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 assessment[1] 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

Sally White

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

(b) (6)
Chief Veterinary Officer
Danish Veterinary and Food Administration
Mørkhøj Bygade 19
DK–2860 Søborg

Dear (b) (6)

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,

Sally White JD

Sally White
Director
International Equivalence Staff
Office of International Affairs

CC:
Steve Huete, Agricultural Attaché, American Embassy, The Hague
(b) (6) [redacted], Minister Counselor, Royal Danish Embassy
(b) (6) [redacted], Director, Directorate E, European Commission, Brussels
(b) (6) [redacted], Counselor, Food Safety and Consumer Affairs, EC
(b) (6) [redacted], EC, DG SANCO - Directorate General for Health and Consumers
Alfred Almanza, Administrator, FSIS
Lisa Wallenda Picard, OA, FSIS
Ronald Jones, Acting Assistant Administrator, OIA
(b) (6) [redacted], EB, State
David Young, Europe Area Director, FAS
Donald Smart, Director, IAS, OIA
Phil Derfler, Assistant Administrator, OPPD
Daniel Engeljohn, Deputy Assistant Administrator, OPPD
Sally White, Director, IES, OIA
Director, IID, OIA
Barbara McNiff, Director, FSIS Codex Programs Staff, OIA
Rick Harries, Director, EPS, OIA
David Smith, OIA, IES
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:

Sally White JD 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		12/18/08.
Dr. Bob Ragland	Bob Ragland	12/18/2008
Dr. David Smith, IES, OIA		12/18/08
Todd Furey, IES, OIA		12/18/2008

Smith, David

From: (b) (6) ((b) (6) 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,

(b) (6)

/ (b) (6) UM.DK
MINISTER COUNSELLOR / FOOD, AGRICULTURE AND FISHERIES DIRECT +1 (202) (b) (6) / CELL (202) (b) (6) FAX (202) 328-1470 ROYAL DANISH EMBASSY / MINISTRY OF FOREIGN AFFAIRS OF DENMARK 3200 WHITEHAVEN ST., N.W. / WASHINGTON, D.C. 20008 PHONE +1 (202) 234-4300 / WWW.DENMARKEMB.ORG

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

FSIS

DIVISION FOR MICROBIOLOGICAL
FOOD SAFETY, HYGIENE
AND ZOONOSES CONTROL

20.11.2008
File: 2008-20-23-02391/(b) (6)

Summary

Visual inspection of fattening pigs – Conference call 14 November 2008

Participants FSIS, USA:
- Todd Furey, FSIS, OIA (TF)
- Fransisco Gonzales (FG)
- David Smith, FSIS, OIA (DS)

Participants, Denmark:
- (b) (6) DVFA (b) (6)
- (b) (6) DMA (b) (6)
- (b) (6) DMA (b) (6)
- (b) (6) , DMA (b) (6)
- (b) (6) DMA (b) (6)

Participants,TheRoyalDanish Embassy, Washington, DC
- (b) (6)

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

(b) (6) 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

(b) (6) 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?

(b) (6) 5 months

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

(b) (6) 90 % - 21. millions

(b) (6) It will be ensured, that pigs raised outdoor etc. will undergo traditional meat inspection.

(b) (6) 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?

(b) (6) 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?

(b) (6) 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?

(b) (6) 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 (b) (6) (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?

(b) (6) 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?

(b) (6) 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?

(b) (6) 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?

(b) (6) As quickly as possible

(b) (6) 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

(b) (6) 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?

(b) (6) We shall describe the production system we have for pigs, including Quality Standards for pig production in Denmark and Code of practice.

Yours faithfully

(b) (6)
Senior veterinary officer, DVM
Direct tel. +(b) (6)
E-mail (b) (6)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 ZOONOSES CONTROL

10.10.2008
File: (b) (6)

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:
- (b) (6) (b) (6) (b) (6)

Participants, Denmark:
- (b) (6) DVFA (b) (6)
- (b) (6), DMA (b) (6)
- (b) (6) DMA (b) (6)
- (b) (6), DMA (b) (6)
- (b) (6) DMA (b) (6)

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

(b) (6) 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.

(b) (6) 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

(b) (6) 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 delisting 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 foodborne.

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

(b) (6) 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?

(b) (6) 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.

(b) (6) stated that it will be possible to make use of the hygiene data (E. coli) – before and after introduction of visual inspection.

(b) (6) asked FSIS about the exact requirements for documentation included in the pending, official Danish request for equivalence approval by FSIS. (b) (6) 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 ZOONOSES CONTROL

02.07.2008
File: 2008-20-23-02391/(b) (6)

RESUME

30. juni 2008

(b) (6)

Visual inspection of fattening pigs – Telephone conference
23 June 2008

(b) (6)

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

- (b) (6) (b) (6) ((b) (6)
- (b) (6) (b) (6)

Participants, Denmark:

- (b) (6) DVFA ((b) (6) fvst.dk)
- (b) (6), National Food Institute ((b) (6) food.dtu.dk)
- (b) (6) DMA ((b) (6) danishmeat.dk)
- (b) (6), DMA ((b) (6) danishmeat.dk)
- (b) (6) DMA ((b) (6) 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

(b) (6) 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.

(b) (6) introduced the Danish participants and TF introduced the American participants.

Ad 3 Description of project on visual inspection of fattening pigs

Time table (b) (6)

Traceability (b) (6)

Study 1 – Status for heart and lymph node study (b) (6)

Tuberculosis (b) (6)

Study 2 - Pilot study (b) (6)

Performance standards (b) (6)

Traditional inspection versus visual inspection (b) (6)

Status and further process (b) (6)

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 weaning[1].

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?

Demark 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 Rhodococus 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 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 (b) (6) 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

(b) (6)
Senior veterinary officer,DVM
Direct tel. +(b) (6)
E-mail (b) (6) 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

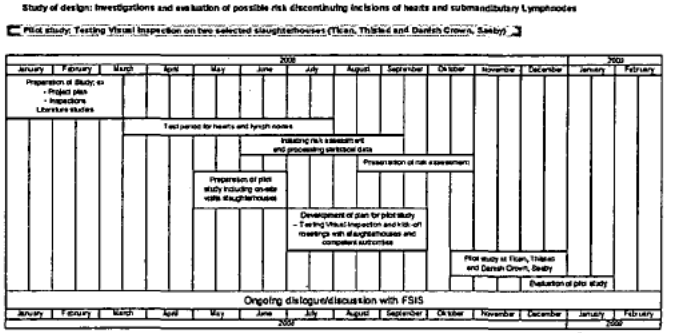
Ministry of Food, Agriculture and Fisheries
Danish Veterinary and Food Administration

Participants from Denmark

- (b) (6)
  - DVM, Senior Veterinary Officer, DVFA
- (b) (6)
  - DVM, Ph.D., Research leader, Senior Scientist, National Food Institute
- (b) (6)
  - DVM, Ph.D., Dipl. ECVPH, DMA
- (b) (6)
  - DVM, Senior Specialist, DMA
- (b) (6)
  - Food Scientist, Specialist, DMA

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

Time table



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

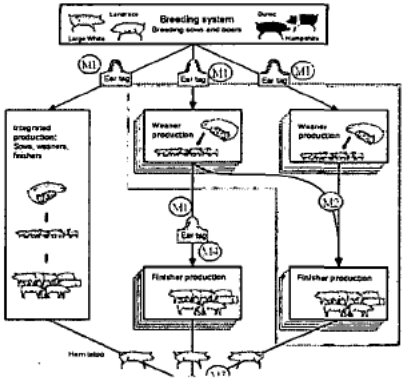
Food chain information

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

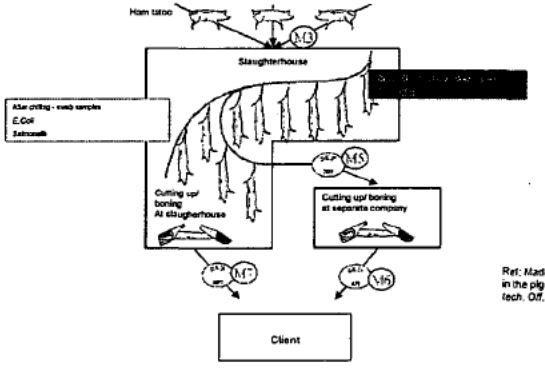
Traceability - Stable



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

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

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

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 generel
  - 0% fecal contamination

Ministry of Food, Agriculture and Fisheries
Danish 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 documentaton and reestablishing the standard

Ministry of Food, Agriculture and Fisheries
Danish 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
Danish 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

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 regulation[2] 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-compliance[3]				
	OK	Not OK Describe non-compliance	Follow-up action	
Inspection of head				
Incision of the mandibullar 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 mestenterial 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-compliances[2]				
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-compliance[3]				
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% fejl[4]				
	OK	Ikke OK - beskriv det observerede	Opfølgning	
Hovedkontrollør:				
Foretages opbladring af de mandibulære lymfeknuder?				
Inspiceres hoved og svælg?				
Kropskontrollør:				
Inspiceres slagtekroppens indvendige og udvendige flader inkl. brysthinde og				
Tarmkontrollør:				
Inspiceres hele tarm-sættet?				
Palperes krøslymfek-nuder?				
Inspiceres milt?				
Fratages 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 % fejl[2]				
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% fejl[3]				
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.

ANNEX 2

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 ±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 ± 4% = 7% ± 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* 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. Veteirn
ary Epidemiology – Principles and Methods. Iowa State University. Ames, Iowa. 22-47.

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 generel
  - 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 documentaton 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 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
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

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 tuberculination 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 fisher 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 assessement (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) 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).

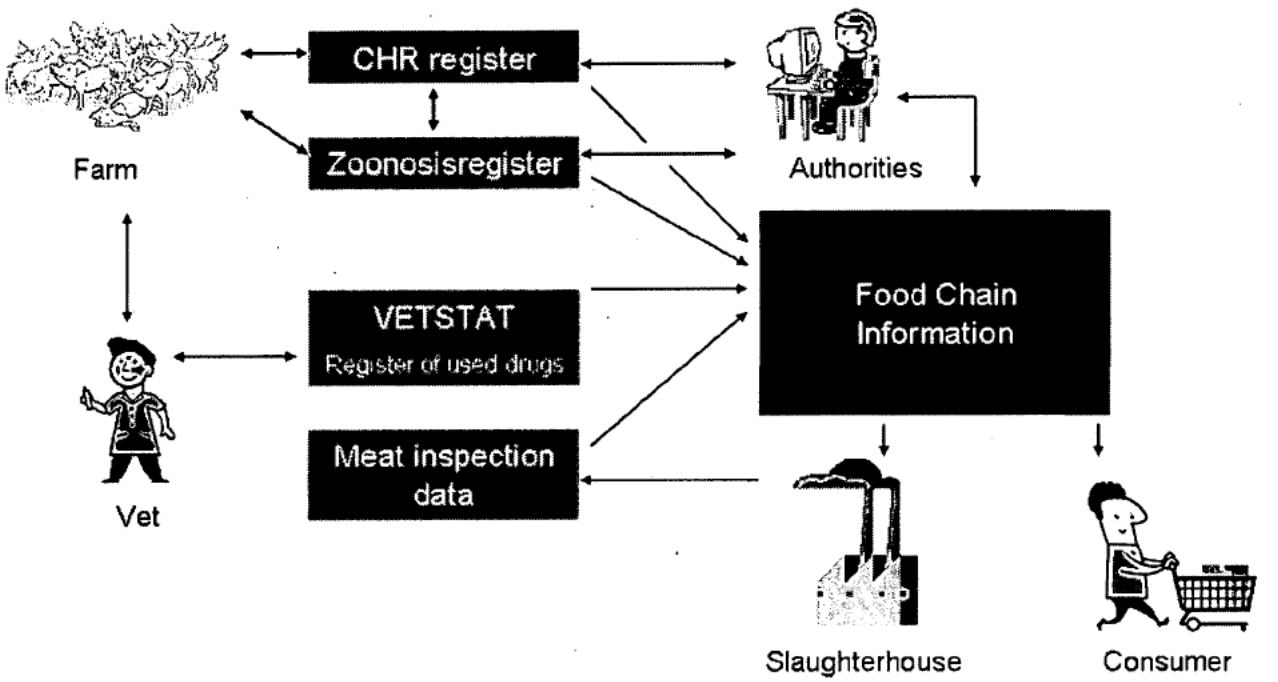


Figure 1
Description of the connection between collection of food chain information during animal production and the slaughterhouse, Denmark, 2008

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: (b) (6) (b) (6) [(b) (6) 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,

(b) (6)

(b) (6) / (b) (6) UM.DK
MINISTER COUNSELLOR / FOOD, AGRICULTURE AND FISHERIES
DIRECT +1 (202) (b) (6) / CELL (202) (b) (6) FAX (202) 328-1470
ROYAL DANISH EMBASSY / MINISTRY OF FOREIGN AFFAIRS OF DENMARK
3200 WHITEHAVEN ST., N.W. / WASHINGTON, D.C. 20008
PHONE +1 (202) 234-4300 / WWW.DENMARKEMB.ORG

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

FSIS

DIVISION FOR MICROBIOLOGICAL
FOOD SAFETY, HYGIENE
AND ZOONOSES CONTROL

02.07.2008
File: 2008-20-23-02391/(b) (6)

RESUME

30. juni 2008

(b) (6)

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
- (b) (6) (b) (6) (b) (6)
- (b) (6) (b) (6)

Participants, Denmark:
- (b) (6) DVFA ((b) (6) fvst.dk)
- (b) (6), National Food Institute ((b) (6) food.dtu.dk)
- (b) (6) DMA ((b) (6) danishmeat.dk)
- (b) (6) DMA ((b) (6) danishmeat.dk)
- (b) (6) DMA ((b) (6) 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

(b) (6) 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.

(b) (6) introduced the Danish participants and TF introduced the American participants.

Ad 3 Description of project on visual inspection of fattening pigs

Time table ((b) (6)

Traceability ((b) (6)

Study 1 – Status for heart and lymph node study ((b) (6)

Tuberculosis ((b) (6)

Study 2 - Pilot study ((b) (6)

Performance standards ((b) (6)

Traditional inspection versus visual inspection ((b) (6)

Status and further process ((b) (6)

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 weaning[1].

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?

Demark 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 Rhodococus 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 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 (b) (6) 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

(b) (6)
Senior veterinary officer,DVM
Direct tel. +(b) (6)
E-mail (b) (6)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

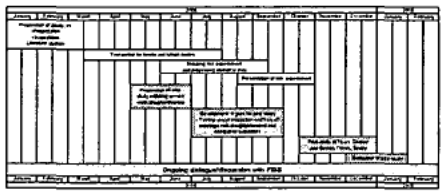
Agenda

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

- (b) (6)
  - DVM, Senior Veterinary Officer, DVFA
- Soren Anbo
  - DVM, Ph.D., Research leader, Senior Scientist, National Food Institute
- (b) (6)
  - DVM, Ph.D., Dipl. ECVPH, DMA
- (b) (6),(b) (6)
  - DVM, Senior Specialist, DMA
- (b) (6)
  - Food Scientist, Specialist, DMA

Time table



Traceability in the danish pig production

A precondition for our meat inspection

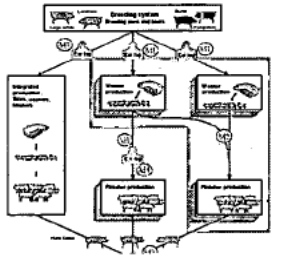
- Covered by a registration, marking and documentation system including:
  - All pig herds are registered with a herd number ***(CHR-number)*** in the Central Register of Domestic Animals
  - Information is exchanged in all parts of the chain ***(food chain information)*** from producer to slaughterhouse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

Food chain information

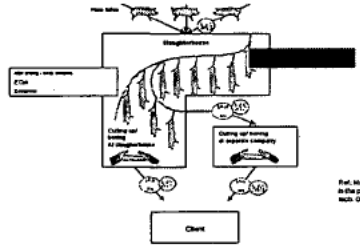
Relevant information provided:

- 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



Traceability - Table



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

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

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 ?

