

- (7) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules <sup>(1)</sup> requires the Member States to ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency. Those controls should take place at appropriate stages of the production, processing and distribution of food to ensure that the criteria laid down in this Regulation are complied with by food business operators.
- (8) The Communication from the Commission on the Community Strategy for setting microbiological criteria for foodstuffs <sup>(2)</sup> describes the strategy to lay down and revise the criteria in Community legislation, as well as the principles for the development and application of the criteria. This strategy should be applied when microbiological criteria are laid down.
- (9) The Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) issued an opinion on 23 September 1999 on the evaluation of microbiological criteria for food products of animal origin for human consumption. It highlighted the relevance of basing microbiological criteria on formal risk assessment and internationally approved principles. The opinion recommends that microbiological criteria should be relevant and effective in relation to consumer health protection. The SCVPH proposed, while awaiting formal risk assessments, certain revised criteria as interim measures.
- (10) The SCVPH issued at the same time a separate opinion on *Listeria monocytogenes*. That opinion recommended that it be an objective to keep the concentration of *Listeria monocytogenes* in food below 100 cfu/g. The Scientific Committee on Food (SCF) agreed with these recommendations in its opinion of 22 June 2000.
- (11) The SCVPH adopted an opinion on *Vibrio vulnificus* and *Vibrio parahaemolyticus* on 19 and 20 September 2001. It concluded that currently available scientific data do not support setting specific criteria for pathogenic *V. vulnificus* and *parahaemolyticus* in seafood. However, it recommended that codes of practice should be established to ensure that good hygiene practice has been applied.
- (12) The SCVPH issued an opinion on Norwalk-like viruses (NLVs, noroviruses) on 30-31 January 2002. In that opinion it concluded that the conventional faecal indicators are unreliable for demonstrating the presence or absence of NLVs and that the reliance on faecal bacterial indicator removal for determining shellfish purification times is unsafe practice. It also recommended using *E. coli* rather than faecal coliforms to indicate faecal contamination in shellfish harvesting areas, when applying bacterial indicators.
- (13) On 27 February 2002 the SCF adopted an opinion on specifications for gelatine in terms of consumer health. It concluded that the microbiological criteria set in Chapter 4 of Annex II to Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A(I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC <sup>(3)</sup> in terms of consumer health were excessive, and considered it sufficient to apply a mandatory microbiological criterion for salmonella only.
- (14) The SCVPH issued an opinion on verotoxigenic *E. coli* (VTEC) in foodstuffs on 21 and 22 January 2003. In its opinion it concluded that applying an end-product microbiological standard for VTEC O157 is unlikely to deliver meaningful reductions in the associated risk for the consumers. However, microbiological guidelines aimed at reducing the faecal contamination along the food chain can contribute to a reduction in public health risks, including VTEC. The SCVPH identified the following food categories where VTEC represents a hazard to public health: raw or undercooked beef and possibly meat from other ruminants, minced meat and fermented beef and products thereof, raw milk and raw milk products, fresh produce, in particular sprouted seeds, and unpasteurised fruit and vegetable juices.
- (15) On 26 and 27 March 2003 the SCVPH adopted an opinion on staphylococcal enterotoxins in milk products, particularly in cheeses. It recommended revising the criteria for coagulase-positive staphylococci in cheeses, in raw milk intended for processing and in powdered milk. In addition, criteria for staphylococcal enterotoxins should be laid down for cheeses and powdered milk.

<sup>(1)</sup> OJ L 165, 30.4.2004, p. 1, corrected by OJ L 191, 28.5.2004, p. 1.

<sup>(2)</sup> SANCO/1252/2001 Discussion paper on strategy for setting microbiological criteria for foodstuffs in Community legislation, p. 34.

<sup>(3)</sup> OJ L 62, 15.3.1993, p. 49. Directive as last amended by Commission Regulation (EC) No 445/2004 (OJ L 72, 11.3.2004, p. 60).

- (16) The SCVPH adopted an opinion on salmonellae in foodstuffs on 14 and 15 April 2003. According to the opinion, food categories possibly posing a high risk to public health include raw meat and some products intended to be eaten raw, raw and undercooked products of poultry meat, eggs and products containing raw eggs, unpasteurised milk and some products thereof. Sprouted seeds and unpasteurised fruit juices are also of concern. It recommended that the decision on the need for microbiological criteria should be taken on the basis of its ability to protect the consumers and its feasibility.
- (17) The Scientific Panel on Biological Hazards (BIOHAZ Panel) of the European Food Safety Authority (EFSA) issued an opinion on the microbiological risks in infant formulae and follow-on formulae on 9 September 2004. It concluded that *Salmonella* and *Enterobacter sakazakii* are the micro-organisms of greatest concern in infant formulae, formulae for special medical purposes and follow-on formulae. The presence of these pathogens constitutes a considerable risk if conditions after reconstitution permit multiplication. Enterobacteriaceae, which are more often present, could be used as an indicator for risk. Monitoring and testing of Enterobacteriaceae was recommended in both the manufacturing environment and the finished product by the EFSA. However, besides pathogenic species the family Enterobacteriaceae includes also environmental species, which often appear in the food manufacturing environment without posing any health hazard. Therefore, the family Enterobacteriaceae can be used for routine monitoring, and if they are present testing of specific pathogens can be started.
- (18) International guidelines for microbiological criteria in respect of many foodstuffs have not yet been established. However, the Commission has followed the Codex Alimentarius guideline 'Principles for the establishment and application of microbiological criteria for foods CAC/GL 21 — 1997' and in addition, the advice of the SCVPH and the SCF in laying down microbiological criteria. Existing Codex specifications in respect of dried milk products, foods for infants and children and the histamine criterion for certain fish and fishery products have been taken account. The adoption of Community criteria should benefit trade by providing harmonised microbiological requirements for foodstuffs and replacing national criteria.
- (19) The microbiological criteria set for certain categories of food of animal origin in Directives that were repealed by Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC<sup>(1)</sup> should be revised and certain new criteria set in the light of the scientific advice.
- (20) The microbiological criteria laid down in Commission Decision 93/51 EEC of 15 December 1992 on the microbiological criteria applicable to the production of cooked crustaceans and molluscan shellfish<sup>(2)</sup> are incorporated in this Regulation. It is therefore appropriate to repeal that Decision. Since Commission Decision 2001/471/EC of 8 June 2001 laying down rules for the regular checks on the general hygiene carried out by the operators in establishments according to Directive 64/433/EEC on health conditions for the production and marketing of fresh meat and Directive 71/118/EEC on health problems affecting the production and placing on the market of fresh poultrymeat<sup>(3)</sup> is repealed with effect from the 1 January 2006, it is appropriate to incorporate microbiological criteria set for carcasses in this Regulation.
- (21) The producer or manufacturer of a food product has to decide whether the product is ready to be consumed as such, without the need to cook or otherwise process it in order to ensure its safety and compliance with the microbiological criteria. According to Article 3 of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs<sup>(4)</sup>, the instructions for use of a foodstuff are compulsory on the labelling when it would be impossible to make appropriate use of the foodstuff in the absence of such instructions. Such instructions should be taken into account by food business operators when deciding appropriate sampling frequencies for the testing against microbiological criteria.
- (22) Sampling of the production and processing environment can be a useful tool to identify and prevent the presence of pathogenic micro-organisms in foodstuffs.
- (23) Food business operators should decide themselves the necessary sampling and testing frequencies as part of their procedures based on HACCP principles and other hygiene control procedures. However, it may be necessary in certain cases to set harmonised sampling frequencies at Community level, particularly in order to ensure the same level of controls to be performed throughout the Community.
- (1) OJ L 157, 30.4.2004, p. 33, corrected by OJ L 195, 2.6.2004, p. 12.
- (2) OJ L 13, 21.1.1993, p. 11.
- (3) OJ L 165, 21.6.2001, p. 48. Decision as amended by Decision 2004/379/EC (OJ L 144, 30.4.2004, p. 1).
- (4) OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15).

(24) Test results are dependent on the analytical method used, and therefore a given reference method should be associated with each microbiological criterion. However, food business operators should have the possibility to use analytical methods other than the reference methods, in particular more rapid methods, as long as the use of these alternative methods provides equivalent results. Moreover, a sampling plan needs to be defined for each criterion in order to ensure harmonised implementation. It is nevertheless necessary to allow the use of other sampling and testing schemes, including the use of alternative indicator organisms, on condition that these schemes provide equivalent guarantees of food safety.

(25) Trends in test results should be analysed, as they are able to reveal unwanted developments in the manufacturing process enabling the food business operator to take corrective actions before the process is out of control.

(26) The microbiological criteria set in this Regulation should be open to review and revised or supplemented, if appropriate, in order to take into account developments in the field of food safety and food microbiology. This includes progress in science, technology and methodology, changes in prevalence and contamination levels, changes in the population of vulnerable consumers, as well as the possible outputs from risk assessments.

(27) In particular, criteria for pathogenic viruses in live bivalve molluscs should be established when the analytical methods are developed sufficiently. There is a need for development of reliable methods for other microbial hazards too, e.g. *Vibrio parahaemolyticus*.

(28) It has been demonstrated that the implementation of control programmes can markedly contribute to a reduction of the prevalence of salmonella in production animals and products thereof. The purpose of Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents<sup>(1)</sup> is to ensure that proper and effective measures are taken to control salmonella at relevant stages of the food chain. Criteria for meat and products thereof should take into account the expected improvement in the salmonella situation at the level of primary production.

(29) For certain food safety criteria, it is appropriate to grant the Member States a transitional derogation, enabling them to comply with less stringent criteria but provided that the foodstuffs would only be marketed on the

national market. The Member States should notify the Commission and other Member States where this transitional derogation is used.

(30) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

#### Article 1

#### Subject-matter and scope

This Regulation lays down the microbiological criteria for certain micro-organisms and the implementing rules to be complied with by food business operators when implementing the general and specific hygiene measures referred to in Article 4 of Regulation (EC) No 852/2004. The competent authority shall verify compliance with the rules and criteria laid down in this Regulation in accordance with Regulation (EC) No 882/2004, without prejudice to its right to undertake further sampling and analyses for the purpose of detecting and measuring other micro-organisms, their toxins or metabolites, either as a verification of processes, for food suspected of being unsafe, or in the context of a risk analysis.

This Regulation shall apply without prejudice to other specific rules for the control of micro-organisms laid down in Community legislation and in particular the health standards for foodstuffs laid down in Regulation (EC) No 853/2004 of the European Parliament and of the Council<sup>(2)</sup>, the rules on parasites laid down under Regulation (EC) No 854/2004 of the European Parliament and of the Council<sup>(3)</sup> and the microbiological criteria laid down under Council Directive 80/777/EEC<sup>(4)</sup>.

#### Article 2

#### Definitions

The following definitions shall apply:

- (a) 'micro-organisms' means bacteria, viruses, yeasts, moulds, algae, parasitic protozoa, microscopic parasitic helminths, and their toxins and metabolites;
- (b) 'microbiological criterion' means a criterion defining the acceptability of a product, a batch of foodstuffs or a process, based on the absence, presence or number of micro-organisms, and/or on the quantity of their toxins/metabolites, per unit(s) of mass, volume, area or batch;

<sup>(1)</sup> OJ L 325, 12.12.2003, p. 1.

<sup>(2)</sup> OJ L 139, 30.4.2004, p. 55, corrected by OJ L 226, 25.6.2004, p. 22.

<sup>(3)</sup> OJ L 139, 30.4.2004, p. 206, corrected by OJ L 226, 25.6.2004, p. 83.

<sup>(4)</sup> OJ L 229, 30.8.1980, p. 1.

- (c) 'food safety criterion' means a criterion defining the acceptability of a product or a batch of foodstuff applicable to products placed on the market;
- (d) 'process hygiene criterion' a criterion indicating the acceptable functioning of the production process. Such a criterion is not applicable to products placed on the market. It sets an indicative contamination value above which corrective actions are required in order to maintain the hygiene of the process in compliance with food law;
- (e) 'batch' means a group or set of identifiable products obtained from a given process under practically identical circumstances and produced in a given place within one defined production period;
- (f) 'shelf-life' means either the period corresponding to the period preceding the 'use by' or the minimum durability date, as defined respectively in Articles 9 and 10 of Directive 2000/13/EC;
- (g) 'ready-to-eat food' means food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing effective to eliminate or reduce to an acceptable level micro-organisms of concern;
- (h) 'food intended for infants' means food specifically intended for infants, as defined in Commission Directive 91/321/EEC <sup>(1)</sup>;
- (i) 'food intended for special medical purposes' means dietary food for special medical purposes, as defined in Commission Directive 1999/21/EC <sup>(2)</sup>;
- (j) 'sample' means a set composed of one or several units or a portion of matter selected by different means in a population or in an important quantity of matter, which is intended to provide information on a given characteristic of the studied population or matter and to provide a basis for a decision concerning the population or matter in question or concerning the process which has produced it;
- (k) 'representative sample' means a sample in which the characteristics of the batch from which it is drawn are maintained. This is in particular the case of a simple random sample where each of the items or increments of the batch has been given the same probability of entering the sample;
- (l) 'compliance with microbiological criteria' means obtaining satisfactory or acceptable results set in Annex I when testing against the values set for the criteria through the

taking of samples, the conduct of analyses and the implementation of corrective action, in accordance with food law and the instructions given by the competent authority.

### Article 3

#### General requirements

1. Food business operators shall ensure that foodstuffs comply with the relevant microbiological criteria set out in Annex I. To this end the food business operators at each stage of food production, processing and distribution, including retail, shall take measures, as part of their procedures based on HACCP principles together with the implementation of good hygiene practice, to ensure the following:

- (a) that the supply, handling and processing of raw materials and foodstuffs under their control are carried out in such a way that the process hygiene criteria are met,
- (b) that the food safety criteria applicable throughout the shelf-life of the products can be met under reasonably foreseeable conditions of distribution, storage and use.

2. As necessary, the food business operators responsible for the manufacture of the product shall conduct studies in accordance with Annex II in order to investigate compliance with the criteria throughout the shelf-life. In particular, this applies to ready-to-eat foods that are able to support the growth of *Listeria monocytogenes* and that may pose a *Listeria monocytogenes* risk for public health.

Food businesses may collaborate in conducting those studies.

Guidelines for conducting those studies may be included in the guides to good practice referred to in Article 7 of Regulation (EC) No 852/2004.

### Article 4

#### Testing against criteria

1. Food business operators shall perform testing as appropriate against the microbiological criteria set out in Annex I, when they are validating or verifying the correct functioning of their procedures based on HACCP principles and good hygiene practice.

2. Food business operators shall decide the appropriate sampling frequencies, except where Annex I provides for specific sampling frequencies, in which case the sampling frequency shall be at least that provided for in Annex I. Food business operators shall make this decision in the context of their procedures based on HACCP principles and good

<sup>(1)</sup> OJ L 175, 4.7.1991, p. 35.

<sup>(2)</sup> OJ L 91, 7.4.1999, p. 29.



hygiene practice, taking into account the instructions for use of the foodstuff.

The frequency of sampling may be adapted to the nature and size of the food businesses, provided that the safety of foodstuffs will not be endangered.

#### Article 5

##### Specific rules for testing and sampling

1. The analytical methods and the sampling plans and methods in Annex I shall be applied as reference methods.

2. Samples shall be taken from processing areas and equipment used in food production, when such sampling is necessary for ensuring that the criteria are met. In that sampling the ISO standard 18593 shall be used as a reference method.

Food business operators manufacturing ready-to-eat foods, which may pose a *Listeria monocytogenes* risk for public health, shall sample the processing areas and equipment for *Listeria monocytogenes* as part of their sampling scheme.

Food business operators manufacturing dried infant formulae or dried foods for special medical purposes intended for infants below six months which pose an *Enterobacter sakazakii* risk shall monitor the processing areas and equipment for Enterobacteriaceae as part of their sampling scheme.

3. The number of sample units of the sampling plans set out in Annex I may be reduced if the food business operator can demonstrate by historical documentation that he has effective HACCP-based procedures.

4. If the aim of the testing is to specifically assess the acceptability of a certain batch of foodstuffs or a process, the sampling plans set out in Annex I shall be respected as a minimum.

5. Food business operators may use other sampling and testing procedures, if they can demonstrate to the satisfaction of the competent authority that these procedures provide at least equivalent guarantees. Those procedures may include use of alternative sampling sites and use of trend analyses.

Testing against alternative micro-organisms and related microbiological limits as well as testing of analytes other than microbiological ones shall be allowed only for process hygiene criteria.

The use of alternative analytical methods is acceptable when the methods are validated against the reference method in

Annex I and if a proprietary method, certified by a third party in accordance with the protocol set out in EN/ISO standard 16140 or other internationally accepted similar protocols, is used.

If the food business operator wishes to use analytical methods other than those validated and certified as described in paragraph 3 the methods shall be validated according to internationally accepted protocols and their use authorised by the competent authority.

#### Article 6

##### Labelling requirements

1. When the requirements for *Salmonella* in minced meat, meat preparations and meat products intended to be eaten cooked of all species set down in Annex I are fulfilled, the batches of those products placed on the market must be clearly labelled by the manufacturer in order to inform the consumer of the need for thorough cooking prior to consumption.

2. As from 1 January 2010 labelling as referred to in paragraph 1 in respect of minced meat, meat preparations and meat products made from poultrymeat will no longer be required.

#### Article 7

##### Unsatisfactory results

1. When the results of testing against the criteria set out in Annex I are unsatisfactory, the food business operators shall take the measures laid down in paragraphs 2 to 4 of this Article together with other corrective actions defined in their HACCP-based procedures and other actions necessary to protect the health of consumers.

In addition, they shall take measures to find the cause of the unsatisfactory results in order to prevent the recurrence of the unacceptable microbiological contamination. Those measures may include modifications to the HACCP-based procedures or other food hygiene control measures in place.

2. When testing against food safety criteria set out in Chapter 1 of Annex I provides unsatisfactory results, the product or batch of foodstuffs shall be withdrawn or recalled in accordance with Article 19 of Regulation (EC) No 178/2002. However, products placed on the market, which are not yet at retail level and which do not fulfil the food safety criteria, may be submitted to further processing by a treatment eliminating the hazard in question. This treatment may only be carried out by food business operators other than those at retail level.

The food business operator may use the batch for purposes other than those for which it was originally intended, provided that this use does not pose a risk for public or animal health and provided that this use has been decided within the procedures based on HACCP principles and good hygiene practice and authorised by the competent authority.

3. A batch of mechanically separated meat (MSM) produced with the techniques referred to in Chapter III, paragraph 3, in Section V of Annex III to Regulation (EC) No 853/2004, with unsatisfactory results in respect of the *Salmonella* criterion, may be used in the food chain only to manufacture heat-treated meat products in establishments approved in accordance with Regulation (EC) No 853/2004.

4. In the event of unsatisfactory results as regards process hygiene criteria the actions laid down in Annex I, Chapter 2 shall be taken.

#### Article 8

##### Transitional derogation

1. A transitional derogation is granted until 31 December 2009 at the latest pursuant to Article 12 of Regulation (EC) No 852/2004 as regards compliance with the value set in Annex I to this Regulation for *Salmonella* in minced meat, meat preparations and meat products intended to be eaten cooked placed on the national market of a Member State.

2. The Member States using this possibility shall notify the Commission and other Member States thereof. The Member State shall:

- (a) guarantee that the appropriate means, including labelling and a special mark, which cannot be confused with the identification mark provided for in Annex II, Section I to Regulation (EC) No 853/2004, are in place to ensure that the derogation applies only to the products concerned when placed on the domestic market, and that products dispatched for intra-Community trade comply with the criteria laid down in Annex I;

- (b) provide that the products to which such transitional derogation applies shall be clearly labelled that they must be thoroughly cooked prior to consumption;
- (c) undertake that when testing against the *Salmonella* criterion pursuant to Article 4, and for the result to be acceptable as regards such transitional derogation, no more than one out of five sample units shall be found to be positive.

#### Article 9

##### Analyses of trends

Food business operators shall analyse trends in the test results. When they observe a trend towards unsatisfactory results, they shall take appropriate actions without undue delay to remedy the situation in order to prevent the occurrence of microbiological risks.

#### Article 10

##### Review

This Regulation shall be reviewed taking into account progress in science, technology and methodology, emerging pathogenic micro-organisms in foodstuffs, and information from risk assessments. In particular, the criteria and conditions concerning the presence of salmonella in carcasses of cattle, sheep, goats, horses, pigs and poultry shall be revised in the light of the changes observed in salmonella prevalence.

#### Article 11

##### Repeal

Decision 93/51/EEC is repealed.

#### Article 12

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2006.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 15 November 2005.

For the Commission

Markos KYPRIANOU

Member of the Commission

## ANNEX I

**Microbiological criteria for foodstuffs**

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# Chapter 1. Food safety criteria

Food category	Micro-organisms/their toxins, metabolites	Sampling-plan <sup>(1)</sup>		Limits <sup>(2)</sup>		Analytical reference method <sup>(3)</sup>	Stage where the criterion applies
		n	c	m	M		
1.1. Ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes <sup>(4)</sup>	<i>Listeria monocytogenes</i>	10	0	Absence in 25 g		EN/ISO 11290-1	Products placed on the market during their shelf-life
1.2. Ready-to-eat foods able to support the growth of <i>L. monocytogenes</i> , other than those intended for infants and for special medical purposes	<i>Listeria monocytogenes</i>	5	0	100 cfu/g <sup>(5)</sup>		EN/ISO 11290-2 <sup>(6)</sup>	Products placed on the market during their shelf-life
		5	0	Absence in 25 g <sup>(7)</sup>		EN/ISO 11290-1	Before the food has left the immediate control of the food business operator, who has produced it
1.3. Ready-to-eat foods unable to support the growth of <i>L. monocytogenes</i> , other than those intended for infants and for special medical purposes <sup>(4)</sup> <sup>(8)</sup>	<i>Listeria monocytogenes</i>	5	0	100 cfu/g		EN/ISO 11290-2 <sup>(6)</sup>	Products placed on the market during their shelf-life
1.4. Minced meat and meat preparations intended to be eaten raw	<i>Salmonella</i>	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.5. Minced meat and meat preparations made from poultry meat intended to be eaten cooked	<i>Salmonella</i>	5	0	From 1.1.2006 Absence in 10 g From 1.1.2010 Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.6. Minced meat and meat preparations made from other species than poultry intended to be eaten cooked	<i>Salmonella</i>	5	0	Absence in 10 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.7. Mechanically separated meat (MSM) <sup>(9)</sup>	<i>Salmonella</i>	5	0	Absence in 10 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.8. Meat products intended to be eaten raw, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	<i>Salmonella</i>	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life

Food category	Micro-organisms/their toxins, metabolites	Sampling-plan <sup>(1)</sup>		Limits <sup>(2)</sup>		Analytical reference method <sup>(3)</sup>	Stage where the criterion applies
		n	c	m	M		
1.9. Meat products made from poultry meat intended to be eaten cooked	<i>Salmonella</i>	5	0	From 1.1.2006 Absence in 10 g From 1.1.2010 Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.10. Gelatine and collagen	<i>Salmonella</i>	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.11. Cheeses, butter and cream made from raw milk or milk that has undergone a lower heat treatment than pasteurisation <sup>(10)</sup>	<i>Salmonella</i>	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.12. Milk powder and whey powder <sup>(10)</sup>	<i>Salmonella</i>	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.13. Ice cream <sup>(11)</sup> , excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	<i>Salmonella</i>	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.14. Egg products, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	<i>Salmonella</i>	5	0	Absence in 25g		EN/ISO 6579	Products placed on the market during their shelf-life
1.15. Ready-to-eat foods containing raw egg, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	<i>Salmonella</i>	5	0	Absence in 25 g or ml		EN/ISO 6579	Products placed on the market during their shelf-life
1.16. Cooked crustaceans and molluscan shell-fish	<i>Salmonella</i>	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.17. Live bivalve molluscs and live echinoderms, tunicates and gastropods	<i>Salmonella</i>	5	0	Absence in 25g		EN/ISO 6579	Products placed on the market during their shelf-life

Food category	Micro-organisms/their toxins, metabolites	Sampling-plan <sup>(1)</sup>		Limits <sup>(2)</sup>		Analytical reference method <sup>(3)</sup>	Stage where the criterion applies
		n	c	m	M		
1.18. Sprouted seeds (ready-to-eat) <sup>(12)</sup>	<i>Salmonella</i>	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.19. Pre-cut fruit and vegetables (ready-to-eat)	<i>Salmonella</i>	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.20. Unpasteurised fruit and vegetable juices (ready-to-eat)	<i>Salmonella</i>	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.21. Cheeses, milk powder and whey powder, as referred to in the coagulase-positive staphylococci criteria in Chapter 2.2 of this Annex	Staphylococcal enterotoxins	5	0	Not detected in 25g		European screening method of the CRL for Milk <sup>(13)</sup>	Products placed on the market during their shelf-life
1.22. Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age, as referred to in the Enterobacteriaceae criterion in Chapter 2.2 of this Annex	<i>Salmonella</i>	30	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.23. Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age, as referred to in the Enterobacteriaceae criterion in Chapter 2.2 of this Annex	<i>Enterobacter sakazakii</i>	30	0	Absence in 10 g		ISO/DTS 22964	Products placed on the market during their shelf-life
1.24. Live bivalve molluscs and live echinoderms, tunicates and gastropods	<i>E.coli</i> <sup>(14)</sup>	1 <sup>(15)</sup>	0	230 MPN/100g of flesh and intra-valvular liquid		ISO TS 16649-3	Products placed on the market during their shelf-life
1.25. Fishery products from fish species associated with a high amount of histidine <sup>(16)</sup>	Histamine	9 <sup>(17)</sup>	2	100 mg/kg	200 mg/kg	HPLC <sup>(18)</sup>	Products placed on the market during their shelf-life

Food category	Micro-organisms/their toxins, metabolites	Sampling-plan <sup>(1)</sup>		Limits <sup>(2)</sup>		Analytical reference method <sup>(3)</sup>	Stage where the criterion applies
		n	c	m	M		
1.26. Fishery products which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with a high amount of histidine <sup>(16)</sup>	Histamine	9	2	200 mg/kg	400 mg/kg	HPLC <sup>(18)</sup>	Products placed on the market during their shelf-life

<sup>(1)</sup> n = number of units comprising the sample; c = number of sample units giving values over m or between m and M.

<sup>(2)</sup> For points 1.1-1.24 m=M.

<sup>(3)</sup> The most recent edition of the standard shall be used.

