no other bacteria of MAC. Only one pig isolate exhibited the bird-type RFLP pattern. MAC isolates from 191 human patients in The Netherlands in 1996 were also typed by RFLP analysis. Computer-assisted analysis showed that the RFLP patterns of 61% of the human isolates and 59% of the porcine isolates were at least 75% similar to the RFLP patterns of the other group of strains. This indicates that pigs may be an important vehicle for *M. avium* infections in humans or that pigs and humans share common sources of infection.

Severe *Mycobacterium avium* complex (MAC) infections in humans, especially in human immunodeficiency virus-positive and other immunodeficient individuals, have been reported (8, 13). The origin of MAC infections in humans is still a matter of speculation. Previous studies have shown that the MAC bacteria are present in birds, soil, compost, water, animals, pigs, and even cigarettes (2, 3, 5, 6, 8, 11, 19). As suggested by the designation *M. avium*, infections were once thought to be derived from birds. Later, serotyping showed that only some of the MAC bacteria isolated from humans represent serotypes 1, 2, and 3, which are the most common serotypes among bird isolates (1, 7).

Recently, new molecular tools like restriction fragment length polymorphism (RFLP) typing with the insertion sequence IS1245 (IS1245 RFLP analysis) have become available (2, 6, 12). Genotyping of *M. avium* strains from various sources in Switzerland indicated that both pigs and humans were infected with strains carrying a large number of IS1245 elements (2). IS901 and IS1245 RFLP typing showed that 47 *M. avium* iso-

lates from birds in The Netherlands invariably belonged to a well-conserved separate taxon within MAC. Bird-type RFLP patterns were observed only as an exception among isolates from other hosts (2, 12). These facts rule birds out as significant sources of *M. avium* infections in humans in The Netherlands (12).

The current study was undertaken to determine the prevalence of MAC in the lymph nodes of pigs. Furthermore, in order to examine the significance of *M. avium* infections in slaughter pigs with regard to public health aspects, the IS1245 RFLP patterns of porcine isolates were compared with those of the *M. avium* strains isolated from humans in The Netherlands in 1996.

MATERIALS AND METHODS

Gross examination of pigs. In an initial study, special attention was given to the gross examination of the submaxillary and mesenteric lymph nodes of pigs in five slaughterhouses during a 2-week period at the end of 1996. The submaxillary lymph nodes were incised, and the mesenteric lymph nodes were palpated. The following information was collected: the farm identification numbers of the pigs slaughtered, the number of pigs slaughtered per farm, the number of pigs with caseous lesions in the submaxillary or mesenteric lymph nodes, and the number of pigs whose spleen, liver, or kidneys were also affected. Whenever possible, up to three specimens per group were studied by microscopic examination of Ziehl-Neelsen-stained smears.

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Sampling, culture, and identification of mycobacteria from pigs. In a follow-up study performed in early 1997, the presence of mycobacteria in caseous lesions was determined by culture. For this purpose, macroscopically positive submaxillary and mesenteric lymph nodes were collected at six slaughterhouses and were frozen at -20°C . In the first part of the follow-up study, samples were taken from each of three to four pigs in 44 groups in which several animals were affected. In the second part of the follow-up study, 144 groups with only one or two affected animals each were sampled. After arrival at the laboratory, the samples were thawed, and direct smears were produced. Ziehl-Neelsen-stained material was then examined microscopically. In addition, cultures were grown from all lesions by the following procedure: all lesions were ground, decontaminated by oxalic acid-sodium hydroxide treatment, and inoculated onto Löwenstein-Jensen medium, Stoenbrink egg medium, and Middlebrook 7H10 agar, followed by incubation for 4 weeks at 37°C .

Subcultures were made from colonies suspected of representing MAC bacteria. The MAC bacteria of the subcultures were identified by the following characteristics: growth after 2 to 4 weeks of incubation, negative or doubtful acid phosphatase reaction, negative nitrate reductase reaction, weakly positive catalase reaction ($<45\text{ mm}$) at room temperature, variable catalase reaction at 68°C , negative β -D-galactosidase reaction, positive nicotinamidase and pyrazinamidase activities, and negative urease activity by the amidase test of Bönicke. All but 1 of the 91 isolated MAC strains contained IS1245, which is characteristic of *M. avium* (2, 6, 12). To ensure this identification, 30 IS1245-containing MAC isolates were subjected to the Accuprobe test specific for *M. avium*, and they were found to be positive.

MAC bacteria from humans. In 1996, 191 MAC isolates originating from 35 peripheral laboratories were received at the National Institute of Public Health and the Environment (RIVM) in The Netherlands. This number covers at least 80% of all human MAC strains isolated in The Netherlands in 1996.

Serotyping. MAC isolates were tested by slide agglutination, as described by Engel et al. (4), to determine their serotypes. The panel of test sera represented serotypes 1 to 4 and 8.

DNA fingerprinting. *M. avium* isolates were DNA fingerprinted by RFLP typing; IS1245 was used as a probe, as described previously (12, 16). Internal and external molecular size markers and high-resolution gels (24 cm) were applied to facilitate computer-assisted analysis.

Computer-assisted RFLP analysis. Analysis of the IS1245 fingerprints was done with computer assistance, using GelCompar software, version 4.1 (Applied Maths, Kortrijk, Belgium), as described in a proposal for standardization of IS1245 RFLP typing (16). The band positions of the IS1245-containing restriction fragments were compared with those of a set of internal molecular weight markers by superimposing the autoradiograms of the IS1245 DNA fingerprints and the autoradiograms of the internal markers. The patterns were compared by the unweighted pair group method with the arithmetic averages clustering method and with the Dice coefficient according to the instructions of the manufacturer of GelCompar.

RESULTS

Examination of affected lymph nodes by microscopy and culture. A total of 158,763 pigs in 2,899 groups were inspected during the initial study at the end of 1996. Each of 154 groups (5%) included at least one pig with caseous lesions in the submaxillary and/or the mesenteric lymph nodes. Altogether, 856 pigs (0.5%) were affected. For practical reasons, only 292 lesion smears were microscopically examined. Acid-fast bacteria were seen in 121 of them. Five or fewer pigs in each of 141 of the affected groups had caseous lesions. Greater numbers of affected pigs were detected in the remaining 13 groups. The average percentage of affected pigs in these 13 groups amounted to 31, and the range was between 8 and 78%. Only four pigs also had macroscopic deviations in the kidney, liver, or spleen.

In order to examine whether *M. avium* was the etiologic agent of these caseous lesions, a follow-up study was planned for early 1997. In the first part of the follow-up study, 239 lymph nodes with caseous lesions from pigs from 44 farms were examined (Table 1). These farms were not the same ones as those in the initial study. MAC bacteria were isolated from 166 of the lymph nodes (69%) from 39 of the groups examined (89%). Seventy-eight percent of the affected mesenteric lymph nodes and 52% of the submaxillary lymph nodes yielded growth of MAC bacteria. In the second part of the follow-up study, lymph nodes from 163 pigs from 144 farms were examined (Table 1). MAC bacteria were isolated from 53 of the pigs

TABLE 1. Correlation of culture results and microscopic examination of affected lymph nodes in the first and second parts of the follow-up study^a

Study part and lymph node	No. of samples	No. (%) of samples with positive cultures			No. (%) of samples with negative cultures		
		Total	ZN pos	ZN neg	Total	ZN pos	ZN neg
First part							
Mesenteric	159	124	100 (81)	24	35	27 (77)	8
Submaxillary	80	42	32 (76)	10	38	30 (79)	8
Total	239	166	132		73	57	
Second part							
Mesenteric	61	30	26 (87)	4	31	24 (77)	7
Submaxillary	102	23	20 (87)	3	79	67 (85)	12
Total	163	53	46		110	91	

^a ZN, microscopic examination of Ziehl-Neelsen-stained material; pos, positive; neg, negative.

(33%), which originated from 46 of all groups examined (32%). Forty-nine percent of the affected mesenteric lymph nodes and 23% of the submaxillary lymph nodes were found to be positive for MAC by culture. From the mesenteric and submaxillary lymph nodes with a positive culture for MAC bacteria, a total of 82 and 80% of the samples, respectively, were also found to be positive by microscopic examination (Table 1). However, also a total of 79 and 83% of the mesenteric and submaxillary lymph nodes with negative cultures for MAC bacteria, respectively, yielded acid-fast bacilli in the microscopic examination (Table 1). Furthermore, rapidly growing mycobacteria from 53 lymph nodes were cultured and were found to have an orange pigment. These non-*M. avium* mycobacteria were mainly (40 of the 53) isolated from the submaxillary lymph nodes.

Serotyping. The serotypes of the MAC isolates were determined by the slide agglutination method, and the results are given in Fig. 1. Most strains were of serotype 3 (18 strains) or 4 (20 strains), and 39 isolates did not react with the panel of sera that we used. A minority of the isolates were of serotype 2, 8, or 4/8. No correlation was found between the serotypes and the IS1245 RFLP patterns.

IS1245 RFLP typing of porcine isolates. To get an impression of the occurrence of IS1245 RFLP types in various geographic regions, 10 to 20 isolates from pigs from each of the six slaughterhouses enrolled in this study were genotyped. Figure 1 shows a dendrogram of all 91 DNA fingerprint patterns. Only one of the IS1245 RFLP patterns, consisting of three bands, represented the bird-type DNA fingerprint (2, 6, 12). One other MAC isolate was devoid of IS1245 DNA, indicating that this strain represents a grouping other than *M. avium* in the MAC. The number of copies for the other 89 strains ranged from 9 to 34, with an average of 21 per strain. In general, the degree of polymorphism among the DNA fingerprints of pig isolates was large. However, most of the isolates could be grouped into genotype families that shared a similarity of at least 75% among the IS1245 RFLP patterns (Fig. 1).