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 auxilliaries (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: (b) (6) (b) (6) [(b) (6) 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 Supplu 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,

(b) (6)

(b) (6) / (b) (6) UM.DK
MINISTER COUNSELLOR / FOOD, AGRICULTURE AND FISHERIES
DIRECT +1 (202) (b) (6) / CELL (202) (b) (6) 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

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: (b) (6) (b) (6) <(b) (6) 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,

(b) (6)

(b) (6) (b) (6) / (b) (6) UM.DK <mailto(b) (6) UM.DK> MINISTER COUNSELLOR / FOOD, AGRICULTURE AND FISHERIES DIRECT +1 (202) (b) (6) / CELL (202) (b) (6) FAX (202) 328-1470

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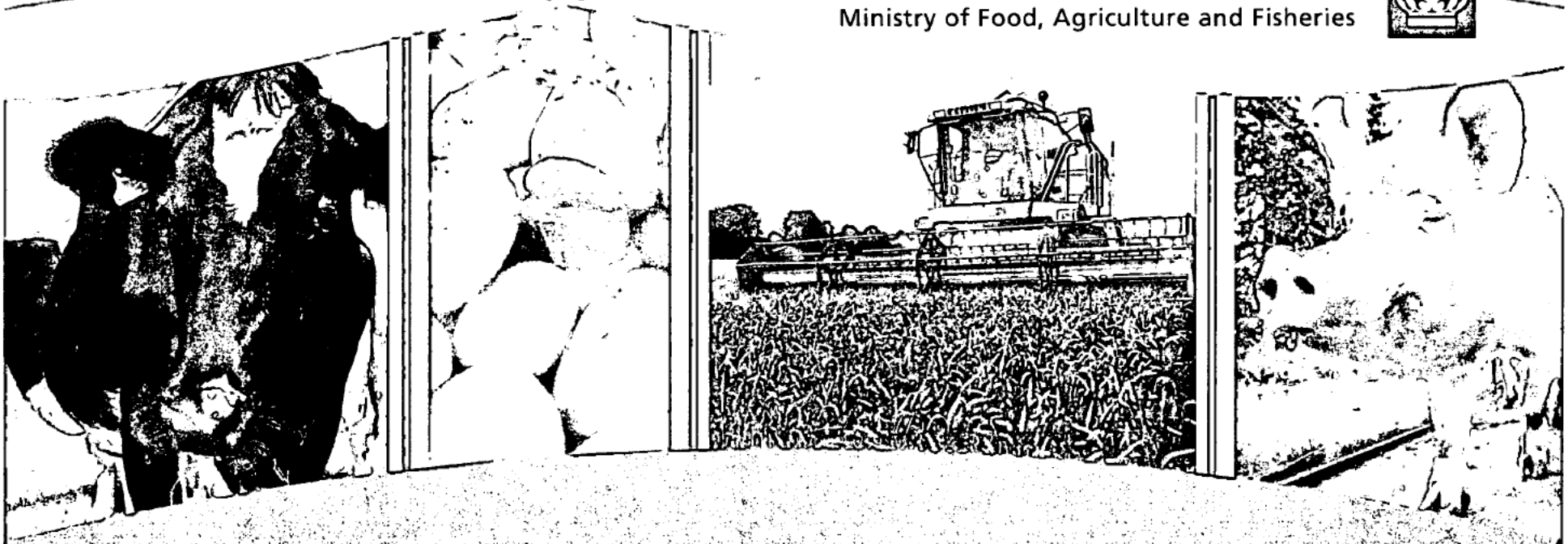
Ministry of Food, Agriculture and Fisheries



How will Meat Inspection change?

(b) (6)
Senior Veterinary Officer, DVM
DVFA

		INSPECTION SYSTEMS	
	Subject	**Traditional meat inspection**	**Supply chain meat inspection**
Prerequisites	Animal health and zoosanitary status	Denmark is officially free from TB	
	Origin of the pigs	Born and raised in Denmark	
	Delivery of pigs for slaughter	All pigs + sows and boars	Only finishers from integrated production systems and 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	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
	Standardized government verification program of the quality of the post mortem inspection – performance standard	*Introduced from January 1 2009* *Ensuring the performance for inspection tasks as well as pathological findings by the official meat inspection*	*Introduced from January 1 2009* *Ensuring the performance for inspection tasks as well as pathological findings by the official meat inspection*

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	- Precondition - Preliminary Schedule - Evaluation and verification	*Precondition* 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 *Preliminary Schedule* - Implementing stepwise – starting with two selected slaughterhouses – January 2009 ? - Stepwise at other slaughterhouses *Evaluation* - Close follow up on the performance in the two selected slaughterhouses	

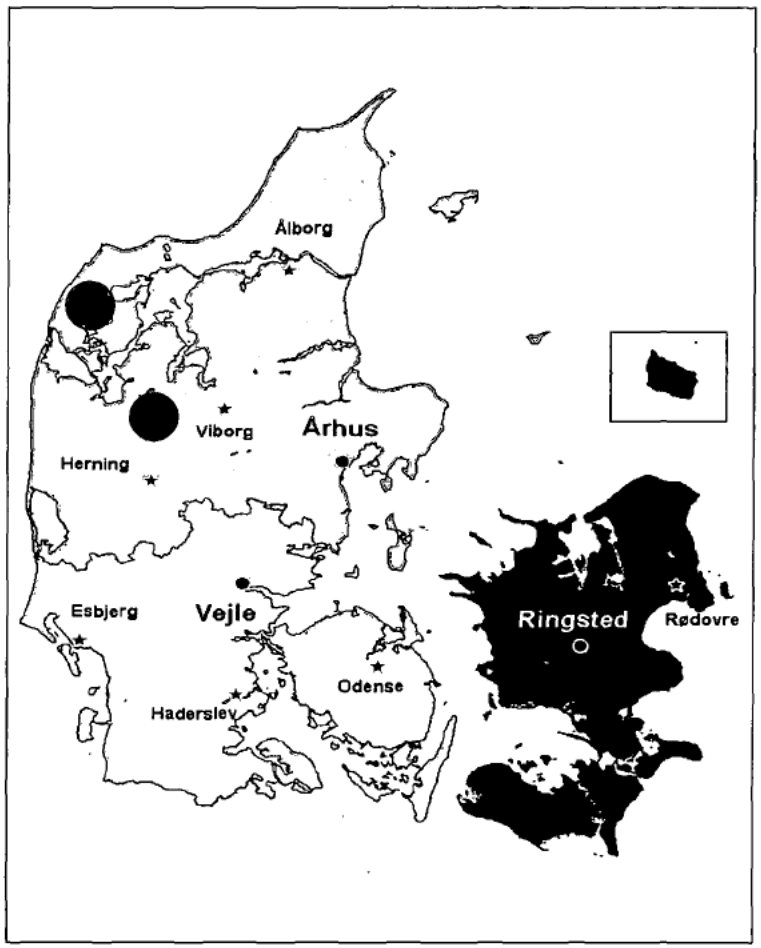
Implementation plan

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

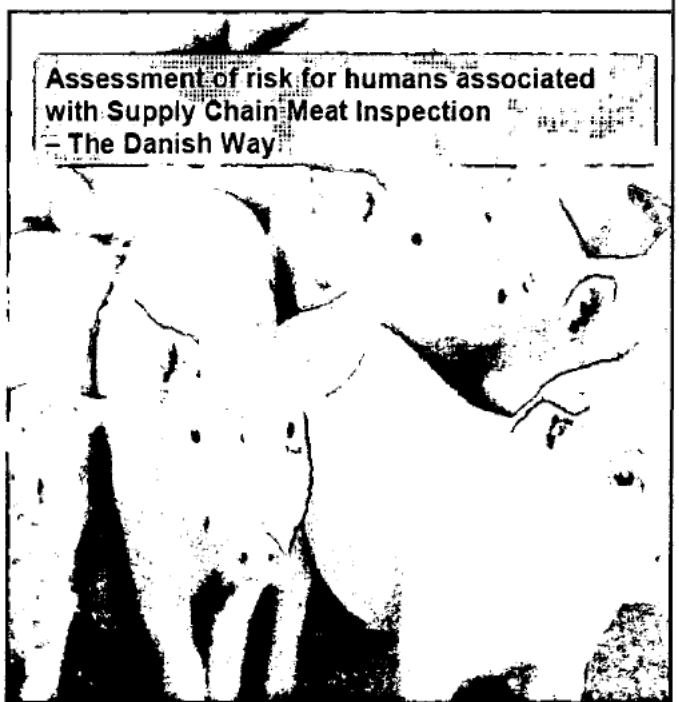
First two months

- 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

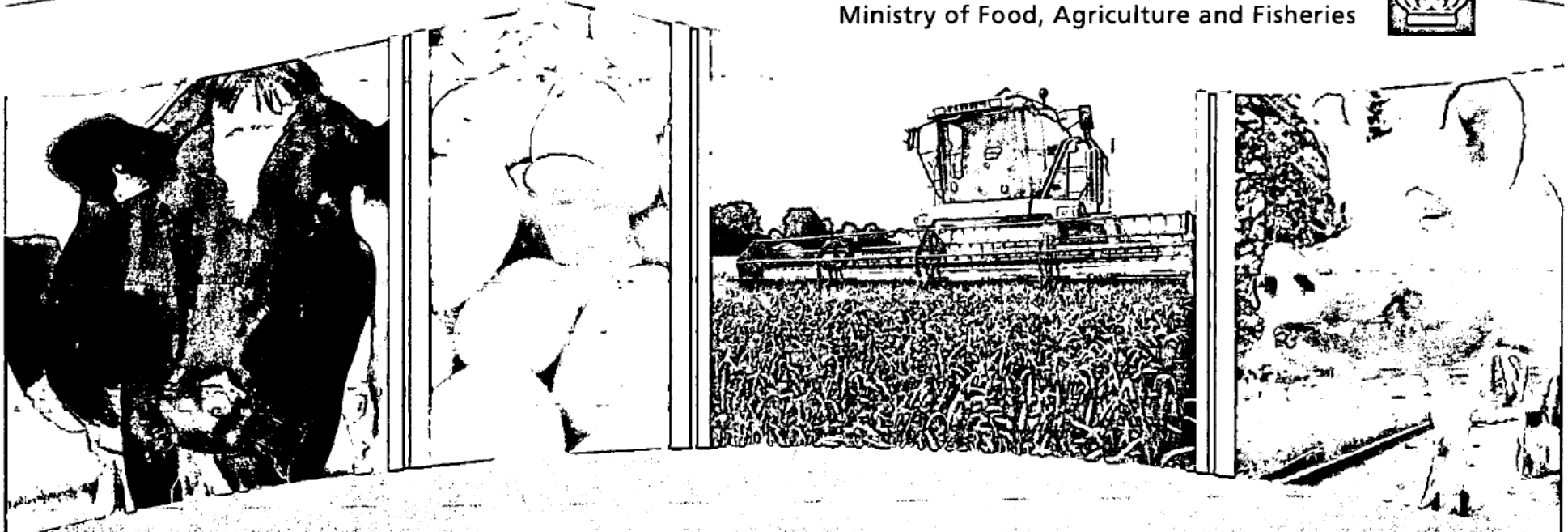
Ongoing

- 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)

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

(b) (6) Deputy Director General, Danish Veterinary and Food Administration

Meeting on December 16 th 2008

Participants from Denmark

- Mrs. (b) (6) Deputy Director General, Danish Veterinary and Food Administration
- Mrs. (b) (6) Senior Veterinary Officer, DVM, Danish Veterinary and Food Administration
- Mr. (b) (6) Deputy CEO, DVM, PhD, Danish Meat Association
- Ms. (b) (6) 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 ([redacted] DVFA)
2. The Danish pig production system ([redacted] DMA)
3. Supply chain meat inspection - risk assessment ([redacted] DMA)
4. How will the meat inspection change? Comparing traditional and supply chain inspection ([redacted] 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

- 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

Farm

CHR register

Zoonosisregister

Authorities

Food Chain Information

VETSTAT
Register of used drugs

Vet

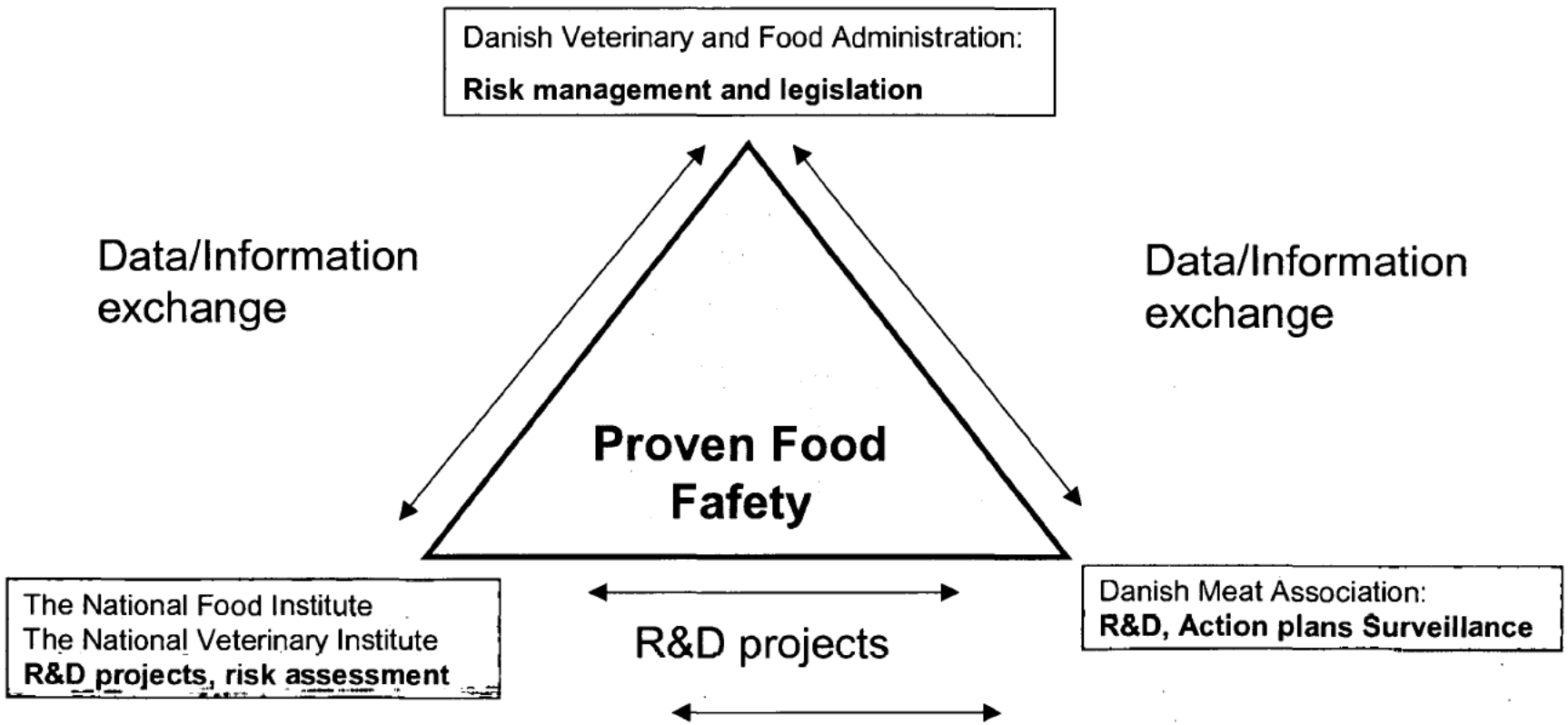
Meat Inspection Data

Indoor / Outdoor information

Slaugtherhouse

Consumer

High Food Safety Standards



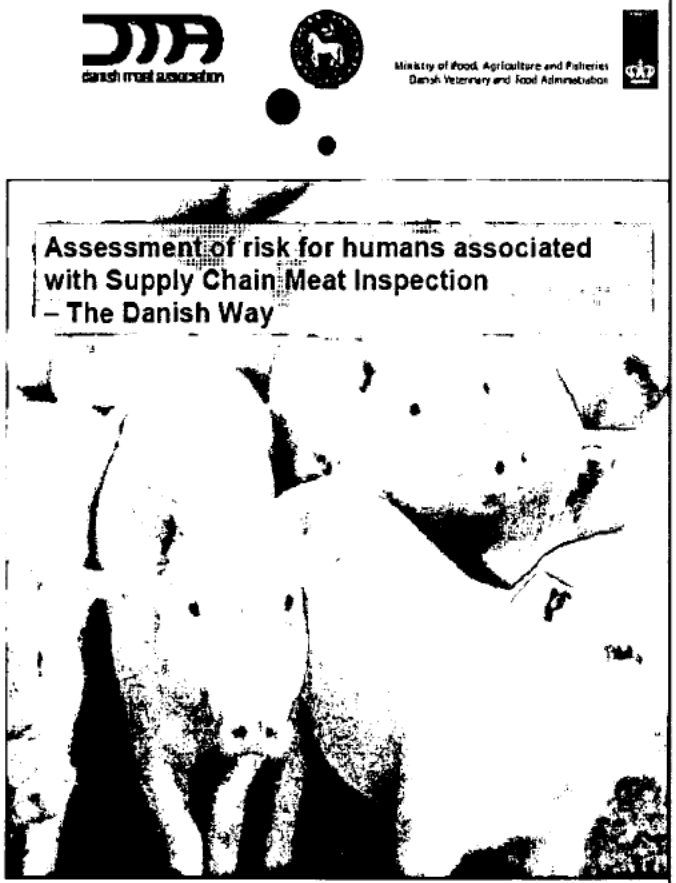
Supply Chain Inspection – the Danish Way