<sup>(4)</sup> Regular testing against the criterion is not useful in normal circumstances for the following ready-to-eat foods:

- those which have received heat treatment or other processing effective to eliminate *L. monocytogenes*, when recontamination is not possible after this treatment (e.g. products heat treated in their final package),
- fresh, uncut and unprocessed vegetables and fruits, excluding sprouted seeds,
- bread, biscuits and similar products,
- bottled or packed waters, soft drinks, beer, cider, wine, spirits and similar products,
- sugar, honey and confectionery, including cocoa and chocolate products,
- live bivalve molluscs.

<sup>(5)</sup> This criterion applies if the manufacturer is able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit 100 cfu/g throughout the shelf-life. The operator may fix intermediate limits during the process that should be low enough to guarantee that the limit of 100 cfu/g is not exceeded at the end of the shelf-life.

<sup>(6)</sup> 1 ml of inoculum is plated on a Petri dish of 140 mm diameter or on three Petri dishes of 90 mm diameter.

<sup>(7)</sup> This criterion applies to products before they have left the immediate control of the producing food business operator, when he is not able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit of 100 cfu/g throughout the shelf-life.

<sup>(8)</sup> Products with pH ≤ 4,4 or  $a_w$  ≤ 0,92, products with pH ≤ 5,0 and  $a_w$  ≤ 0,94, products with a shelf-life of less than five days are automatically considered to belong to this category. Other categories of products can also belong to this category, subject to scientific justification.

<sup>(9)</sup> This criterion applies to mechanically separated meat (MSM) produced with the techniques referred to in Chapter III, paragraph 3, in section V of Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin.

<sup>(10)</sup> Excluding products when the manufacturer can demonstrate to the satisfaction of the competent authorities that, due to the ripening time and  $a_w$  of the product where appropriate, there is no salmonella risk.

<sup>(11)</sup> Only ice creams containing milk ingredients.

<sup>(12)</sup> Preliminary testing of the batch of seeds before starting the sprouting process or the sampling to be carried out at the stage where the highest probability of finding *Salmonella* is expected.

<sup>(13)</sup> Reference: Hennekinne et al., J. AOAC Internat. Vol. 86, No 2, 2003.

<sup>(14)</sup> *E. coli* is used here as an indicator of faecal contamination.

<sup>(15)</sup> A pooled sample comprising a minimum of 10 individual animals.

<sup>(16)</sup> Particularly fish species of the families: *Scombridae*, *Clupeidae*, *Engraulidae*, *Coryfenidae*, *Pomatomidae*, *Scombrosidae*.

<sup>(17)</sup> Single samples may be taken at retail level. In such a case the presumption laid down in Article 14(6) of Regulation (EC) No 178/2002, according to which the whole batch should be deemed unsafe, shall not apply.

<sup>(18)</sup> References: 1. Malle P., Valle M., Bouquelet S. Assay of biogenic amines involved in fish decomposition. J. AOAC Internat. 1996, 79, 43-49.

2. Duflos G., Dervin C., Malle P., Bouquelet S. Relevance of matrix effect in determination of biogenic amines in plaice (*Pleuronectes platessa*) and whiting (*Merlangius merlangus*). J. AOAC Internat. 1999, 82, 1097-1101.

### Interpretation of the test results

The limits given refer to each sample unit tested, excluding live bivalve molluscs and live echinoderms, tunicates and gastropods in relation to testing *E. coli*, where the limit refers to a pooled sample.

The test results demonstrate the microbiological quality of the batch tested <sup>(1)</sup>.

*L. monocytogenes* in ready-to-eat foods intended for infants and for special medical purposes:

- satisfactory, if all the values observed indicate the absence of the bacterium,
- unsatisfactory, if the presence of the bacterium is detected in any of the sample units.

*L. monocytogenes* in ready-to-eat foods able to support the growth of *L. monocytogenes* before the food has left the immediate control of the producing food business operator when he is not able to demonstrate that the product will not exceed the limit of 100 cfu/g throughout the shelf-life:

- satisfactory, if all the values observed indicate the absence of the bacterium,
- unsatisfactory, if the presence of the bacterium is detected in any of the sample units.

*L. monocytogenes* in other ready-to-eat foods and *E. coli* in live bivalve molluscs:

- satisfactory, if all the values observed are  $\leq$  the limit,
- unsatisfactory, if any of the values are  $>$  the limit.

*Salmonella* in different food categories:

- satisfactory, if all the values observed indicate the absence of the bacterium,
- unsatisfactory, if the presence of the bacterium is detected in any of the sample units.

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<sup>(1)</sup> The test results can be used also for demonstrating the effectiveness of the HACCP or good hygiene procedure of the process.



Staphylococcal enterotoxins in dairy products:

- satisfactory, if in all the sample units the enterotoxins are not detected,
- unsatisfactory, if the enterotoxins are detected in any of the sample units.

*Enterobacter sakazakii* in dried infant formulae and dried dietary foods for special medical purposes intended for infants below 6 months of age:

- satisfactory, if all the values observed indicate the absence of the bacterium,
- unsatisfactory, if the presence of the bacterium is detected in any of the sample units.

Histamine in fishery products from fish species associated with a high amount of histidine:

- satisfactory, if the following requirements are fulfilled:
  1. the mean value observed is  $\leq m$
  2. a maximum of  $c/n$  values observed are between  $m$  and  $M$
  3. no values observed exceed the limit of  $M$ ,
- unsatisfactory, if the mean value observed exceeds  $m$  or more than  $c/n$  values are between  $m$  and  $M$  or one or more of the values observed are  $>M$ .

## Chapter 2. Process hygiene criteria

## 2.1. Meat and products thereof

Food category	Micro-organisms	Sampling plan <sup>(1)</sup>		Limits <sup>(2)</sup>		Analytical reference method <sup>(3)</sup>	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.1.1. Carcasses of cattle, sheep, goats and horses <sup>(4)</sup>	Aerobic colony count			3,5 log cfu/cm <sup>2</sup> daily mean log	5,0 log cfu/cm <sup>2</sup> daily mean log	ISO 4833	Carcasses after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
	Enterobacteriaceae			1,5 log cfu/cm <sup>2</sup> daily mean log	2,5 log cfu/cm <sup>2</sup> daily mean log	ISO 21528-2	Carcasses after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
2.1.2. Carcasses of pigs <sup>(4)</sup>	Aerobic colony count			4,0 log cfu/cm <sup>2</sup> daily mean log	5,0 log cfu/cm <sup>2</sup> daily mean log	ISO 4833	Carcasses after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
	Enterobacteriaceae			2,0 log cfu/cm <sup>2</sup> daily mean log	3,0 log cfu/cm <sup>2</sup> daily mean log	ISO 21528-2	Carcasses after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
2.1.3. Carcasses of cattle, sheep, goats and horses	<i>Salmonella</i>	50 <sup>(5)</sup>	2 <sup>(6)</sup>	Absence in the area tested per carcass		EN/ISO 6579	Carcasses after dressing but before chilling	Improvements in slaughter hygiene, review of process controls and of origin of animals
2.1.4. Carcasses of pig	<i>Salmonella</i>	50 <sup>(5)</sup>	5 <sup>(6)</sup>	Absence in the area tested per carcass		EN/ISO 6579	Carcasses after dressing but before chilling	Improvements in slaughter hygiene and review of process controls, origin of animals and of the biosecurity measures in the farms of origin
2.1.5. Poultry carcasses of broilers and turkeys	<i>Salmonella</i>	50 <sup>(5)</sup>	7 <sup>(6)</sup>	Absence in 25 g of a pooled sample of neck skin		EN/ISO 6579	Carcasses after chilling	Improvements in slaughter hygiene and review of process controls, origin of animals and biosecurity measures in the farms of origin

Food category	Micro-organisms	Sampling plan <sup>(1)</sup>		Limits <sup>(2)</sup>		Analytical reference method <sup>(3)</sup>	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.1.6. Minced meat	Aerobic colony count <sup>(7)</sup>	5	2	5x10 <sup>5</sup> cfu/g	5x10 <sup>6</sup> cfu/g	ISO 4833	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
	<i>E.coli</i> <sup>(8)</sup>	5	2	50 cfu/g	500 cfu/g	ISO 16649-1 or 2	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
2.1.7. Mechanically separated meat (MSM) <sup>(9)</sup>	Aerobic colony count	5	2	5x10 <sup>5</sup> cfu/g	5x10 <sup>6</sup> cfu/g	ISO 4833	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
	<i>E.coli</i> <sup>(8)</sup>	5	2	50 cfu/g	500 cfu/g	ISO 16649-1 or 2	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
2.1.8. Meat preparations	<i>E.coli</i> <sup>(8)</sup>	5	2	500 cfu/g or cm <sup>2</sup>	5 000 cfu/g or cm <sup>2</sup>	ISO 16649-1 or 2	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials

<sup>(1)</sup> n = number of units comprising the sample; c = number of sample units giving values between m and M.

<sup>(2)</sup> For points 2.1.3 — 2.1.5 m=M.

<sup>(3)</sup> The most recent edition of the standard shall be used.

<sup>(4)</sup> The limits (m and M) apply only to samples taken by the destructive method. The daily mean log is calculated by first taking a log value of each individual test result and then calculating the mean of these log values.

<sup>(5)</sup> The 50 samples are derived from 10 consecutive sampling sessions in accordance with the sampling rules and frequencies laid down in this Regulation.

<sup>(6)</sup> The number of samples where the presence of salmonella is detected. The c value is subject to review in order to take into account the progress made in reducing the salmonella prevalence. Member States or regions having low salmonella prevalence may use lower c values even before the review.

<sup>(7)</sup> This criterion does not apply to minced meat produced at retail level when the shelf-life of the product is less than 24 hours.

<sup>(8)</sup> *E. coli* is used here as an indicator of faecal contamination.

<sup>(9)</sup> These criteria apply to mechanically separated meat (MSM) produced with the techniques referred to in Chapter III, paragraph 3, in section V of Annex III of Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin.

### Interpretation of the test results

The limits given refer to each sample unit tested, excluding testing of carcasses where the limits refer to pooled samples.

The test results demonstrate the microbiological quality of the process tested.

*Enterobacteriaceae* and aerobic colony count in carcasses of cattle, sheep, goats, horses and pigs:

- satisfactory, if the daily mean log is  $< m$ ,
- acceptable, if the daily mean log is between  $m$  and  $M$ ,
- unsatisfactory, if the daily mean log is  $> M$ .

*Salmonella* in carcasses:

- satisfactory, if the presence of *Salmonella* is detected in a maximum of  $c/n$  samples,
- unsatisfactory, if the presence of *Salmonella* is detected in more than  $c/n$  samples.

After each sampling session, the results of the last ten sampling sessions are assessed in order to obtain the  $n$  number of samples.

*E. coli* and aerobic colony count in minced meat, meat preparations and mechanically separated meat (MSM):

- satisfactory, if all the values observed are  $< m$ ,
- acceptable, if a maximum of  $c/n$  values are between  $m$  and  $M$ , and the rest of the values observed are  $< m$ ,
- unsatisfactory, if one or more of the values observed are  $> M$  or more than  $c/n$  values are between  $m$  and  $M$ .

## 2.2. Milk and dairy products

Food category	Micro-organisms	Sampling plan <sup>(1)</sup>		Limits <sup>(2)</sup>		Analytical reference method <sup>(1)</sup>	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.2.1. Pasteurised milk and other pasteurised liquid dairy products <sup>(4)</sup>	Enterobacteriaceae	5	2	<1 cfu/ml	5 cfu/ml	ISO 21528-1	End of the manufacturing process	Check on the efficiency of heat-treatment and prevention of recontamination as well as the quality of raw materials
2.2.2. Cheeses made from milk or whey that has undergone heat treatment	<i>E.coli</i> <sup>(5)</sup>	5	2	100 cfu/g	1 000 cfu/g	ISO 16649- 1 or 2	At the time during the manufacturing process when the <i>E. coli</i> count is expected to be highest <sup>(6)</sup>	Improvements in production hygiene and selection of raw materials
2.2.3. Cheeses made from raw milk	Coagulase-positive staphylococci	5	2	10 <sup>4</sup> cfu/g	10 <sup>5</sup> cfu/g	EN/ISO 6888-2	At the time during the manufacturing process when the number of staphylococci is expected to be highest	Improvements in production hygiene and selection of raw materials. If values >10 <sup>5</sup> cfu/g are detected, the cheese batch has to be tested for staphylococcal enterotoxins.
2.2.4. Cheeses made from milk that has undergone a lower heat treatment than pasteurisation <sup>(7)</sup> and ripened cheeses made from milk or whey that has undergone pasteurisation or a stronger heat treatment <sup>(7)</sup>	Coagulase-positive staphylococci	5	2	100 cfu/g	1 000 cfu/g	EN/ISO 6888-1 or 2		
2.2.5. Unripened soft cheeses (fresh cheeses) made from milk or whey that has undergone pasteurisation or a stronger heat treatment <sup>(7)</sup>	Coagulase-positive staphylococci	5	2	10 cfu/g	100 cfu/g	EN/ISO 6888-1 or 2	End of the manufacturing process	Improvements in production hygiene. If values > 10 <sup>5</sup> cfu/g are detected, the cheese batch has to be tested for staphylococcal enterotoxins.
2.2.6. Butter and cream made from raw milk or milk that has undergone a lower heat treatment than pasteurisation	<i>E.coli</i> <sup>(5)</sup>	5	2	10 cfu/g	100 cfu/g	ISO 16649- 1 or 2	End of the manufacturing process	Improvements in production hygiene and selection of raw materials

Food category	Micro-organisms	Sampling plan <sup>(1)</sup>		Limits <sup>(2)</sup>		Analytical reference method <sup>(3)</sup>	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.2.7. Milk powder and whey powder <sup>(4)</sup>	Enterobacteriaceae	5	0	10 cfu/g		ISO 21528- 1	End of the manufacturing process	Check on the efficiency of heat treatment and prevention of recontamination
	Coagulase-positive staphylococci	5	2	10 cfu/g	100 cfu/g	EN/ISO 6888-1 or 2	End of the manufacturing process	Improvements in production hygiene. If values > 10 <sup>5</sup> cfu/g are detected, the batch has to be tested for staphylococcal enterotoxins.
2.2.8. Ice cream <sup>(5)</sup> and frozen dairy desserts	Enterobacteriaceae	5	2	10 cfu/g	100 cfu/g	ISO 21528- 2	End of the manufacturing process	Improvements in production hygiene
2.2.9. Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age	Enterobacteriaceae	10	0	Absence in 10 g		ISO 21528- 1	End of the manufacturing process	Improvements in production hygiene to minimise contamination. If Enterobacteriaceae are detected in any of the sample units, the batch has to be tested for <i>E. sakazakii</i> and <i>Salmonella</i>

<sup>(1)</sup> n = number of units comprising the sample; c = number of sample units giving values between m and M.

<sup>(2)</sup> For point 2.2.7 m=M.

<sup>(3)</sup> The most recent edition of the standard shall be used.

<sup>(4)</sup> The criterion does not apply to products intended for further processing in the food industry.

<sup>(5)</sup> *E. coli* is used here as an indicator for the level of hygiene.

<sup>(6)</sup> For cheeses which are not able to support the growth of *E. coli*, the *E. coli* count is usually the highest at the beginning of the ripening period, and for cheeses which are able to support the growth of *E. coli*, it is normally at the end of the ripening period.

<sup>(7)</sup> Excluding cheeses where the manufacturer can demonstrate, to the satisfaction of the competent authorities, that the product does not pose a risk of staphylococcal enterotoxins.

<sup>(8)</sup> Only ice creams containing milk ingredients.

### Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.

Enterobacteriaceae in dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age:

- satisfactory, if all the values observed indicate the absence of the bacterium,
- unsatisfactory, if the presence of the bacterium is detected in any of the sample units

*E. coli*, enterobacteriaceae (other food categories) and coagulase-positive staphylococci:

- satisfactory, if all the values observed are  $< m$ ,
- acceptable, if a maximum of  $c/n$  values are between  $m$  and  $M$ , and the rest of the values observed are  $< m$ ,
- unsatisfactory, if one or more of the values observed are  $> M$  or more than  $c/n$  values are between  $m$  and  $M$ .

**2.3. Egg products**

Food category	Micro-organisms	Sampling plan <sup>(1)</sup>		Limits		Analytical reference method <sup>(2)</sup>	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.3.1. Egg products	Enterobacteriaceae	5	2	10 cfu/g or ml	100 cfu/g or ml	ISO 21528-2	End of the manufacturing process	Checks on the efficiency of the heat treatment and prevention of recontamination

<sup>(1)</sup> n = number of units comprising the sample; c = number of sample units giving values between m and M.

<sup>(2)</sup> The most recent edition of the standard shall be used.

**Interpretation of the test results**

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.

Enterobacteriaceae in egg products:

- satisfactory, if all the values observed are < m,
- acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m,
- unsatisfactory, if one or more of the values observed are >M or more than c/n values are between m and M.



## 2.4. Fishery products

Food category	Micro-organisms	Sampling plan <sup>(1)</sup>		Limits		Analytical reference method <sup>(2)</sup>	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.4.1. Shelled and shucked products of cooked crustaceans and molluscan shellfish	<i>E.coli</i>	5	2	1 cfu/g	10 cfu/g	ISO TS 16649-3	End of the manufacturing process	Improvements in production hygiene
	Coagulase-positive staphylococci	5	2	100 cfu/g	1 000 cfu/g	EN/ISO 6888-1 or 2	End of the manufacturing process	Improvements in production hygiene

<sup>(1)</sup> n = number of units comprising the sample; c = number of sample units giving values between m and M.

<sup>(2)</sup> The most recent edition of the standard shall be used.

## Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.

*E. coli* in shelled and shucked products of cooked crustaceans and molluscan shellfish:

- satisfactory, if all the values observed are  $\leq m$ ,
- acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are  $\leq m$ ,
- unsatisfactory, if one or more of the values observed are  $>M$  or more than c/n values are between m and M.

Coagulase-positive staphylococci in shelled and cooked crustaceans and molluscan shellfish:

- satisfactory, if all the values observed are  $< m$ ,
- acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are  $< m$ ,
- unsatisfactory, if one or more of the values observed are  $>M$  or more than c/n values are between m and M.

## 2.5. Vegetables, fruits and products thereof

Food category	Micro-organisms	Sampling plan <sup>(1)</sup>		Limits		Analytical reference method <sup>(2)</sup>	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.5.1. Pre-cut fruit and vegetables (ready-to-eat)	<i>E.coli</i>	5	2	100 cfu/g	1 000 cfu/g	ISO 16649- 1 or 2	Manufacturing process	Improvements in production hygiene, selection of raw materials
2.5.2. Unpasteurised fruit and vegetable juices (ready-to-eat)	<i>E.coli</i>	5	2	100 cfu/g	1 000 cfu/g	ISO 16649- 1 or 2	Manufacturing process	Improvements in production hygiene, selection of raw materials

<sup>(1)</sup> n = number of units comprising the sample; c = number of sample units giving values between m and M.

<sup>(2)</sup> The most recent edition of the standard shall be used.

### Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.

*E. coli* in pre-cut fruit and vegetables (ready-to-eat) and in unpasteurised fruit and vegetable juices (ready-to-eat):

- satisfactory, if all the values observed are  $\leq m$ ,
- acceptable, if a maximum of  $c/n$  values are between  $m$  and  $M$ , and the rest of the values observed are  $\leq m$ ,
- unsatisfactory, if one or more of the values observed are  $>M$  or more than  $c/n$  values are between  $m$  and  $M$ .



United States Department of Agriculture

Food Safety and  
Inspection Service

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OCT 21 2015

Dr. (b) (6)  
Chief Veterinary Officer  
Ministry of Food, Agriculture and Fisheries  
Danish Veterinary and Food Administration  
Mørkhøj Bygade 19  
DK-2860 Søborg  
Denmark

Dear Dr. (b) (6) :

The Food Safety and Inspection Service (FSIS) has concluded its review of Denmark's September 2013 submission to conduct a visual post-mortem inspection that omits the palpation of the lungs, the liver, and their associated lymph nodes of market hogs that are raised indoors. This submission has been determined to meet United States levels of protection and is therefore equivalent.

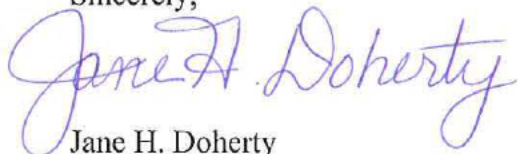
Previously, FSIS has made equivalence determinations for other aspects of Denmark's visual post-mortem inspection system for market hogs. On December 24, 2008, FSIS approved a submission to omit the palpation and incision of mandibular lymph nodes, and on February 29, 2012, a second submission was approved to omit the palpation and incision of mesenteric lymph nodes. These combined equivalence determinations will allow Denmark to perform a full carcass visual post-mortem inspection on indoor raised market hogs.

Visual post-mortem inspection will still allow veterinary inspectors to palpate and incise lymph nodes and organs (as occurs in traditional inspection) at their discretion. Each herd of market hogs that arrives at establishments to be slaughtered is accompanied by historical "Supply-Chain Information." Supply-Chain Information consists of paperwork that documents the health status and history of each herd, complete traceback information, as well as details about the originating farm, such as history of disease, use of medications and other on farm practices that contribute to maintenance of the herd's health. This documentation, as well as any ante-mortem inspection observances, will influence the veterinary inspector's decision whether to perform visual inspection or traditional inspection.

FSIS' reviews were conducted using submitted material provided by Denmark, such as detailed descriptions of their proposed systems, and in-depth risk assessments. These risk assessments considered various food safety hazards such as the risk of exposure to pathogenic organisms, pathology, animal disease, and a study comparing the performance of visual inspection to that of traditional inspection.

Thank you for your assistance and cooperation during the review process. Please feel free to contact me at telephone number 202-708-8769, or by email at [Jane.Doherty@fsis.usda.gov](mailto:Jane.Doherty@fsis.usda.gov) if you have any questions.

Sincerely,



Jane H. Doherty  
International Coordination Executive  
Office of International Coordination



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, D.C.  
20250

Dr. (b) (6)  
Chief Veterinary Officer  
Ministry of Agriculture, Nature and Food Quality  
PO Box 19506  
2500 CM The Hague  
Netherlands

JUL 16 2008

Dear Dr. (b) (6) :

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

- Supply Chain Inspection

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

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

Based on the information provided, FSIS determined that Netherland's use of an alternative post-mortem inspection procedure for market hogs meets the established criteria. Therefore, FSIS is granting the government of the Netherlands approval to use supply chain inspection for the purposes of post-mortem inspection of the meat products exported to the United States.

If you have any questions regarding these equivalence determinations or need additional information, please contact me by telephone at 202-720-3781, by fax at 202-690-4040, or by electronic mail at [sally.white@fsis.usda.gov](mailto:sally.white@fsis.usda.gov).

Sincerely,



Sally White  
Director  
International Equivalence Staff  
Office of International Affairs



CC:

Steve Huete, Attaché, US Embassy, The Hague

(b) (6), Agricultural Counselor, Netherlands Embassy, Wash DC

(b) (6), Agric. / Consumer Affairs, EU Mission to the U.S., Wash DC

(b) (6), Acting Director, Directorate E, European Commission, Brussels

(b) (6), Minister-Counselor, US Mission to the EU in Brussels

OSTA/ FAS

David Young, Europe Area Director, FAS

(b) (6), State Department

Alfred Almanza, Administrator, FSIS

William James, Assistant Administrator, OIA, FSIS

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Country File

FSIS:OIA:IES:TFurey:720.5123:07/09/08:NL – Supply Chain Inspection





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## FILE ASSURANCE CHECKLIST

### CERTIFICATION STATEMENT

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

### COUNTRY

### TYPE OF FILE

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

### CERTIFIED BY

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SENIOR EQUIVALENCE OFFICER, IES

DATE: 11/17/06

### REVIEWED BY

*Sally White*

DIRECTOR, IES

DATE: 11/17/06

## **DECISION MEMORANDUM**

### **ISSUE:**

The Netherlands has developed a system for inspection of market hogs which emphasizes ante-mortem animal disease detection (tuberculosis) by serology on-farm instead of post-mortem inspection for gross lesions at slaughter.

### **BACKGROUND:**

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

A team of FSIS experts met and reviewed the Netherlands Supply Chain Inspection system, the Netherlands reference materials, and information presented by the Netherlands officials during FSIS-Netherlands bilateral meeting of November 1-2, 2006. The FSIS team also reviewed the two FSIS inspection procedures (traditional inspection and HACCP-Based Inspection Model Project-HIMP) employed in establishments slaughtering market age hogs and compared these two inspection procedures with the Netherlands' post-mortem inspection procedure. These two FSIS inspection procedures were used to develop the equivalence criteria used to evaluate the Netherlands' request.

### **SUMMARY OF SUPPLY CHAIN INSPECTION**

The following is a summary of the Netherlands' inspection procedures used in establishments operating under Supply Chain Inspection:

#### **Ante-mortem Inspection**

Ante-mortem inspection on all swine is performed by the official veterinarian using traditional inspection procedures, which are equivalent to FSIS' traditional inspection procedures.

#### **Post-mortem Inspection**

Post-mortem inspection is performed by official auxiliaries (contract inspectors) located at fixed inspection stations for head, viscera and carcass inspection.

- Head Inspection
  - Visual inspection of the head and throat, including the mandibular lymph nodes
  - Visual inspection of the mouth, fauces, and tongue

- Viscera Inspection
  - Visual inspection of the lungs, trachea, and esophagus
  - Visual inspection of the pericardium and heart
  - Visual inspection of the liver and hepatic and pancreatic (portal) lymph nodes
  - Visual inspection of the gastro-intestinal tract, mesentery, gastric and mesenteric lymph nodes
  - Visual inspection of the spleen
  - Visual inspection of genital organs
- Carcass Inspection
  - Visual inspection of the carcass
  - Visual inspection of the pleura and peritoneum (lining of chest and abdominal cavities)
  - Visual inspection of the kidneys
  - Visual inspection of the diaphragm
  - Visual inspection of the udder and its lymph nodes
  - Visual inspection of the umbilical region and joints of young animals

## **SUMMARY OF FSIS TRADITIONAL INSPECTION**

The following is a summary of the FSIS inspection procedures in establishments operating under the traditional swine inspection system.

### **Ante-mortem Inspection**

All swine offered for slaughter in an official establishment are examined and inspected on the day of and before slaughter by an FSIS inspector. Ante-mortem inspection is made in pens on the premises of the establishment. All animals are examined and inspected at rest and in motion; both sides are inspected and observed. Each head, viscera and carcass is inspected as described below.