The *M. avium* isolates subjected to RFLP typing originated from 91 pigs from 75 farms. A single pig from each of 63 farms was examined, and two or three pigs from each of 12 farms were inspected. In the case of 11 of the 12 multiple isolates from the same farm, two or more different DNA fingerprints were found (Fig. 1). This indicates the presence of multiple *M. avium* strains in pigs from 11 of 12 farms from which more than one porcine *M. avium* isolate was obtained. In contrast, identical DNA fingerprints were found among isolates from

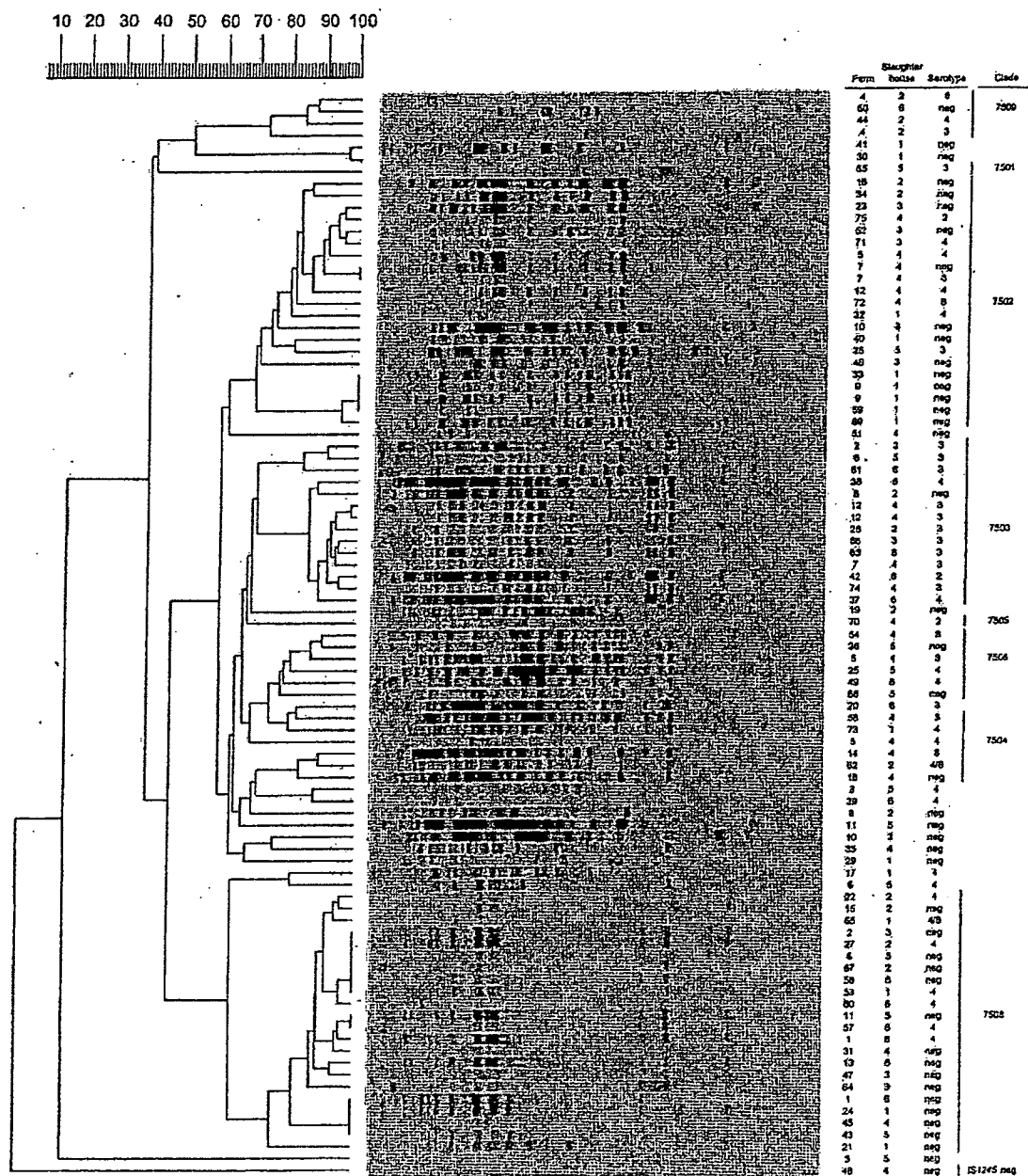


FIG. 1. Dendrogram of the 91 IS1245 RFLP patterns of *M. avium* complex isolates from pigs. The columns indicate (i) the farms where the pigs originated, (ii) the slaughterhouses where the pigs were processed, (iii) the serotypes of the isolates, and (iv) the IS1245 RFLP genotype family (clade) to which the isolate belongs. The numbers at the top represent percent relatedness.

different farms. In total, nine clusters, with a cluster size of two to six isolates, comprised 30 strains originating from 28 farms in a widespread geographic area.

Comparison of RFLP patterns of human and porcine *M. avium* isolates. In 1996, 191 MAC isolates from the same number of human patients were subjected to IS1245-based

RFLP typing in the framework of an epidemiological population-based study on MAC infections in The Netherlands (13). Forty-eight of the 191 isolates (25%) lacked IS1245 DNA, indicating that these strains do not represent *M. avium* but represent other groupings within MAC. Computer-assisted analysis helped compare the 90 porcine *M. avium* isolates with

TABLE 2. Occurrence of MAC isolates from humans and pigs in IS1245 RFLP genotype families with at least 75% similarity

Genotype family	No. of isolates from the following:		
	Total	Pigs	Human
7501	4	1	3
7502	16	14	2
7503	16	8	8
7504	91	20	71
7505	4		4
7506	7	6	1
7507	22	22	
7508	16	4	12
IS1245 negative	41	1	40
Not in a clade	41	15	26
Total	258	91	167

the 143 IS1245-containing human *M. avium* isolates from 1996. Nine genotype families were defined on the basis of at least 75% similarity between the IS1245 RFLP patterns of human and porcine isolates. The occurrence of isolates from both sources in these nine clades is given in Table 2. In total, 59% of the pig isolates and 61% of the human strains were in common genotype families. The largest family (clade 7502) comprised 21 isolates from pigs and 83 isolates from humans (Fig. 2). Two genotype families comprised only four human isolates (clade 7507; data not shown) and only 22 pig isolates (clade 7508; Fig. 1).

DISCUSSION

The average prevalence of caseous lesions in slaughtered pigs was 0.5%, which is unexpectedly high, taking into account the fact that positive pigs were selected only by eye on the basis of deviations in lymph nodes. In an earlier study in Switzerland, Offermann (10) isolated *M. avium* from the mesenteric lymph nodes from 48 of 345 (13.9%) healthy slaughter pigs without any lesions in these lymph nodes. Therefore, the true prevalence of *M. avium* in slaughter pigs in The Netherlands might be much higher.

Molecular typing and computer-assisted analysis facilitate the comparison of human and porcine isolates on a large scale. Although no identical DNA fingerprints of porcine and human origin were found, 60% of the isolates from both sources had a similarity of at least 75% among the IS1245 RFLP patterns. This means that, for IS1245 RFLP patterns consisting of 20 bands, at least 15 band positions are shared. Taking into account the high degree of IS1245-based polymorphism among *M. avium* strains in general, this justifies the conclusion that humans and pigs are infected with the same types of *M. avium* strains. It is currently not clear whether humans and pigs share common sources of infection or that pork products prepared without appropriate heating may infect susceptible humans. Long-term epidemiological studies are needed to examine this hypothesis. Such studies might find direct links between the consumption of contaminated pork products and infections in humans. However, such studies are complicated by the fact that pigs from various parts of The Netherlands are slaughtered at about 26 large and 30 small slaughterhouses scattered over the whole country. In addition, approximately 70% of the pork and pork products are exported.

Isolation of *M. avium* by culture is considered the "gold standard" test for the diagnosis of porcine mycobacterial infections. A sensitivity for microscopic examination of Ziehl-Neelsen-stained smears of 15% for MAC culture-positive

lymph nodes has been reported by Margolis et al. (9). In the follow-up part of the current study, a much greater sensitivity was found by microscopic examination: in total, 80% for the submaxillary lymph nodes and 82% for the mesenteric lymph nodes. However, 81% of all samples with a negative MAC culture result also yielded acid-fast bacilli by microscopic examination. Furthermore, large differences between the predictive value of positive microscopic examinations of submaxillary lymph nodes (26%) and that of positive microscopic examinations of mesenteric lymph nodes (71%) were observed. This low predictive value regarding positive microscopic examinations of the submaxillary lymph nodes is presumably due to a high prevalence of other, non-MAC bacteriological infections caused by injuries as a result of fighting and/or cutting of dents. In our study we found more than 50 positive cultures that yielded orange-pigmented acid-fast mycobacterial rapid growers.

The occurrence of IS1245 is restricted to *M. avium* (6, 12). Only 1 of 91 porcine isolates lacked IS1245 DNA in this study, revealing that the porcine MAC isolates almost invariably represented true *M. avium*. Among the human isolates, 25% of the strains did not hybridize to the IS1245 probe. This indicates that a proportion of the human MAC isolates much larger than that of the porcine isolates represented other groupings within MAC. This presumably reflects the fact that humans have sources of infection not shared with pigs. The identification of the IS1245-negative MAC strains is described elsewhere (13).