- 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 litterature 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 proces will be followed closely by the DMA and DVFA. Supply chain meat inspection can then be introduced stepwise on pig slaughterhouses in DK

END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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

danish meat association

Supply Chain Meat Inspection
Danish Pig Production - Stable to Table

(b) (6)
Deputy Director General, DVM, PhD
Danish Meat Association

15 Dec. 2008

danish meat association

Danish Pigmeat Industry

2007

7.200 farms with pigs
(1.000 - 3.000 pigs per farm medium size)

26.3 m pigs produced
2.0 m tonnes of pig meat

Value: 18.1 DKK bill

Live export
4.9 m pigs

Slaughtering:
Private slaughterhouses:
1.7 m
Cooperative slaughterhouses:
19.6 m
0.85% -organic/ free range

Export: 90 %
27.5 DKK bill

Domestic:
10 %
3.0 DKK bill

Value: 30.5 DKK bill

15 Dec. 2008

Pig Production System in Denmark

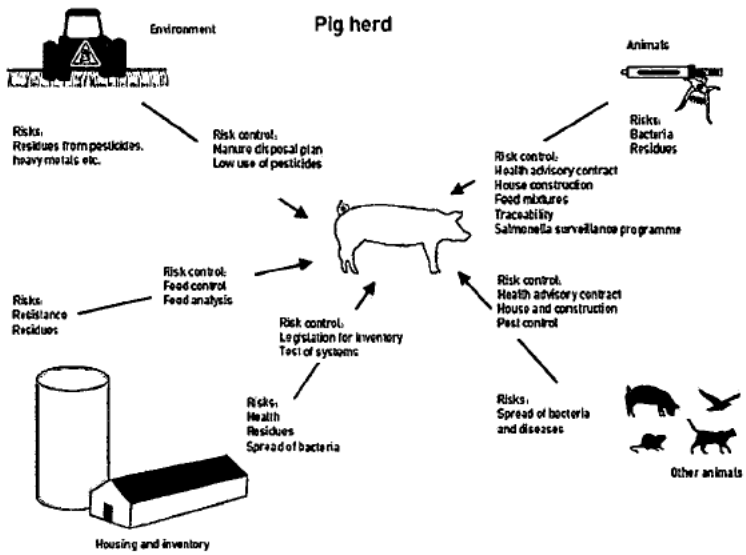
danish meat association

- 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

danish meat association



15 Dec. 2008

Traceability in the Danish pig meat production

danish meat association

- 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

Traceability – Stable to table (1)

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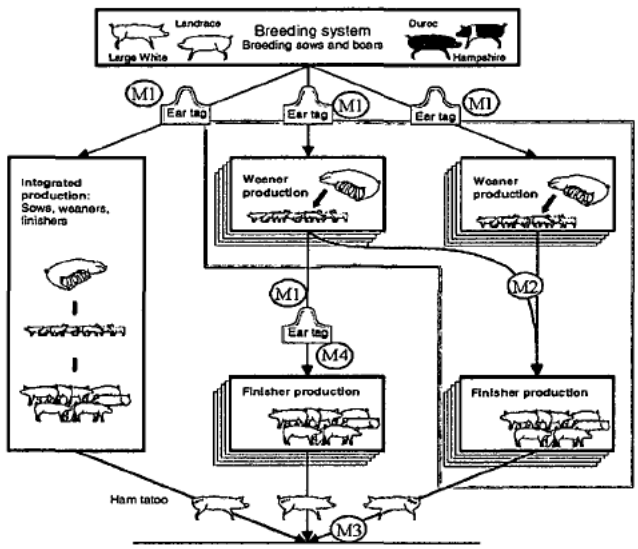

Ref: Madec, F. (2001). – Traceability in the pig production chain. *Rev. sci. tech. Off. Int. Epiz.*, **20** (2)

Traceability – Stable to table (2)

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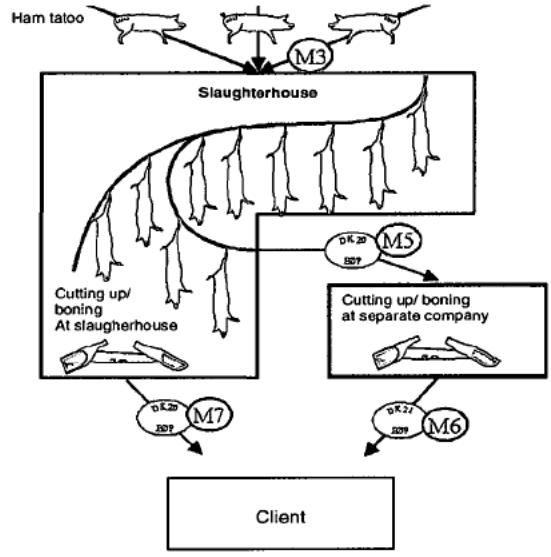

Ref: Made, F. (2001). – Traceability in the pig production chain. *Rev. sci. tech. Off. Int. Epiz.*, **20** (2)

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Traceability – Danish pig production

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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

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Food Chain Information

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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

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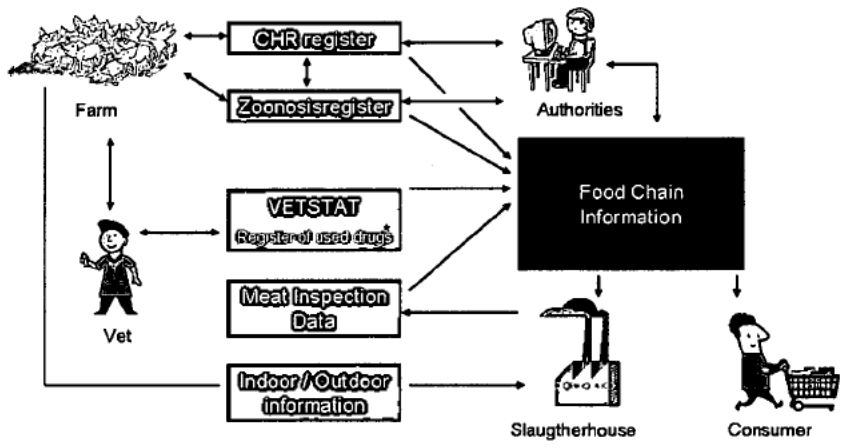
Food Chain Information The Danish Way

danish meat association



* Prescribed medicine

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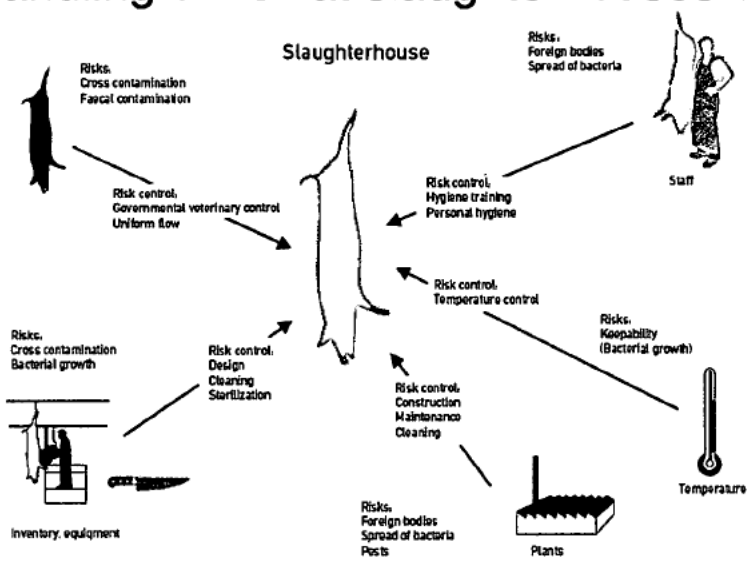
Handling of risk at slaughterhouses

danish meat association



The Danish Salmonella Control Program

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- 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

Salmonella control program – Number of human cases in Denmark

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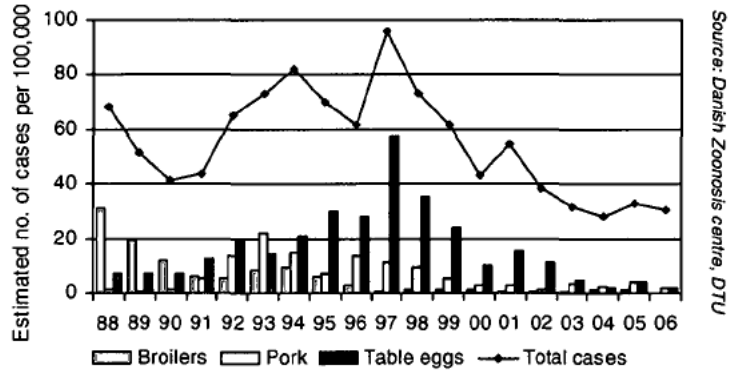

Figures for 2007 not released yet. Further decline demonstrated

High Food Safety Standards – The Danish Way

danish meat association

Danish Veterinary and Food Administration:
Risk management and legislation

Data/Information exchange

Data/Information exchange

Proven Food Safety

Technical University of Denmark
R&D projects, risk assessment

R&D projects

Danish Meat Association:
R&D, Action plans, Surveillance

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

danish meat association

Risk for humans associated with Supply Chain Meat Inspection

(b) (6)

Chief Scientist for Risk Assessment

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

Danish Meat Association

Introduction

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- 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

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- 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

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- 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

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- 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
  - (b) (6) Royal Veterinary College, London
  - (b) (6) Norwegian School of Veterinary Science, Oslo
  - (b) (6) Norwegian School of Veterinary Science, Oslo
    - Comments incorporated into report

Method

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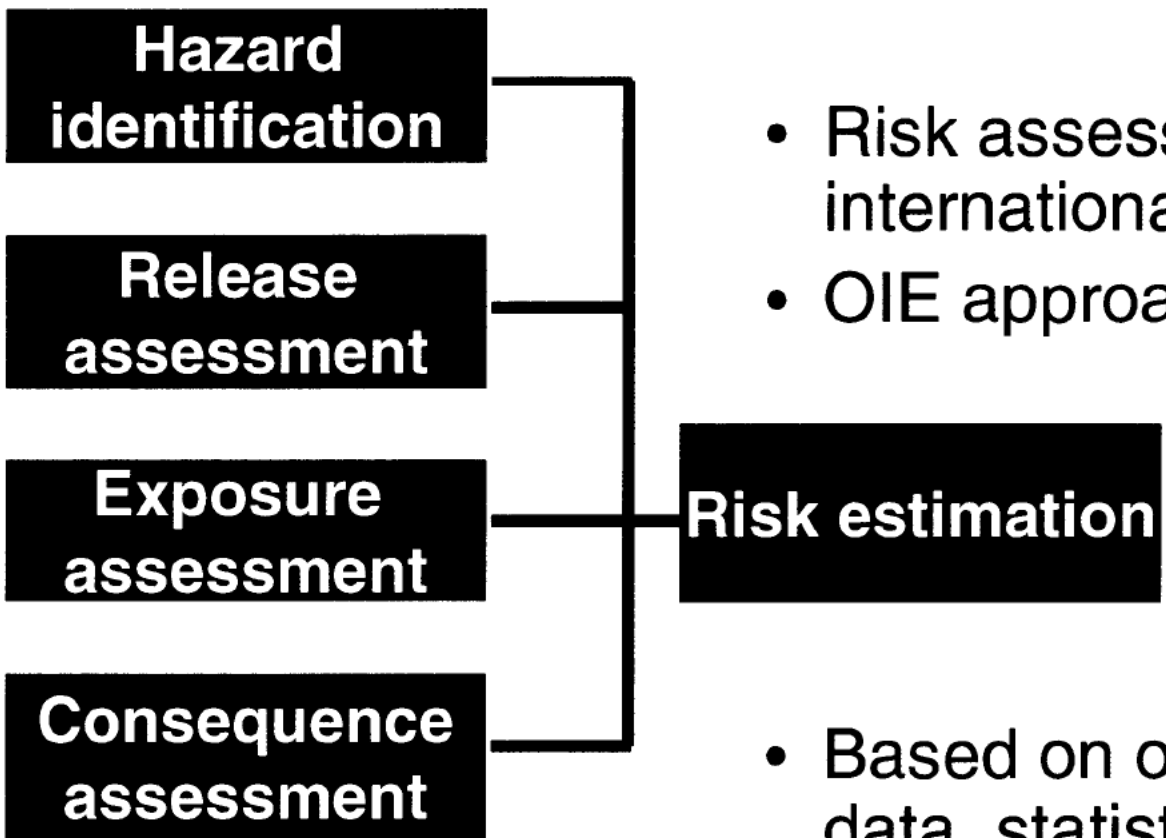

- Risk assessment following international guidelines
- OIE approach used

- Based on own collected data, statistics, literature and expert opinion

Results - Lymph nodes

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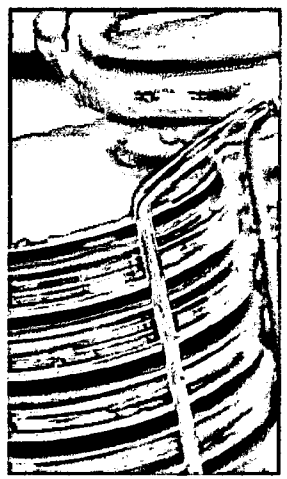
- Bovine tuberculosis (TB) main hazard
  - Denmark has free status since 1980
- TB-like lesions in 0.01% to 0.02% of lymph nodes
  - Primarily due to *Rhodococcus equi*
- Avian TB occasionally observed in Denmark
  - Wild birds, but also zoo-birds and backyard-birds
    - Very low prevalence in pigs
- 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

danish meat association

Meat inspection circular

- Lesions found in other lymph nodes than mandibular and mesenterial => 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

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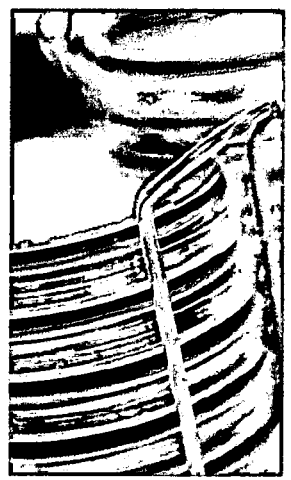
- Endocarditis main lesion of interest
  - Found in 0.01% of hearts



- 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

danish meat association

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

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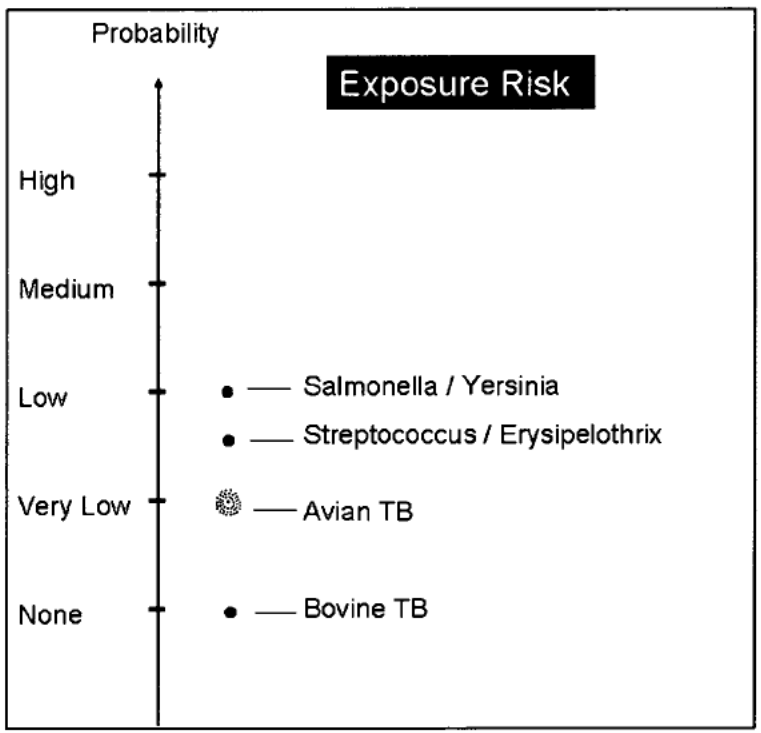