### **Post –mortem Inspection**

FSIS inspectors are located at fixed inspection stations in order to perform inspection of the head, viscera and carcass.

- Head Inspection
  - Observe head and cut surfaces – eyes, fat, cheek muscles, and other tissues for abnormalities
  - Incise and observe mandibular lymph nodes
- Viscera Inspection
  - Observe eviscerated carcass, viscera and parietal (top) surface of spleen
  - Observe and palpate mesenteric lymph nodes
  - Palpate portal lymph nodes

- Observe dorsal (curved) surface of lungs
  - Palpate bronchial lymph nodes
  - Observe mediastinal lymph nodes
  - Turn lungs over and observe ventral (flat) surfaces
  - Observe heart
  - Observe dorsal (curved) surface of liver
  - Turn liver over and observe ventral (flat) surface
- Carcass Inspection
  - Observe back of carcass (turn carcass or use mirror).
  - Observe front and inside of carcass, including:
    - Cut surfaces
    - All body cavities
    - Lumbar region
    - Neck region
    - Grasp, turn, and observe the kidneys

## SUMMARY OF FSIS HIMP INSPECTION

The following is a summary of the FSIS inspection procedures in establishments operating under HIMP.

FSIS conducts three types of inspection activities; Systems Inspection, Carcass Inspection and Verification Inspection in HIMP establishments. Systems Inspection involves the evaluation of in-plant inspection findings and is intended to determine the effectiveness of the overall design and execution of all establishment slaughter processes under the HACCP and process control plans. Carcass Inspection involves the examination of each carcass and its parts to determine if they are unadulterated. Verification Inspection involves the evaluation of the effectiveness of the establishment's HACCP and process control plan in meeting the relevant performance standards. Inspection procedures under HIMP were developed to reduce reliance on organoleptic inspection, to shift to prevention-oriented inspection systems based on risk assessment, and to redeploy inspection resources in a manner that better protects the public from food-borne diseases.

**System Inspection** - The System Inspector (SI) is either the Inspector in Charge (IIC) or the Supervisory Veterinary Medical Officer (SVMO). The SI has overall responsibility to assure that the plant and inspection personnel effectively conduct the required activities under HIMP, as designed.

Specifically, the System Inspector:

- Determines, or assigns to the verification inspector (VI), the daily random sampling schedule.
- Monitors and determines the effectiveness of ante-mortem verification inspection.
- Monitors and determines the effectiveness of the establishment's ante-mortem sorting.

- Determines final disposition of animals designated by the VI as “suspects” at ante-mortem.
- Monitors and determines the effectiveness of the establishment’s post-mortem sorting and dispositions.
- Determines final disposition on carcasses retained by the carcass inspector (CI) or VI on post-mortem.
- Records nonconformance findings on the appropriate HIMP form.
- Determines if the establishment is meeting relevant performance standards.
- Assesses the overall design and execution of the establishment’s HACCP and process control procedures.
- Assures that all adulterated products are condemned in accordance with applicable regulations.
- Determines when unscheduled verification sampling is warranted.
- Maintains communication with the VI and CIs to facilitate coordination of all ante-mortem and post-mortem findings.

**Carcass Inspection** - The Carcass Inspectors (CI) are stationed at fixed locations on the post-mortem line to determine whether a product is adulterated or unadulterated. They inspect each carcass and part on the line, as well as evaluate the on-going effectiveness of the establishment’s food safety and other consumer protection processes.

Specifically, the CI:

- Determines whether each carcass and its parts are adulterated or unadulterated.
- Takes appropriate action to prevent adulterated product from entering into human food channels.
- Notifies the establishment personnel, VI and/or SI of carcass and/or parts defect findings.
- Retains carcasses and parts for further disposition by the SI if food safety and other conditions are identified that could result in condemnation.

**Verification Inspection** - The Verification Inspector (VI) does not have a fixed position on the line, and can move freely.

Specifically, the VI:

- Observes and evaluates the effectiveness of the establishment’s HACCP and process control plans, including the examination of records, to determine whether the establishment is in compliance with applicable regulatory requirements.
- Records all findings of noncompliance with applicable performance standards.
- Investigates potential process control problems.
- Notifies the SI if the process control plan is not being met or if performance standards have been exceeded.
- Retains carcasses and parts for further disposition by the SI if food safety and other conditions are identified that could result in condemnation.

The following is a summary of tasks performed by the CI and VI during ante-mortem and post-mortem inspection in HIMP establishments.

### **Ante-mortem inspection**

The VI conducts ante-mortem inspection of all animals at rest and 5-10 percent of animals in motion.

- Retains animals for further disposition by the SI, if the animal is suspected of having a condition that could result in condemnation.
- Documents ante-mortem findings on the appropriate HIMP form.

The Systems Inspector monitors and determines the effectiveness of the establishment's ante-mortem sorting.

- Monitors and determines the effectiveness of ante-mortem verification inspection.
- Determines final disposition of animals designated by the VI as "suspects" at ante-mortem.

### **Post-mortem inspection**

Post-mortem inspection is performed by the CI for the head, viscera and carcass.

#### **Head Inspection**

Establishments must incise the mandibular lymph nodes before presenting the carcass for inspection.

The CI observes the head, including:

- Incised mandibular lymph nodes
- Cut surfaces, eyes, fat, cheek muscles, and other tissues

#### **Viscera Inspection**

The CI observes the viscera, including:

- Spleen
- Mesenteric and portal lymph nodes
- Liver
- Lungs
- Bronchial and mediastinal lymph nodes
- Heart

#### **Carcass Inspection**

The CI observes the carcass, including:

- Cut surfaces
- All body cavities
- Lumbar region
- Neck region
- Kidneys

## **COMPARISON: FSIS INSPECTION AND SUPPLY CHAIN INSPECTION PROCEDURES**

Netherlands uses a combination of pre-slaughter data collection and post-mortem inspection to ensure the identification and removal of unhealthy animals, adulterated carcasses and parts and resulting products from the food supply. Pre-slaughter data collection is done through a system called the IKB Varkens (IKB) program which is an integrated quality assurance program with comprehensive controls over the production chain in addition to national and EU requirements for feed, hygiene, the use of veterinary drugs, transport of animals, and animal welfare. The IKB requires transfer of animal health records from the farm to both the establishment and inspection officials to reduce animal diseases to provide greater assurance that only wholesome meat products are produced. All market hogs receive ante-mortem and post-mortem visual inspection of the head, viscera, and carcass.

FSIS' post-mortem inspection procedures in the traditional inspection are similar to the Netherlands' post-mortem inspection procedures except FSIS inspectors incise and observe mandibular lymph nodes, observe and palpate portal and bronchial lymph nodes, turn and observe both surfaces of liver and lungs and kidneys.

FSIS post-mortem inspection procedures under HIMP are similar to the Netherlands ante-mortem and post-mortem inspection except that FSIS requires the establishment to incise mandibular lymph nodes. FSIS verifies the accuracy of establishment procedures by system inspection and verification inspection procedures. In addition both systems have inspection verification procedures.

### **FSIS FOOD SAFETY MEASURE:**

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

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

### **OBJECTIVE:**

FSIS inspectors conduct ante-mortem inspection of live swine and post-mortem inspection of carcasses and parts on a carcass by carcass basis. In market age swine, FSIS performs

inspection under either the traditional inspection system or under the HIMP inspection system. In both cases, inspection procedures are intended to identify and remove unwholesome and adulterated carcasses and parts from the food supply.

### **EQUIVALENCE CRITERIA AND EVALUATION:**

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

Netherlands uses a combination of pre-slaughter data collection and post-mortem inspection to ensure the identification and removal of diseased carcasses and parts from the food supply.

Research in the Netherlands has shown that the prevalence of *M. avium* at the farm level has decreased between 1998 and 2003. Actually, *M. avium* has not been detected in a targeted surveillance in the 2003 prevalence study by Komijn *et al.* In a prevalence study performed in 1996, 0.27% of slaughter pigs were found to have *Mycobacterium avium* subsp. *avium* isolated from lesions in the mandibular lymph nodes. In a 2004 study, nine pig farms were selected based on risk. These farms had a recent history of having a high percentage of lesions in the mandibular lymph nodes. From a sample pool of 160 pigs, one had a lesion in the mesenteric lymph nodes, and ninety-eight pigs had lesions in the mandibular lymph nodes. All lesions were negative for *Mycobacterium avium* subsp. *avium*. From these data, it is presumed that the prevalence of *Mycobacterium avium* subsp. *avium* is very low, thus forming the scientific basis for the change in the control of *M. avium* in pork.

Other studies also conducted in the Netherlands have shown that, in slaughter establishments with a high degree of control of fecal contamination, *Salmonella* contamination of carcasses is related to cross-contamination in the slaughterhouse rather than to *Salmonella* present in the intestine. An effective control of cross-contamination is therefore crucial to decrease *Salmonella* contamination of carcasses. The incisions made during the traditional post-mortem inspection contribute to the cross-contamination of *Salmonella*. Omitting these incisions will reduce the risk of cross-contamination.

Information from the reviewed studies and other documents provided by the Netherlands, coupled with the pilot study, shows that reduction in human health hazards predominately lies in the hygiene control programs that are implemented throughout the entire production process (farm to table). This supports their use of a "hands-off" system in the slaughter line and, instead, focuses on risk factors prior to post-mortem inspection.

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



Netherlands has implemented a system of Supply Chain Inspection, which allows visual inspection of market hogs raised under the IKB Varkens (IKB) program. The Dutch IKB program is an integrated quality assurance program with comprehensive controls over the production chain in addition to national and EU requirements for feed, hygiene, the use of veterinary drugs, transport of animals, and animal welfare. The IKB program integrates the swine production process from breeding farm to slaughterhouse. The IKB provides requirements for the transfer of animal health records from the farm to the establishment, qualifications for veterinary practitioners, lists of approved veterinary drugs, feed control practices, and hygiene codes for farms, transporters and processors. The goal of an integrated animal health program is to reduce the occurrence of animal diseases and to provide greater assurance of wholesome meat products.

In addition to the IKB program, the Netherlands also requires swine farms to be subjected to ongoing serological surveillance for *M. avium* as a requirement for participation in Supply Chain inspection. Farms are categorized according to risk of *M. avium* infection based on the results of ongoing sampling results. If a farm has 18 consecutive negative results (sampled from 6 pigs in each of 3 deliveries), it is assigned a neutral risk. Afterwards, when the farm has 18 consecutive negative samples (collected from 2 pigs per herd), it is assigned a low risk. Ongoing monitoring of the low risk category of a farm is conducted by collecting 2 samples from each herd for serological testing. In the event of a positive result the farm loses its' low risk status, and becomes either high risk or neutral risk. If both results are positive the farm will be re-classified as high risk.

Only neutral and low risk farms are eligible to participate in visual inspection. Swine from high risk farms are subject to traditional inspection. In addition, animal health authorities assist the farms in identifying and reducing risk factors for *M. avium* infection.

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

The incidence of swine tuberculosis is lower in the Netherlands than the incidence of the disease in animals in the United States. Diseases that produce lesions in the mesenteric lymph nodes, such as tuberculosis, are very rare in the Netherlands.

*The market swine must be born and raised in the country.*

The swine must be born and raised in the Dutch Territories. In the Netherlands, swine are born and raised on large farms under controlled conditions. Improvements in animal husbandry, preventive medicine, and disease control programs have led to a significant rise in the slaughter of animals at a much younger age, in relatively uniform groups. These young animals have a lower incidence of diseases. However, some countries in Europe have a much higher prevalence of *M. avium*. Therefore, swine slaughtered for export to the United States must be born and raised in the Dutch Territories.

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

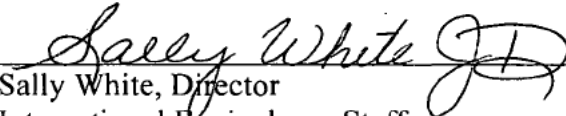
In all slaughterhouses, verification of visual inspection takes place on a daily basis (minimum once a day) and is carried out by the official veterinarian. The location of the verification activities is the on-line inspection platform next to the on-line inspection station. The results of this verification are documented, and the information is used to evaluate performance of online inspectors. These verification activities can be split into two basic standards, 1) standards for inspection procedures and 2) standards for inspection decisions. The official veterinarian verifies appropriate performance of inspection procedures by periodically observing inspectors. Inspectors are required to perform inspection procedures correctly and completely. The standard for the official veterinarian's verification is a maximum of 5% incorrect procedures. The official veterinarian also conducts verification of inspection decisions by periodically observing carcasses and organs for any pathological lesions or hygiene defects. For food safety conditions (feces, ingesta, septicemia-toxemia, cysticercosis), there is zero tolerance. For non-food safety defects, there is a cumulative maximum of 6% of missed pathological abnormalities (2% standard for the carcass, 2% for the stomach/intestines, and 2% for the organs). The inspectors will rail out forty carcasses four times per day, and forty plucks two times per day for verification. The Official Veterinarian also performs verification activities. Two times per day forty carcasses are railed out for the Official Veterinarian to perform verification of the inspection activities of the inspector to ensure that they are making the correct dispositions. The same procedure is conducted once per day on organs from forty carcasses.

In cases where inspectors are not performing as required, the official veterinarian will take corrective actions.

**RECOMMENDATION:**

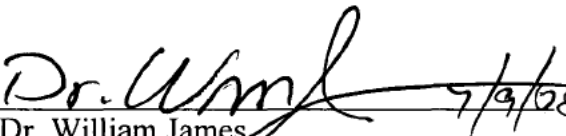
FSIS has determined that the alternate post-mortem procedure for market age hogs submitted by the Netherlands is equivalent to the FSIS post-mortem procedure for market age hogs. Therefore, the Netherlands' equivalence request should be granted.

**DECISION CONFIRMATION AND APPROVAL:**

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

7/9/08  
Date

**CONCURRENCE:**

  
Dr. William James  
Assistant Administrator  
Office of International Affairs, FSIS

7/9/08  
Date

**EQUIVALENCE DETERMINATION  
ALTERNATE POST-MORTEM INSPECTION PROCEDURE FOR MARKET AGE  
HOGS  
November 3, 2006  
Minutes**

**PARTICIPANTS:**

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Nancy Goodwin, Senior Staff Officer, IES, OIA  
David Smith, Staff Officer, IES, OIA  
Scott Seebom, Staff Officer, TSC, OPPED

**DOCUMENTS REVIEWED:**

**FSIS DOCUMENTS**

1. Federal Meat Inspection Regulations, Parts 309, 310 and 311
2. Federal Meat Inspection Regulations, Part 303.2
3. HACCP-Based Inspection Models Project for Market Hogs (6/21/06)

**NETHERLANDS DOCUMENTS**

1. (Draft) Final Report on the data analysis from the "Visual Inspection Pilot."
2. Opinion of the Scientific Committee on Veterinary Measures Relating to Public Health on Revision of Meat Inspection Procedures.
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4. Jelsma A. Food and Consumer Product Safety Authority, Directorate of Inspection and Communication. Project Visual P.M. Inspection Pigs, in Relation to the Hygiene Package in the Netherlands. (Powerpoint presentation)
5. Regulations Governing the IKB Pigs Scheme for Pig Farmers. Netherlands documentation.
6. Certification Criteria for IKB Pigs Scheme. Netherlands documentation.
7. Recognition Terms for IKB Varkens Certifying Bodies. Netherlands documentation.
8. Post-Mortem Inspection in Fattening Pigs – Visual Inspection and Traditional. Netherlands documentation.
9. Answers to Questions FSIS to the Netherlands. Netherlands documentation.
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**Equivalence Request:** FSIS has received a request from the Netherlands to use an alternate post-mortem inspection procedure for market hogs—visual inspection of the carcass and viscera. The procedure does not require incising of the mandibular lymph nodes, palpation of the mesenteric, portal and bronchial lymph nodes, turning of lungs and liver, and grasping and turning of kidneys. The Netherlands has implemented a system of “Food Chain Inspection.” This system allows visual inspection of market hogs raised under an integrated quality control program coupled with a system of verification for checking the accuracy of visually inspected carcasses and organs to ensure that passed carcasses and parts are wholesome and not adulterated.

The team of FSIS experts met and reviewed the Netherlands visual inspection procedures, the Netherlands reference materials, and information presented by the Netherlands officials during FSIS-Netherlands bilateral meeting of November 1-2, 2006. The FSIS team also reviewed the two FSIS inspection procedures (traditional inspection and HACCP-Based Inspection Model Project-HIMP) employed in establishments slaughtering market hogs and compared these two inspection procedures with the Netherlands’ visual post-mortem inspection procedure. These two FSIS inspection procedures will be used to develop equivalence criteria to evaluate the Netherlands’ request.

The following is a summary of the Netherlands’ inspection procedures used in establishments operating under visual inspection.

#### **ANTE-MORTEM INSPECTION**

Ante-mortem inspection on all swine is performed by the official veterinarian using traditional inspection procedures, which are equivalent to FSIS’s traditional inspection procedures.

#### **POST-MORTEM INSPECTION**

Post-mortem inspection is performed by official auxiliaries (contract inspectors) located at fixed inspection stations for head, viscera and carcass inspection.

##### **Head Inspection**

Visual inspection of the head and throat, including the mandibular lymph nodes

- Visual inspection of the mouth, fauces, and tongue

##### **Viscera and carcass inspection**

- Visual inspection of the lungs, trachea, and esophagus
- Visual inspection of the pericardium and heart

- Visual inspection of the liver and hepatic and pancreatic (portal) lymph nodes
- Visual inspection of the gastro-intestinal tract, mesentery, gastric and mesenteric lymph nodes
- Visual inspection of the spleen
- Visual inspection of genital organs

### **Carcass Inspection**

- Visual inspection of the carcass
- Visual inspection of the pleura and peritoneum (lining of chest and abdominal cavities)
- Visual inspection of the kidneys
- Visual inspection of the diaphragm
- Visual inspection of the udder and its lymph nodes
- Visual inspection of the umbilical region and joints of young animals

The following is a summary of the FSIS inspection procedures in establishments operating under the traditional swine inspection system.

## **ANTE-MORTEM INSPECTION**

All swine offered for slaughter in an official establishment are examined and inspected on the day of and before slaughter by an FSIS inspector. Ante-mortem inspection is made in pens on the premises of the establishment. All animals are examined and inspected at rest and in motion; both sides are inspected and observed. Each head, viscera and carcass is inspected as described below.

## **POST-MORTEM INSPECTION**

FSIS inspectors are located at fixed inspection stations in order to perform inspection of the head, viscera and carcass.

### **Head Inspection**

- Observe head and cut surfaces – eyes, fat, cheek muscles, and other tissues for abnormalities.
- Incise and observe mandibular lymph nodes.

### **Viscera Inspection**

- Observe eviscerated carcass, viscera and parietal (top) surface of spleen.
- Observe and palpate mesenteric lymph nodes.
- Palpate portal lymph nodes.
- Observe dorsal (curved) surface of lungs.
- Palpate bronchial lymph nodes.
- Observe mediastinal lymph nodes.
- Turn lungs over and observe ventral (flat) surfaces.
- Observe heart.
- Observe dorsal (curved) surface of liver.

- Turn liver over and observe ventral (flat) surface.

### **Carcass Inspection**

Observe back of carcass (turn carcass or use mirror).

- Observe front and inside of carcass, including.
  - Cut surfaces
  - All body cavities
  - Lumbar region
  - Neck region
  - Grasp, turn, and observe the kidneys

### **The following is a summary of the FSIS inspection procedures in establishments operating under HIMP**

FSIS conducts three types of inspection activities; Systems Inspection, Carcass Inspection and Verification Inspection in HIMP establishments. Systems Inspection involves the evaluation of in-plant inspection findings and is intended to determine the effectiveness of the overall design and execution of all establishment slaughter processes under the HACCP and process control plans. Carcass Inspection involves the examination of each carcass and its parts to determine if they are unadulterated. Verification Inspection involves the evaluation of the effectiveness of the establishment's HACCP and process control plan in meeting the relevant performance standards. Inspection procedures under HIMP were developed to reduce reliance on organoleptic inspection, to shift to prevention-oriented inspection systems based on risk assessment, and to redeploy inspection resources in a manner that better protects the public from food-borne diseases.

**System Inspection** - The System Inspector (SI) is either the Inspector in Charge (IIC) or the Supervisory Veterinary Medical Officer (SVMO). The SI has overall responsibility to assure that the plant and inspection personnel effectively conduct the required activities under HIMP, as designed.

Specifically, the System Inspector:

- Determines, or assigns to the verification inspector (VI), the daily random sampling schedule.
- Monitors and determines the effectiveness of ante-mortem verification inspection.
- Monitors and determines the effectiveness of the establishment's ante-mortem sorting.
- Determines final disposition of animals designated by the VI as "suspects" at ante-mortem.
- Monitors and determines the effectiveness of the establishment's post-mortem sorting and dispositions.
- Determines final disposition on carcasses retained by the carcass inspector (CI) or VI on post-mortem.
- Records nonconformance findings on the appropriate HIMP form.
- Determines if the establishment is meeting relevant performance standards.
- Assesses the overall design and execution of the establishment's HACCP and process control procedures.



- Assures that all adulterated products are condemned in accordance with applicable regulations.
- Determines when unscheduled verification sampling is warranted.
- Maintains communication with the VI and CIs to facilitate coordination of all ante-mortem and post-mortem findings.

**Carcass Inspection** - The Carcass Inspectors (CI) are stationed at fixed locations on the post-mortem line to determine whether a product is adulterated or unadulterated. They inspect each carcass and part on the line, as well as evaluate the on-going effectiveness of the establishment's food safety and other consumer protection processes.

Specifically, the CI:

- Determines whether each carcass and its parts are adulterated or unadulterated.
- Takes appropriate action to prevent adulterated product from entering into human food channels.
- Notifies the establishment personnel, VI and/or SI of carcass and/or parts defect findings.
- Retains carcasses and parts for further disposition by the SI if food safety and other conditions are identified that could result in condemnation.

**Verification Inspection** - The Verification Inspector (VI) does not have a fixed position on the line, and can move freely.

Specifically, the VI:

- Observes and evaluates the effectiveness of the establishment's HACCP and process control plans, including the examination of records, to determine whether the establishment is in compliance with applicable regulatory requirements.
- Records all findings of noncompliance with applicable performance standards.
- Investigates potential process control problems.
- Notifies the SI if the process control plan is not being met or if performance standards have been exceeded.
- Retains carcasses and parts for further disposition by the SI if food safety and other conditions are identified that could result in condemnation.

The following is a summary of tasks performed by the CI and VI during ante-mortem and post-mortem inspection in HIMP establishments.

### **Ante-mortem inspection**

The VI conducts ante-mortem inspection of all animals at rest and 5-10 percent of animals in motion.

- Retains animals for further disposition by the SI, if the animal is suspected of having a condition that could result in condemnation.
- Documents ante-mortem findings on the appropriate HIMP form.

The Systems Inspector monitors and determines the effectiveness of the establishment's ante-mortem sorting.

- Monitors and determines the effectiveness of ante-mortem verification inspection.
- Determines final disposition of animals designated by the VI as "suspects" at ante-mortem.

### **Post-mortem inspection**

Post-mortem inspection is performed by the CI for the head, viscera and carcass.

#### **Head Inspection**

Establishments must incise the mandibular lymph nodes before presenting the carcass for inspection.

The CI observes the head, including:

- Incised mandibular lymph nodes
- Cut surfaces, eyes, fat, cheek muscles, and other tissues

#### **Viscera Inspection**

The CI observes the viscera, including:

- Spleen
- Mesenteric and portal lymph nodes
- Liver
- Lungs
- Bronchial and mediastinal lymph nodes
- Heart

#### **Carcass Inspection**

The CI observes the carcass, including:

- Cut surfaces
- All body cavities
- Lumbar region
- Neck region
- Kidneys

### **Development of Equivalence Criteria**

The team developed equivalence criteria for visual inspection after review of the FSIS inspection procedures (later described in the minutes) and the Netherlands' proposal, taking into account the FSIS food safety measure and objective of the measure.

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

mortem and post-mortem inspection procedures to detect diseases, abnormalities, and contamination of livestock carcasses and parts.

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

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

### **Comparison of the Netherlands visual inspection procedures with the FSIS inspection procedures.**

Netherlands uses a combination of pre-slaughter data collection and post-mortem inspection to ensure the identification and removal of unhealthy animals, adulterated carcasses and parts and resulting products from the food supply. Pre-slaughter data collection is done through a system of "Food Chain Inspection" called the IKB Varkens (IKB) program which is an integrated quality assurance program with comprehensive controls over the production chain in addition to national and EU requirements for feed, hygiene, the use of veterinary drugs, transport of animals, and animal welfare. The IKB requires transfer of animal health records from the farm to both the establishment and inspection officials to reduce animal diseases to provide greater assurance that only wholesome meat products are produced. All market hogs receive ante-mortem and post-mortem visual inspection of the head, viscera, and carcass.

FSIS' post-mortem inspection procedures in the traditional inspection are similar to the Netherlands' visual post-mortem inspection procedures except FSIS inspectors incise and observe mandibular lymph nodes, observe and palpate portal and bronchial lymph nodes, turn and observe both surfaces of liver and lungs and kidneys.

FSIS post-mortem inspection procedures under HIMP are similar to the Netherlands visual ante-mortem and post-mortem inspection except that FSIS requires the establishment to incise mandibular lymph nodes. FSIS verifies the accuracy of establishment procedures by system inspection and verification inspection procedures. In addition both systems have inspection verification procedures.

### **EQUIVALENCE CRITERIA FOR AN ALTERNATE POST-MORTEM INSPECTION PROCEDURE FOR MARKET HOGS**

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

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

#### **APPLICATION OF EQUIVALENCE CRITERIA FOR ALTERNATE POST-MORTEM INSPECTION PROCEDURE FOR MARKET HOGS**

1. **The government inspection service administers an inspection program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass.** Netherlands uses a combination of pre-slaughter data collection and post-mortem inspection to ensure the identification and removal of diseased carcasses and parts from the food supply.

Research in the Netherlands has shown that the prevalence of *M. avium* at the farm level has decreased between 1998 and 2003. Actually, *M. avium* has not been detected in a targeted surveillance in the 2003 prevalence study by Komijn *et al.* In a prevalence study performed in 1996, 0.8% of slaughter pigs were found, upon post mortem inspection, to have lesions in the mandibular lymph nodes. Of these, 20% were found to have *Mycobacterium avium* subsp *avium*. In a 2004 study, nine pig farms were selected based on risk. These farms had a recent history of having a high percentage of lesions in the mandibular lymph nodes. From a sample pool of 160 pigs, one had a lesion in the mesenteric lymph nodes, and ninety-eight pigs had lesions in the mandibular lymph nodes. All lesions were negative for *Mycobacterium avium* subsp *avium*. From these data, it is presumed that the prevalence of *Mycobacterium avium* subsp. *avium* is very low, thus forming the scientific basis for the change in the control of *M. avium* in pork.