In the current study, MAC isolates from pigs at one farm were usually infected with various genotypes of *M. avium*, and identical fingerprints were found among isolates from pigs from different farms. This suggests that there is no ongoing transmission among pigs but, rather, that pigs are infected from environmental sources, and these may be shared by farms at different geographic locations. In a study by Engel et al. (5) of three farms in The Netherlands in 1977, *M. avium* serotype 2 was isolated from 12 of 13 pigs on one farm and occasionally from pigs on two other farms. Since serotypes 1, 2, and 3 were commonly found among bird isolates, this finding at that time strongly suggested a role of birds in the transmission of "avian" tuberculosis. However, in our previous study (12), we found multicopy IS1245 RFLP patterns among *M. avium* serotype 2 and 3 strains apart from the frequently found bird-type RFLP pattern. The multicopy patterns clearly do not represent the bird type RFLP pattern. This means that serotyping is not a reliable method of recognizing *M. avium* strains that originate in birds. The serotyping results in this study also reflect this. Although 21 of the 91 porcine isolates represented serotype 2 or 3, only one of these 21 strains had the bird-type IS1245 RFLP pattern. This finding, combined with the fact that 47 *M. avium* strains from birds in The Netherlands invariably exhibited the bird-type IS1245 RFLP pattern (12), excludes birds as significant sources of MAC infections in pigs.

Engel et al. (5) used a pig infection model to demonstrate that tuberculous lymphadenitis can be induced by feeding pigs compost. However, it is assumed that compost can no longer be suspected as a main factor in the etiology of *M. avium* infections in pigs, because compost is disinfected nowadays by heating and is thought not to contain viable *M. avium* bacteria.

In this study, slaughter pigs were examined by selecting lymph nodes with caseous lesions. Macroscopically negative lymph nodes and the dissemination of MAC infections to other organs must be examined to estimate the true prevalence of MAC bacteria in pigs. Furthermore, detailed studies are need-

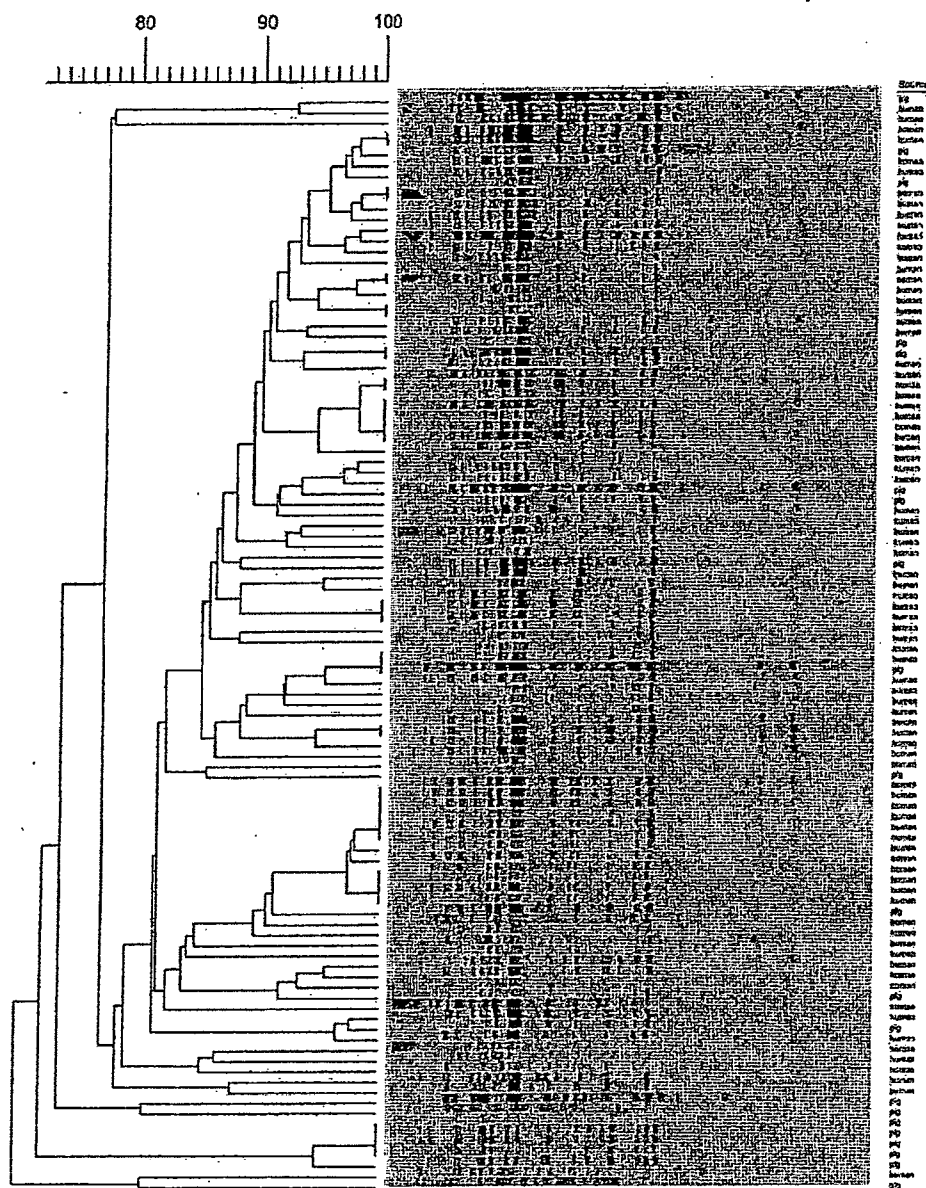


FIG. 2. Dendrogram of IS1245 DNA fingerprints of pig and human isolates in clade 7502. The numbers at the top represent percent relatedness.

ed to further investigate possible sources of infection at farms with a high incidence of MAC-positive pigs.

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Short communication

Granulomatous lesions in lymph nodes of slaughter pigs bacteriologically negative for *Mycobacterium avium* subsp. *avium* and positive for *Rhodococcus equi*

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Abstract

The prevalence of granulomatous lesions in lymph nodes of pigs was studied. From January till August 2004 in two slaughterhouses in The Netherlands 2,116,536 pigs were examined for the presence of granulomatous lesions in the sub-maxillary lymph nodes. In 15,900 (0.75%) of these pigs, lesions could be detected. Nine farms with the highest incidence of lesions were selected for a more detailed pathological and bacteriological examination. On these farms, the prevalence of lesions in sub-maxillary lymph nodes ranged from 2.3 to 5.7% with a mean of 3.0%. From 1276 pigs that were sampled, 98 (7.7%) displayed granulomatous lesions in the sub-maxillary lymph nodes and one (0.1%) pig showed lesions in its mesenteric lymph node. *Mycobacterium avium* subsp. *avium* (MAA) could not be isolated from the lymph nodes of the 99 pigs with lesions and from a selection of lymph nodes ($n = 61$) of pigs without lesions. *Rhodococcus equi* was isolated from 44 out of 98 (44.9%) of the sub-maxillary lymph nodes with granulomatous lesions and from two mesenteric lymph nodes without lesions. A comparison of former studies and the current results indicate that the prevalence of MAA infections in slaughter pigs has strongly decreased over the last decade, whereas *R. equi* is highly prevalent. The high incidence of granulomatous lesions associated with the bacteriological presence of *R. equi* could be considered as a serious cause of misdiagnosis of MAA infections in cases where meat inspection is carried out by inspection for granulomatous changes of lymph nodes only.

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Keywords: *Mycobacterium avium*; Swine mycobacteriosis; Lymphadenitis; Bacteria; Diagnosis; *Rhodococcus equi*

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1. Introduction

Mycobacterium avium subsp. *avium* (MAA) is a potential zoonotic pathogen, which belongs to *M. avium* complex bacteria (MAC). MAA can cause opportunistic infections in humans, especially in those suffering from a HIV infection (Wagner and Young, 2004; Biet et al., 2005). In addition, MAA can cause cervical lymphadenitis in young, otherwise healthy children between 0 and 4 years of age (Haverkamp et al., 2004). The reservoir for infection with MAA in humans is unknown. MAA is ubiquitous and can be isolated from water, soil, compost, bedding materials in stables and other environmental sources (Engel et al., 1978; Thoen, 1992; Matlova et al., 2003, 2004). MAA can also be isolated from animals, most frequently from birds and pigs (Thoen, 1992). Genotyping of MAA strains isolated from humans and pigs revealed that these strains have a high homology (Komijn et al., 1999). This could indicate that pigs are a source of infection for humans or that pigs and humans share common sources of infection, e.g. the environment.

In pigs, infections with MAA are usually limited to the lymph nodes. Especially the sub-maxillary and mesenteric lymph nodes are affected (Thoen, 1992). MAA infections in pigs have no apparent effect on the health of the animal and diagnosis by physical examination of the live pig is usually impossible. Since MAA is a potential zoonotic pathogen it is necessary to exclude MAA from the food chain. In accordance to European Union legislation (Regulation 2004/854/EC), infections caused by *Mycobacteria* in pigs are diagnosed presumptively in slaughter houses by meat inspectors. The sub-maxillary lymph nodes of slaughter pigs are incised and examined at post-mortem inspection for granulomatous lesions. Furthermore, the mesenteric lymph nodes are inspected for granulomatous lesions visually, by palpation and if necessary by incision.