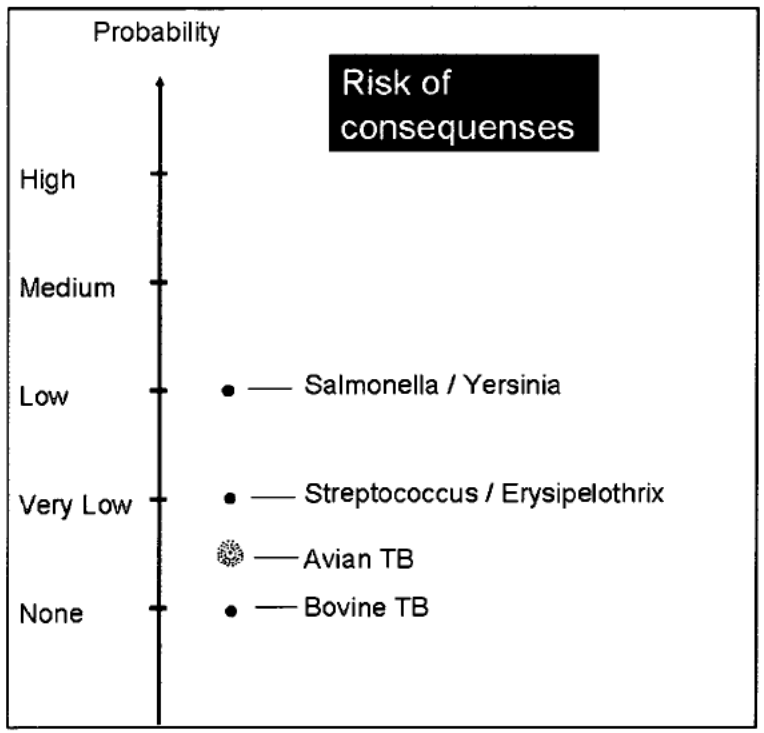

- • = High certainty linked to estimate of probability
- = Some uncertainty linked to estimate

danish meat association

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

List of contents

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) (b) (6) Professor, Veterinary Public Health, the Royal Veterinary College, London,
2) (b) (6) Professor, Food Safety, the Norwegian School of Veterinary Science, Oslo,
3) (b) (6) 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
Lis Alban[1], Charlotte Vilstrup[2], Birthe Steenberg[1], Henrik Elvang Jensen[3],
Bent Aalbæk[3], Flemming Thune-Stephensen[1] and Susanne Jensen[1]

[1] Danish Meat Association, Axelborg, Axeltorv 3, DK-1609 Copenhagen V, Denmark
[2] Danish Veterinary and Food Administration, Mørkhøj Bygade 19, DK-2860 Søborg, Denmark
[3] Department of Disease Biology, Faculty of Life Sciences, University of Copenhagen, Grønnegårdsvej 15, DK-1870 Frederiksberg C, Denmark

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) 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* a 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).

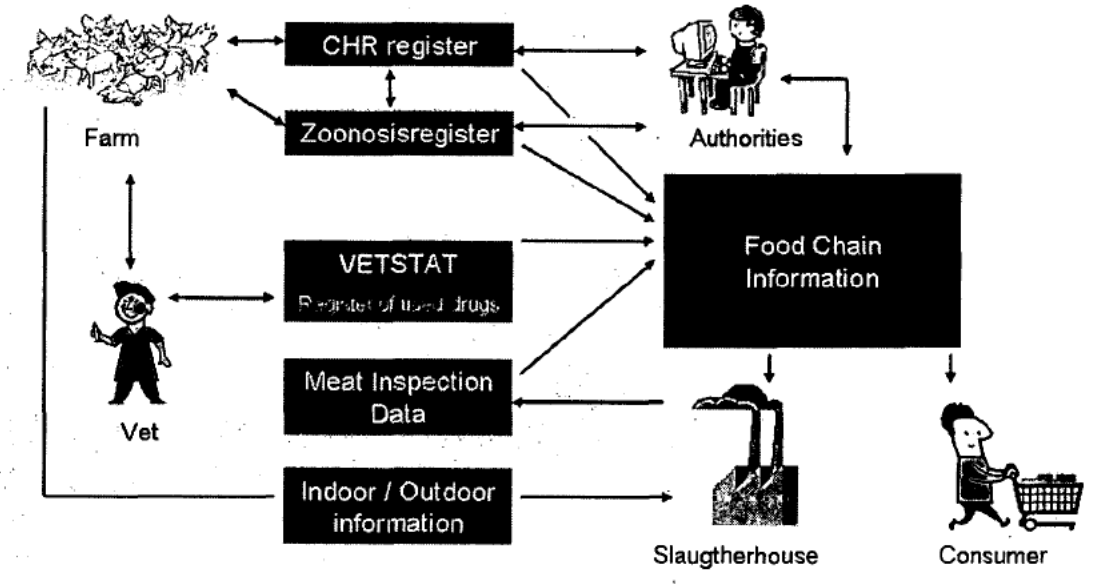

Figure 1
Description of the connection between collection of food chain information during animal production and the slaughterhouse, Denmark 2008

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 physically 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.

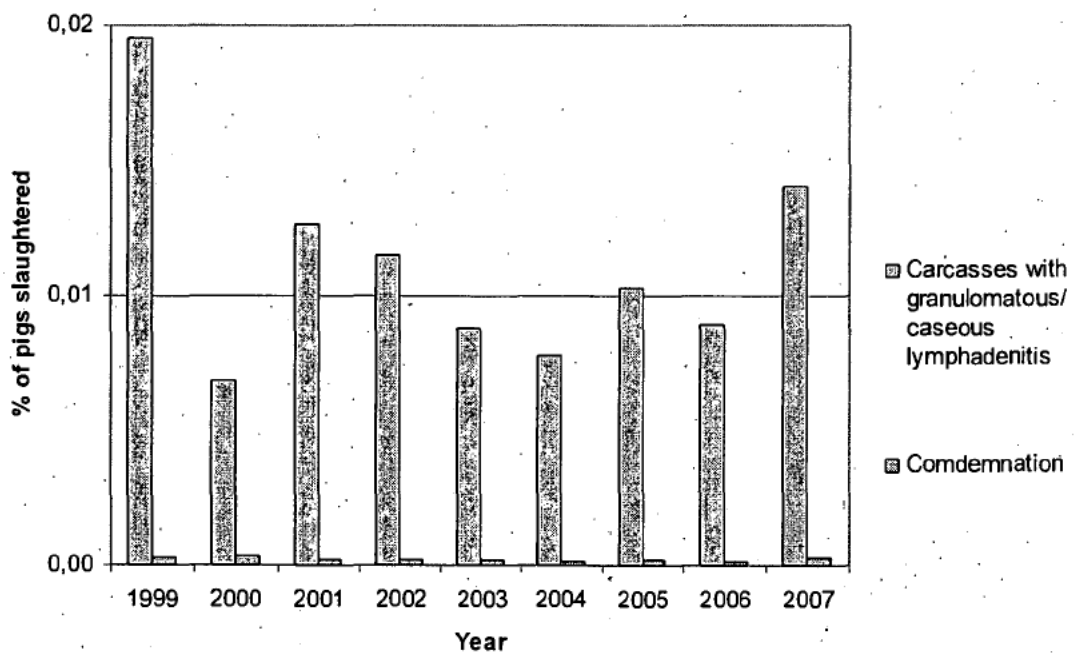

Figure 2
Prevalence of pig carcasses with granulomatous/caseous lymphadenitis and prevalence of condemnation as result of these lesions. Denmark, 1999-2007. Source: Danish Meat Association

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.

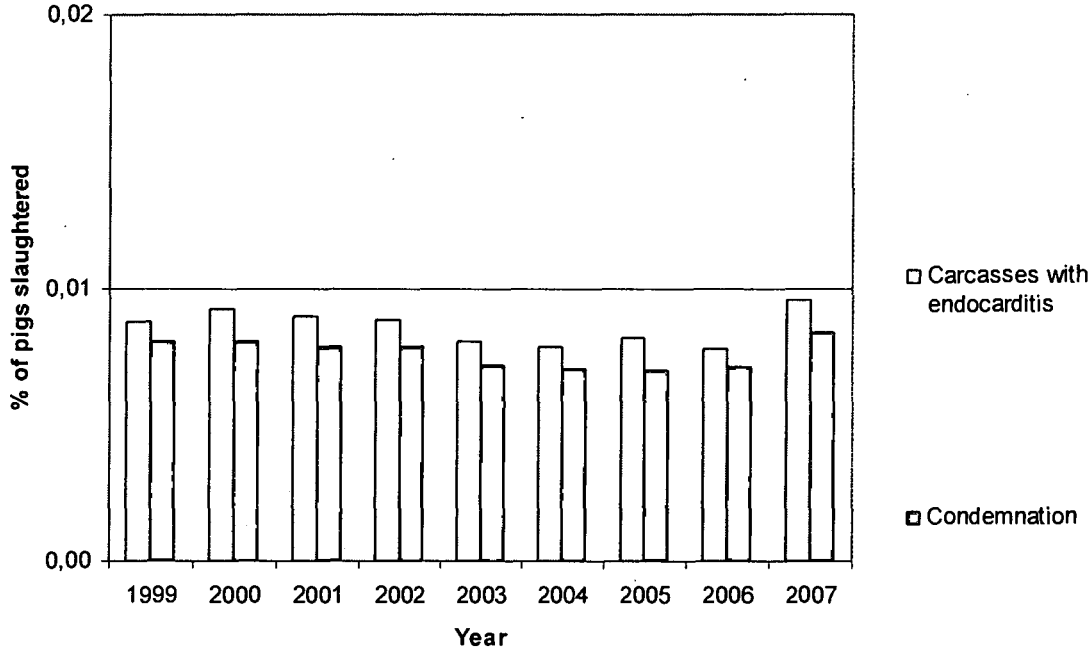

Figure 3
Prevalence of pig endocarditis and the prevalence of condemnation as a result of this finding. Denmark, 1999-2007. Source: Danish Meat Association

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 mesenterial 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 granulosis/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 *Staphyloccous* 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 erysipeloid. 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 is 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 *Mycobacterium* spp.	43 (100)
Rhodococcus equi	27 (63)
Nocardia farcinica	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 revaled 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 mesenterial 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

	No. of hearts with organism (%)	
Organism	With endocarditis	Without endocarditis
Streptococcus suis like	40 (45.5)	
Erysipelothrix rhusiopathiae	28 (31.8)	
Beta-hemolytic *Streptococci**	5 (5.7)	
Mixed culture with *Streptococcus*		2 (3.5)
Lactobacillus garvieae	4 (4.5)	
Proteus		1 (1.8)
Arcanobacterium pyogenes	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, immunosuppresed 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
Streptococcus suis	Mild to Severe
Staphylococcus aureus	Mild
Erysipelothrix rhusiopathiae	Mild
Mycobacterium bovis	Severe
Mycobacterium avium	Severe among vulnerable groups
Campylobacter spp.	Moderate
Salmonella spp.	Moderate
Yersinia enterocolitica	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
Streptococcus suis	<0.02	<1 per year	100%	Occupational hazard	Statens Serum Institut, 2005
Staphylococcus aureus	Not notifiable[b]	Unknown	Unknown	Two routes: Occupational hazard and foodborne[c]	Statens Serum Institut, 2008, Sutherland & Varnam, 2002.
Erysipelothrix rhusiopathiae	Not notifiable[b]	Unknown	Unknown, probably very low[d]	Occupational hazard	Reboli & Farrar, 1989
Mycobacterium bovis	0.05	3 cases – all elderly people	Zero	Reactivation of latent infection acquired long ago	Anon., 2006
Mycobacterium avium	2[e]	100[e]	Unknown, probably close to zero	Primarily environmental exposure	Thomsen et al., 2002
Campylobacter	60	3,242	Minority of cases	Batch cooling after slaughter kills *Campylobacter*	Anon., 2006
Salmonella spp.	30.5	1,658	6.1%	Food-borne	Anon., 2006
Yersinia	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. Eliasen, 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).

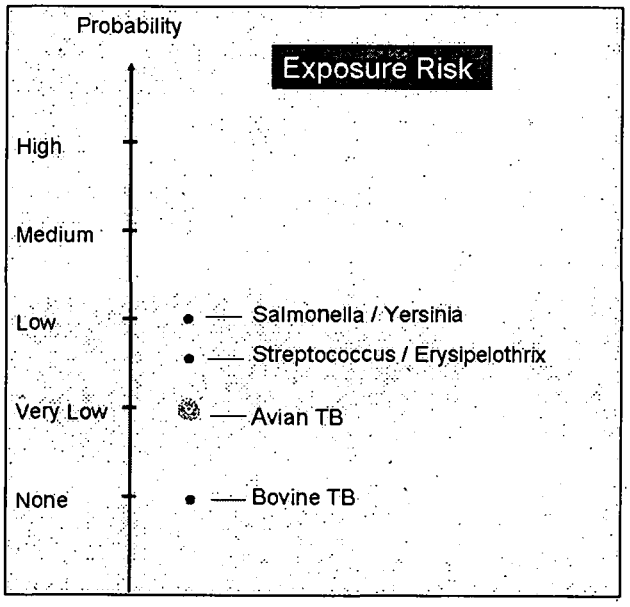

Figure 4
Exposure risk – Probability of exposure of consumers due to consumption of Danish pork, irrespective of type of meat inspection, Denmark 2008

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

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

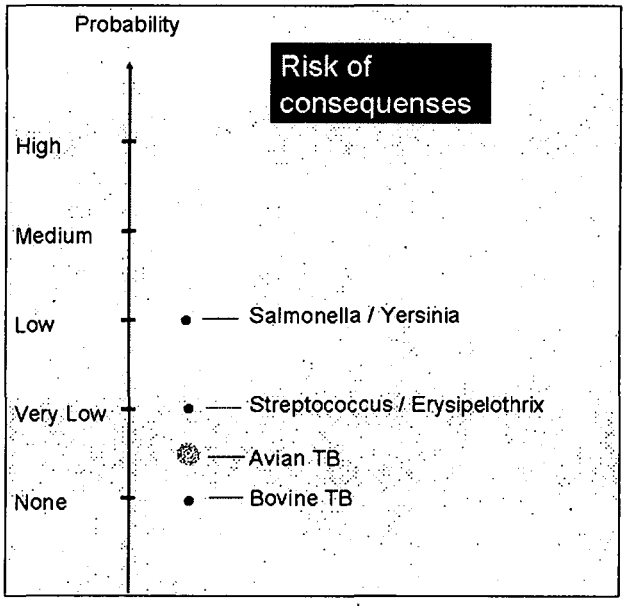

Figure 5
Risk of consequences – Probability of getting ill from consumption of Danish pork, irrespective of type of meat inspection, Denmark 2008

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 mesenterial area of a pig, local condemnation of the affected organ is required. The finding of lesions indicative of tuberculosis outside the head and the mesenterial 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 trombosing 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

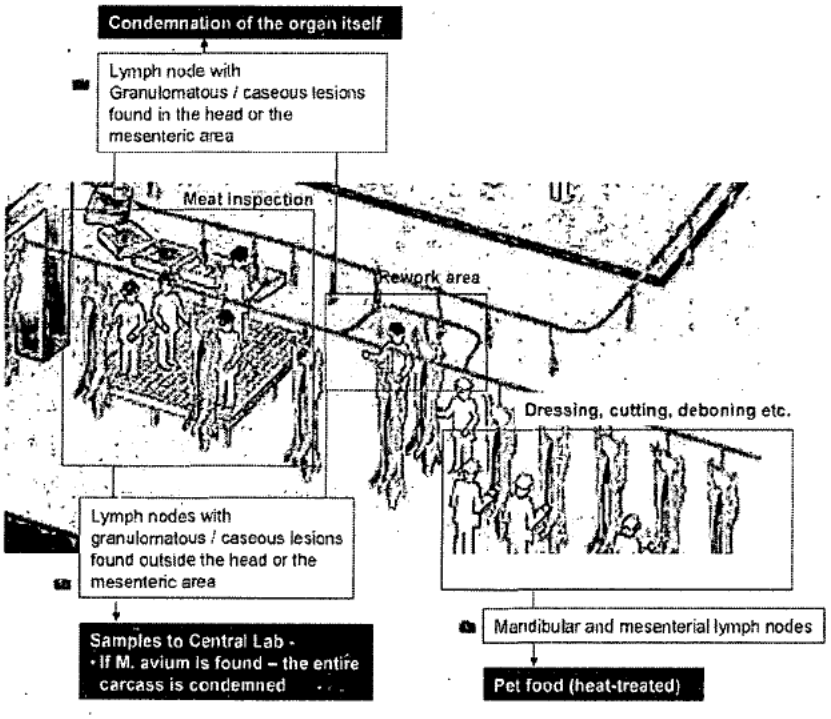

Figure 6
Graphical description of how traditional meat inspection is conducted with respect to the mandibular lymph nodes, Denmark 2008

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.