Other studies also conducted in the Netherlands have shown that, in slaughter establishments with a high degree of control of fecal contamination, *Salmonella* contamination of carcasses is related to cross-contamination in the slaughterhouse

rather than to *Salmonella* present in the intestine. An effective control of cross-contamination is therefore crucial to decrease *Salmonella* contamination of carcasses. The incisions made during the traditional post-mortem inspection contribute to the cross-contamination of *Salmonella*. Omitting these incisions will reduce the risk of cross-contamination.

Information from the reviewed studies and other documents provided by the Netherlands coupled with the pilot study shows that reduction in human health hazards predominately lies in the hygiene control programs that are implemented throughout the entire production process (farm to table). This supports their use of a “hands-off” system in the slaughter line and, instead, focusing on controlling risk factors prior to post-mortem inspection.

2. **The government inspection system requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market hog carcasses presented for inspection.** Netherlands has implemented a system of “Food Chain Inspection,” which allows visual inspection of market hogs raised under the IKB Varkens (IKB) program. The Dutch IKB program is an integrated quality assurance program with comprehensive controls over the production chain in addition to national and EU requirements for feed, hygiene, the use of veterinary drugs, transport of animals, and animal welfare. The IKB program integrates the swine production process from breeding farm to slaughterhouse. The IKB provides requirements for the transfer of animal health records from the farm to the establishment, qualifications for veterinary practitioners, lists of approved veterinary drugs, feed control practices, and hygiene codes for farms, transporters and processors. The goal of an integrated animal health program is to reduce the occurrence of animal diseases and to provide greater assurance of wholesome meat products.

In addition to the IKB program, the Netherlands also requires swine farms to be subjected to ongoing serological surveillance for *M. avium* as a requirement for participation in visual inspection. Farms are categorized according to risk of *M. avium* infection based on the results of ongoing sampling results. If a farm has 18 consecutive negative results (sampled from no more than 6 pigs in each of 3 deliveries), it is assigned a neutral risk. When the farm has 18 additional negative samples (collected from 2 pigs in each of 9 deliveries), it is assigned a low risk. When a farm has a single positive result or two intermediate results within 18 samples, it is placed in the high risk category. Only neutral and low risk farms are eligible to participate in visual inspection. Swine from high risk farms are subject to traditional inspection. In addition, animal health authorities assist the farms in identifying and reducing risk factors for *M. avium* infection.

3. **The incidence of diseases in market hogs, such as TB, is no higher than the incidence in the United States.** The incidence of swine tuberculosis is lower in the Netherlands than the incidence of the disease in animals in the United States.

Diseases that produce lesions in the mesenteric lymph nodes, such as tuberculosis, are very rare in the Netherlands.

4. **The market swine must be born and raised in the country.** The swine must be born and raised in the Dutch Territories. In the Netherlands, swine are born and raised on large farms under controlled conditions. Improvements in animal husbandry, preventive medicine, and disease control programs have led to a significant rise in the slaughter of animals at a much younger age, in relatively uniform groups. These young animals have a lower incidence of diseases. However, some countries in Europe have a much higher prevalence of *M. avium*. Therefore, swine slaughtered for export to the United States must be born and raised in the Dutch Territories.
5. **The government inspection service must implement a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects).** In all slaughterhouses, verification of visual inspection takes place on a daily basis (minimum once a day) and is carried out by the official veterinarian. The location of the verification activities is the on-line inspection platform next to the on-line inspection station. The results of this verification are documented, and the information is used to evaluate performance of online inspectors. These verification activities can be split into two basic standards, 1) standards for inspection procedures and 2) standards for inspection decisions. The official veterinarian verifies appropriate performance of inspection procedures by periodically observing inspectors. Inspectors are required to perform inspection procedures correctly and completely. The standard for the official veterinarian's verification is a maximum of 5% incorrect procedures. The official veterinarian also conducts verification of inspection decisions by periodically observing carcasses and organs for any pathological lesions or hygiene defects. For food safety conditions (feces, ingesta, septicemia-toxemia, cysticercosis), there is zero tolerance. For non-food safety defects, there is a cumulative maximum of 6% of missed pathological abnormalities (2% standard for the carcass, 2% for the stomach/intestines, and 2% for the organs). The number of carcasses plus stomach-intestines plus organs to be verified on a daily basis is distributed over the day with a minimum of 2 batches and a minimum of 50 pigs. In cases where inspectors are not performing as required, the official veterinarian will take corrective actions.

<u>Name</u>	<u>Signatures</u>	<u>Date</u>
Ghias Mughal, Senior Staff Officer, IES, OIA	<i>Ghias Mughal</i>	11/3/06
Nancy Goodwin, Senior Staff Officer, IES, OIA	<i>Nancy Goodwin</i>	11/3/06
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Scott Seebohm, Staff Officer, TSC, OPPED	<i>Scott Seebohm</i>	11/3/06

## **DECISION MEMORANDUM**

### **ISSUE:**

FSIS has received a request from the Netherlands to use an alternate post-mortem inspection procedure for market hogs—visual inspection of the carcass and viscera. The procedure does not require incising of the mandibular lymph nodes, palpation of the mesenteric, portal and bronchial lymph nodes, turning of lungs and liver, and grasping and turning of kidneys.

### **BACKGROUND:**

The Netherlands has implemented a system of “Supply Chain Inspection.” This system allows visual inspection of market hogs raised under an integrated quality control program coupled with a system of verification for checking the accuracy of visually inspected carcasses and organs to ensure that passed carcasses and parts are wholesome and not adulterated.

A team of FSIS experts met and reviewed the Netherlands’ visual inspection procedures, the Netherlands’ reference materials, and information presented by Netherlands’ officials during the FSIS-Netherlands bilateral meeting of November 1-2, 2006. The FSIS team also reviewed the two FSIS inspection procedures (Traditional Inspection and HACCP-Based Inspection Models Project (HIMP)) employed in establishments slaughtering market-age hogs and compared these two inspection procedures with the Netherlands’ visual post-mortem inspection procedure. These two FSIS inspection procedures were used to develop the equivalence criteria used to evaluate the Netherlands’ request.

The following is a summary of the Netherlands’ visual inspection procedure pilot tested in an establishment which is not certified for export to the United States.

### **ANTE-MORTEM INSPECTION**

Ante-mortem inspection on all market hogs is performed by the official veterinarian using traditional inspection procedures, which are equivalent to FSIS’ traditional inspection procedures.

### **POST-MORTEM INSPECTION**

Visual post-mortem inspection of the head, viscera and carcass is performed by official auxiliaries (contract inspectors) located at three fixed inspection stations.

#### **Head Inspection**

- Visual inspection of the head and throat, including the mandibular lymph nodes
- Visual inspection of the mouth, fauces, and tongue

#### **Viscera Inspection**



- Visual inspection of the lungs, trachea, and esophagus
- Visual inspection of the pericardium and heart
- Visual inspection of the liver and hepatic and pancreatic (portal) lymph nodes
- Visual inspection of the gastro-intestinal tract, mesentery, gastric and mesenteric lymph nodes
- Visual inspection of the spleen
- Visual inspection of the genital organs

#### **Carcass Inspection**

- Visual inspection of the carcass
- Visual inspection of the pleura and peritoneum (linings of chest and abdominal cavities)
- Visual inspection of the kidneys
- Visual inspection of the diaphragm
- Visual inspection of the udder and its lymph nodes
- Visual inspection of the umbilical region and joints of young animals

The following is a summary of FSIS' inspection procedures in establishments operating under traditional inspection for market hogs.

#### **ANTE-MORTEM INSPECTION**

All market hogs offered for slaughter in an official establishment are examined and inspected on the day of and before slaughter by an FSIS inspector. Ante-mortem inspection is made in pens on the premises of the establishment. All animals are examined and inspected at rest and in motion; both sides are inspected and observed. After slaughter, each head, viscera and carcass is inspected as described below.

#### **POST-MORTEM INSPECTION**

FSIS inspectors are located at fixed inspection stations to perform inspection of the head, viscera and carcass.

##### **Head Inspection**

- Observe the head and cut surfaces – eyes, fat, cheek muscles, and other tissues for abnormalities
- Incise and observe the mandibular lymph nodes

##### **Viscera Inspection**

- Observe the eviscerated carcass, viscera and parietal (top) surface of spleen
- Observe and palpate the mesenteric lymph nodes
- Palpate the portal lymph nodes
- Observe the dorsal (curved) surface of lungs
- Palpate the bronchial lymph nodes
- Observe the mediastinal lymph nodes

- Turn the lungs over and observe ventral (flat) surfaces
- Observe the heart
- Observe the dorsal (curved) surface of liver
- Turn the liver over and observe ventral (flat) surface

### **Carcass Inspection**

- Observe the back of the carcass (turn carcass or use mirror)
- Observe the front and inside of the carcass, including:
  - Cut surfaces
  - All body cavities
  - Lumbar region
  - Neck region
- Grasp, turn and observe the kidneys

The following is a summary of the FSIS inspection procedures in establishments operating under HIMP.

FSIS conducts three types of inspection activities in the HIMP establishments; Systems Inspection, Carcass Inspection and Verification Inspection. Systems Inspection involves the evaluation of in-plant inspection findings and is intended to determine the effectiveness of the overall design and execution of all establishment slaughter processes under HACCP and process control plans. Carcass Inspection involves the examination of each carcass and its parts to determine if they are adulterated. Verification Inspection involves the evaluation of the effectiveness of the establishment's HACCP plan and process control plan in meeting the relevant performance standards. Inspection procedures under HIMP were developed to reduce reliance on organoleptic inspection, to shift to prevention-oriented inspection systems based on risk assessment, and to redeploy inspection resources in a manner that better protects the public from food-borne diseases.

**System Inspection** - The System Inspector (SI) is either the Inspector in Charge (IIC) or the Supervisory Veterinary Medical Officer (SVMO). The SI has overall responsibility to assure that the plant and inspection personnel effectively conduct the required activities under HIMP, as designed.

Specifically, the System Inspector:

- Determines, or assigns to the verification inspector (VI), the daily random sampling schedule.
- Monitors and determines the effectiveness of ante-mortem verification inspection.
- Monitors and determines the effectiveness of the establishment's ante-mortem sorting.
- Determines final disposition of animals designated by the VI as "suspects" at ante-mortem.
- Monitors and determines the effectiveness of the establishment's post-mortem sorting and dispositions.
- Determines final disposition of carcasses retained by the Carcass Inspector or VI on post-mortem inspection.
- Records nonconformance findings on the appropriate HIMP form.

- Determines if the establishment is meeting relevant performance standards.
- Assesses the overall design and execution of the establishment's HACCP plan and process control procedures.
- Assures that all adulterated products are condemned in accordance with applicable regulations.
- Determines when unscheduled verification sampling is warranted.
- Maintains communication with the VI and CIs to facilitate coordination of all ante-mortem and post-mortem findings.

**Carcass Inspection** - The Carcass Inspectors (CI) are stationed at fixed locations on the post-mortem line to determine whether a product is adulterated or unadulterated. They inspect each carcass and part on the line, as well as evaluate the on-going effectiveness of the establishment's food safety and other consumer protection processes.

Specifically, the CI:

- Determines whether each carcass and its parts are adulterated or unadulterated.
- Takes appropriate action to prevent adulterated product from entering into human food channels.
- Notifies the establishment personnel, VI and/or SI of carcass and/or parts defect findings.
- Retains carcasses and parts for further disposition by the SI if food safety and other conditions are identified that could result in condemnation.

**Verification Inspection** - The Verification Inspector (VI) does not have a fixed position on the line and can move freely throughout the plant.

Specifically, the VI:

- Observes and evaluates the effectiveness of the establishment's HACCP plan and process control plans, including the examination of records, to determine whether the establishment is in compliance with applicable regulatory requirements.
- Records all findings of noncompliance with applicable performance standards.
- Investigates potential process control problems.
- Notifies the SI if the process control plan is not being met or if performance standards have been exceeded.
- Retains carcasses and parts for further disposition by the SI if food safety and other conditions are identified that could result in condemnation.

The following is a summary of tasks performed by the CI and VI during ante-mortem and post-mortem inspection in the HIMP establishments.

### **Ante-mortem inspection**

The VI conducts ante-mortem inspection of all animals at rest and 5-10 percent of animals in motion and retains animals for further disposition by the SI, if the animals are suspected of having a condition that could result in condemnation.

## **Post-mortem inspection**

Post-mortem inspection is performed by the CI for the head, viscera and carcass.

### **Head Inspection**

Establishments must incise the mandibular lymph nodes before presenting the carcass for inspection.

The CI observes the head, including:

- Incised mandibular lymph nodes
- Cut surfaces, eyes, fat, cheek muscles, and other tissues

### **Viscera Inspection**

The CI observes the viscera, including:

- Spleen
- Mesenteric and portal lymph nodes
- Liver
- Lungs
- Bronchial and mediastinal lymph nodes
- Heart

### **Carcass Inspection**

The CI observes the carcass, including:

- Cut surfaces
- All body cavities
- Lumbar region
- Neck region
- Kidneys

## **Comparison of the Netherlands Visual Inspection Procedures with the FSIS Inspection Procedures**

Netherlands uses a combination of pre-slaughter data collection and post-mortem inspection to ensure the identification and removal of unhealthy animals, adulterated carcasses and parts and resulting products from the food supply. Pre-slaughter data collection is done through a system of “Supply Chain Inspection” called the IKB Varkens (IKB) program which is an integrated quality assurance program with comprehensive controls over the production chain in addition to national and EU requirements for feed, hygiene, the use of veterinary drugs, transport of animals, and animal welfare. The IKB requires transfer of animal health records from the farm to both the establishment and inspection officials to provide greater assurance that only wholesome meat products are produced. All market hogs receive ante-mortem and post-mortem visual inspection of the head, viscera, and carcass.

FSIS’ post-mortem inspection procedures under traditional inspection are similar to the Netherlands’ visual post-mortem inspection procedures except FSIS inspectors incise and

observe mandibular lymph nodes, observe and palpate portal and bronchial lymph nodes, and turn and observe both surfaces of the liver, the lungs and the kidneys.

FSIS post-mortem inspection procedures under HIMP are similar to the Netherlands visual ante-mortem and post-mortem inspection except that FSIS requires the establishment to incise mandibular lymph nodes. FSIS verifies the accuracy of establishment procedures by system inspection and verification inspection procedures. In addition both systems have inspection verification procedures.

#### **FSIS FOOD SAFETY MEASURE:**

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

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

#### **OBJECTIVE:**

For market hogs slaughtered in the United States, FSIS requires that ante-mortem inspection of live market hogs and post-mortem inspection of carcasses and parts be conducted on a carcass-by-carcass basis. In market hogs, FSIS performs post-mortem inspection under the traditional inspection system or the HIMP inspection system. Post-mortem inspection procedures under traditional inspection include incision, observation and palpation, as applicable, of the head, viscera and carcass. Under HIMP, FSIS post-mortem inspection procedures involve only a visual inspection, with no incisions or palpation. In both cases, inspection procedures are intended to identify and remove unwholesome and adulterated carcasses and parts from the food supply.

#### **EQUIVALENCE CRITERIA:**

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

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

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

## **EQUIVALENCE EVALUATION:**

### **Application of Equivalence Criteria for an Alternate Post-Mortem Inspection Procedure for Market Hogs**

1. The Netherlands' inspection service administers a program that is at least as effective at identifying and removing unhealthy animals, adulterated carcasses, parts and resulting products from the food supply chain as are the FSIS post-mortem inspection procedures for the head, viscera and carcass. This determination is based on the following information: The Netherlands uses a combination of pre-slaughter data collection and post-mortem inspection to ensure the identification and removal of sick animals and diseased carcasses and parts from the food supply.

In January 2006, the Netherlands Ministries of Agriculture, Nature and Food Quality and Health, Welfare and Sport and the Food and Consumer Product Safety Authority completed a pilot study in one market hog establishment that was intended to evaluate the effectiveness of visual inspection procedures through the use of pre-slaughter data and post-mortem inspection procedures. During this pilot study, epidemiological data or other history, such as data in regard to *M. avium*, was provided to the official veterinarian immediately prior to slaughter of the herd. After slaughter, each carcass first underwent a visual post-mortem inspection. The inspector did not palpate or make any incisions on the carcass at this point. If the inspector observed an abnormality on a carcass or the viscera, the carcass and viscera were railed out for traditional post-mortem examination. If an inspector did not detect any abnormalities, the carcass and viscera continued moving on the slaughter-line. The carcass then reached the inspector who incised the mandibular lymph nodes. If the inspector discovered abnormalities in the mandibular lymph nodes, the head and the viscera were rejected. The inspector would also rail out the carcass for further traditional post-mortem inspection, if needed. In addition, if the inspector performing visual inspection or the inspector performing traditional inspection detected any abnormality in any organ or carcass that required further examination, all viscera and the corresponding carcass were railed out.

Information from the published studies and other documents provided by the Netherlands, coupled with the pilot study, shows that reduction in human health hazards predominately lies in the hygiene control programs that are implemented throughout the entire production process (farm to table). This supports Netherlands' use of a "hands-off"

system in the slaughter line and, instead, focuses on risk factors prior to post-mortem inspection.

2. The Netherlands' inspection service requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market-age hog carcasses presented for inspection. This determination is based on the following information: The Netherlands has implemented a system known as "Supply Chain Inspection," which allows visual inspection of market hogs raised under the Dutch IKB Quality Assurance Program. The Dutch IKB program is an integrated quality assurance program with comprehensive controls over the production chain in addition to national and EU requirements for feed, hygiene, the use of veterinary drugs, transport of animals, and animal welfare. The IKB program integrates the market hogs production process from breeding farm to slaughterhouse, and provides requirements for the transfer of animal health records from the farm to the establishment, qualifications for veterinary practitioners, lists of approved veterinary drugs, feed control practices, and hygiene codes for farms, transporters and processors. The goal of an integrated animal health program is to reduce the occurrence of animal diseases and to provide greater assurance of wholesome meat products.

In addition to the IKB program, the Netherlands also requires market hogs farms to be subjected to ongoing serological surveillance for *M. avium* as a requirement for participation in visual inspection. Farms are categorized according to risk of *M. avium* infection based on the results of ongoing sampling results. If a farm has 18 consecutive negative results (sampled from no more than 6 pigs in each of 3 deliveries), it is assigned a neutral risk. When the farm has 18 additional negative samples (collected from 2 pigs in each of 9 deliveries), it is assigned a low risk. When a farm has a single positive result or two intermediate results within 18 samples, it is placed in the high risk category. Only neutral and low risk farms are eligible to participate in visual inspection. Market hogs from high risk farms are subject to traditional inspection. In addition, animal health authorities assist the farms in identifying and reducing risk factors for *M. avium* infection.

3 The incidence of diseases in market hogs, such as Tuberculosis (TB), is no higher than the incidence in the United States. FSIS slaughter data from July 2005-June 2006 showed no detection of TB lesions in market hogs. Research in the Netherlands has shown that the prevalence of *M. avium* at the farm level has decreased between 1998 and 2003. In a 2004 study, 2,116,536 market hogs were examined in the Netherlands for the presence of *M. avium*. Nine pig farms were selected based a recent history of having a high percentage of lesions in the mandibular lymph nodes. From a sample pool of 160 pigs, one had a lesion in the mesenteric lymph nodes, and 98 pigs had lesions in the mandibular lymph nodes. All lesions were negative for *M. avium* subsp *avium*. From these data, it is concluded that the prevalence of *M. avium* subsp. *avium* is very low, thus forming the scientific basis for the change in the control of *M. avium* in pork. From this information, FSIS concluded that the incidence of diseases in market hogs, such as Tuberculosis (TB), is no higher than the incidence in the United States

4. Market hogs slaughtered in the Netherlands are from animals born and raised only in the Netherlands. These animals are raised under controlled conditions, which have led to

a significant increase in the slaughter of animals at a much younger age and in relatively uniform groups. However, some countries in Europe have a much higher prevalence of *M. avium*. Therefore, market hogs slaughtered for export to the United States must be born and raised in the Netherlands.

5. The Netherlands' inspection service has implemented a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (other consumer protection defects). This determination is based on the following information: In the Netherlands', verification of visual inspection takes place on a daily basis (minimum once a day) and is carried out by the official veterinarian. The location of the verification activities is the on-line inspection platform next to the on-line inspection station.

These verification activities are split into two basic standards: 1) standards for inspection procedures and 2) standards for inspection decisions. All inspectors are required to perform inspection procedures correctly and completely. The official veterinarian verifies appropriate performance of inspection procedures by periodically observing inspectors. The standard for the official veterinarian's verification is a maximum of 5% incorrect procedures. The official veterinarian also conducts verification of inspection decisions by periodically observing carcasses and organs for any pathological lesions or hygiene defects. For food safety conditions (feces, ingesta, septicemia-toxemia, cysticercosis), there is zero tolerance. For non-food safety defects, there is a cumulative maximum of 4% of missed pathological abnormalities (2 % standard for the carcass and, 2 % for the stomach/intestines/organs). The number of carcasses plus stomach-intestines-organs to be verified on a daily basis is distributed over the day with a minimum of 2 batches and a minimum of 50 pigs. In cases where inspectors are not performing as required, the official veterinarian will take corrective actions. The results of this verification are documented, and the information is used to evaluate the performance of online inspectors. In addition, the Netherlands' inspection service has a program in place to conduct a system audit of the establishment on a regular basis.

#### **RECOMMENDATION:**

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



**DECISION CONFIRMATION AND APPROVAL:**

Sally White JD 12/6/06

Sally White, Director

International Equivalence Staff

Office of International Affairs, FSIS

~~CONCURRENCE:~~

Dr. Uhm

~~Karen Stuck~~

Assistant Administrator

Office of International Affairs

7/8/08

Do not concur.

Issue is not sufficiently  
characterized.

## **EQUIVALENCE CRITERIA FOR ALTERNATE POST-MORTEM INSPECTION PROCEDURE FOR MARKET HOGS**

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

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

## SUMMARY OF THE OF THE TELECONFERENCE

DATE: June 19, 2006

COUNTRY: Netherlands

FSIS PARTICIPANTS: Steve McDermott, Office of International Affairs, FSIS, Ghias Mughal, OIA, FSIS, Bobby Palesano, OPPED, FSIS, Karlease Kelly, OPPED, FSIS, Roger Wentzel, FAS, The Hague

NETHERLANDS PARTICIPANTS: Dr. (b) (6), Deputy CVO, LNV (b) (6), (b) (6), LNV, Dr. (b) (6), (b) (6), LNV, (b) (6), Cluster International, LNV, (b) (6), VWA (Netherlands Food and Consumer Product Safety Authority), Dr. (b) (6), VWA (Netherlands Food and Consumer Product Safety Authority), Prof. Dr. (b) (6), Director Quality and Environment, (b) (4) Food, (b) (6), Royal Netherlands Embassy, Washington, DC

### FOLLOWING AGENDA TOPICS WERE DISCUSSED:

- FSIS Strategic Implementation Plan for Strengthening Small and Very Small Plant Outreach: *Karlease Kelly*
- KDS Pilot : Dr. (b) (6), VWA and (b) (6) Deputy CVO
- HACCP-based Pork Chain Pilot Project: Dr. (b) (6)
- FSIS project on Risk-Based Verification Audits of Foreign Countries Meat and Poultry Inspection Programs: *Steve McDermott*
- Update on Use of Alternate post mortem Inspection Procedure in market age swine in the Netherlands: *Ghias Mughal*
- FSIS Initiative of Enhanced Risk-Based Inspection System: *Bobby Palesano*

### DISCUSSIONS:

FSIS informed the Netherlands' officials that visual inspection and the use of auxiliaries in slaughter establishments must not be implemented in the Netherlands establishments certified for export to the United States until FSIS has made an equivalence determination. FSIS stressed this point several times during the conference call including advising Caroline Feitel of the Netherlands' Embassy immediately after the completion of the conference call.

It was also agreed by the parties to have another conference call in a few weeks, on a mutually agreed date, to further discuss the KDS HACCP Pilot project relating to visual inspection and use of auxiliaries Project and its application in other swine establishments in the Netherlands.

Minutes by  
Ghias Mughal  
6/19/2006

## SUMMARY OF MEETING

DATE: October 12, 2006

COUNTRY: Netherlands

FSIS PARTICIPANTS: Bill James, Deputy Assistant Administrator, OIA, Sally White, Director, IES, OIA, Steve McDermott, Deputy Director, IES, OIA Ghias Mughal, Senior Staff officer, IES, OIA; Nancy Goodwin, Senior Staff Officer, IES, OIA

NETHERLANDS AND EU PARTICIPANTS: Dr. (b) (6), Deputy CVO, LNV Ir. R.C.A., Dr. (b) (6), Director, Inspections VWA & Food and Consumer Product Safety, Dr. (b) (6), Counselor Food Safety, Health and Consumer Affairs, EU Delegation, Washington, DC, (b) (6), Agricultural Counselor, Royal Netherlands Embassy, Washington, DC

- SUMMARY: This meeting took place at the request of Dr. (b) (6), Deputy CVO to follow up on FSIS letter of Oct. 2, 2006 in which FSIS had asked Netherlands to suspend exports, from, young swine slaughter/processing, establishments in which Netherlands had implemented use of Visual Inspection or use of auxiliaries to conduct post mortem inspection.
  - Netherlands provided for explanation for implementation of Visual Inspection and stated that it was implemented in swine slaughter establishments because it provided extra food safety and it was found equivalent by other EU member States.
  - FSIS asked for further explanation on several issues such as:
  - Rate of condemnation was higher under the old system compared to results of the pilot which was attributed to variation seasonal changes and Netherlands reply was it is true that condemnations rate was higher in traditional inspection but those condemnations were for disease that were of no public health significance.
  - IKB scheme of quality control used in the Pilot which was not clearly defined in the submitted and more information would be helpful to FSIS. Netherlands agreed to send it.
  - Other FSIS questions related to getting further explanation or justification of conclusion drawn during the pilot and both parties agreed to have a follow up meeting of the Technical experts.
  - FSIS also requested Netherlands to provide a written response to FSIS' previous request for information on the type of verification that in-plant inspection officials will perform on the carcasses and viscera passed by the on-line inspectors performing visual inspection of mesenteric lymph nodes. Netherlands officials agreed to send this information in near future.