It is considered that granulomatous lesions in lymph nodes are typical for an infection with mycobacteria (Brown and Neuman, 1979). However, *Rhodococcus equi* is also frequently isolated from lesions in sub-maxillary lymph nodes of pigs with granulomatous lymphadenitis (Prescott, 1991; Takai et al., 1996a; Hondalus, 1997; Dvorska et al., 1999). *R. equi* can cause disease in horses, especially in young

foals. In humans, it mainly causes disease in those infected with HIV, and the infection occurs mainly in lungs (Prescott, 1991; Hondalus, 1997). The reservoir of the human infection is not elucidated. *R. equi* is a robust soil organism widespread in the environment and will potentially multiply in the presence of horse manure (Takai et al., 1996b). Prescott (1991) reviewed the history of 32 AIDS patients suffering from an infection with *R. equi* and found a possible animal source of infection for 12 of these patients, confirming the zoonotic potential of this species.

The prevalence of granulomatous lesions in the sub-maxillary and/or mesenteric lymph nodes of Dutch slaughter pigs was determined in 1996 to be 0.5% (Komijn et al., 1999). From 54.2% of these lesions, MAA was isolated. This study was performed to determine the prevalence of granulomatous lesions in pigs in The Netherlands in 2004 and to compare the results with the previous study performed in 1996. Furthermore, on selected farms, sub-maxillary and mesenteric lymph nodes with and without lesions were sampled at slaughter and examined bacteriologically for MAA and *R. equi*.

2. Materials and methods

2.1. Lesions of pigs at post-mortem meat inspection

The prevalence of granulomatous lesions in slaughter pigs was determined for the period January till August 2004. Two slaughterhouses (I and II), where a system was used to register lesions during the post-mortem meat inspection, were selected. Both slaughterhouses were located in the southern part of The Netherlands and in each slaughterhouse approximately 6000 pigs were slaughtered daily. The total number of pigs slaughtered and the number of pigs from which the heads were condemned for reasons of granulomatous lesions in the sub-maxillary lymph nodes were counted and prevalence of lesions was calculated.

2.2. Selection of farms and sampling

In order to obtain a considerable number of lymph nodes with granulomatous lesions for bacteriological

and pathological examination, farms were selected with a recent history for such lesions. Therefore data were used from the registration of lesions at post-mortem meat inspection in slaughterhouse I for the period September till December 2003. Nine farms were selected and in January and February 2004 in several deliveries from these farms the sub-maxillary and mesenteric lymph nodes were examined pathologically for granulomatous lesions at slaughter. From each delivery, at least five pigs without and all pigs with granulomatous lesions in the sub-maxillary lymph nodes were sampled for further examination.

2.3. Bacteriological examination

To culture for MAA the lymph nodes were ground, decontaminated by 1 M sodium hydroxide for 15 min at room temperature followed by a 5% oxalic acid treatment also for 15 min at room temperature. Samples were inoculated onto Löwenstein-Jensen medium, Stonebrink egg medium and Middlebrook 7H10 agar followed by incubation for 12 weeks at 37 °C. Ziehl-Neelsen stain was performed to identify acid-fast bacilli. To culture for *R. equi*, lymph nodes were inoculated onto normal blood agar plates supplemented with 5% sheep blood and incubated for 48 h at 37 °C. Suspected colonies were tested for a synergistic hemolytic reaction (CAMP test) with *Staphylococcus aureus* on 5% sheep blood agar plates, which is an essential criterion for identification of *R. equi* (Prescott, 1991). To confirm the identification of *R. equi*, 16S ribosomal sequencing was performed. In short: DNA was purified using QIAquick spin columns, according to the procedure described by the manufacturer (Qiagen). Target DNA sequence was amplified by PCR using universal primers 8FPL and 806R (Relman, 1993). DNA analysis was performed using an ABI carried out on 3100 Avant genetic analyzer and compared with the NCBI database using BLAST (Applied Biosystems).

3. Results

3.1. Prevalence of lesions

During meat inspection at two slaughterhouses in The Netherlands for the period January till August

2004 in total 2,116,536 pigs were examined for the presence of granulomatous lesions in the sub-maxillary lymph nodes. In 15,900 (0.75%) of these pigs, lesions were detected. The prevalence of granulomatous lesions in slaughterhouse I was higher than in slaughterhouse II. From 898,858 pigs slaughtered in slaughterhouse I 9649 (1.05%) pigs displayed lesions in the sub-maxillary lymph nodes whereas from the 1,217,678 pigs slaughtered in slaughterhouse II 6,251 (0.51%) pigs showed lesions.

3.2. Selection of farms and sampling

Nine farms with the highest incidence of lesions in the sub-maxillary lymph nodes were selected for a more detailed pathological and bacteriological examination. During the period September to December 2003 the prevalence of lesions in lymph nodes on these farms ranged from 2.3 to 5.7% with a mean of 3.0%. Prevalence on these farms was calculated on the basis of results at meat inspection in slaughterhouses of minimal 5 and maximal 27 successive deliveries of slaughter pigs, in total 111 deliveries and 18,855 pigs. In January and February 2004 the sub-maxillary- and mesenteric lymph nodes from 1276 pigs from these nine farms were sampled.

3.3. Pathological and bacteriological examination

The results of the pathological examination showed that 98 (7.7%) out of the 1276 examined pigs had granulomatous lesions in the sub-maxillary lymph nodes and only one pig had lesions in its mesenteric lymph node. The remaining 1177 (92.2%) pigs were free of lesions in their lymph nodes. Bacteriological examination of the lymph nodes of the 99 pigs with lesions and from a selection of lymph nodes ($n = 61$) of pigs without lesions showed that they were all negative for Mycobacteria, including MAA. However, *R. equi* was isolated from 44 out of 98 (44.9%) sub-maxillary lymph nodes with granulomatous lesions (Table 1). In sub-maxillary lymph nodes without lesions no *R. equi* was detected. From the 160 examined mesenteric lymph nodes, *R. equi* was isolated from two lymph nodes in which no lesions were detected during pathological examination (Table 1). *R. equi* was isolated from affected lymph

Table 1

Pathological and bacteriological examination from sub-maxillary and mesenteric lymph nodes of 160 pigs originating from nine farms with a recent history of granulomatous lesions

Lymph node	No. (%) of lymph nodes							
	Pathological positive				Pathological negative			
	MAA ^a positive	<i>R. equi</i> ^b positive	MAA and <i>R. equi</i> negative	Total	MAA positive	<i>R. equi</i> positive	MAA and <i>R. equi</i> negative	Total
Sub-maxillary	0 (0.0)	44 (44.9)	54 (55.1)	98 (100)	0 (0.0)	0 (0.0)	62 (100)	62 (100)
Mesenteric	0 (0.0)	0 (0.0)	1 (100)	1 (100)	0 (0.0)	2 (1.3)	157 (98.7)	159 (100)

^a *Mycobacterium avium* subsp. *avium*.

^b *Rhodococcus equi*.

nodes from all nine sampled farms (Table 2). The number of lymph nodes with lesions varied from 3 to 28 per farm and the number of isolations of *R. equi* from 3 to 12 (Table 2).

The isolated *R. equi* strains showed a synergetic hemolytic reaction on 5% sheep blood agar with *S. aureus*. To confirm the identification, from one isolate the 16S rDNA was amplified by PCR and sequenced. Its sequence showed that the isolate was identical to *R. equi*.

4. Discussion

In 1996 the prevalence of granulomatous lesions in lymph nodes of slaughter pigs in The Netherlands was

0.5% and in 54.2% of the cases MAA was isolated (Komijn et al., 1999). The results of this study showed that the prevalence of granulomatous lesions in lymph nodes in 2004 was 0.75%, an increase in comparison to the results of 1996. However, in contrast to the results of the study in 1996, in 2004 no MAA bacteria could be detected in lymph nodes after bacteriological examination. Apparently, the prevalence of MAA infections in The Netherlands in 2004 was considerably less when compared with the prevalence in 1996. One of the reasons for the decrease in prevalence of MAA infections could be the change in use of compost on pig farms. Pigs fed with compost can develop granulomatous lymphadenitis (Engel et al., 1978). In a search for possible sources of MAA infections in pigs on two farms of the survey of 1996 it appeared that

Table 2

Distribution of pigs with granulomatous lesions in sub-maxillary and mesenteric lymph nodes across farms and their outcome after bacteriological examination for *Mycobacterium avium* subsp. *avium* (MAA) and *Rhodococcus equi*

Farm	No. of examined pig carcasses	No. (%) of pigs with lesions					
		Sub-maxillary lymph nodes			Mesenteric lymph nodes		
		Pathological	Bacteriological		Pathological	Bacteriological	
			MAA	<i>R. equi</i>		MAA	<i>R. equi</i>
1	155	5 (3.2)	0 (0.0)	3 (1.9)	0	0 (0.0)	0 (0.0)
2	114	11 (9.6)	0 (0.0)	3 (2.6)	0	0 (0.0)	2 (0.0) ^a
3	68	3 (4.4)	0 (0.0)	2 (2.9)	0	0 (0.0)	0 (0.0)
4	117	7 (5.6)	0 (0.0)	3 (2.6)	1	0 (0.0)	0 (0.0)
5	69	3 (4.3)	0 (0.0)	3 (4.3)	0	0 (0.0)	0 (0.0)
6	153	14 (9.2)	0 (0.0)	7 (4.6)	0	0 (0.0)	0 (0.0)
7	139	19 (13.7)	0 (0.0)	12 (8.6)	0	0 (0.0)	0 (0.0)
8	235	28 (11.9)	0 (0.0)	8 (3.4)	0	0 (0.0)	0 (0.0)
9	226	8 (3.5)	0 (0.0)	3 (1.3)	0	0 (0.0)	0 (0.0)
Total	1276	98 (7.7)	0 (0.0)	44 (3.4)	1	0 (0.0)	2 (0.0) ^a

^a No percentages are given because the two lymph nodes bacteriologically positive for *R. equi* showed no lesions after pathological examination.

samples of compost contained MAA bacteria (Komijn, 1999). At present no pig farms, except for organic pig farms in The Netherlands use compost anymore including the nine farms from which we sampled lymph nodes for bacteriological examination.