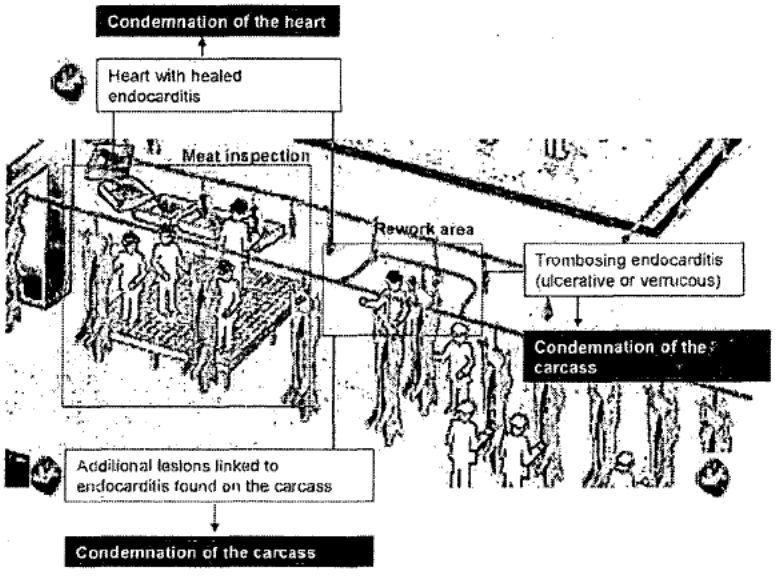

Figure 7
Graphical description of how traditional meat inspection is conducted regarding hearts, Denmark 2008

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 zoosanitary 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 rhusiopatiae*, 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 carcase) 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 is modified to 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 lever might be a differential diagnosis to *M. avium* in the lever (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

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

a. 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
b. Denmark is officially free from bovine Tuberculosis since 1980 (Anon., 2007c)
c. The mandibular lymph nodes are used for pet food after adequate heat-treatment
d. 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, Aujezsky'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 (Bronsvoort et al., 2004; Bronsvoort 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* not *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 lead 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 form 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 (*B. abortus*)	Officially free[b] since 1979	1962
Brucellosis in pigs (*B. suis*)		Outdoor herd 1999 Wild hares 2002
Brucellosis in sheep and goats (*B. melitensis*)		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 physically 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 particularly, 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 physically 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 ensures 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 mesenterial 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 mesenterial 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% *Rhodococcus equi* main cause. 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	Denmark officially free from bovine tuberculosis since 1980. Lymph nodes not eaten but used for pet food only Probably very low probability of exposure to avian tuberculosis and *R. equi*	The number of cases* related to *Salmonella* spp and *Yersinia enterocolitica* will not increase but maybe decrease No risk of bovine tuberculosis Avian tuberculosis and *R. equi* not considered meat-borne	No risk for consumers associated with omission of routine palpation, incision of the mandibular lymph nodes

*: 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% *Streptococcus* spp. and *Erysipelothrix rhusiopathiae* main causes	Low probability of exposure to *Streptococcus* spp. and *Erysipelothrix rhusiopathiae*. Even lower probability if hearts with lesions are disposed of*	*Streptococcus* spp. and *Erysipelothrix rhusiopathiae* are not meat-borne but occupational hazards The number of cases related to *Salmonella* spp and *Yersinia enterocolitica* 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 mesenterial lymph nodes than in the mandibular lymph node, hence, there were very few cases of granulomatous lymphadenitis is 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"

(b) (6) 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 been 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 immunosuppresed 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 Eliasen, 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"

(b) (6) 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 *lnn. 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

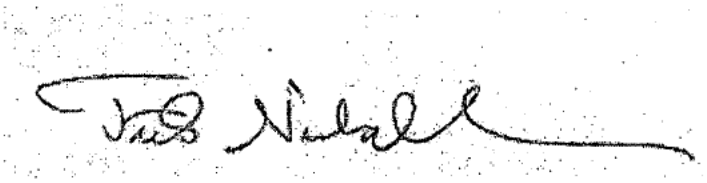
Alfredsen, S.A, 1992. Differentiation between parasitic interstitial hepatitis and mycobacterial lesions in pig livers. Bull. Scand. Soc. Parasitol. 2, 33-35. ***Used in section 6.2.1, The mandibular lymph node, and cited in the reference list***

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., (b) (6) 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***



(b) (6)

Professor, Food safety

Norwegian School of Veterinary Science, Oslo

(b) (6)
Professor, Epidemiology of Food-borne Diseases
Norwegian School of Veterinary Science
P.O. Box 8146 dep., 0033 Oslo
Norway
Mail: (b) (6) veths.no
Phone: (b) (6) 844/
Mobile: (b) (6)

Oslo 26.11.2008

Danish Meat Association
Att. Dr. (b) (6)
Axelborg, Axeltorv 3,
DK-1609 Copenhagen V,
Denmark

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. (b) (6) 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

(b) (6)
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 hearth 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 ad 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 suing 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 to 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]
Streptococcus suis	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
Staphylococcus aureus	Vomiting, diarrhoea, headache[c]	1 day[c] <2 days[e]	No	No	Close to 0%	Mild
Erysipelothrix rhusiopathiae	Localized cutaneous infection or diffuse cutaneous disease			No	Close to 0%	Mild
Mycobacterium bovis	Fever, weight loss, fatigue. Lung-tuberculosis: coughing and expectorate	Months to years		Yes		Severe
Mycobacterium avium	Small children: glandular symptoms. People with pre-exisitng 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
Campylobacter 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
Salmonella spp.	Gatroenteritis, 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 Salmonella strain	Moderate
Yersinia enterocolitica	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 form 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

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

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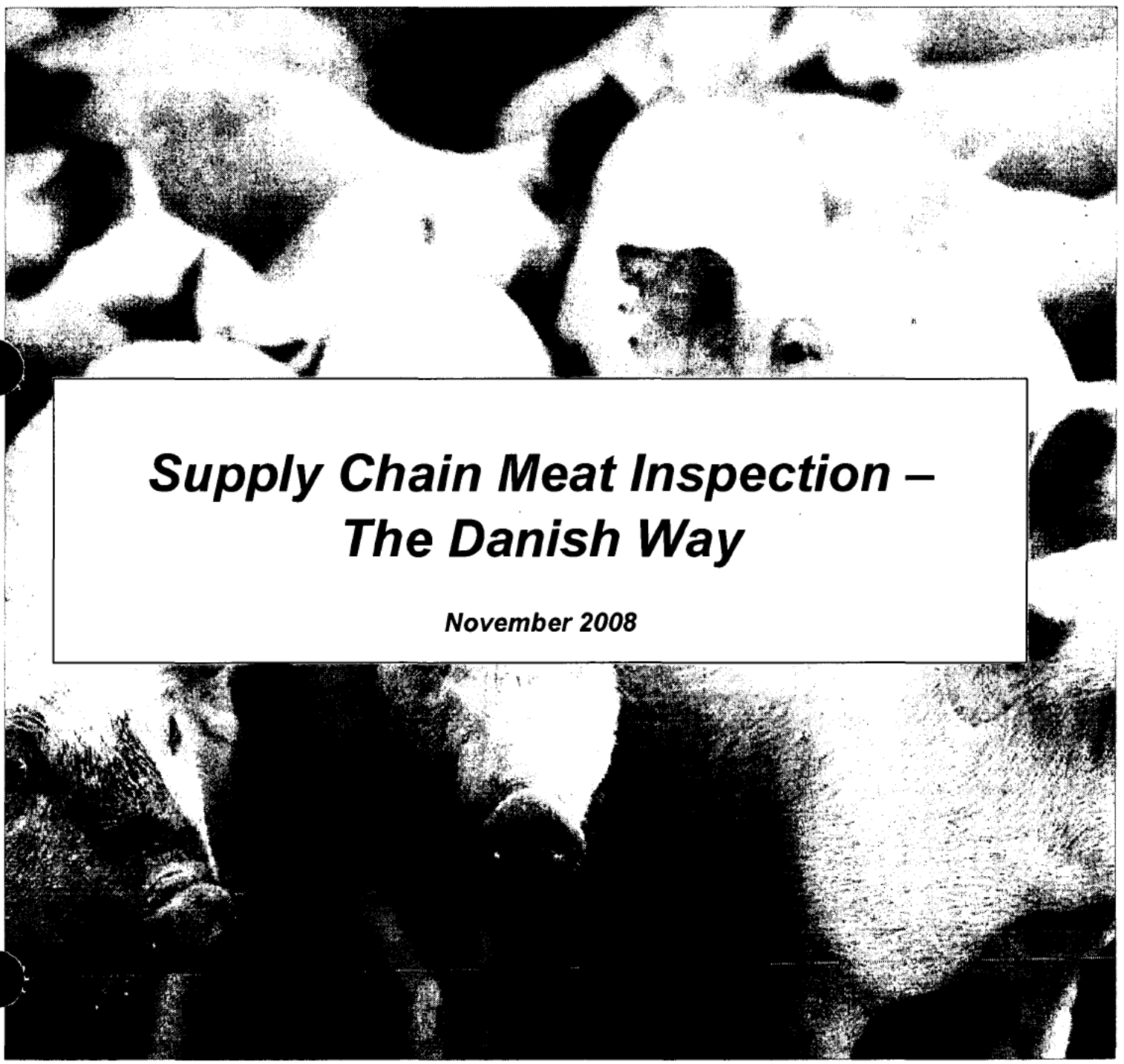

Supply Chain Meat Inspection – The Danish Way

November 2008

List of contents

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 information[1].

[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

<u>The DANISH Standard</u>
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.

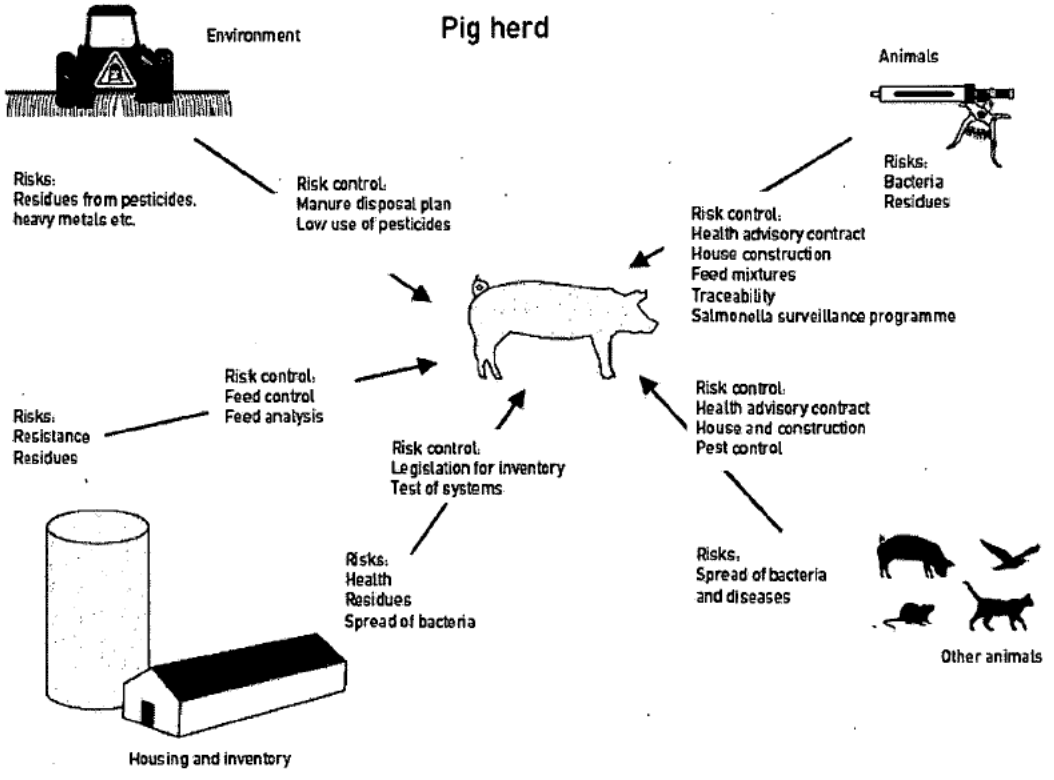

Fig.1. Pig Production System in Denmark

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

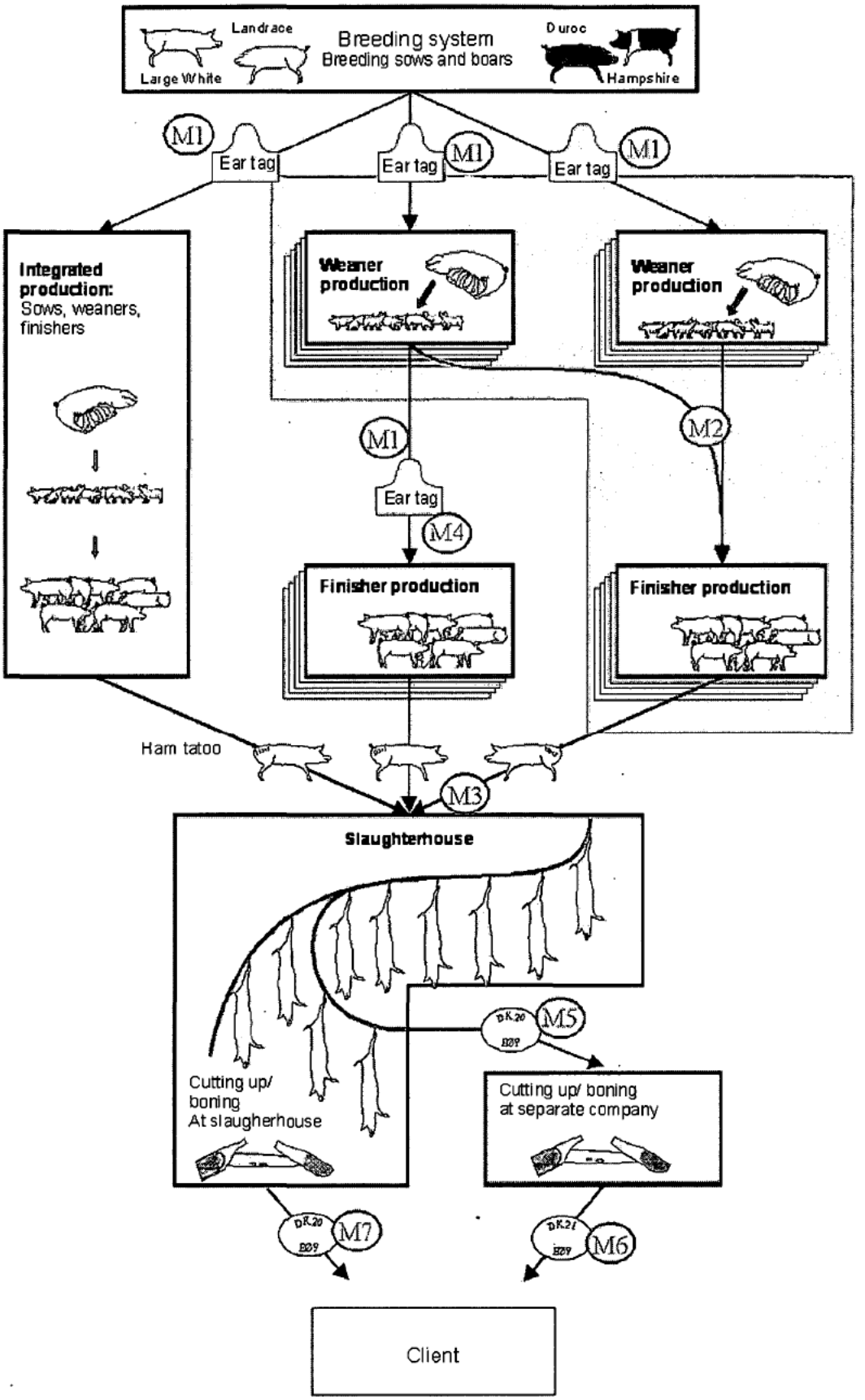

Fig. 2 Traceability stable to table

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 carcases 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.