- THE SECOND ISSUE discussed during the meeting was the use of auxiliaries in establishments certified for export to the US.
- Netherlands explained that although the documents sent to FSIS for employment of auxiliaries referred to new EC Directives 852 and 854, the use of auxiliaries was really under provision of the EC 64/433 which had been previously deemed equivalent by FSIS and that has now been converted in to these new directives. They requested that FSIS reconsider their request and allow use of auxiliaries. Their role has been explained in the document “ The new Organization of the red meat Inspection System in the Netherlands 2006”
- FSIS re-examined the document in light of the Dutch explanation, looked at the relationship between the Netherlands Inspection Service (VWA) and contractors that employs the auxiliaries (KDS) and concluded that relationship between the VWA and KDS is clearly stated. It also narrates the financial structure, training of the auxiliaries and appears to provide adequate government (VWA) oversight on their daily activities.
- FSIS agreed to immediately permit VWA to use auxiliaries in establishments certified for export to the US and will follow verbal permission with written letter.
- Both parties agreed to have a meeting of the technical experts from both sides to resolve the issue of Visual Inspection of the young swine. This meeting was tentatively scheduled to take place in Washington, DC during the first week of November 2006

Minutes by:  
 Ghias Mughal, IES, OIA  
 10/13/06

## **Summary of FSIS Pre-Meeting on Visual Inspection in Market age swine**

Date: October 31, 2006

Country: Netherlands

Participants: Sally White, Director, IES, OIA,  
Steve McDermott, Deputy Director, IES, OIA  
Ghias Mughal, Senior Staff Officer, IES, OIA  
Nancy Goodwin, Senior Staff Officer, IES, OIA  
David Smith, Staff Officer, IES, OIA  
Scott Seebohm, Staff Officer, TSC, OPED

The following items were discussed:

1. Comparison Table: Swine Inspection Procedures
2. Netherlands responses to FSIS questions: "Answers to Questions FSIS to the Netherlands"

Clarification from the NL officials is needed on the following additional follow-up questions:

- Q. 1 The U.S. legal definition of adulteration includes both food safety and non-food safety criteria. How does the Netherlands inspection system address the issue of adulteration for non-food safety conditions?
- Q. 2 What are the provisions for government oversight of the IKB production scheme? When would the government get involved, and what actions could they take?
- Q. 3 OK
- Q. 4 The response to Question 4 refers to several reference documents not previously provided to FSIS. We request copies of the additional documents that are relevant to the response (in English, if possible)
- Q. 5 OK
- Q. 6 Need more specific explanation/clarification of how the Farm Risk Profile is calculated. How does it incorporate farm level information on *Salmonella* and *M. avium* ? What specific criteria are used to determine whether a slaughter lot is eligible for visual inspection?

- Q. 7 Need clarification on the verification procedures. Explain how, where, and when the procedures are accomplished.  
During FSIS audits, where would FSIS auditors be able to find verification documents/records?
- Q. 8 It was not clear as to how the Farm Risk Profile considers *Salmonella* sample results? What criteria for these samples would dictate switching from visual to traditional inspection?
- Q. 9 When a group of pigs is sampled for antimicrobial residues, based on pathology levels (as described in response to Q6)? Need more information on the sampling procedures. Will all animals in the lot be sampled? If not, what method will be used to select sampled animals?
- Q 10. Response appears to address FSIS question. Need to get copies of the relevant references listed in the response to Q10 (in English, if possible).
- Q. 11 OK
- (Q12) Response appears to address FSIS question. Need to have get copies of the relevant references (in English, if possible).

Ghias Mughal

10-31-2006



DRAFT  
**MARKET HOGS**



**HIMP**  
**(HACCP-BASED INSPECTION  
MODELS PROJECT)**

## **HIMP MARKET HOG INSPECTION**

### **Background**

FSIS collected data to determine the current food safety and other consumer protection achievements of the traditional inspection system in five market hog slaughter plants. The data were used to develop performance standards that volunteer plants in the HACCP-based Inspection Models Project (HIMP) must meet. The performance standards were published in a Federal Register Notice on November 2, 2000. A total of six performance standards were developed: three Food Safety categories (FS 1-3) and three Other Consumer Protection categories (OCP 1-3). The performance standards for the Food Safety categories (FS-1-3) were set at zero. The performance standards for the Other Consumer Protection categories (OCP 1-3) were based on the 75<sup>th</sup> percentile of the ranges of baseline data. (See Attachment 1)

### **Types of Inspection Activities**

The Market Hog HIMP pilot consists of three types of inspection activities: system inspection, carcass inspection, and verification inspection. System inspection involves the evaluation of in-plant inspection findings and determines the effectiveness of the overall design and execution of all establishment slaughter processes under the HACCP and process control plans. Carcass inspection involves the examination of each carcass and its parts to determine that they are unadulterated. Verification inspection involves the evaluation of the effectiveness of the establishment's HACCP and Process Control plan in meeting the relevant performance standards. These three types of inspection are discussed in further detail below.

**System Inspection** - The System Inspector (SI) is either the Inspector in Charge (IIC) or the Supervisory Veterinary Medical Officer (SVMO). The SI has overall responsibility to assure that the plant and inspection personnel effectively conduct the required activities under the HIMP, as designed. The SI sends verification data to headquarters and provides overall feedback on how the project is working. Specifically, the SI:

- Determines (or assigns to the verification inspector (VI))\* the daily random sampling schedule and provides the schedule to the VI.
- Monitors and determines the effectiveness of ante-mortem verification inspection.
- Monitors and determines the effectiveness of the establishment ante-mortem sorting.
- Determines final disposition of animals designated by the VI as "suspects" at ante-mortem.
- Monitors and determines the effectiveness of the establishment's post-mortem sorting and disposition.
- Determines final disposition on carcasses retained by the carcass inspector (CI) or VI on post-mortem.\*
- Records FS-1 and FS-3 nonconformance findings on the appropriate HIMP form.
- Determines if the establishment is meeting relevant performance standards.
- Assesses the overall design and execution of the establishment's HACCP and process control procedures.
- Assures that all adulterated products are condemned in accordance with applicable regulations.
- Determines when unscheduled verification sampling is warranted.

- Maintains communication with the VI and CIs to facilitate coordination of all ante-mortem and post-mortem findings.

**Carcass Inspection** - The Carcass Inspectors (CI) are stationed at up to 3 fixed locations on the post-mortem line to determine whether a product is adulterated or unadulterated. They inspect each carcass and part on the line, as well as evaluate the on-going effectiveness of the establishment's food safety and other consumer protection processes. Specifically, the CIs:

- Determine whether each carcass and its parts are adulterated or unadulterated.
- Take appropriate action to prevent adulterated product from entering into human food channels.
- Notify the establishment personnel, VI and/or SI of carcass and/or parts defect findings.
- Examine sample sets when notified by the VI and verbally inform the VI during sampling when defects are found.
- Contact the SI if there are any concerns about process control.
- Retain carcasses and parts for further disposition by the SI if food safety and other conditions are identified that could result in condemnation.
- Maintain communication with the VI and SI to facilitate coordination of all post-mortem findings.

**Verification Inspection** - The Verification Inspector (VI) does not have a fixed position on the line, and can move freely. Specifically, the VI:

- Observes and evaluates the effectiveness of the establishment's HACCP and process control plans, including the examination of records, to determine whether the establishment is in compliance with applicable regulatory requirements.
- Conducts ante-mortem inspection of all animals at rest and 5-10 percent of animals in motion.
- Retains animals for further disposition by the SI, if the animal is suspected of having a condition that could result in condemnation.
- Documents ante-mortem findings on HIMP FORM 9.
- Takes verification samples to determine if establishment is complying with relevant performance standards, including scheduled and unscheduled sampling.
- Records all findings of noncompliance with applicable performance standards.
- Notifies the CI when verification samples are required and records the findings in each sample set during post-mortem. Evaluates the noncompliance findings and records in the appropriate category on HIMP form 7.
- Investigates potential process control problems.
- Notifies SI if the process control plan is not being met or if performance standards have been exceeded.
- Retains carcasses and parts for further disposition by the SI if food safety and other conditions are identified that could result in condemnation.
- Maintains communication with the CI and SI.

## **MARKET HOG INSPECTION STATION**

### Facilities required at each inspection station include:

1. The conveyor and/or rail shall be level for the entire length of the inspection station.
2. Floor space shall be adequate along the conveyor and rail.
3. Conveyor and rail stop/start switches shall be readily accessible.
4. A minimum of 50 foot-candles of shadow-free lighting shall exist at each inspection station.

### Inspection Stations will be established at up to 3 locations:

FSIS personnel are responsible for inspecting each head, viscera, and carcass. These locations will be:

1. After the mandibular lymph node incision step and before the head removal step for the Head Inspection Station.
2. After the establishment's viscera sorting step and before the viscera harvesting step for the Viscera Inspection Station.
3. After the final trim and sorting step and before the carcass wash step for the Carcass Inspection Station.

Inspection locations may be combined if carcass and/or parts (head and viscera) can be inspected at a single location. (Example: combining the viscera with carcass inspection if they can be inspected at one location.). Proposals for less than three inspector locations must be presented to the HIMP Project Manager.

## DOCUMENTATION

The forms used for the HIMP Market Hog project are:

- HIMP FORM-7, Postmortem Verification Inspection Activities
- HIMP FORM 8-1 OCP-1 25 Day Results
- HIMP FORM 8-2 OCP-2 25 Day Results
- HIMP FORM 8-3OCP-3 25 Day Results
- HIMP FORM-9 Ante-Mortem Verification Inspection Activities
- HIMP FORM-10 HIMP Verification/Corrective Action Log
- FSIS Form 5400-4 Noncompliance Record (NR)
- 

### **FS-1 and FS-3 nonconformance documentation -**

- The SI makes the final disposition on carcasses retained by inspection personnel on FS-1 and FS-3 categories and documents the FS-1 and FS-3 nonconformance on a NR as ISP code 03J01.
- If the SI finds additional noncompliance for **this specific slaughter production lot**, the SI will document the findings on separate NR's.
  - All findings must be taken into consideration after the NR is written. The SI also checks the plant's corrective actions. All findings and plant's corrective actions are to be documented on the NR.
- The 03J02 procedure is considered to be complete when inspection personnel have verified the establishment's pre-shipment review.
- The SI will inform the VI to document FS-1 non-conformances on the daily HIMP Form 7
- The SI will document FS-3 non-conformances on the HIMP form 9.

### **FS-2 nonconformance documentation -**

- An FS-2 nonconformance is documented when feces, ingesta or milk are identified during verification activities.(according to the identification guidelines in FSIS Directive 6420.2).\*
- The CI at the final carcass inspection station will follow FSIS Directive 6420.2 *Livestock Post-Mortem Inspection Activities-Enforcing the Zero Tolerances for Fecal Material, Ingesta, and Milk* Section II. B. 1 as it pertains to the final rail inspector.\*
- The VI, when performing FS-2 verification, will document an FS-2 nonconformance on a NR as ISP code 03J01.
- If the VI finds additional noncompliance for **this specific slaughter production lot**, the VI will document their findings on additional NR's.
- All findings must be taken into consideration by the VI that found the noncompliance or another VI. The VI also checks the plant's corrective actions. All findings and plant's corrective actions are to be documented on the NR.
- The 03J02 procedure is considered to be complete when the VI has verified the establishment's pre-shipment review.
- The FS-2 nonconformance is also to be documented by the VI on HIMP FORM-7.

**OCP nonconformance documentation –**

The VI or SI will document the OCP nonconformance findings during the shift on Draft HIMP form 7.

- If the establishment exceeds the daily maximum limit (See Table 1) for a specific OCP category, the VI will notify the SI.
- At the end of each shift, the SI will document the number of defects and pass/fail for each OCP category on HIMP FORMS 8- 1 through 8-3.

## **VERIFICATION PROCEDURES**

FSIS conducts verification inspection to assure that plants are meeting the performance standards. Verification inspection occurs in ante-mortem and post-mortem.

### **ANTE-MORTEM**

- Establishment ante-mortem records for the FS-3 category are to be reviewed by the VI or SI.
- The VI or the SI will inspect 100% of live animals at rest that are presented by the establishment for slaughter.
- The SI (or assigns to VI) randomly selects ante-mortem sampling times throughout the shift. Ante-mortem sampling times can be scheduled if the entire kill is available prior to start of shift. Usually live animals continue to be shipped to the establishment throughout the day and it is not possible to schedule the times for random sampling. Therefore, it is left to the discretion of the SI to determine randomness of sampling throughout the shift when live animals are available.
- The VI or SI will inspect 5-10% of the live animals in motion randomly throughout the shift after establishment sorting for slaughter.
- The VI or SI will assess sorting activities and humane handling practices.
- The SI will assess plant activities at the suspect pen.
- The VI will retain as suspect for SI disposition any animal that could result in condemnation.
- FS-3 deficiency determined by the SI will be documented by the SI on a NR and the establishment follows HACCP procedures in 9 CFR 417.3.
- The SI will document or notify the VI to document any FS-3 deficiency on HIMP Form 9.
- Other deficiencies found on ante-mortem sampling by the VI will be reported to establishment and the SI (such as humane handling).
- A NR is to be documented for humane handling violation. The ISP procedure code for violations related to humane handling and slaughter is **04C02**. \*

### **POST-MORTEM**

The verification sampling procedures for both food safety and other consumer protection performance standards will be conducted on 24 randomly selected samples for each shift. This procedure can be conducted either off-line or on-line. If conducted on-line, the VI will identify the samples and have the CI's examine each part and carcass, starting with the head inspection station. The VI will follow the samples through the entire process and record all defects found during the CI examination. The VI will record a maximum of one defect in each performance standard category per sample unit (e.g., a sample having bile and a bruise on the carcass would be identified as 1 OCP-3 defect. A sample having arthritis and fecal contamination of the viscera would be identified as 1 OCP-1 and 1 OCP-2).

In addition, the VI or SI will review establishment post-mortem records for FS-1. The SI and/or VI will review other establishment post-mortem records.

## 1) General

- A sample consists of a carcass with corresponding head and viscera.
- The SI or the VI will notify the on-line CI when to inspect verification samples during the shift.
- The CI, when notified by the VI, will inspect the verification samples of the carcass with corresponding viscera and head per shift and verbally inform the VI of their findings during sampling.
- The 24 unit samples per shift may be taken in subsets.
  - Sample subsets may be randomly taken in one of the following manners:
    - 3 samples 8 times per shift.
    - 4 samples 6 times per shift.
    - 6 samples 4 times per shift.
    - 8 samples 3 times per shift.
- Any OCP defects, which are identified at the inspection stations, should be identified to the establishment but not scored toward plant performance unless it is part of a scheduled or unscheduled sample subset.
- Sample times and sample subsets are to be selected randomly prior to the start of the shift.
- The VI or SI will record findings on DRAFT HIMP Form-7. It is not necessary to record a specific condition within a performance standard category (i.e., localized lung or heart conditions would be recorded as a noncompliance of the OCP-1 performance standard category).
- If the establishment is engaged in product/process action at the time the random sample is to be taken, the VI will suspend random sampling until the establishment has completed its actions.

## 2. FS1 and FS 2

- Establishment post-mortem records for FS-1 and FS-2 categories are to be reviewed by the VI or SI in accordance with 9 CFR 417.8.
  - The CI, when notified by the VI, will examine the sample subsets for indications of FS-1 and FS-2 defects and verbally relay the information to the VI.
    - 1) FS-2 defects are recorded at the post-mortem rail inspection station.
    - 2) The CI will retain carcasses with potential FS-1 defects for final disposition by the SI. If the VI/SI finds additional non-compliance for this slaughter production lot, the VI/SI will document each additional FS-2 defect findings on separate NR's. \*
    - 3) The CI at the Pre-Wash Verification Location Inspection Station will identify potential FS-1 and FS-2 defects. The CI will retain the carcass for final disposition by the SI. The CI will identify FS-2 defects and take the appropriate action consistent with established HACCP procedures. The VI/SI will document the FS-2 defect that was found by the CI on a NR. If the VI/SI finds additional non-compliance for this slaughter production lot, the VI/SI will document each additional FS-2 defect findings on separate NR's. \*
- No carcasses are allowed to exhibit FS-2 defects at the post-mortem rail inspection station. The CI will follow instructions for "on-line inspection personnel" in FSIS Directive 6420.2. The CI will have the defect removed either by riling the carcass out or having it trimmed on-line. Notify the SI/VI for possible unscheduled verification sampling. \*
- The SI will write a NR for FS-1 noncompliance.
- The VI will write a NR for FS-2 noncompliance observed during verification sampling in accordance with FSIS Directive 6420.2.\*



### 3. OCP

- The CI or VI will retain a carcass for final disposition by the SI when OCP defects are found that could result in condemnation.
- If the VI or SI determines that defects in an OCP category exceed the performance standard as stated in Table 1, the VI or SI will check the establishment's process control records for the same time frame. If the establishment results show a potential or actual loss of control as defined in the establishment's process control plan (PCP), the VI or SI will check the establishment's records to determine whether corrective actions described in the PCP were taken.

**TABLE 1: OCP Maximum defects allowed Per Shift**

<b>SAMPLE SIZE</b>	<b>24 SAMPLES (Head, Viscera, carcass)</b>	<b>UNSCHEDULED 27 SAMPLES</b>	<b>UNSCHEDULED 30 SAMPLES</b>	<b>UNSCHEDULED 33 SAMPLES</b>
<b>OCP-1</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>2</b>
<b>OCP-2</b>	<b>3</b>	<b>3</b>	<b>3</b>	<b>3</b>
<b>OCP-3</b>	<b>7</b>	<b>7</b>	<b>8</b>	<b>9</b>

- If the establishment failed to take proper corrective action according to their PCP, the establishment should detail what new corrective and preventive action will be implemented to prevent recurrence. Any samples that exhibit defects in any of the OCP performance standard categories should be pointed out to establishment personnel.

### Unscheduled Verification Inspection

When the SI determines that an unscheduled inspection should occur, the SI will notify the VI to conduct the inspection. Each unscheduled verification inspection will be three carcasses with corresponding viscera and head.

- Unscheduled verification sampling done at the direction of the SI will also be recorded on Draft HIMP Form 7.
- Unscheduled verification sampling will count toward the establishment's performance evaluation (See Table 1).
- The SI may call for unscheduled verification inspection because a CI has identified a potential problem.
- The SI may call for unscheduled verification inspection after the establishment has had sufficient opportunity to correct an establishment identified problem. This would confirm that the problem has been corrected.
- The establishment is notified of unscheduled verification inspection.
- The SI and/or VI will notify the establishment of the results of unscheduled verification sampling and establishment record examinations.

## EXAMINATION OF PLANT SAMPLING RECORDS FOR OCP'S

- In addition to the 24 OCP samples, VI will review establishment's records for OCP sampling results at least three times per day.
- Examples of plant records evaluation may also include observations of the plant selecting samples and data recording procedures.
- The VI or SI should record the results on the Draft HIMP Form 10.
- The VI will notify the SI of any discrepancies in the record examination.

### SI evaluation of OCP 1 through 3 for 25 day performance

- To evaluate whether the establishment maintains process control, the SI will track the performance of OCP 1 through 3 for a 25-day period using Draft HIMP Form 8-1 through 8-3 and Table 1.
- Each OCP will be tracked each shift and referenced to the Table 1 values.
- The SI will record that the plant passed or failed each of the 3 OCP categories on the appropriate HIMP form 8 and notify the plant of their findings.
- For an entire 25-day period, the maximum number of days on which the Table 1 performance standards can be exceeded is given in Table 2.

**TABLE 2: Maximum Days (OCP's)  
(Number of Days Above maximum defects  
allowed Per 25-Day Period)**

<b>OCP-1</b>	<b>2 days</b>
<b>OCP-2</b>	<b>4 days</b>
<b>OCP-3</b>	<b>3 days</b>

- If the plant exceeds the maximum days for any OCP category listed in table 2 for a 25-day period, at any point during the 25 days, the SI will write a NR coded 04C01. The plant should detail what new corrective and preventive actions are implemented to prevent recurrence. The plant will provide this information to the SI.

Note: A 25 day period will end at a full 25 days provided that the Table 2 Maximum Number of Days are not exceeded. If the Table 2 Maximum Number of Days are exceeded before 25 days are completed, e.g. on the 13th day, the period stops then while the plant responds as described above. A new 25-day period will begin when those conditions are satisfied.

## Correlation

The SI and/or VI will meet regularly with plant management to conduct correlation activities during the transition period. Regular correlation will aid FSIS and the plant in establishing a common basis for both FS and OCP determinations.

**Attachment 1****Model Performance Standards for Market Hogs Plants**

<b><u>Performance Standard Categories</u></b>	<b><u>Plant Performance Standards</u></b>
<b>FS-1—Condition – Infectious</b> (for example: septicemia/toxemia, pyemia, cysticercus)	<b>Zero</b>
<b>FS-2 – Condition – Digestive Content/Milk</b> (for example: fecal material, ingesta, milk)	<b>Zero</b>
<b>FS-3 – Ante-mortem Suspect</b> (for example: neurologic conditions, moribund, pyrexia, severe lameness)	<b>Zero</b>
<b>OCP-1 – Carcass- Pathology*</b> (for example: arthritis, emaciation, erysipelas, localized abscess, mastitis, metritis, mycobacteriosis [M Avium], neoplasms, pericarditis, pleuritis, pneumonia, uremia)	<b>4.1%</b>
<b>OCP-2 – Visceral Pathology*</b> (for example: cystic kidneys, enteritis/gastritis, fecal contamination of viscera, nephritis/pyelonephritis, parasites—other than Cysticercus, peritonitis)	<b>7.2%</b>
<b>OCP-3 – Miscellaneous</b> (for example: anemia, bile, bruise, edema, external mutilation, fractures, icterus, odor, skin lesions, scabs, toenails not removed)	<b>20.5%</b>

**\*Conditions exhibiting a septicemia or toxemia are considered food safety hazards**

## PLANT PERFORMANCE

### Ante-mortem Verification Inspection Activities (FS-3)

Shift: 1 2      Est. number: \_\_\_\_\_      Date: \_\_\_\_\_

Inspection Activity	1			2		
	Deficiency	FS-3	NR	Deficiency	FS-3	NR
Inspect 100% of hogs at rest						
Inspect 5-10% of hogs in motion, passed by plant for slaughter (at or after CCP location)						
Inspect suspects, as required (done by SI )						
Observe humane slaughter practices						
Examine Ante-mortem records						
Additional Comments:						

1. Circle **Shift**
2. Enter **Establishment #**
3. Enter **Date**
4. For each of the **Inspection Activities** listed, indicate if a **deficiency** is found. Also, indicate if the deficiency constitutes a **FS-3** and/or an **NR** by writing a **yes** or **no** in the space provided.

## PLANT PERFORMANCE

### Postmortem Verification Inspection Activities – FS and OCP Conditions

Date	Shift 1 2	Est #	Est. Name																								Unscheduled Verifications				
Performance Standard Categories			Scheduled Verification																								Total	Set 1	Set 2	Set 3	Total
<b>FS-1 Condition – Infectious (SI ONLY)</b> (for example: septicemia/toxemia, pyemia, cysticercosis) <div style="text-align: right;">Max 0</div>			1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24																												
<b>FS-2 Condition – Digestive Content/Milk (Carcass only)</b> (for example: fecal material, ingesta, milk) <div style="text-align: right;">Max 0</div>			1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24																												
<b>OCP-1 Carcass – Pathology*</b> (for example: arthritis, erysipelas, localized abscess, mastitis, metritis, mycobacteriosis, [M avium] neoplasms, pericarditis, pleuritis, pneumonia, (SI only emaciation, uremia) <div style="text-align: right;">Max 2</div>			1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24																												
<b>OCP-2 Visceral – Pathology* (Head and Viscera)</b> (for example: cystic kidneys, enteritis/gastritis, fecal contamination of viscera, nephritis/pyelonephritis, parasites - other than cysticercus, peritonitis) <div style="text-align: right;">Max 3</div>			1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24																												
<b>OCP-3 Miscellaneous</b> (for example: Anemia/Pale Soft Exudative pork, bile, bruise, edema, external mutilation, fractures, icterus, odor, skin lesions, scabs, toenails not removed) <div style="text-align: right;">Max 7</div>			1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24																												

\* Conditions exhibiting a septicemia or toxemia are considered food safety hazards.

DRAFT 7 HIMP FORM 7 5/24/01  
MARKET HOGS

1. Enter **Date**
2. Enter **Shift**
3. Enter **Establishment # and name**
4. For **FS** and **OCP** deficiencies, circle the number corresponding to the sample with the defect (condition). Enclose in brackets the sample subset (i.e. a three sample subset would be bracketed as [1 2 3] [4 5 6]...

A 4 sample subset may also be taken 6 times per shift, or 6 a sample subset 4 times per shift, or a 8 sample subset 3 times per shift.

Sample times and sample subsets are to be selected randomly **prior** to the start of the shift.

**TABLE 1: OCP Maximum defects allowed Per Shift**

<b>SAMPLE SIZE</b>	<b>24 SAMPLES (Head, Viscera, carcass)</b>	<b>UNSCHEDULED 27 SAMPLES</b>	<b>UNSCHEDULED 30 SAMPLES</b>	<b>UNSCHEDULED 33 SAMPLES</b>
<b>OCP-1</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>2</b>
<b>OCP-2</b>	<b>3</b>	<b>3</b>	<b>3</b>	<b>3</b>
<b>OCP-3</b>	<b>7</b>	<b>7</b>	<b>8</b>	<b>9</b>

EST. # \_\_\_\_\_

**MARKET HOGS****DRAFT HIMP FORM 8-1**

5/10/01

**OCP-1****25 Day Results**

Directions: Using the data from DRAFT HIMP Form 7 for OCP-1, determine plant performance per shift using Table 1. Record No. of Hogs with defects and indicate Pass or Fail for OCP-1 for each shift. The Maximum number of days on which this performance standard can be exceeded per 25 day window is given in Table 2.