A difference in prevalence of granulomatous lesions between the two slaughterhouses was observed. A possible explanation for this finding is a true difference in prevalence of lesions in lymph nodes of pigs on farms. Another explanation may be a difference in methodology of scoring for lesions between slaughterhouses. Lesions are scored visually at slaughter and it cannot be excluded that such subjective observation will influence the outcome of the scoring.

R. equi was frequently isolated from granulomatous lesions in sub-maxillary lymph nodes (44 out of 98) and no other bacteria were detected. Apparently, in this survey *R. equi* was the most important bacterium in causing lymphadenitis in pigs. As *R. equi* is also known as a bacterial species with zoonotic potential, the presence of *R. equi* and the food borne attribution to human *R. equi* infections should be analysed in more detail.

The isolation of *R. equi* was nearly exclusively from the sub-maxillary lymph nodes (44 out of 160) and not from the mesenteric lymph nodes (2 out of 160). These findings are in agreement with reports of others indicating that isolation of *R. equi* was usually limited to respiratory tract lymph nodes (Prescott, 1991; Dvorska et al., 1999). Furthermore, we found that isolation of *R. equi* was nearly exclusively from lymph nodes with granulomatous lesions (44 out of 46). Several reports confirm these findings but and in contrast to our findings, *R. equi* may also be recovered from normal sub-maxillary lymph nodes in healthy pigs (Prescott, 1991; Takai et al., 1996a; Dvorska et al., 1999).

A high number of lymph nodes with granulomatous lesions (54 out of 98) was bacteriologically negative for MAA and *R. equi*. Similar observations have been made earlier in The Netherlands (Komijn et al., 1999), in the US (Brown and Neuman, 1979) and in Czech Republic (Dvorska et al., 1999). Reasons for these observations could be that the granulomatous lesion are merely aesthetic or that the process had healed and no living bacteria were present. Another possible explanation was given by Dvorska et al. (1999), who suggested that during the immune response of the host

organism to the infection, the subsequent lesion forming results in a total devitalisation of the agent. Experimental infections with MAA in pigs with bacteriological, pathological and immunological examinations at different time intervals after infection might reveal whether this is the case.

The results from our study show that detection of granulomatous lesions in pig lymph nodes by eye is not a reliable diagnostic test to determine an infection with MAA. Furthermore, additional examinations by culture methods appear to be necessary to estimate the true prevalence of MAA infections in pigs. However, this approach is time-consuming and laborious. Therefore, other more fast and reliable tests for the detection of MAA infections in pigs are strongly needed. Finally, the high occurrence of *R. equi* in lymph nodes of pigs provokes the question to the risk of *R. equi* transmission from pigs to the human population.

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Serodiagnosis of *Mycobacterium avium* subsp. *avium* infections in pigs

Henk Wisselink, Conny van Solt-Smits, Norbert Stockhofe-Zurwieden, Herma Bergen-Buys and Jelle Thole



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Content

- Introduction *M. avium* subsp. *avium*
- Prevalence studies in the Netherlands
- Experimental infection in pigs
- Development of a serological ELISA assay
- Validation ELISA assay
- Scientific publications

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***Mycobacterium avium* subsp. *avium* (MAA)**

- Humans
 - Opportunistic infections
 - HIV infected
 - Suffering from COPD
 - Cervical lymphadenitis in healthy children between 0 and 4 years of age
- Pigs
 - Lymph node lesions
 - Mesenteric and mandibular lymph nodes

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Mycobacterium avium complex (MAC)

- MAC: 28 serotypes
- Serotypes 1-6, 8-11 and 21 belong to MAA
- Serotypes 1, 2 and 3: MAA "bird" type (naming avium)
- Other serotypes MAC "non-bird" types
 - Isolated from humans and pigs
 - But also from the environment (soil, compost, water)

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Reservoir of infection

- MAA strains isolated from humans and pigs
 - Genotyping
 - High agreement
- Conclusions
 - Humans and pigs share reservoirs either/or
 - Pigs can form a reservoir

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Diagnosis

- Diagnosis in live pigs usually not possible
 - MAA infection no apparent effect on the health of pig
- Diagnosis in slaughterhouse
 - During meat inspection
 - Mandatory incision of lymph nodes EU legislation
 - Mandibular lymph nodes
 - Incision and assessment of lesions
 - If lesions are observed the heads are condemned
 - Mesenteric lymph nodes
 - Visual inspection for lesions
 - If lesions are observed intestine is condemned

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Test characteristics slaughterhouse inspection

- Laborious
- Low specificity
 - *Rhodococcus equi* is also a cause of lesions
- Low sensitivity
 - Lesions can easily be missed
 - Lymph nodes bacteriologically positive for MAA without lesions

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Prevalence of MAA in the Netherlands in 1996 and 2004

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Prevalence MAA 1996

- 0.8 % of slaughterpigs lesions mandibular lymph nodes on the basis of pm inspection (VWA)

Targeted sampling

- From 20% of the lesions, MAA were isolated

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Sources of infection 1996

- Search for possible sources on two farms:
 - Samples of compost contained MAA-bacteria
- 2001
 - IKB: only compost, free for viable MAA was allowed as bedding for pigs

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Prevalence 2004

- 0.75% of slaughterpigs on the basis of pm inspection of mandibular lymph nodes (VWA)
- Period: Jan. – August 2004

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Prevalence MAA 2004 (1)

- Targeted sampling based on risk
- Selection of 9 pig farms
 - Recent history of high percentage of lesions in mandibular lymph nodes
 - Period Sept. – Dec. 2003
 - Sampling of 160 pigs
 - Mandibular and mesenteric lymph nodes
 - Period Jan. – Febr. 2004

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Prevalence MAA 2004 (2)

- Lesions
 - 98 pigs with lesions in mandibular lymph nodes
 - 1 pig with lesions in mesenteric lymph node
- Bacteriological examination of lymph nodes
 - Negative for MAA
 - Isolation of *R. equi*
 - 44 out of 98 mandibular lymph nodes with lesions
 - 1 out of 159 mesenteric lymph nodes without lesions

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Summary and conclusions

- Prevalence of MAA infections in the Netherlands in 2004 probably very low
- A strong decrease in MAA infections in the Netherlands during the last decade

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Pathological and bacteriological examination of lymph nodes of pigs after experimental infection with *Mycobacterium avium* subsp. *avium*

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Goal

- Correlation between bacteriological and pathological status of lymph nodes
- Influence of an early and late infection on bacteriological and pathological status of lymph nodes

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MAA strain and pigs

- MAA strain
 - Serotype 4
 - Isolated from a lymph node of a field pig in The Netherlands (1996)
- Pigs
 - High health status farm
 - 4 groups of 8 pigs

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Groups of pigs experimentally infected

Group	Age of pigs experimental infection (weeks)		
	2.5	4.5	18
1	X		
2		X	
3			X
4	X	X	X

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Inoculation

- Inoculum
 - 5 ml MAA (10^9 CFU) suspension
- Inoculation
 - Deposition of inoculum in the caudal area of the pharynx
- Pharynx epithelial tissue
 - Scarified with a cotton swab

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MAGNETIC FIELD

Skin tuberculation

- Carried out 72 hours before autopsy
- Intradermal tuberculin test in the ear
 - MAA strain D4
- Assessment after 24, 48 and 72 hours
- Results:
 - 31 out of 32 pigs positive (red, swelling)

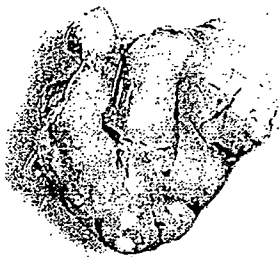
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MAGNETIC FIELD

Evaluation experimental infection

- Autopsy at an age of 24 weeks
- Pathological and bacteriological examination of
 - Lnn mandibularis
 - Lnn mesenterialis
 - Lnn inguinalis
 - Lnn trachea-bronchialis (left and right)
 - Lnn retro-pharyngeal
 - Tonsil

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MAGNETIC FIELD

Granulomatous lesions in Lnn mandibularis



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Granulomatous lesions in Lnn mesenterialis



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PASADENA, CA 91106

Pathological examination of lymph nodes (1)

Group	Age exp. infection (weeks)			Lesions in lymph nodes	
	2.5	4.5	18	Mean (n)	Pigs (n)
1	X			2.1	7
2		X		2.5	7
3			X	0	0
4	X	X	X	0.3	2

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PASADENA, CA 91106

02/11/2006

Pathological examination of lymph nodes (2)							
Group	Number of pathological lesions in lymph nodes per group						
	Tonsil	Mand.	Mes.	Ing.	Trach. br. (le)	Trach. br. (ri)	Retro- phar.
1	1	3	6	0	2	2	3
2	0	7	7	0	0	2	4
3	0	0	0	0	0	0	0
4	0	0	2	0	0	0	0
Total	1	10	15	0	2	4	7