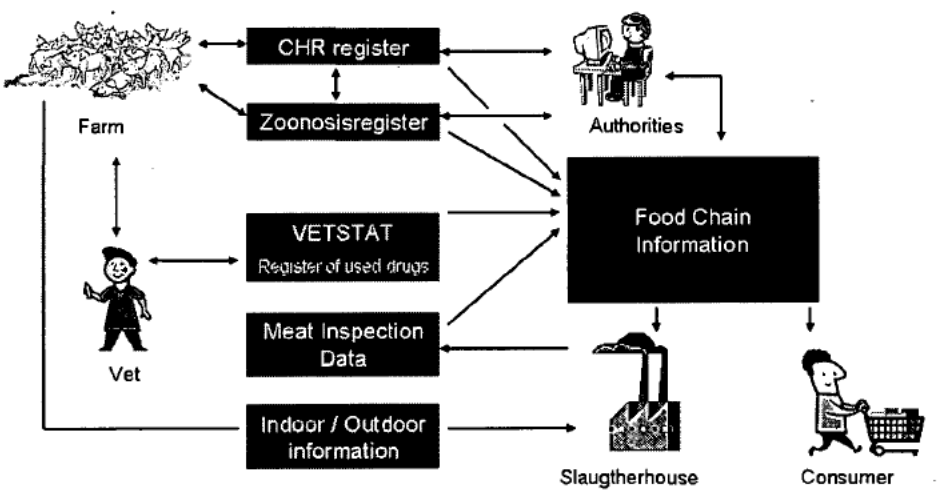

Fig. 3 Description of the connection between the collection of food chain information during animal production and at the slaughterhouse, Denmark, 2008).

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 regulations[2], 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 reinstructed 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

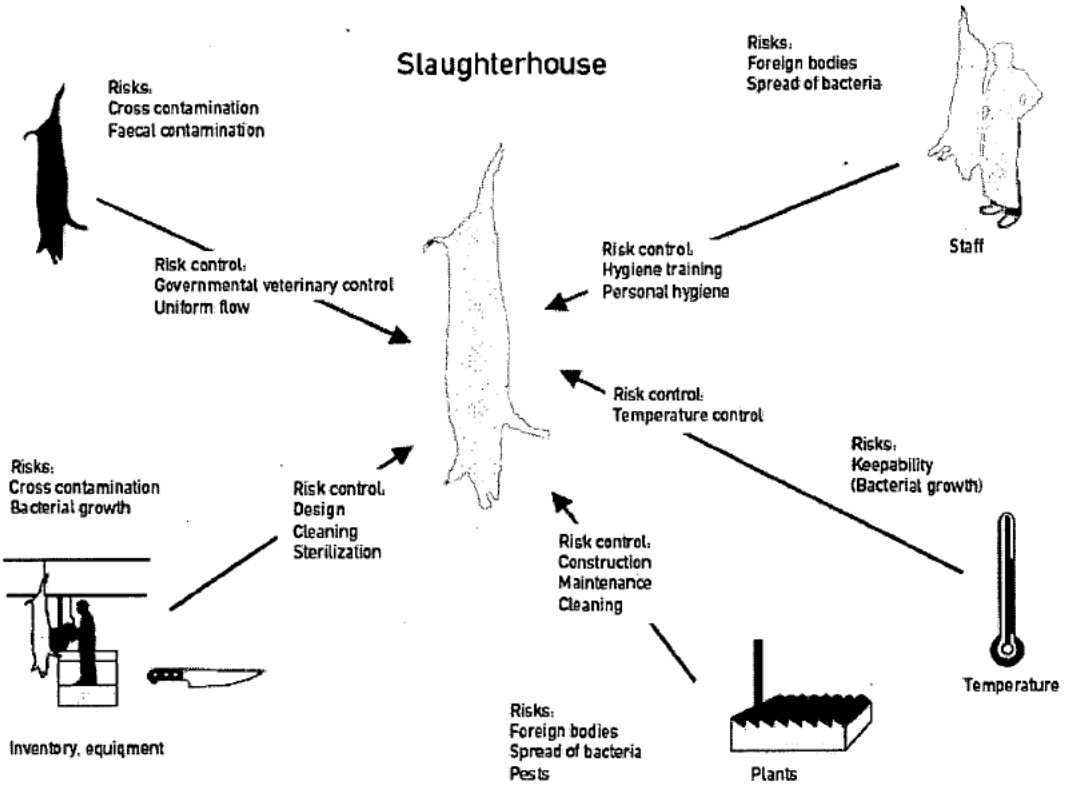

Fig. 6 - Handling of risks at the slaughterhouse

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 carcases 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 mandibullar 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 mestenterial 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-compliances[2]				
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 intes-tines				
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-compliance[3]				
Hygiene (for all inspection locations)				
Is contamination regis-tered 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 re-moved parts for in-spection?				
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:
$L = (4*pq/n)^{0.5}$

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 ±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 ± 4% = 7% ± 4% = 95% confidence interval: 3-11%

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

Supply Chain Meat Inspection – The Danish Way
–
An overview including references and links to Regulations etc

		INSPECTION SYSTEMS		References and links related to the specific sections
	Subject	**Traditional meat inspection**	**Supply chain meat inspection**	
	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 *(enclosed)*
	Origin of the pigs	Born and raised in Denmark		2). The DANISH Standard- December 2007 *(enclosed pdf-file)* –further information: http://www.dansksvineproduktion.dk/Services/DANISH_Produktstandard/Bilag_Produktstandard.html 3). Danish Quality Assurance (*enclosed pdf-file)*
	Delivery of pigs for slaughter	All pigs + sows and boars	***Only finishers from integrated production systems and kept indoor since weaning***	
Prerequisites 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***	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) 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** • 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_surveilla/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 *(pdf-fil enclosed)* 10). Sørensen et al., 2007; Estimation of *Salmonella* prevalence on individual-level based upon pooled swab samples from swine carcasses *(pdf fil enclosed)*

	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 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
	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	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 14). Danish Veterinary and Food Administration Export Inspection Guideline, 2008 export inspection guidance
	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 indooa/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
	Standardized government verification program of the quality of the post mortem inspection – performance standard	*Introduced from January 1 2009* *Ensuring the performance for inspection tasks as well as pathological findings by the official meat inspection*	*Introduced from January 1 2009* *Ensuring the performance for inspection tasks as well as pathological findings by the official meat inspection*	17). See Section 3 b in the document Supply Chain Meat Inspection – The Danish Way -
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	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 *Section 3 b* 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	- Precondition - Preliminary Schedule - Evaluation and verification	*Precondition:* - 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 *Preliminary Schedule:* - Implementing stepwise – starting with two selected slaughterhouses – January 2009 ? - Stepwise at other slaughterhouses *Evaluation:* - Close follow up on the performance in the two selected slaughterhouses		21) See *Section 8* 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

Lis Alban[a,*], Helle Stege[b], Jan Dahl[a]

[a]*Danish Bacon and Meat Council, The National Committee for Pig Production, Axelborg, Axeltorv 3, DK-1609 Copenhagen V, Denmark*

[b]*Danish Veterinary Laboratory, 27 Bülowsvej, DK-1790 Copenhagen V, Denmark*

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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 ≥index 40, and the limit between Levels 2 and 3 to ≥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.

Keywords: Pig; *Salmonella enterica*; Control program; Sample size; Detection level; Herd classification

* Corresponding author. Tel.: +45-33-732693; fax: +45-33-145756.
E-mail address: lia@danishmeat.dk (L. Alban).

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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 (*N*)	% Pigs to be examined (% of *N*)	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):

$$D = [1 - a^{1/n}][N - \tfrac{1}{2}(n - 1)]$$

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 (N)	Previous program		New program			Distribution of Danish herds 1 June to 31 August 2000		
	Number of pigs examined (n)	Detection limits[a] for Salmonella (%)	% Pigs to be examined (% of N)	Number of pigs examined (n)	Detection limits[a] for Salmonella (%)	Number of Danish herds in each stratum	Predicted number of samples per year using	
							Previous scheme[b]	New scheme (n = 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					
	0–100[b]		101–200		Total herds or animals	
	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.
	b	S.E.	*P*	*b*	S.E.	*P*	*b*	S.E.	*P*		
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*, *100*, 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.

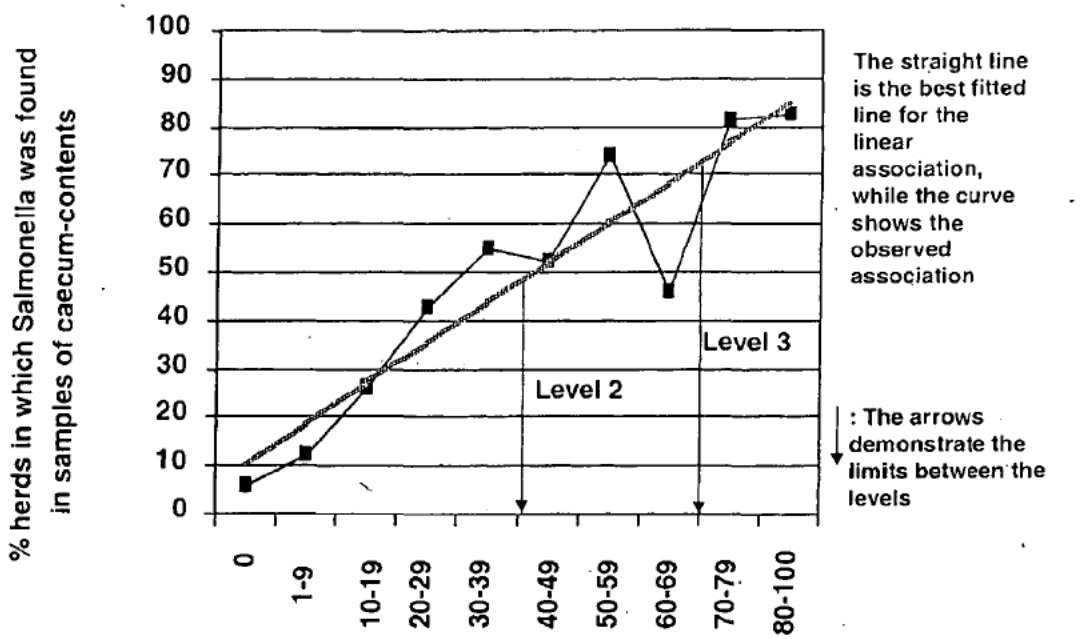

Fig. 1. Observed association between serological Salmonella index (a weighted average of the previous 3 months serological results) and bacteriology among 1902 Danish finisher herds ($r^2 = 85\%$).

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 *new* 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 *previous* 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 $\leq$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 $\geq$40, and the limit between Levels 2 and 3 will be index $\geq$70.

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Estimation of *Salmonella* prevalence on individual-level based upon pooled swab samples from swine carcasses

L.L. Sørensen *, H. Wachmann, L. Alban

Danish Meat Association, Axelborg, 3 Axeltorv, DK-1609 Copenhagen V, Denmark

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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.

Keywords: *Salmonella*; Sensitivity; Carcass swabs; Sample pooling; Swine

* Corresponding author. Tel.: +45 33 73 25 29; fax: +45 33 13 53 25.
E-mail address: lls@danishmeat.dk (L.L. Sørensen).

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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 carcases 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 cm^2 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 *Salmonella* 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 Møgelmose, 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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UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
OFFICE OF INTERNATIONAL AFFAIRS
INTERNATIONAL EQUIVALENCE STAFF
WASHINGTON, DC 20250

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
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Denmark
EQUIVALENCE DETERMINATION
FOR Individual Sanitary Measure

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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:

DIRECTOR, INTL. EQUIVALENCE STAFF

DATE 1.20.2012

2

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 assessment[1] 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.

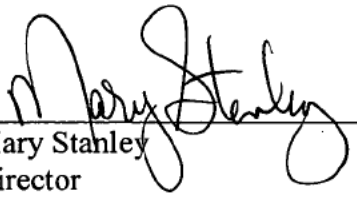
RECOMMENDATION:

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

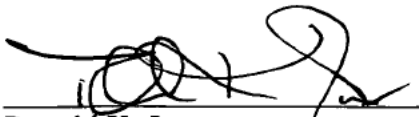
1.10.12
Date



Mary Stanley
Director
International Policy Division
Office of Policy and Program Development, FSIS

11 January 2012
Date

CONCURRENCE/OIA:

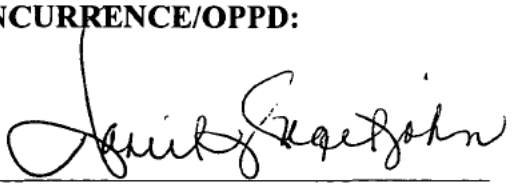


1-18-12

Ronald K. Jones
Assistant Administrator
Office of International Affairs, FSIS

Date

CONCURRENCE/OPPD:



1/31/12

Daniel Engeljohn
Assistant Administrator
Office of Policy and Program Development, FSIS

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, Axeltorv 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 assessment[1] 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
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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.

(b) (5)

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 tandards November.


Denmark decision memo for visu...

Things to be aware of in the future:

1. (b) (5)
2.
3.

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 meseneteric 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 (b) (5) [redacted] We discussed the (b) (5) [redacted] 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, EIAO
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 (b) (6) 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; 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: 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. (b) (5) [redacted] 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: (b) (6) (b) (6)@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
(b) (6)

From: Kadam, Priya [mailto:Priya.Kadam@fsis.usda.gov]
Sent: 31 January 2011 13:22
To: (b) (6)
Cc: (b) (6)
Subject: RE: Request for confirmation of equivalence of next step in supply chain meat inspection in Denmark.

Hello Mr. (b) (6)

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: (b) (6) [mailto(b) (6)@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

(b) (6)

(b) (6) / (b) (6) @UM.DK
MINISTER COUNSELLOR, FOOD & AGRICULTURE
DIRECT (202) (b) (6)

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

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 tracheobracial 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.Naugle@aphis.usda.gov; Kadam, Priya
Subject: RE: Request from FSIS: inspection procedure in finished hogs

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They maintain that palpation of the LN is unnecessary because:

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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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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
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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 by 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 in 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.

I think it might help to know domestically, if we inspect mesenteric lymph nodes of slaughtered pigs, why we inspect, and how 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 some thing 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 meseneteric lymph node 11-09-2011.docx

Importance: High

Hello Shannon:

This is the third reminder since Nov. 9, 2011 from Mr. (b) (6) 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. (b) (6) the reasons for the delay.

Thank You,
Priya

Priya Kadam Ph.D.
Senior Microbiologist
USDA/FSIS/OIA/IES
Tel: 202.690.1353

From: (b) (6) [mailto(b) (6)@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

(b) (6)

Kadam, Priya - FSIS

From: (b) (6) [(b) (6)@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
(b) (6)

From: Kadam, Priya - FSIS [mailto:Priya.Kadam@fsis.usda.gov]
Sent: 09 November 2011 11:39
To: (b) (6)
Subject: RE: Letter for Dr. Priya Kadam - Performance standards - Denmark

Dear Mr. (b) (6)

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: (b) (6) [mailto(b) (6)@um.dk]
Sent: Wednesday, November 09, 2011 11:37 AM
To: Kadam, Priya - FSIS
Cc: (b) (6); (b) (6); (b) (6)
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. (b) (6) 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

(b) (6) [redacted]

Kadam, Priya - FSIS

From: (b) (6)(b) (6) (b) (6)@um.dk]
Sent: Wednesday, November 09, 2011 11:37 AM
To: Kadam, Priya - FSIS
Cc: (b) (6); (b) (6); (b) (6)
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. (b) (6) 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

(b) (6)

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. (b) (6) 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

(b) (6)

(b) (6) Deputy Director General

(b) (6)

Kadam, Priya

From: (b) (6) (FVST) [(b) (6) fvst.dk]
Sent: Monday, May 23, 2011 10:04 AM
To: Kadam, Priya
Cc: (b) (6) (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,
(b) (6) 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

(b) (6)
Senior Veterinary Officer

Division for Microbiological Food Safety, Hygiene and Zoonoses Control

Tlf +(b) (6)
Email: (b) (6) 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 ZOONOSES 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, (b) (6) 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

(b) (6)
(b) (6) (b) (6)
Deputy Director

Danish Veterinary and Food Administration
Mørkhøj Bygade 19
DK-2860 Søborg
Tel +45 33 95 60 00
Fax +45 33 95 60 01
fvst@fvst.dk
www.fvst.dk

Kadam, Priya - FSIS

From: Kadam, Priya - FSIS
Sent: Monday, January 09, 2012 12:05 PM
To: (b) (6)
Cc: Oestmann, Daniel - FSIS
Subject: RE: Happy New Year - Re. Performance standards - Denmark.

Dear (b) ((b) (6)

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: (b) (6) [mailto(b) (6)@um.dk]
Sent: Friday, January 06, 2012 10:58 AM
To: Kadam, Priya - FSIS
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Dear Ms. Kadam,

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Best regards

(b) (6)

Kadam, Priya

From: (b) (6) (b) (6)@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
(b) (6)

From: Kadam, Priya [mailto:Priya.Kadam@fsis.usda.gov]
Sent: 23 February 2011 16:25
To: (b) (6)
Cc: Keller, Andreas
Subject: RE: Request for confirmation of equivalence of next step in supply chain meat inspection in Denmark.