Date of Collection	OCP-1	Date of Collection	OCP-1	Date of Collection	OCP-1
1		1		1	
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	
7		7		7	
8		8		8	
9		9		9	
10		10		10	
11		11		11	
12		12		12	
13		13		13	
14		14		14	
15		15		15	
16		16		16	
17		17		17	
18		18		18	
19		19		19	
20		20		20	
21		21		21	
22		22		22	
23		23		23	
24		24		24	
25		25		25	
TOTAL # PASSED		TOTAL # PASSED		TOTAL # PASSED	
TOTAL # FAILED		TOTAL # FAILED		TOTAL # FAILED	

**TABLE 1: OCP-1 Performance Standard Per Shift (24 head, carcass, & viscera samples)**

CONDITION	MAXIMUM DEFECTS ALLOWED
OCP-1	2

**TABLE 2: Maximum # of Days OCP-1 is Allowed Above Performance Standard (Per 25-Day Period)**

CONDITION	MAX. # DAYS PER 25 DAY PERIOD
OCP-1	2 days

EST. # \_\_\_\_\_

**MARKET HOGS****DRAFT HIMP FORM 8-2**

5/10/01

**OCP-2****25 Day Results**

Directions: Using the data from DRAFT HIMP Form 7 for OCP-2, determine plant performance per shift using Table 1. Record No. of Hogs with defects and indicate Pass or Fail for OCP-2 for each shift. The Maximum number of days on which this performance standard can be exceeded per 25 day window is given in Table 2.

Date of Collection	OCP-2	Date of Collection	OCP-2	Date of Collection	OCP-2
1		1		1	
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	
7		7		7	
8		8		8	
9		9		9	
10		10		10	
11		11		11	
12		12		12	
13		13		13	
14		14		14	
15		15		15	
16		16		16	
17		17		17	
18		18		18	
19		19		19	
20		20		20	
21		21		21	
22		22		22	
23		23		23	
24		24		24	
25		25		25	
TOTAL # PASSED		TOTAL # PASSED		TOTAL # PASSED	
TOTAL # FAILED		TOTAL # FAILED		TOTAL # FAILED	

**TABLE 1: OCP-2 Performance Standard Per Shift (24 head, & viscera samples)**

CONDITION	MAXIMUM DEFECTS ALLOWED
OCP-2	3

**TABLE 2: Maximum # of Days OCP-2 is Allowed Above Performance Standard (Per 25-Day Period)**

CONDITION	MAX. # DAYS PER 25 DAY PERIOD
OCP-2	4 days



EST. # \_\_\_\_\_

**MARKET HOGS****DRAFT HIMP FORM 8-3**

5/10/01

**OCP-3****25 Day Results**

Directions: Using the data from DRAFT HIMP Form 7 for OCP-3, determine plant performance per shift using Table 1. Record No. of Hogs with defects and indicate Pass or Fail for OCP-3 for each shift. The Maximum number of days on which this performance standard can be exceeded per 25 day window is given in Table 2.

Date of Collection	OCP-3	Date of Collection	OCP-3	Date of Collection	OCP-3
1		1		1	
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	
7		7		7	
8		8		8	
9		9		9	
10		10		10	
11		11		11	
12		12		12	
13		13		13	
14		14		14	
15		15		15	
16		16		16	
17		17		17	
18		18		18	
19		19		19	
20		20		20	
21		21		21	
22		22		22	
23		23		23	
24		24		24	
25		25		25	
TOTAL # PASSED		TOTAL # PASSED		TOTAL # PASSED	
TOTAL # FAILED		TOTAL # FAILED		TOTAL # FAILED	

**TABLE 1: OCP-3 Performance Standard Per Shift (24 head, carcass, & viscera samples)**

CONDITION	MAXIMUM DEFECTS ALLOWED
OCP-3	7

**TABLE 2: Maximum # of Days OCP-3 is Allowed Above Performance Standard (Per 25-Day Period)**

CONDITION	MAX. # DAYS PER 25 DAY PERIOD
OCP-3	3 days

Comparison Table: Swine Inspection

<b>FSIS Swine Inspection Procedures (traditional):</b> <ul style="list-style-type: none"> <li>• Authority: 21 USC 604 (FMIA), 9 CFR 310.1</li> <li>• Procedures: Slaughter Inspection Training Materials (1/14/2005)</li> </ul>	<b>FSIS Swine Inspection Procedures for Plants Operating Under HIMP:</b> <ul style="list-style-type: none"> <li>• Authority: 21 USC 604 (FMIA), 9 CFR 303.2</li> </ul>	<b>Netherlands Swine Inspection Procedures for Plants Operating Under Visual Inspection:</b> <ul style="list-style-type: none"> <li>• Authority: EC 854/2004</li> <li>• Procedures: "The New Organization of the Red Meat Inspection System in the Netherlands (2006)"</li> </ul>	<b>EU Swine Inspection Procedures (traditional):</b> <ul style="list-style-type: none"> <li>• Authority: EC 854/2004</li> <li>• Procedures: Annex I; Sec IV; Chap IV: Domestic Swine, B.—Post mortem Inspection</li> </ul>
<b>General:</b> <ul style="list-style-type: none"> <li>• For all swine</li> </ul>	<ul style="list-style-type: none"> <li>• For market hogs slaughtered in plants operating under the HACCP-based Inspection Models Project (HIMP).</li> <li>• Carcasses must be presented for inspection with the mandibular lymph nodes incised.</li> </ul>	<ul style="list-style-type: none"> <li>• For fattening pigs housed under controlled housing in integrated production systems since weaning.</li> <li>• At the discretion of the competent authority based on epidemiological or other data from the holding [farm].</li> <li>• Data from the farm must include food chain information, results of testing for <i>M. avium</i>, and certain additional requirements to control hazards in the food supply chain.</li> </ul>	<ul style="list-style-type: none"> <li>• For all swine except those identified under paragraph (2).</li> </ul>

<b>Head Inspection:</b> <ul style="list-style-type: none"> <li>• Observe head and cut surfaces – eyes, fat, cheek muscles, and other tissues for abnormalities.</li> <li>• Incise and observe mandibular lymph nodes.</li> </ul>	<ul style="list-style-type: none"> <li>• Visual inspection of the head and throat.</li> <li>• Visual inspection of the incised mandibular lymph nodes.</li> <li>• Visual inspection of mouth, fauces, tongue.</li> </ul>	<ul style="list-style-type: none"> <li>• Visual inspection of the head and throat, including the mandibular lymph nodes.</li> <li>• Visual inspection of mouth, fauces, tongue.</li> </ul>	<ul style="list-style-type: none"> <li>• Visual inspection of the head and throat.</li> <li>• Incision and examination of the submaxillary lymph nodes (Lnn mandibulares).</li> <li>• Visual inspection of the mouth, fauces and tongue.</li> </ul>
<b>Viscera Inspection:</b> <ul style="list-style-type: none"> <li>• Observe eviscerated carcass, viscera and parietal (top) surface of spleen.</li> <li>• Observe and palpate mesenteric lymph nodes.</li> <li>• Palpate portal lymph nodes.</li> <li>• Observe dorsal (curved) surface of lungs.</li> <li>• Palpate bronchial lymph nodes.</li> <li>• Observe mediastinal lymph nodes.</li> <li>• Turn lungs over and observe ventral (flat) surfaces.</li> <li>• Observe heart.</li> <li>• Observe dorsal (curved) surface of liver.</li> <li>• Turn liver over and observe ventral (flat) surface.</li> </ul>	<ul style="list-style-type: none"> <li>• Visual inspection of the lungs, trachea, and oesophagus.</li> <li>• Visual inspection of the pericardium and heart.</li> <li>• Visual inspection of the liver and hepatic and pancreatic (portal) lymph nodes.</li> <li>• Visual inspection of the gastro-intestinal tract, mesentery, gastric and mesenteric lymph nodes.</li> <li>• Visual inspection of the spleen.</li> </ul>	<ul style="list-style-type: none"> <li>• Visual inspection of the lungs, trachea, and oesophagus.</li> <li>• Visual inspection of the pericardium and heart.</li> <li>• Visual inspection of the liver and hepatic and pancreatic (portal) lymph nodes.</li> <li>• Visual inspection of the gastro-intestinal tract, mesentery, gastric and mesenteric lymph nodes.</li> <li>• Visual inspection of the spleen.</li> <li>• Visual inspection of genital organs.</li> </ul>	<ul style="list-style-type: none"> <li>• Visual inspection of the lungs, trachea and oesophagus.</li> <li>• Palpation of the lungs and the bronchial and mediastinal lymph nodes (Lnn. bifurcationes, eparteriales and mediastinales).</li> <li>• 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.</li> <li>• Visual inspection of the liver and the hepatic and pancreatic lymph nodes, (Lnn portales).</li> <li>• Palpation of the liver and its lymph nodes.</li> <li>• Visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (Lnn gastrici, mesenterici, craniales and caudales).</li> <li>• Palpation and, if necessary,</li> </ul>

			incision of the gastric and mesenteric lymph nodes. <ul style="list-style-type: none"> <li>• Visual inspection and, if necessary, palpation of the spleen.</li> </ul>
<b>Carcass Inspection:</b>			
<ul style="list-style-type: none"> <li>• Observe back of carcass (turn carcass or use mirror).</li> <li>• Observe front and inside of carcass, including               <ul style="list-style-type: none"> <li>○ Cut surfaces,</li> <li>○ All body cavities,</li> <li>○ Lumbar region,</li> <li>○ Neck region.</li> </ul> </li> <li>• Grasp, turn, and observe the kidneys.</li> </ul>	<ul style="list-style-type: none"> <li>• Visual inspection of the carcass.</li> <li>• Visual inspection of the pleura and peritoneum [lining of chest and abdominal cavities].</li> <li>• Visual inspection of the kidneys.</li> <li>• Visual inspection of the diaphragm.</li> <li>• Visual inspection of the udder and its lymph nodes.</li> <li>• Visual inspection of the umbilical region and joints of young animals.</li> </ul>	<ul style="list-style-type: none"> <li>• Visual inspection of the carcass.</li> <li>• Visual inspection of the pleura and peritoneum [lining of chest and abdominal cavities].</li> <li>• Visual inspection of the kidneys.</li> <li>• Visual inspection of the diaphragm.</li> <li>• Visual inspection of the udder and its lymph nodes.</li> <li>• Visual inspection of the umbilical region and joints of young animals.</li> </ul>	<ul style="list-style-type: none"> <li>• Visual inspection of the carcass.</li> <li>• Visual inspection of the pleura and peritoneum.</li> <li>• Visual inspection of the kidneys.</li> <li>• Incision, if necessary, of the kidneys and the renal lymph nodes (Lnn. renales).</li> <li>• Visual inspection of the diaphragm.</li> <li>• Visual inspection of the udder and its lymph nodes (Lnn. supramammarii).</li> <li>• Incision of the supramammary lymph nodes in sows.</li> <li>• Visual inspection and palpation of the umbilical region and joints of young animals.</li> <li>• In the event of doubt, the umbilical region must be incised and the joints opened.</li> </ul>

## ANSWERS TO QUESTIONS FSIS TO THE NETHERLANDS

### GENERAL

Before providing specific answers to the questions that have been asked by FSIS, it is important to take into account the following general remarks:

- Specific focus of the pilot project regarding visual inspection was to identify relevant risks for food safety resulting from the new method and to answer the question whether the level of food safety was (at least) the same as with the traditional method. Thus the focus was not a complete scientific comparison between two p.m. inspection methods, but a risk-based approach regarding food safety. Others have already carried out scientific research concerning public health aspects of post mortem inspection in market hogs.
- Several documents concerning visual meat inspection in the Netherlands have already been sent to FSIS this year. In these documents detailed information is available about the results of our pilot project and relevant procedures of meat inspection. When providing answers to the questions we will therefore refer to the relevant text in these documents. Furthermore we will include these reference documents with this report.

## SPECIFIC

### 1. Question

**The pilot study concludes that visual inspection failed to reject 9 of 174,250 (0052%) carcasses that were inspected. However, this also represents 9 of 43 (20.9%) carcasses rejected during the pilot study. Therefore visual inspection failed to detect a significant portion (21%) of carcasses affected with pathological conditions that warranted rejection. It appears that the Netherlands considers it acceptable to pass one fifth of all carcasses that should be condemned for pathology. Is this correct? Can human factors of visual-only inspection be an aggravating factor?**

To put the question about the acceptability of missed pathological conditions into the right perspective, it is important to note the aim of the pilot project. The central question was whether the new method could be operated at (at least) the same level of food safety as the traditional method. So we have not done a complete scientific comparison between two methods of p.m. investigation. Such comparison has already been done in different scientific projects in several countries and these were summarized in the "Opinion on Meat Inspection Procedures" of the European "Scientific Committee on Veterinary Measures"<sup>1</sup>. An important conclusion has been that p.m. inspection of pigs from industrialized production in general will assist little in improving meat safety. Reduction of the prevalence of human hazards mainly lies in the hygiene control programs throughout the whole supply chain. This supports the importance of "hands-off" systems in the slaughter line and securing possible risks concerning meat safety by other means than p.m. inspection. That's why we focused on meat safety with a risk-based approach. So we have (for example) not examined the portion of carcasses that were passed by traditional investigation, but may have been rejected by visual inspection. This was not possible because of the logistical organization of the pilot where visual inspection was followed by traditional inspection, and visual inspection was a part of the traditional inspection.

From a risk point of view it is important to put the proportion of carcasses missed by visual inspection and rejected by traditional inspection into relation with the total number of inspected carcasses.

Besides we want to give you specific information regarding the 9 carcasses that have not been detected by the visual inspectors during the pilot:

The reasons for condemnation were:

- Serious generalised pathological conditons (2 carcasses) and icterus (1 carcass):

It is clear that these 3 carcasses should have been detected by the visual inspectors and cannot be seen as "missed by the system". It seems logical to look for the cause of these missed abnormalities primarily at the human level. As stated above we have not investigated the "human factor" of the traditional method but seen the small number of rejected carcasses in relation to the total number of inspected carcasses the human factor has to be taken into account with both, visual and traditional inspection methods.

- Positive bacteriological test on *arcobacterium pyogenes* (3 carcasses) :
- Positive bacteriological test on *haemolytic streptococci* (1 carcass):

From a public health view the question is, whether these 4 carcasses with a positive BE (bacteriological examination) do indeed represent a food safety risk? For a closer look at the bacteria's found and their relevance for food safety please see the answer to question 10.

- Failed bacteriological test (1 carcass) :

It is difficult to say something about the carcass were the bacteriological test failed. The test may have been negative and consequently the carcass would have passed trough.

- Positive test on antibiotics (1 carcass)

The carcass had been railed out for further testing because of inflammation of a carpus/ tarsus and multiple abscesses in the lung found by traditional inspection. The bacteriological test was negative.

<sup>1</sup> Opinion of the Scientific Committee on Veterinary Measures relating to Public Health on "Revision of meat inspection Procedures, 24-2-2000.

- Further remarks:

Figure 4 from the draft report (page 14, chapter 5.1) shows that in the beginning of the pilot project there were relatively more pathological findings not detected by the visual inspectors. Possibly it took some time before everyone was used to the new situation. This would be another, (specific) aspect of the "human factor".

As stated above it can be concluded from scientific literature that some findings will not be detected by visual inspection. During the pilot project we have tried to identify the relevant food safety risks and to secure them also by other means. But it is important to note that both, visual and traditional inspection methods have not a very high sensitivity with respect to the detection of possible food safety risks (opinion of the SC on revision of meat inspection procedures, 2000). This has been one of the main reasons for looking for ways to secure food safety risks by other means within the supply chain.

## 2. Question

**The paper mentions that pigs from farms meeting requirements laid down in the Code of Practice of the IKB Scheme or an equivalent quality assurance scheme were used. Further information on the scheme is needed. For example, what records are available related to ongoing disease surveillance, treatment records, production methods to reduce exposure to specific pathogens, etc?**

The Dutch IKB scheme is an integrated quality assurance scheme for production chain control with additional requirements on top of national and EU legislation for feed, hygiene, the use of veterinary drugs, transport and animal welfare. The integrated chain approach of the program means, that all activities in pork production are closely linked to one another, from breeders to pig farmers to slaughterhouses. The work carried out by vets, the requirements for veterinary medicines and the standards for animal feed and animal welfare are also covered within the program.

In addition, all of the professional contacts of pig farmers in the industry must comply with the requirements that are laid down in separate quality regulations: the Quality Regulations governing Livestock Trading, the Quality Regulations governing the Transport of Livestock, the Good Manufacturing Practice regulations for feed manufacturers and the Good Veterinary Practice regulations for Accredited Pig Veterinary Surgeons. Within the quality system there are regulations governing each type of establishment. These include both system requirements and product requirements. The system requirements relate to the established way of working (the manual) and the implementation of the system in practice. The product requirements relate to every link in the production chain. As far as animal health and food safety are concerned, these focus on aspects such as:

- Transfer of records on animal health
- GVP (Good Veterinary Practice) approved veterinarians
- Limited list of approved veterinary drugs compared with EU legislation
- Feed control according to food safety based GMP+ system including HACCP for pig feed
- Hygiene codes for farms, transport and processors

### Data exchange animal health

Within the IKB system information about the state of health of an animal accompanies the animal in question to the next link in the chain. Both the breeder and the pig farmer record all important data concerning the health of their animals in an IKB farm logbook, i.e. identification and registration details, the origin of the sows and the fattening pigs and the length of time the animals have spent on the farm.

Other details that are recorded include any purchases, the nature of any health problems, every veterinary medicine administered, the date and duration of the treatment, the medicine dosage, the recommended withdrawal period and all vaccinations of piglets and fattening pigs. Both the breeder and the pig farmer keep copies of delivery documents. All data is kept for a minimum of 12 months.

At the slaughterhouse relevant data of post mortem inspection such as carcass lesions and organ lesions, as reported in the letter of 25-07-2006 from the Dutch Deputy Chief Veterinary Officer (reference 06.2092/IH), are collected and subsequently reported back to the farmer.

### Good Veterinary Practice

Pig farmers may only make use of the services of vets who operate in accordance with the Code of Good Veterinary Practice (GVP) and are accredited pig veterinary surgeons. This Code is administered by an independent body, the Veterinary Quality Body (VKO), in collaboration with the Royal Netherlands Veterinary Association. The pig farmer concludes an exclusive contract with a GVP-certified pig veterinary surgeon. This Code contains guidelines for vets on how to handle animals carefully and in an ethical manner.

### Approved medicines

Veterinary medicines may only be used on IKB pig farms if prescribed by a vet. Only veterinary medicines that appear on the 'positive list of veterinary medicines for IKB pig farms' may be used. The effect of this measure is that when an animal is slaughtered, there are no residues or injection marks in the meat. To guarantee that this is in fact the case, in a great many instances the withdrawal period is longer than the withdrawal period provided for by EU law. The requirements imposed on medicines on the positive list are more stringent than the statutory requirements. For example, the use of sulphonamides (sulpha drugs) is extremely restricted on the positive list.

The positive list indicates per product the active substance, the dosage form, the registration number, the registration holder, the product name and the withdrawal period in days. All veterinary medicines on the positive list have to undergo additional testing before they can be accepted on the list.

### GMP+ Feed

Pigs on IKB farms may only be given feed that comes from companies that operate in accordance with the Code of Good Manufacturing Practice+ (GMP+Feed). The Code is a quality scheme that has been set up by the Product Board for Animal Feed. The Code contains regulations concerning the use of additives and veterinary medicines, the prevention of undesirable substances and controls on the microbiological condition of the feed. Quality assurance within the GMP+ scheme is based on the international standard HACCP, which has been prescribed in Europe for the food industry.

The aim of the IKB quality system is to provide guarantees in the areas of product safety, traceability and audits. IKB is a flexible system that is constantly being further developed, tightened up and adapted. It provides an infrastructure within which changes can be introduced relatively easily. This means that the system is capable of adapting to new developments.

Important changes were made in April 2003, when the IKB system was extended to include additional regulations covering the layout of pig units, hygiene, independent auditing (EN 45011) and ISO-based pig husbandry procedures. In April 2004 the IKB system was extended to include SAFE, a program of extensive testing for unauthorized substances in pig farming.

An English translation of the IKB Code of Practice for pig farmers is attached to this report.

### **3. Question**

**The paper did not provide adequate historical data to support that there are enhancements of visual-only inspection over traditional inspection. It was stated that total number of condemnations during the previous year differed significantly in comparison with data of the pilot. It was concluded that this difference could be explained by the fact that the supply of fattening pigs during the previous year did not match the supply during the pilot. This suggests and does support that source has a significant impact on "risk." More information is needed to support if such decisions can be maintained regularly and predictably in the future. It is difficult to make a comparison of inspection methods if the source animals are not from the same source.**

It was concluded that comparison of results of visual inspection with historical data of traditional inspection was not preferable because of a possible bias. It couldn't be excluded that the type of fattening pigs that was inspected in the year before (and whose inspection results were the basis of the historical data) was different



from that inspected during the pilot<sup>2</sup>. For this reason a comparison was made within the same group of animals, the fattening pigs that were presented for inspection during the pilot. All these animals underwent a double inspection regime, they were both visually and traditionally inspected. So for the duration of the pilot, source as a reason for bias could be effectively excluded.

Source cannot be excluded as a possible risk factor, but this aspect was – and had to be! – incorporated in the visual inspection pilot. For instance only fattening pigs from farms that met all the requirements (see below) were admitted to this double inspection regime. The justification of visual inspection lies in Regulation (EC) 854/2004 where it is stated that:

*'The competent authority may decide, on the basis of epidemiological or other data from the holding, that fattening pigs housed under controlled housing conditions in integrated production systems since weaning need, in some or all of the cases referred to in paragraph 1, only undergo visual inspection.'*<sup>3</sup>

The minimum requirements for participation in visual inspection are:

- it concerns only fattening pigs
- they may not have had outdoor access
- they should come from farms that have implemented the system of food chain information
- they should come from farms that have implemented pro-active measures against *Mycobacterium avium*
- they should have been raised under controlled housing conditions and in integrated systems of production.(IKB).

#### 4. Question

**The report indicates that decision making was made primarily on farm data and history. A serological test would need to be reliable as a predictor for evaluating the TB herd status. It was not clear if reliability and value of an antibody test for *M. avium* had been established. The report indicates that antibody testing should be, for the time being, be considered as the most sensible diagnostic tool. However, no specific data was presented supporting serological testing as an effective or practical herd monitoring tool for TB.**

Before we address your specific questions regarding serological testing we want to give you some general information about the epidemiology of *Mycobacterium avium* in the Netherlands and relevant research that has been done regarding the relation between positive bacteriological tests with *M. avium*, the presence of macroscopic lesions in lymph nodes and serological conversion.

Furthermore, we will provide information about the procedures for serological testing of pigs within the chain supply chain inspection scheme and the follow-up of serological positive farms.

*Mycobacterium avium* is a bacterium that can cause harm to man. Several scientific publications and health statistics show the relevance of *M. avium*, see references (Inderlied et al, 1993, Wallace and Hannah 1988). The Dutch government and scientific research organizations have carried out already for years research into this bacterium. Results of the prevalence studies on *M. avium* in market hogs are published by Komijn et al (1999, and 2007), see the enclosures.

The Dutch pork producers aimed to contain the prevalence of *M. avium* through preventing the introduction of this bacterium at the hog farm. Measures to realize this were implemented in the IKB code of practice at farm level (see also respons to Question 2). Within the code of practice pest control and hygiene of feed and bedding material are most relevant with respect to the control of *M. avium* at farm level.

Research showed that the prevalence of *M. avium* at farm level has decreased between 1998 and 2003. Actually *M. avium* has not been detected in a targeted surveillance in the 2003 prevalence study of Komijn et al (publication accepted in 2006, will be published in 2007), thus the prevalence in the Netherlands is very low.

These data form the scientific basis for the change in the control of *M. avium* in pork.

In order to gain more insight in the development of granulomatous lesions in pigs an infection experiment was done (Wisselink et al, 2006). The results showed that all pigs inoculated with *M. avium* had one or more lymph nodes bacteriological positive with *M. avium* at slaughter age. From the pigs inoculated once below 5 weeks of

<sup>2</sup> See also: 'Final report on the data analysis from the 'Visual inspection Pilot', page 12 and further.  
FOIA\_NED 2006-01-25/2004, Annex I, section IV, chapter IV, B Post-mortem inspection, paragraph 2

age 14 out of 16 showed granulomatous lesions in one or more lymph nodes. However only 2 out of 8 pigs inoculated 3 times (at 2½, 4½ and 18 weeks of age) showed granulomatous lesions. Of all pigs inoculated, 23 out of 32 showed seroconversion at market age, see table 1, 2 and 5.

Lipids of a *M. avium* strain harvested from pigs in the Netherlands (strain MAA 17404) were used to develop an antibody test. Polar lipids were used as antigen in the Elisa. The highest value of percentage positivity measured in known MMA-free pigs was 16%. See for the results of the serological test tables 3 to 5.

**Table 1: Macroscopic evaluation of Lnn of pigs at 24 weeks of age after experimental infection with *Mycobacterium avium* subsp. *avium***

Group	Number pigs	age experimental infection (wks)			Lesions in lymphnodes	
		2,5	4	18	Mean (n)	pigs (n)
1	8	X			2,1	7
2	8		X		2,5	7
3	8			X	0	0
4	8	X	X	X	0,3	2

**Table 2: Macroscopic lesions on lymphnodes in pigs after experimental infection with *Mycobacterium avium* subsp. *avium***

Group	Number pigs	Number of macroscopic lesions in lymphnodes per infection group:						
		Tonsil	Mand.	Mes.	Ing.	Trach.-br. (li)	Trach.-br. (re)	Retro-phar
1	8	1	3	6	0	2	2	3
2	8	0	7	7	0	0	2	4
3	8	0	0	0	0	0	0	0
4	8	0	0	2	0	0	0	0

Legenda: Mand = Lnn mandibularis; Mes = Lnn mesenterialis; Ing = Lnn inguinalis; Trach. br. = Lnn trachea-bronchialis; Retro-phar = Lnn retro-pharyngeal

**Table 3: Sera originating of pigs that showed to be negative in bacteriological examination on *Mycobacterium avium* subsp. *avium* (MAA), tested in an ELISA with antibodies against the polar lipids of MAA**

Percentage Positivity (serology)	Number of samples (%)
< 0%	80 (52.3)
0 - 5%	60 (39.2)
5 - 10%	10 (6.5)
10 - 15%	2 (1.3)
15 - 20%	1 (0.7)
> 25%	0 (0)
Totaal	153 (100)

**Table 4: Test levels in percentage positivity (PP%) at different targeted levels of specificity**

Specificity		Test levels (PP%)	
Mean	Range	Mean	Range
0.90	0.84 – 0.94	4.4	2.4 – 7.7
0.95	0.90 – 0.97	7.5	5.1 – 14.4
0.975	0.94 – 0.99	8.9	7.4 – *
0.99	0.96 – 1.00	12.3	8.8 – *

\* dataset insufficient

**Table 5: Evaluation of macroscopic lesions, bacteriological examination and serology of 32 pigs experimentally infected with MAA**

Group	Number of pigs positive						
	Lymphnode lesions macroscopic			Lymphnode bacteriological			Serology (> 7,5 PP%)
	Mand.	Mes.	Mand.+ Mes.	Mand.	Mes.	Mand.+ Mes.	
1	3	6	7	5	8	8	8
2	7	7	7	8	7	8	5
3	0	0	0	8	5	8	2
4	0	2	2	7	7	8	8
Total	10	15	16	28	27	32	23

Legenda: Mand = Lnn mandibularis; Mes = Lnn mesenterialis

#### Procedures for testing of pig serum within the supply chain inspection

From each lot of pigs supplied to the slaughterhouse two or six blood samples are taken. A farm can only be qualified to deliver pigs that satisfy the requirements of supply chain inspection when at least 18 subsequent blood samples showed to be negative in the MAA-Elisa. Whenever one or more blood samples are positive the lots of pigs of that farm will be slaughtered at a slaughterhouse that conducts traditional meat inspection.