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Bacteriological examination of lymph nodes							
Group	Number of pigs bacteriologically positive for MAA per group						
	Tonsil	Mand.	Mes.	Ing.	Trach. br. (le)	Trach. br. (ri)	Retro- phar.
1	2	5	8	0	2	3	7
2	2	8	7	2	1	1	6
3	8	8	5	0	0	0	6
4	4	6	7	0	1	0	3
Total	16	27	27	2	4	4	22

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Diagnosis of pigs experimentally infected with MAA						
Group	Number of pigs					
	Lnn mandibularis		Lnn mesenterialis		Lnn mand + Lnn mes	
	Path.	Bact.	Path.	Bact.	Path.	Bact.
1	3	5	6	8	7	8
2	7	8	7	7	7	8
3	0	8	0	5	0	8
4	0	6	2	7	2	8
Total	10	27	15	27	16	32

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Summary and conclusions

- The infection model works fine
- Lesions visible 20 and 22 weeks after infection
- Six weeks too short to develop lesions
- Pathological examination less sensitive than bacteriological examination, especially in pigs recently infected

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Development of an ELISA test for the serodiagnosis of *M. avium* subsp. *avium* infections in pigs

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Meat inspection

- Legislation EU 2004
 - Authorities may decide:
 - On the basis of epidemiological data
 - To refrain from incision of lymph nodes

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Serological test for MAA

- Development serological assay
 - Detection of antibody titers in blood of slaughterhouse pigs (26 weeks)
- Little is known of immuneresponse against MAA
 - Experimental infection with MAA (Thoene et al., 1979):
 - Pigs became bacteriological positive for MAA
 - Immunoresponse 10-12 weeks after infection

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Lipids

- Cellwall of Mycobacteria
 - Rich with lipids
 - Outside cellwall glycolipidstructure
- Glycolipids of Mycobacteria
 - Many of them are species specific
 - Glycopeptidolipids (GPL's) of MAC
 - Immunodominant antigens
 - Serological diagnosis of human MAC infections

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Materials

- MAA field strain (1996) for isolation of lipids
- Sera obtained from:
 - Pigs bacteriologically negative for MAA
 - Prevalence study of 2004
 - Pigs experimentally infected with MAA
 - Longitudinal sera

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Fractionating lipids

- Culture MAA field strain
- Extraction of lipids
 - Crude fraction tested in ELISA
 - High titers in sera of pigs experimentally infected
 - Low titers in field sera of pigs bacteriologically negative for MAA
 - Comparison of polair and apolair fraction in ELISA
 - Polair fraction most important

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SAGELAND 002

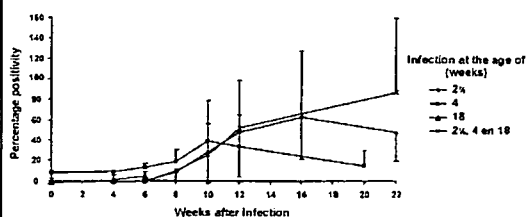
Execution of ELISA

- Coating ELISA plates with polair lipids
- Serum of pigs tested in dilution of 1:200
- In each plate a negative and positive control serum (in duplo)
 - Negative: Pig (field) bacteriologically negative for MAA
 - Positive: Pig experimentally infected
- Calculation of PP%:

$$\frac{\text{OD (sample)} - \text{OD (negative control)}}{\text{OD (positive control)} - \text{OD (negative control)}} \times 100\%$$

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SAGELAND 002

Antibody titers in pigs experimentally infected with *Mycobacterium avium* subsp. *avium*



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SAGELAND 002

Summary and conclusions

- Development of a serological assay
 - Use of polar lipid fraction
- Experimental infected pigs (single infection)
 - Increase in antibody titer from 6-8 weeks after infection
 - Highest titers 10-12 weeks after infection

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Validation ELISA assay

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Calculation of cut off

- For application of the test calculation of cut off needed
- Use of field sera of pigs
 - Bacteriologically negative for MAA, 2004 (N=153)
- Result ELISA field sera
 - 150 (98%) PP% < 10
 - Highest result 16 PP%
- Calculation of cut off
 - 7.5 PP% (5.0 -14.4)

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Diagnosis of pigs experimentally infected with MAA

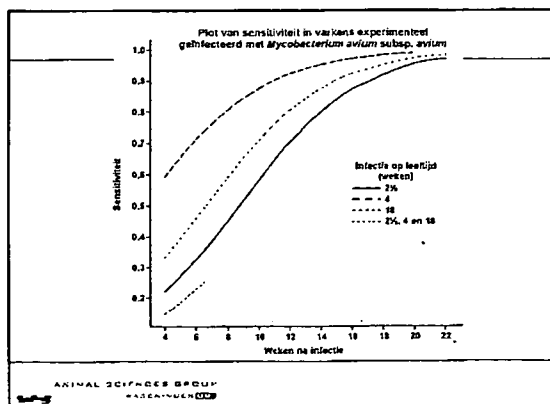
Group	Number of pigs						
	Lnn mand		Lnn mes		Lnn mand + Lnn mes		Serological (> 7.5 PP%)
	Mac	Bt	Mac	Bt	Mac	Bt	
1	3	5	6	8	7	8	8
2	7	8	7	7	7	8	5
3	0	8	0	5	0	8	2
4	0	6	2	7	2	8	8
Total	10	28	15	27	16	32	23

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Sensitivity of the assay

- Calculated with sera of pigs experimentally infected (longitudinal)

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Continuous improvement

- A follow up on positive farms

e.g.

- Positive farms identified on serology
- Skin tuberculation
- Management review on farm, adjustment of procedures
- Sampling of lymph nodes and blood in slaughterhouse
- Bacteriological and serological examination

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Summary and conclusions

- Sensitivity of ELISA test sera pigs experimentally infected
 - 0.1 – 0.6 at 4 weeks after infection
 - 0.9 – 0.95 at 20 weeks after infection
- Procedure for follow-up positive farms

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Scientific publications MAA The Netherlands

- Komijn et al., 2000
 - J. of Clinical Microbiology
 - Content: Prevalence of MAA in 1996
- Wisselink et al., 2006
 - IPVS Conference Copenhagen, Denmark
 - Content: Experimental infection with MAA in pigs
- Komijn et al., 2007
 - Accepted for publication in Veterinary Microbiology
 - Content: Prevalence of MAA in 2004

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NL Visual Inspection of Market hogs- Briefing for the Under Secretary

August 2, 2007

- **We reviewed the visual inspection documents and found visual inspection to be equivalent because it met the following criteria:**
 1. The government has an inspection program that is at least as effective at identifying and removing, adulterated carcasses, parts as FSIS inspection procedures..
 2. The incidence of diseases in market hogs no higher than the incidence in the United States.
 3. The market hogs must be born and raised in the country.
 4. The government implements a inspection verification program to check the accuracy of the visual inspection program.
 5. The government requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market hog carcasses.

During our last briefing, you had asked a question on the use of ELISA test, which is one part of the prerequisite program. We received further information from Netherlands. This information was reviewed with technical expert and found acceptable. This information is provided in Attachment 2.

Would you like me to briefly discuss this information?

If answer is NO, then I will STOP.

However,

If answer is yes, then I will say the following:

- Based on the Netherlands data, ELISA test was about 75% sensitive in hogs infected with *M. avium* subspecies *avium* (MAA).
- Netherlands data did not address the **specificity** of the ELISA method. (They only used one strain of *M. avium*.)
 - Based on the Netherlands' data, the ELISA test, by itself, is not the most reliable test for the detection of MAA. However, it can become a dependable if it is combined with the following safeguards.:
 - i. The production/slaughter is a vertically integrated operation,
 - ii. There is a established frequency of follow-up testing for MAA.

- iii. Only hogs born and raised in Netherlands are allowed in the program.
- iv. There is a TB testing program for the farm workers.
- v. There is an environmental testing program for MAA
- vi. Companies have a program for controlling insects and other pests.

Netherlands has proposed these safeguards as part of its equivalence request.

NOTES for Ghias Mughal for any follow up discussion.

NB: They have not reduced number of inspectors from the post mortem line)

Q. 1 Why was this Criteria selected?

Ans. Based on food safety objective to remove unwholesome and adulterated carcasses and parts from human food supply.

Q. 2 What is testing frequency for ELISA test?

Ans.

Only neutral and low risk farms are eligible to participate in visual inspection.

2 pigs per lot from a low risk farm.

Q. What is the reason for this submission?

Ans.

To reduce salmonella.

(Literature suggests that cross contamination with salmonella is increased after incision of Mandibular LN)

Comparison between:

HIMP and NL Visual Inspection

FSIS post-mortem inspection procedures under HIMP are similar to the Netherlands visual ante-mortem and post-mortem inspection except that FSIS requires the establishment to incise mandibular lymph nodes.

FSIS traditional inspection and NL Visual Inspection

FSIS' post-mortem inspection procedures under traditional inspection are similar to the Netherlands' visual post-mortem inspection procedures except FSIS inspectors incise and observe mandibular lymph nodes, observe and palpate portal and bronchial lymph nodes, observe liver, lungs and kidneys.

HIMP:

FSIS conducts three types of inspection activities in the HIMP establishments; Systems Inspection, Carcass Inspection and Verification Inspection.

Systems Inspection involves the evaluation of in-plant inspection findings and is intended:

To determine the effectiveness of the overall design and execution of all establishment slaughter processes under HACCP and process control plans.

Carcass Inspection involves the examination of each carcass and its parts to determine if they are adulterated.

Verification Inspection involves the evaluation of the effectiveness of the establishment's HACCP plan and process control plan in meeting the relevant performance standards.