Hello Mr. (b) (6)

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: (b) (6) [mailto(b) (6)@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
(b) (6)

From: Kadam, Priya [mailto:Priya.Kadam@fsis.usda.gov]
Sent: 31 January 2011 13:22
To: (b) (6)
Cc: Keller, Andreas
Subject: RE: Request for confirmation of equivalence of next step in supply chain meat inspection in Denmark.

Hello Mr. (b) (6)

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: (b) (6) [mailto(b) (6)@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

(b) (6)

(b) (6) / (b) (6) @UM.DK
MINISTER COUNSELLOR, FOOD & AGRICULTURE
DIRECT (202) (b) (6)

ROYAL DANISH EMBASSY, WASHINGTON DC
3200 WHITEHAVEN STREET / WASHINGTON, DC 20008
PHONE +1 (202) 234 4300 / WWW.AMBWASHINGTON.UM.DK

Kadam, Priya

From: (b) (6) (b) (6)@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
(b) (6)

From: Kadam, Priya [mailto:Priya.Kadam@fsis.usda.gov]
Sent: 31 January 2011 13:22
To: (b) (6)
Cc: Keller, Andreas
Subject: RE: Request for confirmation of equivalence of next step in supply chain meat inspection in Denmark.

Hello Mr. (b) (6)

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: (b) (6) [mailto(b) (6)@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

(b) (6)

(b) (6) / (b) (6) @UM.DK
MINISTER COUNSELLOR, FOOD & AGRICULTURE
DIRECT (202) (b) (6)

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

From: (b) (6) (b) (6) [(b) (6) um.dk]
Sent: Tuesday, July 06, 2010 10:37 AM
To: Kadam, Priya
Cc: Keller, Andreas; (b) (6) (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. (b) (6)
E-mail: (b) (6) fvst.dk
Direct Tel. +45 33 95 62 75

Thanks,

(b) (6)

(b) (6) / (b) (6) UM.DK
MINISTER COUNSELLOR / FOOD, AGRICULTURE AND FISHERIES
DIRECT +1 (202) (b) (6) / CELL (202) (b) (6) FAX (202) 328-1470

ROYAL DANISH EMBASSY / MINISTRY OF FOREIGN AFFAIRS OF DENMARK
3200 WHITEHAVEN ST., N.W. / WASHINGTON, D.C. 20008
PHONE +1 (202) 234-4300 / WWW.DENMARKEMB.ORG
FACEBOOK.COM/AMBWASHINGTON

From: Kadam, Priya [mailto:Priya.Kadam@fsis.usda.gov]
Sent: 21 June 2010 16:57
To: (b) (6) (b) (6)
Cc: Keller, Andreas
Subject: RE: Request for Confirmation of Equivalence of Next Step in Supply Chain Meat Inspection in Denmark

Hello Mr. (b) (6):

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 mesenterial 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: (b) (6) (b) (6)
Cc: Kadam, Priya
Subject: RE: Request for Confirmation of Equivalence of Next Step in Supply Chain Meat Inspection in Denmark

Hi (b) (6)

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: (b) (6) (b) (6) [mailto (b) (6) 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,

(b) (6)

(b) (6) / (b) (6) UM.DK
MINISTER COUNSELLOR / FOOD, AGRICULTURE AND FISHERIES
DIRECT +1 (202) (b) (6) / CELL (202) (b) (6) FAX (202) 328-1470

From: Walker, Harry [mailto:Harry.Walker@fsis.usda.gov]
Sent: 20 May 2010 10:59
To: (b) (6) (b) (6)
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
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: (b) (6) (b) (6) [mailto(b) (6) 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 og 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.

(b) (6)

From: Walker, Harry [mailto:Harry.Walker@fsis.usda.gov]
Sent: 20 May 2010 10:29
To: (b) (6) (b) (6)
Subject: RE: Request for Confirmation of Equivalence of Next Step in Supply Chain Meat Inspection in Denmark

Thank you (b) (6) 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: (b) (6) (b) (6) [mailto(b) (6) 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,

(b) (6)

From: (b) (6) (b) (6)
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. (b) (6)

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,

(b) (6)

(b) (6) / (b) (6) UM.DK
MINISTER COUNSELLOR / FOOD, AGRICULTURE AND FISHERIES
DIRECT +1 (202) (b) (6) / CELL (202) (b) (6) FAX (202) 328-1470

ROYAL DANISH EMBASSY / MINISTRY OF FOREIGN AFFAIRS OF DENMARK
3200 WHITEHAVEN ST., N.W. / WASHINGTON, D.C. 20008
PHONE +1 (202) 234-4300 / WWW.DENMARKEMB.ORG
FACEBOOK.COM/AMBWASHINGTON

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 ZOONOSES 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

(b) (6)
Deputy Director

Danish Veterinary and Food Administration
Mørkhøj Bygade 19
DK-2860 Søborg
Tel +45 33 95 60 00
Fax +45 33 95 60 01
fvst@fvst.dk
www.fvst.dk

(b) (6)
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

(b) (6) (b) (6)

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 lever 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 & Fool Council, Axeltorv 3, DK-1609 Copenhagen V, Denmark.

September 24, 2009

- Translated into English July 2, 2010

Content

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 nymph 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 nymph 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 are 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 Insepction – 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 carcases 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 pyogranulomatous 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).

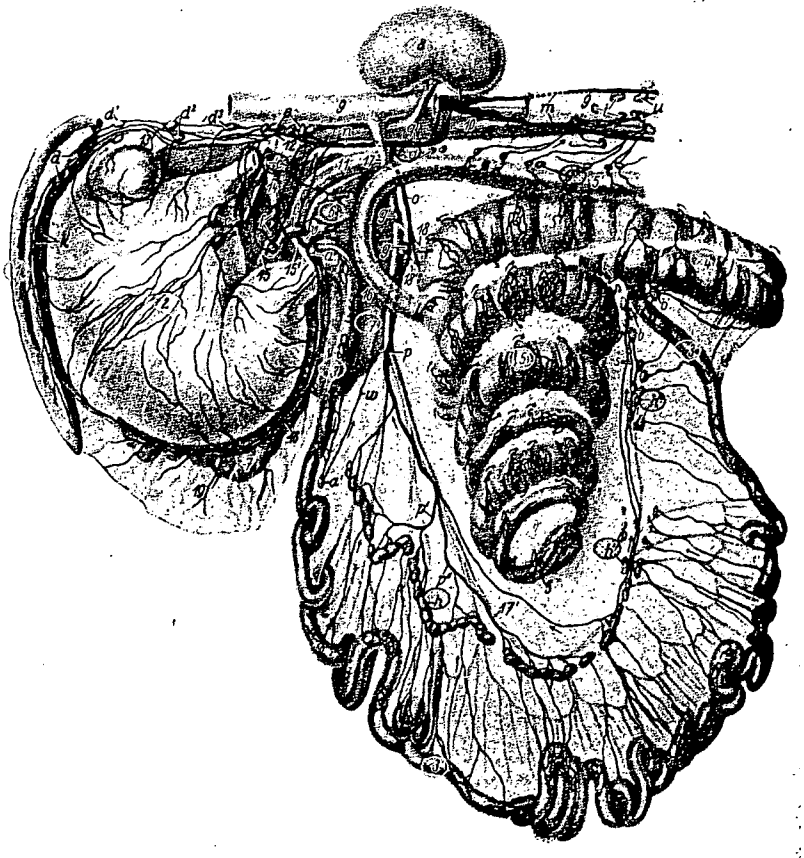
3.1.2 Organ lymph nodes and meat lymph nodes

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. jejunales) 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
①Milt, ②Mavesæk, ③Tyndtarm, ④Blindtarm, ⑤Tyktarm, ⑥Bugspytkirtel, ⑦Lever, ⑧Venstre nyre, Tarmlymfeknuder c, c' NII. gastrici g NII. mesenterici caudalis g' NII mesenterici cranialis h, h' og h'' NII. jejunales. 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 (Mycoplasma, *Streptococcus suis*) Cerebrospinal meningitis (*Streptococcus suis*) Gläser's disease (*Hæmophilus parasuis*) Sequelae to tail bite infection	With an agent involved in these disorders the clinical symptoms are primarily seen in other organs than the gastro-intestinal tract
Diarrhea	Diarrhea *(E. Coli)* Spirochaetal diarrhea *(Brachyspira pilosicoli)* Proliferative enteropathy *(Lawsonia intracellularis)* Dysenteria *(Brachyspira hyodysenteriae)*	All agents in this group affect the gastro-intestinal tract
Respiratory disease	Atrophic rhinitis (*Bordetella bronchoseptica*, *Pasteurella*) Pneumonia (*Mycoplasma hyopneumoniae* APP, *Pasteurella, Streptococus* spp.) Pertussis (*Bordetella bronchoseptica*) Gläser's disease (*Hæmophilus parasuis*)	With an agent involved in these disorders the clinical symptoms are primarily seen in other organs than the gastro-intestinal tract

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 be 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.

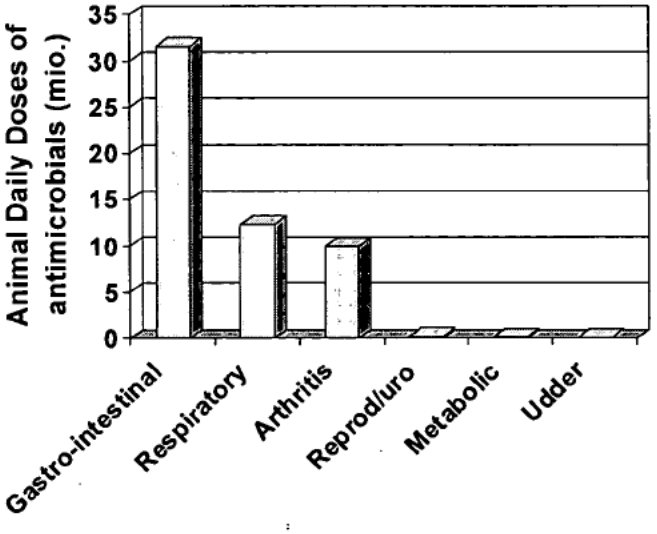


Figure 2. Animal daily doses of antimicrobials (ADD) reported to the VETSTAT database for treatment for a variety of disorders in all Danish finisher pigs during 2008

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 offical 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 nymph 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

		2006		2007		2008	
Lesion	Code	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 totally 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 mesenterial 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.

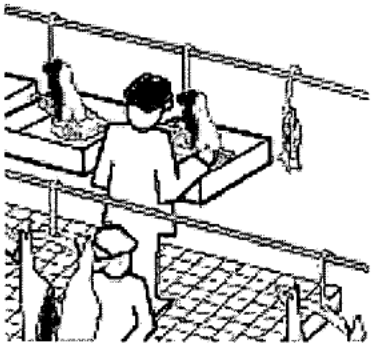
Table 4 presents the most frequently reported causes for condemnation sorted accordance to frequency of local condemnation. Chronic pleuritis is observed in nearly 25 % of all finisher pigs. This lesion hereby makes up far most of all local condemnations (73 %). All other causes for local condemnation 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

	Registrations of finisher pigs			
	Local condemnation		Total condemnation	
Code of remark / lesion	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 Acurw 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 nymph 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.

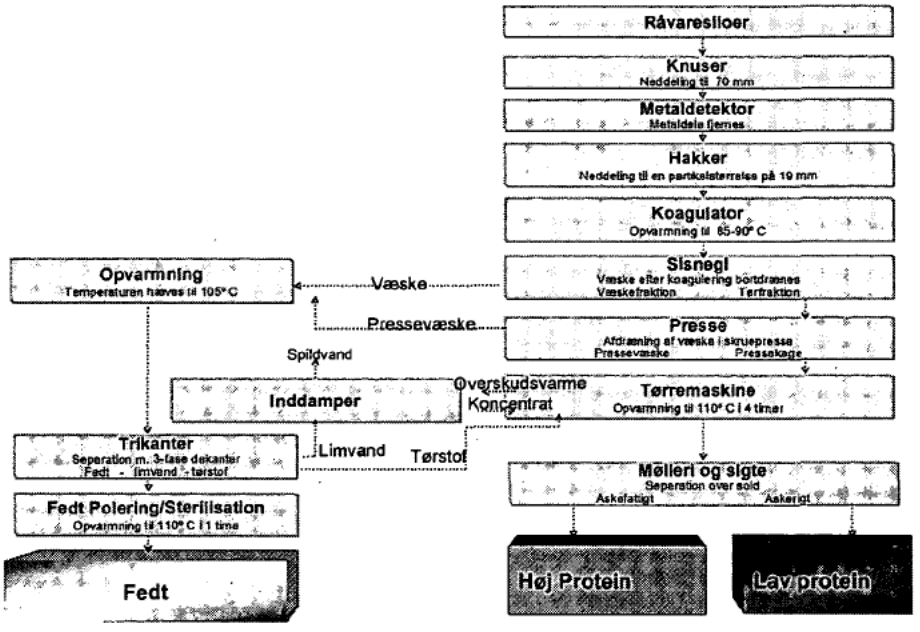


Figure 4. Description in Danish of the wet pressing process in the production at Daka Proteins. Source: M. Englund, 2009

5.2 Production of spray-dried protein

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 ((b) (6) 2009).

The process of production will need to be approved by the authorities as well as a own-control program will be designed and put inplace. It is assessed that the process effectively ensures the elimination of all pathogens.
Authors comment after finalisation of report: The production has not been initiated by July 2010

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	*Salmonella* spp., *Y. Enterocolitica, Campylobacter* spp.,	Bovine tuberculosis, *Trichinella spiralis, Brucella abortus, B. suis*, B. melitensis*
No	*L. intracellularis, Oesophagostomum dentatum* and *O. quadrispinulatum, Hyostrongylus rubidus, Brachyspira hyodysenteriae* and *B. pilosicoli*	Foot and mouth disease, African and classical swine fever, Aujeszky's disease, Swine vesicular disease, Transmissible gastroenteritis
Limited	*E. rhusiopathiae* (occupational risk), *S. suis* (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 / Contussion
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 biclaws, degenerative arhtritis
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/Dyrlaegen/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 nymph 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 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 mesenterial 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

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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	

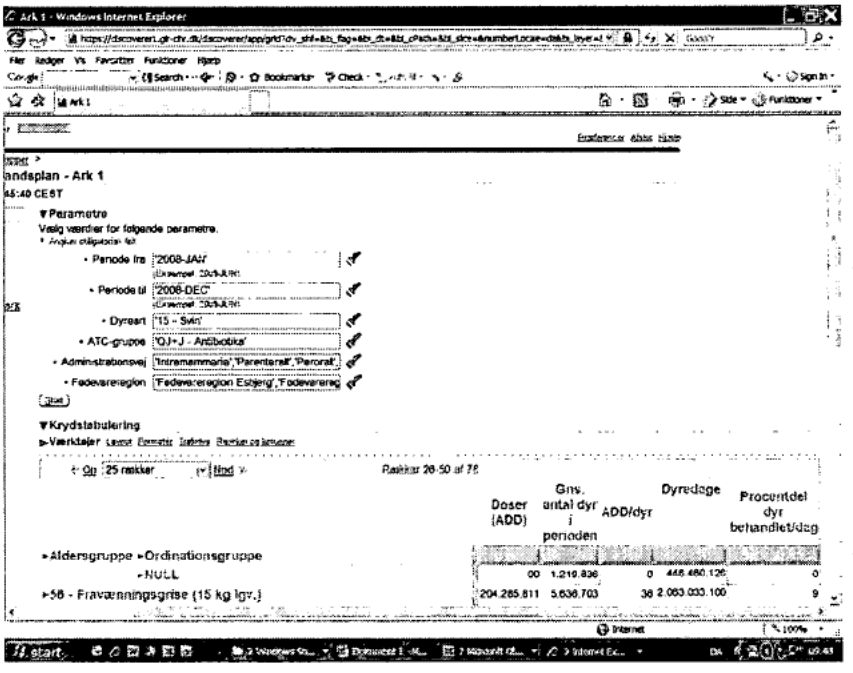
*: LR: local rejection, TR: total rejection, UA: unconditioned approval, AM: approved for manufacturing