#### Follow up of *Mycobacterium avium* serological positive farms.

When lots of the same farm repeatedly have positive results when tested serologically for *M. avium* this could be indicative for the presence of *M. avium*. (b) (4) will assist the farm to become *M. avium* free again. In the traditional meat inspection incision of the lymphnodes occurs, additionally at this slaughterhouse of every market hog lot six blood samples are taken and analyzed for the presence of antibodies against *M. avium*.

The farms are being visited by a (b) (4) employee who, together with the farmer, will assess the risk factors for *M. avium*. The farmer is being encouraged to alter his management. If problems persist the farm is visited by a veterinarian who will conduct additional tests. These tests consist of tuberculation of the hogs and a further evaluation of the risk factors at the farm. If the extended evaluation of the risk factor shows indications for contamination routes, samples of the environment (e.g. soil, feed and water) are taken. Of the tuberculated hogs mesenteric lymphnodes are being sampled in the slaughterhouse and these are analyzed for the presence of *M. avium*.

#### References:

Inderlied CB, Kemper CA, Bermudez LE. The *Mycobacterium avium* complex. Clin Microbiol Rev. 1993 Jul;6(3):266-310. Review.

Komijn, RE., PEW de Haas, ME Schneider, T Eger, JHM Nieuwenhuis, RJ van den Hoek, D. Bakker, FG van Zijderveld and D van Soolingen. Prevalence of *Mycobacterium avium* in Slaughter Pigs in The Netherlands and Comparison of IS1245 Restriction Fragment Length Polymorphism Patterns of Porcine and Human Isolates. J of Clin Microb, 1999, 37, 1254-1259

Komijn, RE., HJ. Wisselink, VMC. Rijsman, N. Stockhofe-Zurwieden, D. Bakker, FG. van Zijderveld, T. Eger, JA. Wagenaar, FF. Putirulan and BAP. Urlings, Prevalence of *Mycobacterium avium subsp. avium* in lymphnodes of slaughter pigs in The Netherlands. Accepted for publication in Veterinary Microbiology (2007)

Wallace JM, Hannah JB. *Mycobacterium avium* complex infection in patients with the acquired immunodeficiency syndrome. A clinicopathologic study. Chest. 1988 May;93(5):926-32.

Wisselink, HM, C van Solt-Smits, N Stockhofe-Zurwieden, H Bergen-Buys, P. Overduin, M van Prehn, D van Soolingen and J Thole. Comparison of visual and bacteriological examination of mandibular and mesenteric lymphnodes in pigs, experimentally infected with *Mycobacterium avium subsp. Avium*. IPVS Conference Copenhagen 2007.

#### **5. Question**

**It is not clear if visual inspection would be used for non-market weight hogs, such as sows and boars. Since the basis for deciding not to incise lymph nodes is based on epidemiological data of pigs raised since weaning, and TB, if present, is more or less likely to be seen in older animals, detection in sows might be more important in evaluating the risk of TB. Are incisions to be performed in older animals (non-market hogs)?**

The visual inspection is not used for non market weight hogs, such as sows and boars. They follow the traditional inspection. Visual inspection can be only in place for fattening pigs kept under controlled housing conditions in integrated production systems in line with the legal European framework as mentioned in the answer to question no. 3.

#### **6. Question**

**It is not clear if/how the Farm Risk Profile considers previous slaughter results? What criteria will be used to determine whether a particular slaughter lot requires more intensive inspection procedures? How rapidly will those criteria be re-evaluated based on information from previous slaughter lots (or even the current slaughter lot)? Is the data real time?**

#### **9. Question**

**Will verification testing for residues be based on history of treatment? It is not clear what value the history of "group treatments" has on supporting visual-only inspection to rule out whether non-TB abscesses or drug residues are likely to be present.**

In the answer below we address question no 6 and no 9 at the same time:

The Farm Risk Profile (FRP) is an index used for estimating the risk of *Mycobacterium avium* in future market hog lots. The way the FRP is calculated is described in the answers to question 4.

To assess if a supplied lot needs to be analyzed in more detail for residues of anti-microbiological agents, the slaughter results of the previous slaughtered lots of the same farm are used.

If the percentage affected lungs and/or pleuritis of the farm (calculated over the last 4 weeks; if less then 2 deliveries in these last 4 weeks, then the last 2 deliveries of the farm to (b) (4) is at least double the percentage of affected lungs and/or pleuritis in comparison to the slaughter plant average, the current lot is being sampled and analyzed for residues of anti-microbiological agents.

Because the percentage of affected lung/pleurisy is calculated over the last 4 weeks, seasonal changes are incorporated in the estimation.

The slaughter lesions found in a market hog lot is being presented to the farmer. (b) (4) uses an internet based application called Farmingnet. The data from lots slaughtered will be available to the farmer within 24 hours. Farmers can use this information to improve their management and the health of the pigs subsequently on the farm.

**Table 1: (b) (4) Helmond versus National Plan at (b) (4) Helmond**

Period: January untill June 2006

Animal species: market hogs

Total no. pigs slaughtered: n=697.394	positive NAT-screening	NAT post-screening kidney	NAT post-screening meat	Chemical analyses meat	
				<MRL	>MRL
Supply chain meat inspection (samples taken n=439)	36 (8,2 %) 26 x tetracycline 1x $\beta$ -lactam 3x aminoglycoside 1x quinolonen 5x sulfonamiden	7 (1,6 %)	7 (1,6 %)	5 4xtetra 1xsulfa	2 1xtetra 1xsulfa
National Plan (n=147)	7 (4,8 %) 7xtetracyclines	2 (1,3 %)	2 (1,3 %)	1 1xtetra	1 1xtetra

NAT-screening: microbiological analyses pré-urine

NAT post-screening kidney: microbiological analyses kidney tissue

NAT post-screening meat: microbiological analyses muscular tissue

Chemical analyses: liquid chromatography in combination with mass-spectrometry or diode-array detection.

In table 1, the results of residue analyses due to supply chain meat inspection (targeted sampling) and the results of residue analyses of the National Plan random sampling (coordinated by the Government) are shown. It is concluded that because of the risk based approach of the supply chain meat inspection, the percentage of residues found in meat has increased in the targeted cohort.

Whenever values above MRL are detected, the agriculture police will take immediate action. In case of results of analyses of values below MRL, the Food Chain Information will be taken into account. A follow up to the farm will be initiated, in order to part he control of the absence of residues at a higher level.

## 6. Question

**How will scheduling of verification procedures occur to ensure that visual inspection continues to protect food safety? Verification procedures should be initiated based on random and biased factors. Verification lots of market hogs where abscess/granulomas are observed in the mesenteric lymph nodes would be an excellent way to rule out M. avium lesions that might have been missed by not incising the mandibular lymph nodes.**

In the case of the slaughterhouses in general and slaughterhouses which export to the USA specifically there are several types of verification:

- Permanent (daily) visual verification of hygienic process conditions by the VWA
- Permanent (daily) bacteriological verification of hygienic process conditions by the slaughterhouse, supervision by the VWA.

- Salmonella monitoring (USA-exporting slaughterhouses)
- Monitoring of residues in the framework of the National Plan (random sampling)

Also there are verifications on meat inspection:

General (all slaughterhouses):

1. Verification of quality of inspection (has the right decision been made by the on-line inspector) does take place on a daily basis (minimum once a day) and is carried out by the official veterinarian.
2. The location of the verification activities is the on-line inspection platform next to the on-line inspection.
3. The results of this verification are documented. This information will be used for verification of inspection performance of official auxiliaries that is set as a cumulative maximum of 6% of missed pathological abnormalities (2% standard for the carcass, 2% for the stomach/intestines, and 2% for the organs). In case of insufficient performance the official veterinarian will take action.
4. The number of carcasses + stomach-intestines + organs to be verified on a daily basis are calculated as the square-root of the number of slaughtered pigs, distributed over the day with a minimum of 2 batches and a minimum of 50 pigs.
5. No (normal) carcasses /stomach-intestines/ organs will be "railed out" for verification purposes; the verification occurs on-line next to the normal inspection, not off-line.

A detail description of the verification procedures on the quality level of the post mortem inspection as performed by the official auxiliaries is described below.

The standards can be distinguished into two basic elements, i.e. standards for inspection procedures and standards for inspection decisions:

Inspection procedures

The starting point is that inspection procedures have to be carried out in compliance with Regulation (EC) 854/2004. Verification of the execution of official controls has to be done on the inspection station. The standard for the correct execution of the inspection procedures is fixed at 5% per inspection position. By this standard is meant the maximum number of deviations of the number of inspection procedures. The size of the random sample is determined at  $\sqrt{n}$  ( $n$ =number of animals in a one-day production cycle) over two batches.

**1. Inspection decisions**

The verification of the correct execution of the inspection decisions distinguishes two parts, i.e. pathological abnormalities and hygienic slaughtering. The verification of pathological abnormalities takes place on the inspection station, as long as the carcass and the organs where running synchronically. The verification of hygienic slaughtering takes place between the trimming station and the end of the slaughtering line.

***Pathological abnormalities***

Regulation (EC) 854/2004, annex 1, section II, chapter V describes which pathological abnormalities are reason to declare meat unfit for human and/or animal consumption. The standard for missed pathological abnormalities is determined at 6% cumulative and is in fact a check on wrongly approved material. This standard consists for the traditional pm. inspection of a 2% standard for the carcass, 2% for the pluck, and 2% for the intestines. For the supply chain inspection this standard consist of a 2% standard for the carcass and a 2 standard for the plucks and intestines together. This cumulative standard is based on the fact that this was found to be very realistic in New Zealand. New Zealand is the only country that has experience in this area with meat.

The size of the random sample per inspection position to test the standard of 6% cumulative for traditional inspection and 4% cumulative for supply chain inspection is fixed at  $\sqrt{n}$  ( $n$ =number of animals in a one-day-production cycle) over two batches. If the result of  $\sqrt{n}$  exceeds 50, these batches will be divided in two batches of a minimum of 25 carcasses per inspection position. The cumulative standard of 6% for missed pathological abnormalities is a guidance standard for the assessment of the post mortem inspection quality.

Together with the size of the random sample, a statistically justifiable picture of the post mortem inspection quality is created.

#### Hygienic slaughtering

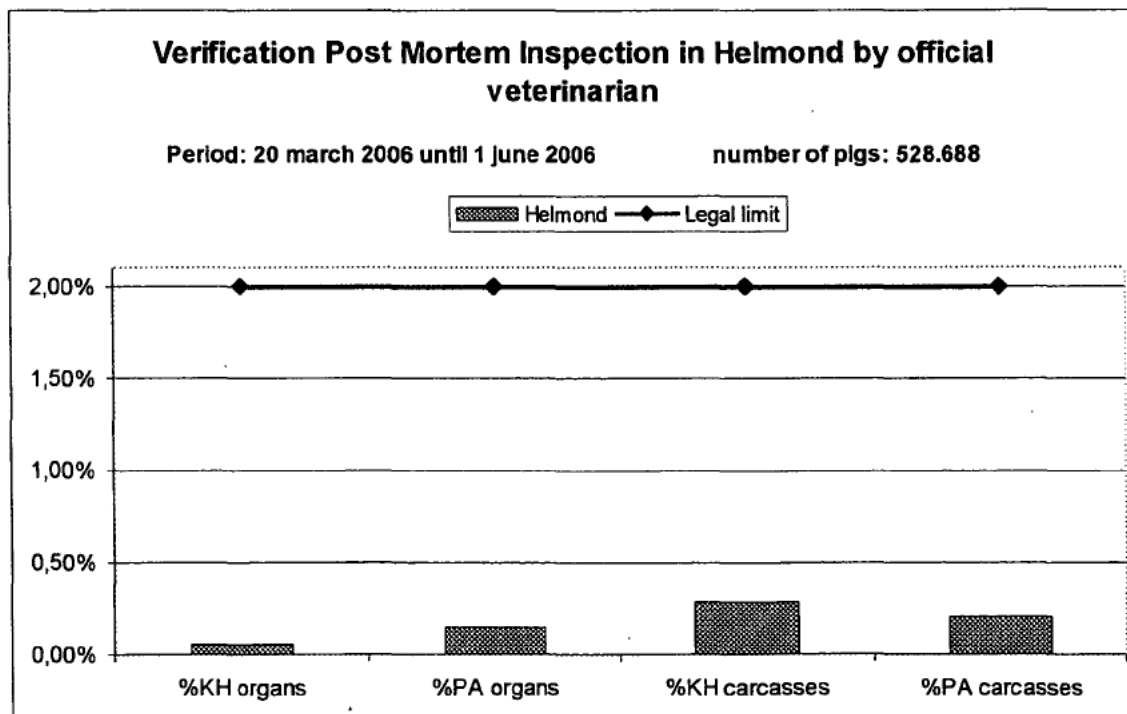
In the first place it needs to be clear that faecal contamination is a Critical Control Point in the HACCP-system (EC Regulation 852/2004, article 5). The slaughterhouse is responsible for the guaranteeing of this CCP.

In addition, slaughter animals with deviations as a result of errors in the slaughtering hygiene are offered for inspection, which require an inspection decision. The standard per carcass for slaughtering defects is fixed at 2% total and 0% for faecal contamination. The faecal contamination will always have to be 0% at the end of the slaughtering line! The size of the random sample to test the standards of 2% and 0% is fixed at  $2\sqrt{n}$  (n=number of animals in a one-day-production cycle) over four batches. If the result of  $\sqrt{n}$  exceeds 50, these batches will be divided in four batches of a minimum of 25 carcasses.

Results of the verifications described above have shown that there are no indications that visual inspection is performing less on the basis of these results.<sup>4</sup>

In Annex 1 tables are presented of monthly summaries for verifications inspection procedures and inspection decisions. When comparing location Helmond (supply chain inspection) with (b) (4) location Bostel (traditional inspection) it becomes clear that the level of inspection both for inspection procedures and inspection decisions was adequate.

In graph 1, the results of the verification of the p.m. inspection at (b) (4) Helmond are shown in detail. KH represents a wrong inspection performance or a wrong inspection decision. PA represents missed pathological abnormalities. The performance of the inspection meets the standards (<2% standard for plucks and intestines, <2% standard for carcasses, which makes total cumulative below 6 %) as in the verification procedure of the Food and Consumer Product Safety Authority (VWA).



Legenda: KH = wrong inspection performance or a wrong inspection decision; PA = missed pathological abnormalities

**Graph 1**      results of the verification of the p.m. inspection at (b) (4) Helmond.

<sup>4</sup> See Annex I



From this graph it becomes clear that visual inspection at (b) (4) location meets the VWA standards.

Verification procedures in the framework of supervision on the (b) (4) supply chain inspection pilot project:

In the supervision protocol activities of the VWA are two parts described in this protocol: VWA external and VWA internal with four types of supervision.

VWA external

1. Audits on the execution of protocols stated (external audits)
  - Audit on Food Chain Information submission
  - Audit on implementation at the slaughterhouse
2. Verification at slaughterhouse level
3. Verification at farm level

VWA internal

4. Audit on supervision carried out by the VWA as described here under 'internal audit'.

The verification procedures mentioned above are described in the Supervisory framework on the (b) (4) chain management pilot project: see annex

In addition to the standard procedures for all slaughterhouses, specifically in the case of supply chain inspection also verification is in place on the overall performance of inspections including handling and correction of all defects on the trimming station.

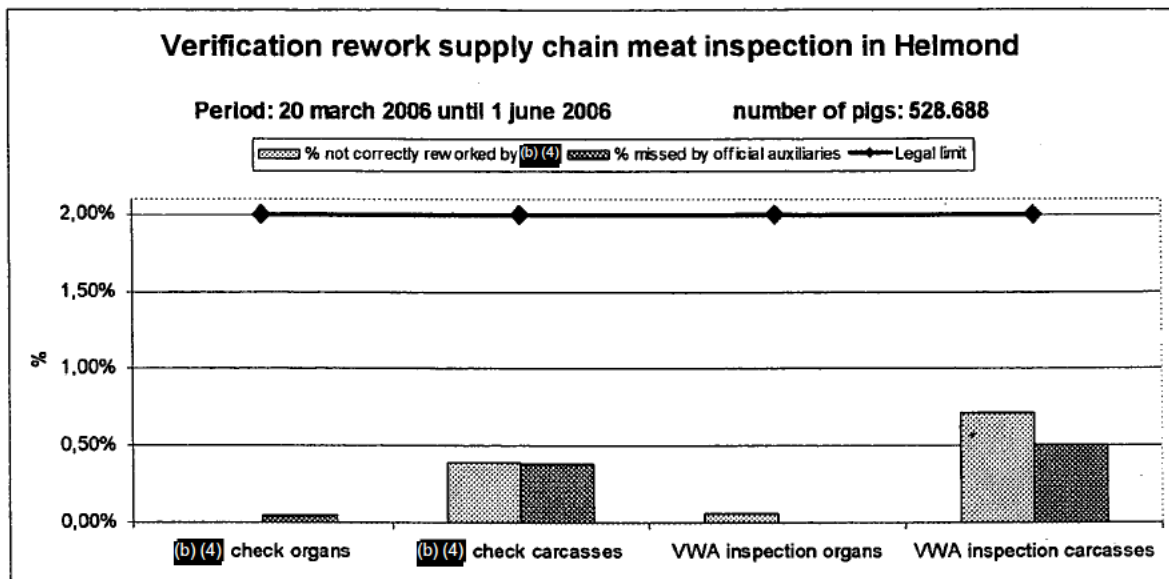
The performance standard is set at compliance levels of 98% a day and 98% a week of the checked carcasses to be up to specification. This standard is set up for the deviations marked by the official auxiliaries. Deviations which have not been marked by the official auxiliaries are registered and if needed corrected and will be passed on to the official veterinarian of the Dutch Product and Food Safety Authority, but will not count in the total score to determine the performance standard of the slaughterhouse.

When the above-mentioned performance standards are not met at the monitoring, next to above-mentioned measures (including additional instruction), the frequency will be increased. In the case of more than 2% deviations a day, the next day an additional check will be performed. When in 2 occasions (or more) with more than 2% deviations in a week, the frequency for checks on carcasses will be increased to 5 checks a day (in stead of 4 checks) for the period of 1 week and for the plucks and the organs, the frequency will be increased to 3 checks a day (in stead of 2 checks) for the period of 1 week.

The official veterinarian of the Food and Consumer Product Safety Authority will perform verification on above-mentioned working method. When deviations are found, (b) (4) will perform the same measures as if the deviation was observed by (b) (4)

In the period of 20 March 2006 until 1 September 2006, it only occurred once, that 3 carcass had deviations after rework in one day. The correct measures were taken. In the same period, it did not occur that organs (plucks and intestines) showed deviations after rework.





Graph 2 Results of verification rework supply chain meat inspection at (b) (4) Helmond

#### 8. Question

How does the Farm Risk Profile factor impact *M. avium*, *Salmonella*, etc. without validated blood testing or historical slaughter data under traditional inspection? It is reasonable to factor seasonal changes in calculating risk of disease (pneumonia) and need for additional residue testing.

This question has been dealt with in the answers to questions 4 and 6.

#### 9. Question

Will verification testing for residues be based on history of treatment? It is not clear what value the history of "group treatments" has on supporting visual-only inspection to rule out whether non-TB abscesses or drug residues are likely to be present.

Please see answer to question no 6.

#### 10. Question

A discussion on the impact of visual inspection on detection of endocarditis lesions and some of the causative agents has been provided in the draft report. Results indicate that inspectors will not be able to identify as many lesions as during traditional inspection. Although some possible reasons have been mentioned, further information and discussion on this issue are needed, especially discussion on *Strep. suis* and other microorganisms of zoonotic concern.

It is correct that not all endocarditis lesions will be detected by visual only p.m. inspection. However, scientific literature concludes that detecting large part of endocarditis lesions is possible with visual only inspection (especially by focussing on kidney infarcts). We have found support for that in our pilot as well. On the other hand it is important as well to note that also with standard incision of the heart it will not be possible to detect every case of endocarditis because of the speed of the slaughter line.

According to the risk-based approach as explained in answer to question 1 we carried out a risk analysis on endocarditis (appendix 2 of the data analysis report) with the following results:

- The prevalence of endocarditis is very low (0,005-0,007%), data source: pilot project + other meat inspection data (Netherlands, 2004)

- We also found that only 33-50% leads to condemnation of the carcass because a positive bacteriological test.
- The microorganisms usually associated with endocarditis (*E. rhusiopathiae*, *A. pyogenes* and Haemolytic streptococci) are not known as important food born zoonotic agents. But off-course this cannot be ruled out for a 100%.

When looking at the micro-organisms that can be found in association with endocarditis, *E. rhusiopathiae* en *Streptococcus suis II* are of zoonotic concern.

For *E. rhusiopathiae* it can be said that:

- Was not detected during the pilot and in the year before.
- Is not a big issue in Dutch pig husbandry (i.a. because of vaccination)
- Is mostly of zoonotic concern in contact infections (farmworkers, slaughterhouse employees)
- In some cases *E. rhusiopathiae* also gives generalised symptoms like the typical skin lesions. These carcasses will be detected with visual p.m. inspection.

For *Streptococcus suis* it can be said that:

- Especially *S. suis II* is a zoonotic micro organism.
- It is not known if *S. suis II* is associated with endocarditis in the market hogs in the Netherlands. Because further serotyping is not done streptococci isolated in slaughterhouses.
- *suis II* is known to give animal health problems in Dutch pig husbandry and would therefore be detected in the live animal at farm level or at ante-mortem.
- *suis II* is known as a relevant zoonotic risk for slaughterhouse employees, butchers, farm workers, because the infection occurs through contact.
- Foodborne infection can not be ruled out 100%, but is not likely.

For *A. pyogenes* can be said that:

- It's not seen as a zoonotic microorganism
- Is sporadically found in human
- There are no indications that food born infections are possible

In a risk-based approach we concluded that the risk of not detecting all endocarditis lesions is not relevant for food safety.

The conclusions we drew about the micro organisms mentioned above are based on our literature research (see below). Our conclusions are also supported by a literature research done on different microorganisms concerning meat inspection by the National Institute for Public Health and the Environment (RIVM) in 1989. They also concluded that *A. pyogenes*, *S. suis* and *E. rhusiopathiae* are not relevant as foodborne zoonotic microorganisms.

#### Literature:

1. W. Wouda et. al. , Endocarditis en vleeskeuring bij slachtvarkens, Tijdschrift voor Diergeneeskunde, deel 112, afl. 21, 1987, p. 1226-1235
2. Masanori Katsumi et. al, Bacterial Isolation from slaughtered pigs associated with endocarditis, especially the isolation of *Streptococcus suis*, Journal of veterinary medical science, vol. 59, 1997, p. 75-78
3. U. narucka et. al., Afwijkingen bij slachtdieren, Tijdschrift voor Diergeneeskunde, deel 110, afl. 19, 1985, p. 776-779
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6. C. Tarrads et. al., Identification of Streptococcus suis Isolated from Swine: Proposal for Biochemical Parameters, journal of clinical microbiology, vol. 32, 1994, p. 578-580
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#### 11. Question

**It is not clear if farm workers are subject to health testing. This may be of concern in cases where there is a high turnover rate and there are migrant workers from other EU countries and non EU countries that work on farms. What is the normal turnover rate for the work force at the farms. There could be a potential risk of farm or abattoir workers introducing TB, especially drug-resistant TB, to livestock or food products.**

In practice, most farmers work alone or have personnel which are contracted for a long period. Therefore, it rarely happens that new personal is hired (especially foreign personnel because of communication problems).

People from non EU countries are allowed to work in the Netherlands, provided that they have a working permit. This working permit is only given when strict conditions are met. One condition is that the employer can not find an employee in the Netherlands to fill in the job vacancy. When farmers do not act according this law, severe fines are given by the government.

People from other EU countries are allowed to work in the Netherlands, where they have to work according Dutch law. The Dutch law concerning labour, is supervised by the Labour Inspection of the Dutch Government. The Labour Inspection is authorized to sanction the concerning employer when the conditions are not met.

In addition, people who are working in the (b) (4) slaughter establishments have to fill in two documents:

1. a health declaration, provided with a signature of the employee and the medical doctor (see appendix 1).
2. the (b) (4) hygiene regulations, signed by the employee that he has read and understood the hygiene regulations. In these hygiene regulations is described how to deal with illness and injuries (see appendix 2)

According to public health regulations concerning Tuberculosis (TBC) in man in the Netherlands, TBC must be reported to the government when TBC has been diagnosed. When TBC has been diagnosed, the government will take immediate actions to control and eliminated the disease (as stated in a report of the National coordinator infectious disease control).

## Appendix 1

### 2.6 Health declaration for persons working in the food industry

Name: .....  
First name: .....  
Date of birth: .....-.....-.....  
Place of birth: .....  
Address: .....

Have you ever suffered from, or do you still suffer from:

- |                            |                          |                           |
|----------------------------|--------------------------|---------------------------|
| A. typhoid fever           | <input type="radio"/> no | <input type="radio"/> yes |
| B. paratyphoid fever       | <input type="radio"/> no | <input type="radio"/> yes |
| C. tuberculosis            | <input type="radio"/> no | <input type="radio"/> yes |
| D. infectious skin disease | <input type="radio"/> no | <input type="radio"/> yes |

If yes, which one: .....

- |                                 |                          |                           |
|---------------------------------|--------------------------|---------------------------|
| E. any other infectious disease | <input type="radio"/> no | <input type="radio"/> yes |
|---------------------------------|--------------------------|---------------------------|

If yes, which one: .....

The undersigned states to have given the above information to the best of his/her knowledge.

The undersigned also states that during his/her employment he/she will immediately report to management and to ArboUnie (Working Conditions Union) when he/she is suffering or believes to be suffering from an infectious disease.