Inspection procedures under HIMP were developed to reduce reliance on organoleptic inspection, to shift to prevention-oriented inspection systems based on risk assessment, and to redeploy inspection resources in a manner that better protects the public from food-borne diseases.

Farms are categorized according to risk of *M. avium* infection based on the results of ongoing sampling results. If a farm has 18 consecutive negative results (sampled from no more than 6 pigs in each of 3 deliveries), it is assigned a neutral risk. When the farm has 18 additional negative samples (collected from 2 pigs in each of 9 deliveries), it is assigned a low risk. When a farm has a single positive result or two intermediate results within 18 samples, it is placed in the high risk category. Only neutral and low risk farms are eligible to participate in visual inspection. Market hogs from high risk farms are subject to traditional inspection. In addition, animal health authorities assist the farms in identifying and reducing risk factors for *M. avium* infection.

SENSITIVITY: An operating characteristic of a diagnostic test that measures the ability of a test to detect a disease (or condition) when it is truly present. Sensitivity is the proportion of all diseased patients for whom there is a positive test, determined as the number of true positives divided by the sum of true positives + false negatives. (Contrast with specificity.)


SPECIFICITY: An operating characteristic of a diagnostic test that measures the ability of a test to exclude the presence of a disease (or condition) when it is truly not present. Specificity is the

proportion of nondiseased patients for whom there is a correctly negative test, expressed as the number of true negatives divided by the sum of true negatives + false positives. (Contrast with sensitivity.)

EQUIVALENCE DETERMINATION

ALTERNATE POST-MORTEM INSPECTION PROCEDURE FOR MARKET HOGS

The equivalence determination book was handed over to the Assistant Administrator, OIA, during the first week of December 2006 for concurrence on the decision. IES is still waiting for a decision from the Assistant and the book has not been returned to the IES staff.


M.. Ghias Mughal, DVM; Ph.D.
Senior Equivalence Officer,
IES, OIA
11-1-07

U.S. Department of Agriculture
Food Safety and Inspection Service
Office on International Affairs
Director, Ms. Sally White
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UNITED STATES OF AMERICA



landbouw, natuur en
voedselkwaliteit

Your letter of	your reference	our reference	date
April 23, 2007		VD 07.1265.IH	May 29, 2007
re:		extension no.	enclosures
Establishment 193 - VION Meppel		+31(0)70 3785435	

Dear Ms. White,

In reply to your letter of April 23, 2007, concerning the eligibility of pork, which has been subjected to visual post-mortem inspection, for export to the United States, I have taken due note of your decision that product, which has already been produced under those conditions in USA-approved establishments, and which is currently being stored pending the completion of the equivalency determination of the pertinent EU legislation, will not allowed to be exported to the United States.

Your letter of October 12, 2006, in particular your remarks on the suspension of exports of pork from U.S. certified establishments, which are producing with use of visual post-mortem inspection of swine carcasses, has also been considered.

As you know, as a result of this letter, those U.S. certified establishments, which are operating with visual post-mortem inspection, have voluntary suspended exports to the United States since then. Needless to say, I am looking forward to continued progress on the equivalence determination of visual post-mortem inspection, based on data from the production chain.

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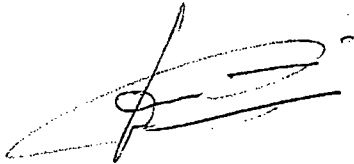
Date	Reference	Following page
May 29, 2007	VD 07.1265.IH	2

I have now received official confirmation from the Food and Consumer Product Safety Authority (VWA) in The Netherlands, that one of these establishments, i.e. est. 193 VION Meppel, has reversed its post-mortem inspection method effective May 21, 2007, and brought it back in compliance with the US-EC Veterinary Equivalency Agreement which currently still uses Directive 64/433 as its legal basis.

In view of this action, est. 193 is now fully eligible for exports to the United States and certification of their product to the U.S. will be resumed shortly. I would very much appreciate receiving your confirmation of this information.

Sincerely,

THE CHIEF VETERINARY OFFICER,



Dr. Peter W. de Leeuw

Cc: VWA: Ate Jelsma, VWA: Joost van Wijk, Agriculture Councillor in Washington: Ir. W.L.A.G. Tacken

2007 Certification FOREIGN OFFICIAL MEAT ESTABLISHMENT CERTIFICATE

I hereby certify that the establishments listed below fully comply with requirements of The Netherlands equivalent to all the inspection, building construction standards, and other requirements for the slaughter and preparation of the carcasses, parts thereof, meat and meat food products of cattle, sheep, swine, goats and equines applied to official establishments in the United States under the Federal Meat Inspection Act and otherwise meet the requirements of 327.2(a) of the regulations governing meat inspection of the U.S. Department of Agriculture.

ESTABLISHMENT #	NAME	ADDRESS	TYPE OF OPERATION
61	Vion Boxtel B.V.	Boseind 10 5281 RM Boxtel	Slaughterhouse & cutting plant/hogs
82	Vion Scherpenzeel B.V.	't Zwarte Land 13 3925 CK Scherpenzeel (Gld.)	Cutting plant/pork
124	Vion Beuningen B.V.	Zilverwerf 8 6641 TD Beuningen (Gld.)	Cutting plant/pork
129	Zwanenberg Food Group Almelo	Sluisweg 7 7602 PR Almelo	Processing plant/pork
153	Zwanenberg Food Group B.V.	Westdorplaan 225 8101 PN Raalte	Processing plant/pork
193	Vion Meppel B.V.	Galgenkampsweg 10A 7942 HD Meppel	Slaughterhouse/hogs
236	Vion Druten B.V.	Kerkstraat 40 6651 KG Druten	Slaughterhouse & cutting plant/hogs
312	Vion Apeldoorn B.V.	Laan van Malkenschoten 77 7333 NP Apeldoorn	Slaughterhouse & cutting plant/hogs
378	Vion Helmond B.V.	Graandijk 5 5704 RB Helmond	Slaughterhouse & cutting plant/hogs
404	Vion Doetinchem B.V.	Voltastraat 21 7006 RS Doetinchem	Cutting plant/pork
584	Lau van Haren Coldstores B.V.	Metaalweg 15 6551 AC Weurt	Cutting plant & cold storage/pork
589	Bussink Vrieshuis	Van Weerden Poelmanweg 5 7602 PC Almelo	Cutting plant & cold Storage/pork

slaughter Pro
5 + 3
8

Date : January 30, 2007

Signature:

Official Title: Chief Veterinary Officer

12

[2 cold stores
2 Processing Z. JP]

**MINUTES OF REVIEW —
INDIVIDUAL SANITARY MEASURE
Denmark**

Daniel Oestmann and Priya Kadam
David Smith and Kevin Gillespie

EQUIVALENCE REQUEST:

Denmark requested an equivalence determination for an alternative post-mortem inspection i.e. visual inspection instead of palpation and incision of lung and liver and their associated lymph nodes of slaughtered market hogs.

BACKGROUND:

On December 16, 2008 in an FSIS-Denmark bilateral meeting a team of FSIS experts met and reviewed Denmark's Supply Chain Inspection system, and presentations by Danish officials. The Supply Chain Inspection system allows inspection of market hogs raised under an integrated quality control program coupled with an on-site verification at slaughter establishments of visually inspected carcasses and organs to ensure that passed carcasses and parts are wholesome and not adulterated. As a part of this inspection system, on December 24, 2008, FSIS approved Denmark's use of an alternative post-mortem inspection procedure i.e. to omit the incision of mandibular lymph nodes for market hogs.

As a part of this Supply Chain Inspection system, in April 2010, Denmark proposed another alternate post mortem inspection procedure, i.e. visual inspection instead of palpation of mesenteric lymph nodes of slaughtered market hogs. After reviewing a risk assessment supporting this alternate procedure, FSIS approved it on February 29, 2012.

On September 13, 2013 Denmark proposed an additional alteration in the post-mortem inspection procedure i.e. visual inspection instead of palpation of lung and liver and their associated lymph nodes of slaughtered market hogs. The following evaluation is for this inspection procedure. Granting equivalence for this alternate post mortem inspection will result in visual inspection in the entirety of the finisher pigs from controlled housing to the slaughter house.

FSIS FOOD SAFETY MEASURE:

The purpose of post-mortem inspection of livestock is to protect the public health by ensuring that carcasses and parts that enter commerce are wholesome and not adulterated. To achieve this goal, in swine slaughter establishments operating under traditional inspection or in those establishments operating under the HACCP-Based Inspection Models Project (HIMP), FSIS inspectors perform ante-mortem and post-mortem inspection procedures to detect diseases, abnormalities, and contamination of livestock carcasses and parts.

In establishments operating under HIMP, FSIS requires that the establishment implement ante-mortem and post-mortem sorting procedures and present to FSIS only normal and healthy-appearing animals and carcasses and parts that are wholesome and free of defects. HIMP also requires additional FSIS verification procedures to ensure that the establishment produces only safe, wholesome products.

OBJECTIVE OF THE FOOD SAFETY MEASURE:

FSIS inspectors conduct ante-mortem inspection of live swine and post-mortem inspection of carcasses and parts on a carcass by carcass basis. In market age swine, FSIS performs inspection under either the traditional inspection system or under the HIMP inspection system. In both cases, inspection procedures are intended to identify and remove unwholesome and adulterated carcasses and parts from the food supply.

EQUIVALENCE CRITERIA:

The criteria used for making an equivalence determination for an alternative post-mortem inspection procedure for market-age hogs are set forth below:

1. The government inspection service administers an inspection program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass.
2. The government inspection system requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market hog carcasses presented for inspection.
3. The incidence of diseases in market hogs, such as TB, is not higher than the incidence in the United States.
4. The market swine must be born and raised in the country.
5. The government inspection service must implement a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects).