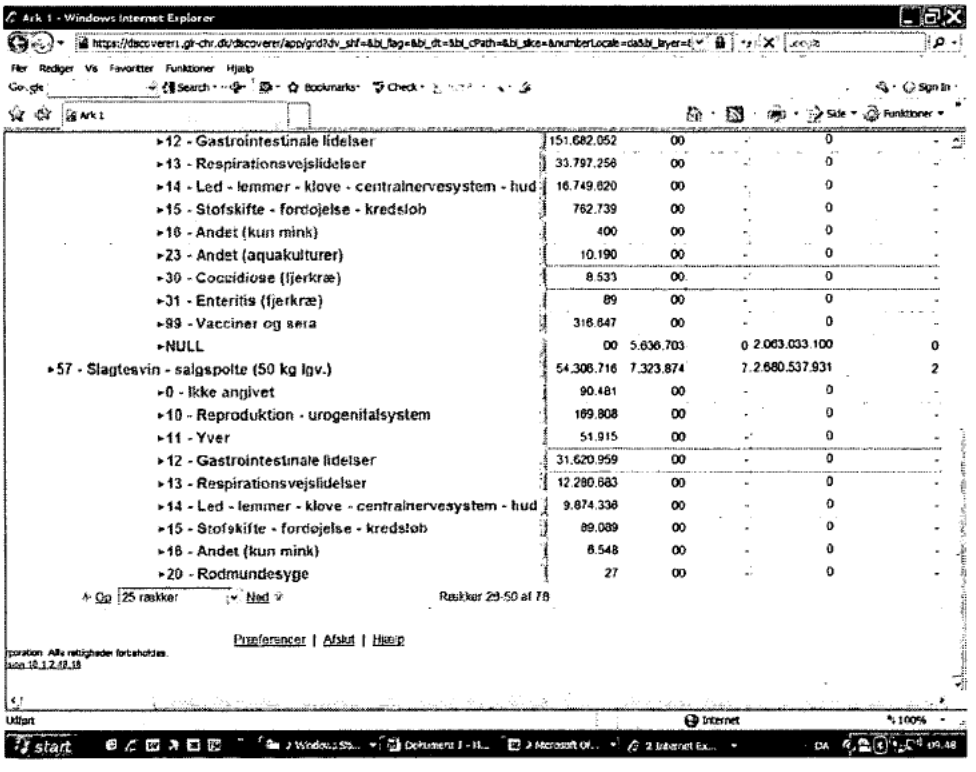
Appendix B - Dataudtræk fra VETSTAT

- In Danish

Udtrækket er foretaget d. 23. juni 2009. Følgende parametre er anvendt: Hele året 2008, dyreart svin, kun antibiotikabehandlinger, alle administrationsveje, alle regioner i landet,

(b) (6)) Københavns Universitet, for assistance i forbindelse med udtræk.





Appendix C - Patologiske manifestationer i slagterkroppen

- In Danish

Der refereres i følgende afsnit fra Jensen et al. (2006) samt Jepsen (1968). I enkelte tilfælde er der også benyttet ekspertvurdering.

Akutte infektioner i maven kan være en følge af kronisk mavesår, som hos svin især skyldes foderets formalingsgrad. Ukomplicerede tilfælde betinger lokal kassation. Det vurderes, at denne læsion ingen betydning har for fødevaresikkerhed eller eksotiske smitsomme husdyrsygdomme.

Idiopatiske tilstande: Universel tarmblødning er en idiopatisk hæmoragisk non-inflammatorisk intestinal tilstand hos svin. Den viser sig ved pludselig massiv blødning til tarmlumen. Tilstanden er som hovedregel kompliceret med sekundær anæmi eller choklignende symptomer, hvilket betinger totalkassation af slagtekroppen. Ukomplicerede tilfælde betinger lokal kassation. Det vurderes at tilstanden kan observeres visuelt. Tilstanden har ingen betydning for fødevaresikkerhed eller udbredelsen af eksotiske smitsomme husdyrsygdomme.

Akutte tarminfektioner ses sjældent hos slagtesvin. Årsagen til uspecifik mave-tarm infektion kan hos voksne dyr skyldes diætetiske fejl, der betinger ubetinget godkendelse af slagtekroppen. Lette, ukomplicerede tilfælde betinger lokal kassation. Akut, svær betændelse kan dog ses hos alle husdyrarter (især meget unge dyr) og forårsages typisk af *Salmonella* spp. Tilstanden kan erkendes visuelt og betinger total kassation. Salmonellainfektioner hos lidt større dyr forekommer dog typisk som subkliniske infektioner, der ikke kan erkendes visuelt. Det vurderes, at læsioner som følge af infektion med *Salmonella* spp. har betydning for fødevaresikkerhed, idet mennesker kan smittes gennem svinekød. Tarmens udseende afhænger af, hvor alvorlig den bagvedliggende tilstand er. Milde tilfælde medfører ingen eller kun let svullent udseende, men mere alvorlige tilstande medfører svulne, røde, kar-injicerede tarme og røde eller stærkt svulne lymfeknuder.

Kroniske tarminfektioner forekommer hyppigt hos svin. De hyppigste udgøres af proliferativ enteropati, svinedysenteri, og spirokætal diarré. I ukomplicerede tilfælde foretages lokal kassation. Den hyppigste komplikation er afmagring. Proliferativ enteropati, hvor *Lawsonia intracellularis* er involveret, forekommer i tre former hos slagtesvin: Proliferativ enteritis, nekrotiserende enteritis og regional ileitis. Den tilgrundliggende tilstand er en hyperplasi af tyndtarmens mucosa, som i visse tilfælde undergår nekrose. Svinedysenteri og spirokætal diarré er begge karakteriseret ved kroniske hyperplastiske og nekrotiserende læsioner i blindtarm og tyktarm. Sidstnævnte tilstande forårsages af henholdsvis *Brachyspira hyodysenteriae* og *B. pilosicoli.* Det vurderes, at de ovennævnte læsioner i tarmene vil være visuelt erkendelige i en del tilfælde. Mere afhelede tilfælde – eller mindre voldsomme tilfælde – vil derimod være mindre visuelt erkendelige. De ovennævnte patogener har betydning for dyresundhed, men ikke for fødevaresikkerhed eller eksotiske smitsomme husdyrsygdomme.

Lejeforandringer inkluderer rektalprolaps, broktilstande og tarminvaginationer. Sådanne forandringer bedømmes ud fra omfanget af cirkulationsforstyrrelse, disses alder samt komplikationer. Dette vil også gøre sig gældende for tilfælde af tarmslyng.

Parasitære infektioner som følge af *Oesophagostomum dentatum* og *O. quadrispinulatum* kan manifestere sig i tarmen hos slagtesvin i form af dannelse af subserøse granulomatøse noduli i tyktarmen. Sådanne læsioner betinger lokal kassation. I tilfælde af at mange dyr har voldsomme læsioner, er der tale om en betydning for dyresundhed i besætningen. Læsionerne har der imod ingen betydning for fødevaresikkerhed eller eksotiske smitsomme husdyrsygdomme. I udendørsdrevne svinebesætninger kan der forekomme infektion med svinets røde maveorm (*Hyostrongylus rubidus*). Den er dog ikke observeret i Danmark i de sidste 25 år (J. Boes,

personlig meddelelse, 2009). Ukomplicerede tilfælde vil betinge lokal kassation. Tilstanden har ingen betydning for fødevaresikkerhed eller eksotiske smitsomme husdyrsygdomme. Der skal her erindres, at alene slagtesvin fra indendørs besætninger vil kunne indgå i integreret kødkontrol. Spolorm er meget udbredt blandt danske svin. Infektionen manifesterer sig i form af ormepletter på leveren eller ophobning af voksne orm i tyndtarmen. Tarmvæggen kan være fortykket i tilfælde af massiv ormebyrde. Spolormene vaskes ud af tarmene i forbindelse med tarmrensning. Der er ingen betydning for fødevaresikkerhed, fordi de voksne orm ikke smitter, og fordi æg fra spolorm skal modnes uden for grisen i 3-4 uger før de er infektive (J. Boes, personlig meddelelse, 2009).

Afmagring og hungerødem er kroniske generaliserede komplikationer, der optræder som følgetilstande til funktionsforstyrrelse i fordøjelseskanalen eller utilstrækkelig fodring. Disse to tilstande, der optræder samtidigt, er karakteriserede ved mangel på organ- og depotfedt, serøs fedtvævsatrofi, systemisk atrofi af muskelvæv, samt mørkpigmentering af lever, hjerte- og skeletmuskulatur. Det er vurderingen, at disse tilstande er visuelt erkendelige, og at de er uden betydning for fødevaresikkerhed. Slagtekroppen fremstår ikke som egnet til menneskeføde, æstetisk set. Tilstanden betinger derfor total kassation.

Anæmi optræder som følgetilstand til hæmoragiske tilstande i fordøjelseskanalen. Hos svin er der hyppigst tale om en følge af blodtab til tynd- og tyktarm i forbindelse med universel tarmblødning eller hæmoragisk enteropati (hos søer og gylte) som følge af *L. interacellularis*. Anæmi betinger total kassation af slagtekroppen. Selv om slagtekroppen vurderes som værende uegnet til menneskeføde, er der ikke tale om en egentlig betydning for fødevaresikkerhed, men snarere at kroppen fremstår som uæstetisk. Tilstanden kan erkendes visuelt.

United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

(b) (6)
Chief Veterinary Officer
Danish Veterinary and Food Administration
Mørkhøj Bygade 19
DK–2860 Søborg

Dear (b) (6)

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).

0.5
6.7

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,

Sally White JD

Sally White
Director
International Equivalence Staff
Office of International Affairs

CC:
Steve Huete, Agricultural Attaché, American Embassy, The Hague
(b) (6) (b) (6) , Minister Counselor, Royal Danish Embassy
(b) (6) [redacted], Director, Directorate E, European Commission, Brussels
(b) (6) Counselor, Food Safety and Consumer Affairs, EC
(b) (6) [redacted], EC, DG SANCO - Directorate General for Health and Consumers
Alfred Almanza, Administrator, FSIS
Lisa Wallenda Picard, OA, FSIS
Ronald Jones, Acting Assistant Administrator, OIA
Ann Ryan, EB, State
David Young, Europe Area Director, FAS
Donald Smart, Director, IAS, OIA
Phil Derfler, Assistant Administrator, OPPD
Daniel Engeljohn, Deputy Assistant Administrator, OPPD
Sally White, Director, IES, OIA
Director, IID, OIA
Barbara McNiff, Director, FSIS Codex Programs Staff, OIA
Rick Harries, Director, EPS, OIA
David Smith, OIA, IES
Office of Science and Technical Affairs, FAS
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:

Sally White JD 12/20/08

Sally White, Director
International Equivalence Staff
Office of International Affairs, FSIS

CONCURRENCE:

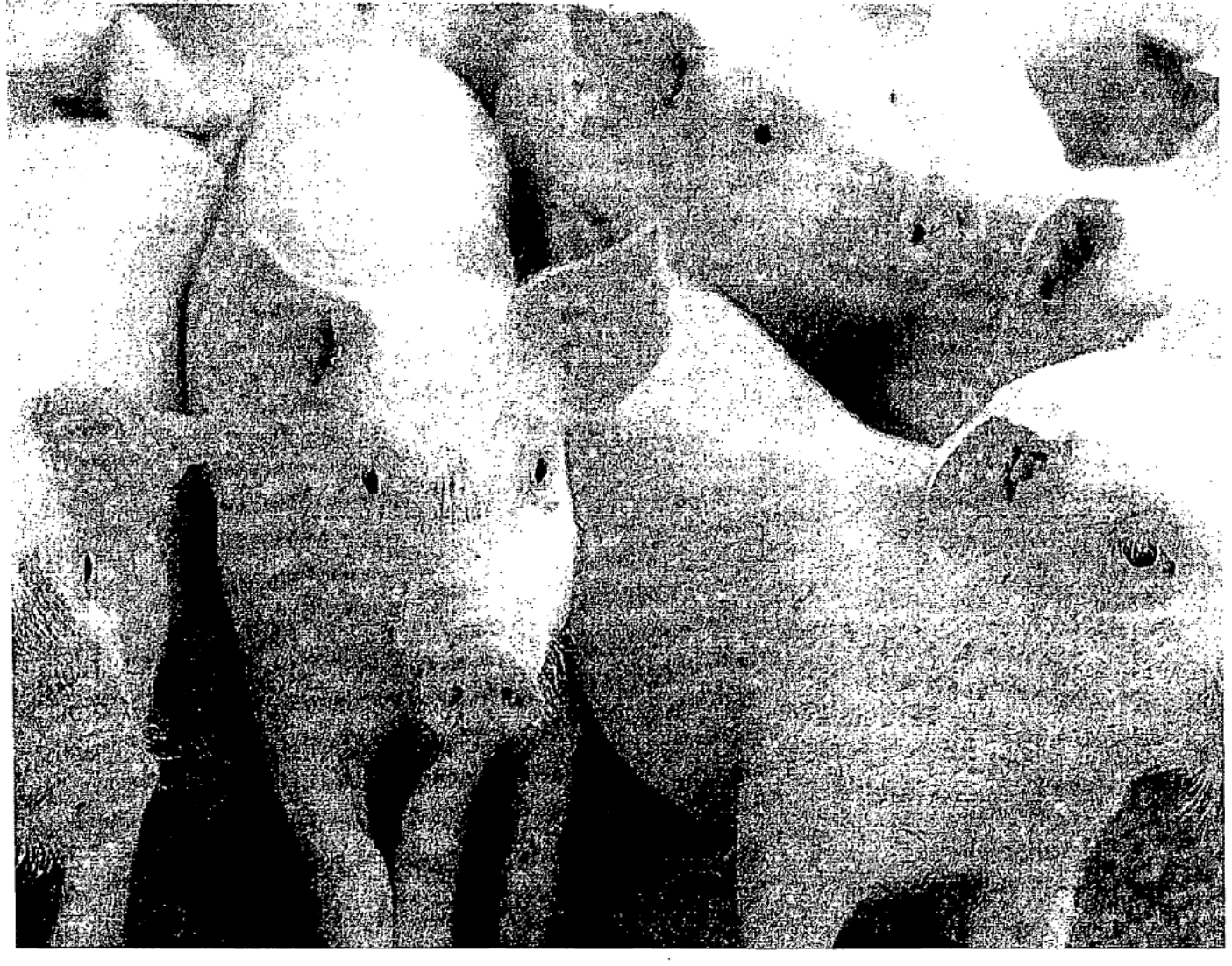
12-23-08

Ronald Jones
Acting Assistant Administrator
Office of International Affairs

danish meat association

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) (b) (6) Professor, Veterinary Public Health, the Royal Veterinary College, London,
2) (b) (6) Professor, Food Safety, the Norwegian School of Veterinary Science, Oslo,
3) (b) (6) 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
Lis Alban[1], Charlotte Vilstrup[2], Birthe Steenberg[1], Henrik Elvang Jensen[3],
Bent Aalbæk[3], Flemming Thune-Stephensen[1] and Susanne Jensen[1]

[1] Danish Meat Association, Axelborg, Axeltorv 3, DK-1609 Copenhagen V, Denmark
[2] Danish Veterinary and Food Administration, Mørkhøj Bygade 19, DK-2860 Søborg, Denmark
[3] Department of Disease Biology, Faculty of Life Sciences, University of Copenhagen, Grønnegårdsvej 15, DK-1870 Frederiksberg C, Denmark

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

(b) (5)

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.

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:

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 assessment[1] 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

6.16.11
Date

Mary Stanley
Director
International Policy Division
Office of Policy and Program Development, FSIS

6 January 2012
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.

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).

[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).

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 carcases of domestic ungulates, farmed game mammals other than lagomorphs, and large wild game, as well as half-carcases, quarters and cuts produced by cutting half-carcases 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 conceming 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 c+hapter 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.

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;

(b) Regulation (EC) No 853/2004

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 carcases 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 8532004 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 carcase 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 carcases 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, toxaemia 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 carcases 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 121, 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 retropharyngiales*); 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. bifucationes, 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 he 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. bifucationes, 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. bifucationes, 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 submaxillary, 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. bifucationes, 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. Carcases 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. bifucationes, 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 carcases 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 carcases. When such carcases 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 carcases

Species: .....

Number: .....

2. Provenance of uneviscerated carcases

Address of holding: .....

3. Destination of uneviscerated carcases

The uneviscerated carcases will be transported to the following cutting plant: .....

.....

4. Declaration

I, the undersigned, declare that:

— the uneviscerated carcases 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 carcase 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. Carcases 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 carcases, 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 carcase 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 carcase, only the affected organ or part of the carcase 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 carcases, 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.

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 capable of directly or indirectly affecting the health quality of food;

(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.

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.

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 (EMEA) 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 EMEA 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 foodstuff 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.

[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 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.

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).

I

(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.

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[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).