EQUIVALENCE EVALUATION:

The government inspection service administers an inspection program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass.

This criterion is met. As per Denmark's Supply Chain Inspection system, Denmark uses a combination of pre-slaughter data collection and post-mortem inspection to ensure the identification and removal of diseased carcasses and parts from the food supply. Pre-slaughter data must be presented to the slaughter establishment prior to slaughter of the

swine. The Official Veterinarian at the slaughter establishment will verify that this information is supplied to the slaughter establishment. Without this information, swine will not undergo slaughter. This system allows for full traceability of swine and provides the health information of all swine prior to slaughter. Ante-mortem inspection occurs in the same way as conducted by FSIS. The proposed alteration to post-mortem inspection is related to the visual inspection instead of palpation of the lung and liver and their associated lymph nodes of slaughtered market hogs. Denmark has conducted, and submitted to FSIS, a risk assessment¹ which focused on the areas of swine carcass inspection that will be altered under their “Supply-Chain Inspection” proposal. This risk assessment was conducted on the visual inspection of the lungs and liver and their associated lymph nodes instead of palpation of slaughtered market hogs.

Denmark conducted a study on comparing visual and traditional inspection (palpation) of the lungs and liver. A sample size of 3000 was assessed. Embolic pneumonia in lungs and liver abscesses were identified as the lesions that might be overlooked if visual inspection was conducted because of their small size and location behind the backside of the organ.

The outcome of this risk assessment study was that the changes proposed:

1. Did not have a significant impact on food safety. Neither did it have a negative impact on the assessment of animal health as well as the assessment of the welfare of the pigs.
2. According to the slaughter house statistics embolic pneumonia in lungs and liver abscesses lesions occur at a low prevalence.
3. Denmark typically slaughters about 18 million finisher pigs. The risk assessment found that one of three cases of embolic pneumonia was missed when conducting visual inspection. It was estimated that, in a worst case scenario, 1800 cases of embolic pneumonia will be missed per year.
4. The study concluded that the risk of human exposure related to the hazards identified in embolic pneumonia were negligible because:
 - a. lungs are not considered edible tissue
 - b. meat from pigs with embolic pneumonia that escape detection seems low, because the bacteria are normally not present in the muscle tissue and if present it is in low numbers, and these bacteria are not food borne
 - c. low numbers of abscesses present in the carcasses associated with pyaemia are most likely found during cutting
 - d. hazards found in relation to the embolic pneumonia did not have a significant zoonotic potential and do not show up in the human statistics – hence they do not seem to have a relevance for food safety

¹ Assessment of risk associated with a change in meat inspection- Is mandatory palpation of the liver and lungs a necessary part of meat inspection of finisher pigs? By Pacheco Goncalo, Amanda Brinch Kruse, Lis Alban, and Jesper Valentin Petersen. Danish Agricultural & Food Council and University of Copenhagen, Denmark. Translated into English February 28, 2013

5. The study concluded that the risk of human exposure related to the liver abscesses is very low because:
 - a. prevalence of liver abscesses is very low
 - b. will most likely be identified during meat inspection. Livers that are intended for human consumption undergo manual inspection; therefore abscesses or any other lesions of the liver would be found.

Therefore, there is only a negligible risk involved in visual inspection of lungs and liver and their associated lymph nodes. This assessment covers only finisher pigs that originated in controlled housing farms where the animals were raised under controlled conditions. Thus this alternate post-mortem inspection is effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain. There is a separate criterion below that requires that the swine be market age hogs that are raised under controlled housing so an equivalence determination of this inspection procedure would require that this condition be met.

The government inspection system requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market hog carcasses presented for inspection.

This criterion is met. As described above, Denmark uses a combination of pre-slaughter data collection and post-mortem inspection to ensure the identification and removal of diseased carcasses and parts from the food supply. This information includes but is not limited to: feed, pathogen testing, medical treatments, etc., exchanged between primary producers, the slaughterhouses and the competent authority. Pre-slaughter Supply Chain Information data must be presented to the official inspector, and any information that may cause health concerns must be presented to the official veterinarian prior to ante-mortem inspection of the swine. The Official Veterinarian at the slaughter establishment will verify that this information is supplied to the slaughter establishment. Without this information, swine will not undergo slaughter. Official veterinarians at the slaughter establishment are allowed to use their own professional opinion in deciding if the herd of swine should be allowed to undergo visual inspection or traditional inspection. Any findings that would affect the inspection method (visual vs. traditional) will become historical data connected to the supplying farm, and will be presented as Supply Chain Information for the next herd of swine arriving at the slaughter establishment from that farm. This system allows for full traceability of swine and provides the health information of all swine prior to slaughter.

The incidence of diseases in market hogs, such as Tuberculosis (TB), is no higher than the incidence in the United States.

This criterion is met. Denmark has been recognized as free of *Mycobacterium bovis* (bovine tuberculosis) since 1980. A large-scale surveillance program in cattle in Denmark is in place ensuring a constant documentation of the free status. Denmark has acknowledged the rare occurrence of *Mycobacterium avium*. Because it is known that *M. avium* can be spread by bedding material EU countries require that bedding material

(traditionally peat) be heat treated to mitigate this risk. If the bedding is not heat treated it is not allowed to be used.

The market hogs must be born and raised in the country.

This criterion is met. In order to qualify for this program, the producer must demonstrate that the market hogs are of Danish origin. Only swine that have been raised indoors since weaning, and are raised under controlled circumstances are eligible for this inspection procedure. There is complete segregation of the swine from other species while on the farm, during transport to the slaughter establishment, during lairage and slaughter.

The government inspection service must implement a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects).

This criterion is met. In 2008 the Danish Veterinary and Food Administration (DVFA) submitted performance standards for verifying inspection for the removal of both food safety and non-food safety defects. These standards were introduced for all market hog slaughterhouses on January 1, 2009. The standards include: 1) not more than 5% non-compliances for inspection tasks (palpation, incision and hygienic behavior), 2) not more than 6% cumulative non-compliances for pathological findings (2% for the carcass, 2% for the plucks and 2% for other organs), and 3) for hygienic slaughter not more than 2% non-compliances for contamination in general and 0% fecal contamination. The quality of the meat inspection is conducted by the official veterinarian by checking 100 carcasses including organs per line per shift after post mortem inspection. If non-compliances exceed the performance standards then additional instructions are given to the staff and the frequency of checks is increased.

In 2011 the DVFA revisited the standards and made changes.

Main changes in the new performance standards:

- The standard is covering the overall performance monitoring of the whole meat organization, however the daily check of the official auxiliaries is not part of this standard. Their performance continues to be checked daily by the official veterinarian, but it is no longer considered a performance standard.
- Greater focus on evaluation and corrective actions
- Key performance indicators to compare between slaughterhouses
- New sample frequencies according to the principles in DS/ISO 2859-1
- New procedures for supervision

Number of samples:

- Number of samples is statistically calculated and depends on the number of pigs slaughtered at a particular slaughterhouse. One sample consists of 'one animal' i.e. ante-mortem, post-mortem (carcasses, plucks, intestines, etc.) inspection and inspection on the rework platform.

- At a minimum 5 procedures for each sample. The supervisor makes an inspection of the procedures (palpation, incision, behavior), and the supervisor makes an ordinary inspection of carcasses which have already been through post-mortem control to make sure the right decisions are made by the inspectors.
- If food safety is compromised there will be an immediate correction. Furthermore there will be a monthly evaluation. At the monthly evaluation a 3% differentiation is accepted without changing sample size. If more than 3% the frequency will go up. Focus will be on follow-up to make sure the right corrective actions are made.

Other verification procedures:

- The absence of visible fecal contamination is monitored on a daily basis. The inspection is done after post-mortem inspection but before the carcasses enter the chilling room.
- Evaluation of individual staff members takes place every third year and is used as a tool for development of the individual staff member. *This does not pertain to slaughter establishments so it plays no role in a determination of equivalence for this program. It is only relevant to small food businesses, i.e., restaurants.
- The official veterinarian checks the work of official auxiliaries on a daily basis.

Denmark has observed that these performance standards have been a viable tool to supervise and assess the quality of the meat inspection at each slaughterhouse. There are no changes in the verification programs and this was verified by e-mail correspondence on January 17, 2014.

The Danish risk assessment verified that when an official inspector finds ingesta and/or bile on one organ it is linked to other organs (other pluck and visceral offal) and the carcass. This could cause concern regarding generalized sanitary dressing procedures. In this case the food business operator and the official inspectors heighten their focus on the dressing procedures. Corrective actions and preventive measures will be implemented as needed, and will be verified by the official inspector.

FSIS asked Denmark if DVFA provides for inspection during processing, and if the official personnel are trained to identify pathology of the liver during further harvesting procedures. Denmark responded that the meat inspection is sufficient and meets all relevant requirements. The standards and verification procedures that Denmark has implemented are viable tools to assess the meat inspection and secure food safety. There is an on-going and monthly evaluation of the Key Performance Indicators with focus on corrective actions.

Denmark has implemented a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects. Therefore, this criterion meets FSIS requirement.

RECOMMENDATION:

FSIS has determined that Denmark's request for an equivalence determination for an alternative post-mortem inspection i.e. visual inspection instead of palpation of lungs and liver and their associated lymph nodes of slaughtered market hogs meets the established criteria. Therefore, Denmark's equivalence request should be granted.