Town: .....  
Date: .....-.....-.....  
Signature: .....

#### Health certificate (to be completed by the physician)

The undersigned states to have no objections against issuing the "Health certificate food industry" on the basis of the supplied information.

The certificate is valid until.....

Name of physician.....

Town .....

Date .....

Signature .....

**Appendix 2    Hygiene regulations (b) (4) (Pro-ALG-NL-10091)**

**Illness and injuries**

- Infections, eczema, diarrhoea and contagious diseases which can be spread through food should be reported immediately to the management. The company management will assess availability for work, but if there is a risk of direct or indirect contamination of the product, no access to the production hall will be permitted. Reports will be handled confidentially.
- Cuts and grazes should be treated at once, using a blue, detectable plaster or bandage if necessary (preferably by a First Aid official). The loss of a blue plaster or bandage during production must be reported to the manager.
- In the case of cuts, grazes, etc. on hands or lower arms, wear a glove (Latex disposable gloves or examination glove).
- Always wear gloves if you have warts.
- If you have a cold, wash your hands after any contact with mucus/discharge (for example after coughing, sneezing); use disposable tissues.
- It is forbidden to bring personal medication into the production hall.
- Anyone who suffers from external bleeding, vomiting or other form of human discharge must be removed from the department immediately. If the product, workplace, tools or packaging material are contaminated/soiled in the process, the department manager must act according to PRO-ALG-NL-10034

## 12. Question

The report indicated that the supply of food chain information was at a high rate of compliance, but it did not indicate what information was provided. The report also indicated that visual inspection resulted in a minimal loss of food safety. Food safety improvements were based on increased risk based testing for residues (regardless of the new scheme). The claim that, omitting incision of mandibular lymph nodes reduced the spread of *Salmonella*, was not supported. The claim that the incision of mandibular lymph nodes to detect *M. avium* is "not very meaningful" is without support. Further information is needed.

The food chain information (FCI) that was presented along with the animals can be found in the (b) (4) procedure 'Food chain information (in regard to supply chain meat inspection)'<sup>5</sup>

This procedure was designed by (b) (4) on the basis of VWA-directives. Before implementation it was checked again by the VWA to see if it covered:

- Legal demands for FCI coming from Reg. (EC) 853/2004
- The specific information related to the *Mycobacterium avium* status of the holding<sup>6</sup>
- Information on possible risk factors like historic data of percentages of lung and liver inflammation and pleurisy, as it was suspected that the chance of finding antibiotics residues was higher in animals coming from holdings with higher percentages<sup>7</sup>. This assumption was confirmed later.<sup>8</sup> The testing for antibiotic residues could of course also have been in place in the case of traditional inspection only but it was seen as a logic consequence of the broader concept of supply chain inspection which aims at improving food safety by reducing both sources of cross contamination and other hazards.

The influence of omitting the incisions of the mandibular lymph nodes on *Salmonella* contamination was tested. It proved to lead to a significant reduction of contamination.<sup>9</sup>

The conclusion on meaningfulness of incision of the mandibular lymph nodes for detecting *Mycobacterium avium* was based on a literature study<sup>10</sup>.

Finally, one of the three objectives of the pilot was to answer the question:

**'Does the system safeguard that at least the same level of food safety is guaranteed?'**<sup>11</sup>

The evaluation of this question can be found in the 'Final report 'Pilot Pork Supply Chain Inspection (b) (4)' in the paragraph 'Evaluation food safety balance'. It was concluded that there was a food safety benefit and not a

<sup>5</sup> page 2/3:

'The following information will be present at the slaughterhouse at least the day before slaughter:

On the plan list the following information will at least be present:

- The *Mycobacterium avium* Farm Risk Profile (FRP). Farms without FRP or farms with an FRP 'high' are not allowed to the system of supply chain meat inspection;
- Certified IKB farms, or equivalent quality assurance scheme; if not, these farms cannot participate in the system;
- The percentage affected lungs and/or pleuritis (calculated over the last 4 weeks, if less then 2 deliveries in these 4 weeks, then the last 2 deliveries of the farm (identified with farm identification number). If an additional sample is analysed as positive for the first screening of antibiotics, the next delivery of that farm, 1 pig of that delivery will be analysed again.

The following information will be present at the slaughterhouse at least before the physical slaughter of the pigs:

- Compliance to IKB standard of the individual pigs;
- Information about the origin of the animal feed;
- Information about the group treatments in the period of 2 months before slaughter until the slaughter date of the pigs.'

<sup>6</sup> See also the procedure 'Food chain information (in regard to supply chain meat inspection)', page 2.

<sup>7</sup> See also the procedure 'Food chain information (in regard to supply chain meat inspection)', page 2: 'When percentages of lung and liver inflammation and pleurisy are higher than twice the slaughterhouse average, additional checks for antibiotic residues will take place. A risk-based control is performed regarding a higher risk of group treatments.'

<sup>8</sup> See: 'Detecting antibiotics in pork'

<sup>9</sup> See: 'Salmonella monitoring'

<sup>10</sup> See: 'Final report on the data analysis from the 'Visual inspection Pilot', appendix 3: 'The food safety implications of *Mycobacterium avium*'; Comparison of visual- and bacteriological examination of mandibular and mesenteric lymph nodes in pigs, experimentally infected with *Mycobacterium Avium* subsp. *Avium*, Wisselink H, e.a.

<sup>11</sup> See: 'Final report 'Pilot Pork Supply Chain Inspection (b) (4)' page 2

minimal loss of food safety as is stated in your question! These results are in line with the SCC "Opinion on Meat Inspection Procedures".

In this opinion it was concluded that hygienic conditions are of utmost importance during the slaughter and inspection process to reduce hazards to human health. From this point of view it was also concluded that the introduction of 'hands off' systems is preferable above maintaining the current inspection procedures which are an important source of cross contamination. A testing for *Salmonella* contamination confirmed this assumption.

In the pilot the possible loss of sensitivity for detecting *Mycobacterium avium* infections was compensated by serological testing. Based on current scientific insights this serological method does not only have a higher sensitivity but also a higher specificity.

Also additional food chain information, like results from prior slaughterings, to detect more precisely antibiotics residues, turned out to be a food safety benefit.

The conclusion was that these benefits led to an improved food safety as the loss of sensitivity caused by visual inspection compared to traditional inspection, was minimal and only in a certain percentage could be related to loss of food safety. More over, this loss of sensitivity could also largely have been explained by the 'human factor' in the starting phase of the pilot.

The VWA judged the pork supply chain inspection as a whole and come to the conclusion that:

- There was an improved food safety
- The conditions for visual inspection mentioned in Regulation (EC) 854/2004, Annex I, section IV, chapter IV, B Post-mortem inspection, paragraph 2, were fulfilled.



## ANNEX

### Salmonella

Salmonella can be present in the intestine, oral cavity and lymphatic tissue of market hogs delivered at slaughter plants.(1,2) Studies showed 21% of the market hogs are infected with salmonella in the lymphatic tissue around the oral cavity.(6,8)

In slaughter plants with a high degree of control of fecal contamination, salmonella contamination of carcasses is related to cross contamination in the slaughterhouse rather than to salmonella present in the intestine (2,3). An effective control of cross contamination is therefore crucial to decrease salmonella contamination of carcasses. To illustrate the performance of the slaughter plant figure 1 has been added to this report. It shows the percentage of salmonella positive analysis performed as a result of the standard food safety monitoring of carcasses.

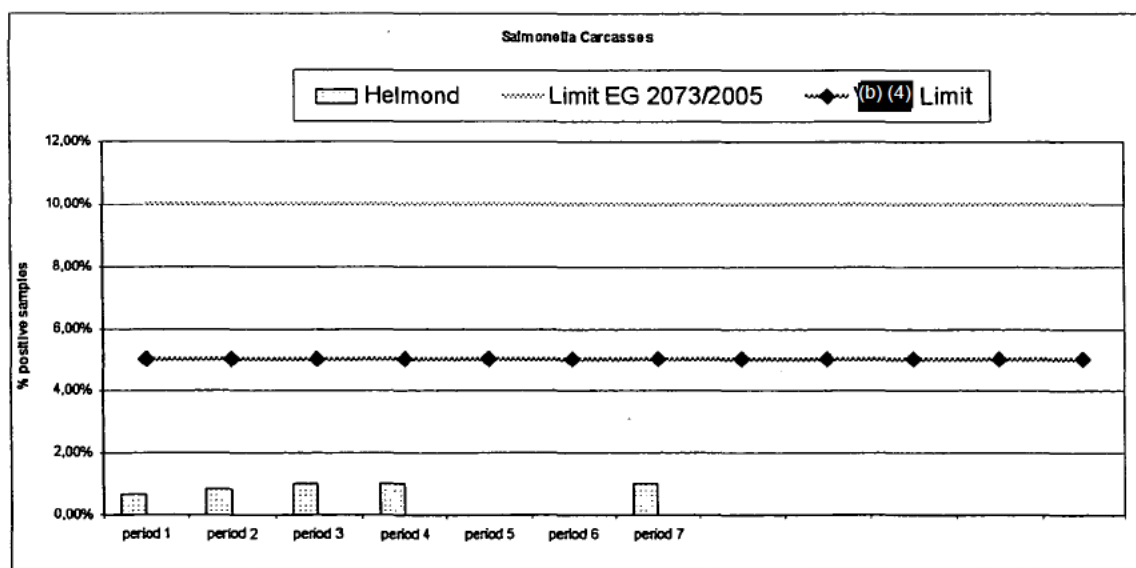
The incisions made during the traditional post mortem meat inspection are contributing to the cross contamination of salmonella (4). Omitting these incisions would therefore be an improvement in relation to the risk of cross contamination.

To visualize the effect of incision of the lymphnodes on cross contamination we conducted an experiment during the pilot in Helmond. Right before the incision of the lymphnodes the entire inner head area (which has been cut open during the process) was being swabbed with a sterile whirl-pack sponge. The procedure was being repeated right after the incisions in the head were made. Results showed an increase in salmonella present right after cutting (7) These results are illustrated in fig 2.

The increase can be explained by the opening of the lymphnodes containing salmonella in combination with manual handling of the head area by the inspection personnel.

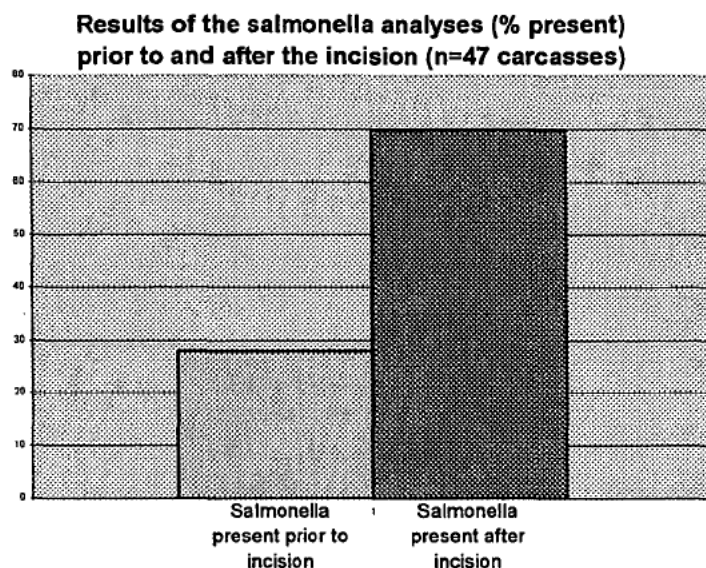
These incisions are made to detect relevant hazards that pose a risk to food safety. The relevance of this instrument can be doubted in regard to many of the suspected risks. Many relevant risks are hardly detectable by visual inspection of the cut lymphnodes (1)

Other means of controlling these risks, like serological verification of *Mycobacterium avium*, are potentially more effective.



Graph 1 Average results in the standard food safety monitoring in the slaughter plant in Helmond. Each day 5 carcasses are being sampled and analyzed for the presence of salmonella. One "period" represents a period of 4 or 5 weeks. Period 1 represents weeks 1,2,3, and 4 in 2006 etc. Period 7 represents week 27,28,29 and 30 in 2006





**Graph 2 Results of the salmonella analysis in the head-swabbing experiment during the pilot in Helmond.**

#### Literature

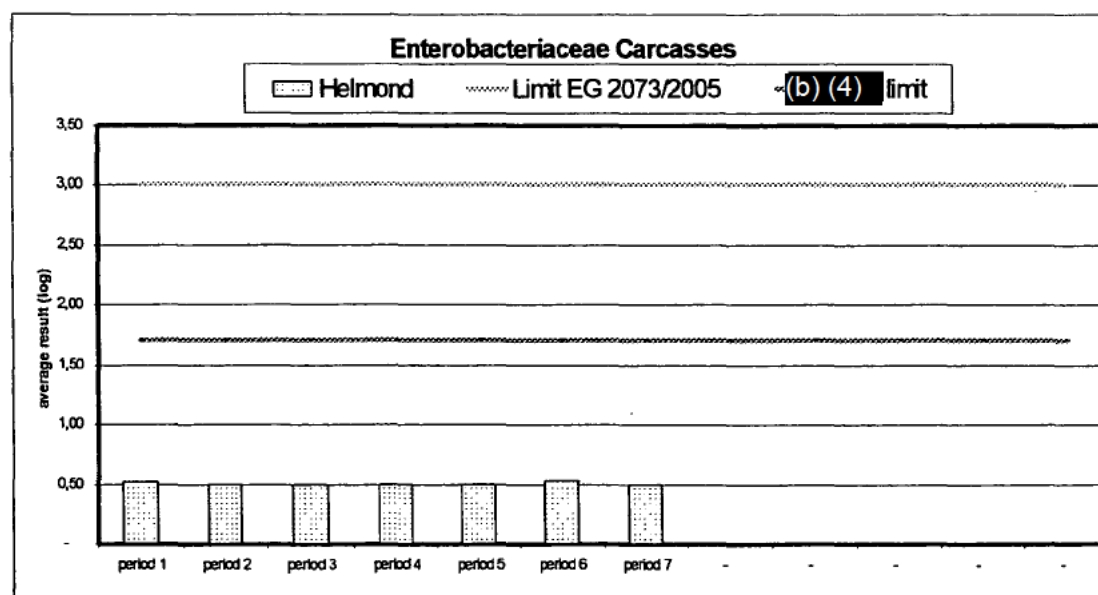
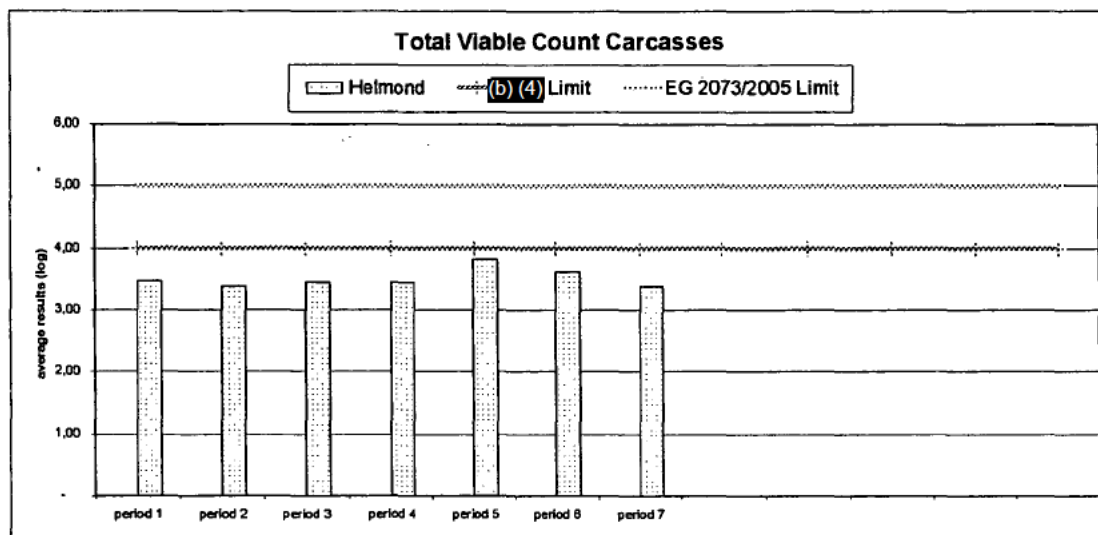
- 1.) Petersen JV, Andersen JK, Sorensen F, Knudsen H. Food safety on the slaughterline: inspection of pig heads. Vet Rec. 2002 Jun 22;150(25):782-4. Review.
- 2.) Swanenburg M, van der Wolf PJ, Urlings HA, Snijders JM, van Knapen F. Salmonella in slaughter pigs: the effect of logistic slaughter procedures of pigs on the prevalence of Salmonella in pork. Int J Food Microbiol. 2001 Nov 8;70(3):231-42.
- 3.) Swanenburg M, Berends BR, Urlings HA, Snijders JM, van Knapen F. Epidemiological investigations into the sources of Salmonella contamination of pork. Berl Munch Tierarztl Wochenschr. 2001 Sep-Oct;114(9-10):356-9.
- 4.) Berends BR, Van Knapen F, Snijders JM, Mossel DA. Identification and quantification of risk factors regarding Salmonella spp. on pork carcasses. Int J Food Microbiol. 1997 May 20;36(2-3):199-206.
- 5.) Swanenburg M, Urlings HA, Snijders JM, Keuzenkamp DA, van Knapen F. Salmonella in slaughter pigs: prevalence, serotypes and critical control points during slaughter in two slaughterhouses. Int J Food Microbiol. 2001 Nov 8;70(3):243-54.
- 6.) Swanenburg M, Urlings HA, Snijders JM, Keuzenkamp DA, van Knapen F. Salmonella in the lairage of pig slaughterhouses. J Food Prot. 2001 Jan;64(1):12-6.
- 7.) "salmonella monitoring" report made during the pilot "supply chain inspection" 2005-2006 in Helmond, the Netherlands
- 8.) Oosterom J, Dekker R, de Wilde GJ, van Kempen-de Troye F, Engels GB Prevalence of Campylobacter jejuni and Salmonella during pig slaughtering. Vet. Quarterly 7, 31-34.

## Overall contribution of supply chain inspection to food safety.

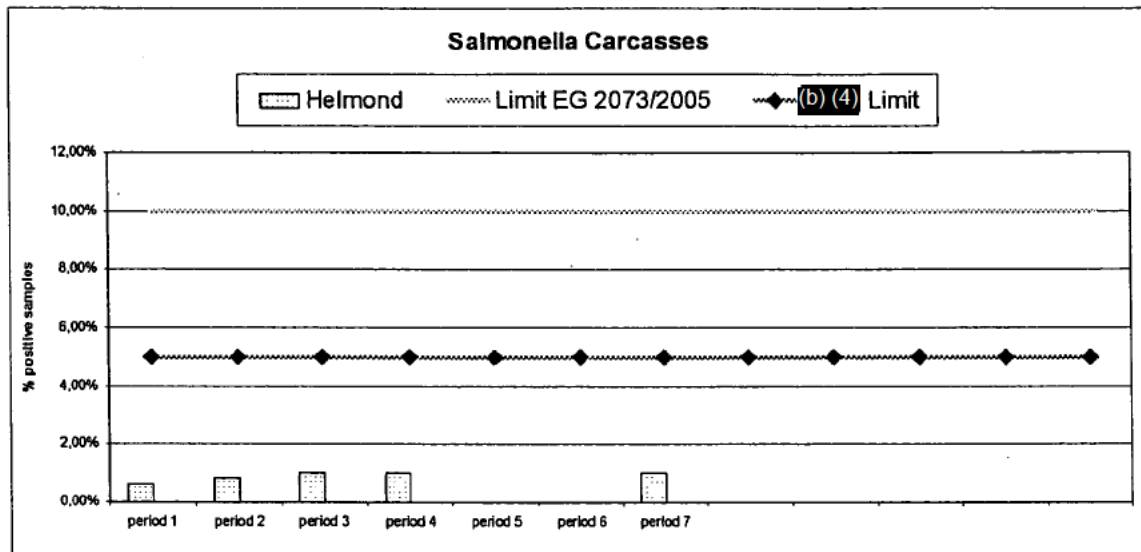
The program of supply chain inspection is based on the current EU legislation and combines control schemes at different parts of the supply chain in order to achieve a higher level of food safety in consumer products derived out of pork.

Current data of the newly implemented system of supply chain inspection system at the slaughterhouse in Helmond, show that:

1. The performance of the slaughterhouse Helmond with respect to hygiene is at a high level, according to the results of the official inspections and verifications as mentioned before in this document. Additional to that the results of the microbiological monitoring of the hygienically status of the carcasses confirms these observations



2. The contamination of carcasses with salmonella showed to be at a low level in the slaughterhouse Helmond. Samples for carcass monitoring of salmonella at the slaughterhouse are taken on a daily basis the next figure shows the performance of salmonella.



3. The results of the random screening on residues of antibiotics in market hogs in the Netherlands showed that the percentage of positive carcasses in Helmond is in the screening on kidney tissue and on meat samples both 1.3% (showing residues of antibiotics, not being above MRL) and in the general random sampling in the Netherlands for all market hogs these figures are 2,4% for kidney tissue and 2,0 for meat samples. The contribution of the supply chain inspection to control the use of antibiotics at farm level is obvious.

## Summary of FSIS-Netherlands Bilateral Meeting on Visual Inspection of Market-Age Swine

Date: November 1, 2006

Country: Netherlands

FSIS Participants: Sally White, Director, IES, OIA, Steve McDermott, Deputy Director, IES, OIA, Ghias Mughal, Senior Staff Officer, IES, OIA, Nancy Goodwin, Senior Staff Officer, IES, OIA, David Smith, Staff Officer, IES, OIA, Scott Seeborn, Staff Officer, TSC, OPED

Netherlands and EU Participants: (b) (6), DVM, PhD, Specialist Veterinary Public Health (b) (6), DVM, VWA, Inspection Systems, (b) (6), PhD, Wageningen University and Research, Prof. (b) (6), DVM, PhD, Specialist Veterinary Public Health, (b) (6), DMV, DABT, Delegation of the European Commission, (b) (6), Agricultural Trade Counselor

The following items were discussed:

1. Presentation: "Project Visual P.M. Inspection in Pigs, in Relation to the Hygiene Package in the Netherlands," by (b) (6)
2. Presentation: "Serodiagnosis of *Mycobacterium avium* susp. *avium* infections in pigs," by (b) (6)
3. Description of FSIS Market Swine HIMP pilot by Ghias Mughal.
4. Comparison Table: Swine Inspection Procedures
5. FSIS follow-up questions to Netherlands responses to FSIS questions: "Answers to Questions FSIS to the Netherlands" (See below)

FSIS asked these additional questions to follow-up on "Answers to Questions FSIS to the Netherlands":

- Q. 1. The U.S. legal definition of adulteration includes both food safety and non-food safety criteria. How does the Netherlands inspection system address the issue of adulteration for non-food safety conditions?

Response: The Netherlands inspection service verifies that the company implements programs to control pathological or hygiene defects through observation and review of records

- Q. 2. What are the provisions for government oversight of the IKB production scheme? When would the government get involved, and what actions could they take?

Response: There are both internal IKB audits, as well as audits by the government of Food Chain Information and on-farm conditions. Government audits occur on-farm approximately twice per year, or more frequently if needed.

The government is able to require additional steps in the IKB scheme, or exclude farms from participation when necessary.

- Q. 4. The response to Question 4 refers to several reference documents not previously provided to FSIS. We request copies of the additional documents that are relevant to the response (in English, if possible).

Response: Relevant references will be provided later.

- Q. 6. Please provide more specific explanation of how the Farm Risk Profile is calculated. How does it incorporate farm level information on *Salmonella* and *M. avium*? What specific criteria are used to determine whether a slaughter lot is eligible for visual inspection?

Response: The Farm Risk Profile is based on the history of *M. avium* serological testing. If a farm has 18 consecutive negative results (sampled from no more than 6 pigs in each of 3 deliveries), it is assigned to Neutral risk. When the farm has 18 additional negative samples (collected from 2 pigs in each of 9 deliveries), it is assigned to Low risk. To be eligible for visual inspection, swine must come from a farm with neutral or low Farm Risk Profile and must be accompanied by the Food Chain Information required under the IKB scheme.

- Q. 7. Please expand on the verification procedures. Explain how, where, and when the procedures are accomplished.

Response: Netherlands inspection personnel conduct audits in accordance with ISO 4511. Documented audit procedures will be provided to FSIS.

- Q. 7. During FSIS audits, where would we be able to find verification documents/records?

Response: Both company records and Inspection personnel records would be available for FSIS to verify performance and results of audit/verification activities.

- Q. 8. (Follow-up) How does the Farm Risk Profile consider *Salmonella* sample results and *M. avium* serology? What criteria for these samples would dictate traditional inspection?

Response: The Farm Risk Profile does not currently consider any organisms beside *M. avium*. *Salmonella* surveillance in live pigs is not considered to significantly improve food safety. *Salmonella* is controlled through hygienic slaughter procedures and prevention of fecal contamination. Documentation (thesis) to support these conclusions about *Salmonella* will be provided to FSIS later.

- Q. 9. When a group of pigs is sampled for antimicrobial residues, based on pathology levels (as described in response to Q6), please explain the sampling procedures. Will all animals in the lot be sampled? If not, what method will be used to select sampled animals?

Response: Because of the uniformity of intensively raised market swine, a single animal is sampled from any lot. The lots to be sampled are selected randomly under traditional inspection, but selected based on prevalence of pathological conditions in Food Chain Inspection. The results of these samples are then used to follow up with on-farm practices that resulted in violative residues.

- Q. 10. Response to a previous question to address this question. However, Please supply copies of the relevant references listed in the response to Q10 (in English, if possible).

Response: Relevant references will be provided.

- Q. 12 Response appears to address FSIS question. Please supply copies of the relevant references (in English, if possible).

Response: Relevant references will be provided.

Ghias Mughal  
11-2-06

**Mughal, Ghias**

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**From:** Seebohm, Scott  
**Sent:** Monday, November 27, 2006 2:19 PM  
**To:** Mughal, Ghias  
**Cc:** Smith, David; Goodwin, Nancy  
**Subject:** RE: visual inspection in the Netherlands: translated articles reg Q10 and ref for Q6 revised answer

Ghias,

I have read the documents you sent this morning. Here are my comments:

1. "System Audit from Start to End," Food and Consumer Product Safety Authority:  
 This document describes more fully the Dutch government (VWA) approach to auditing a food establishment's food safety (HACCP) system. It appears to be analogous to FSIS Comprehensive Food Safety Assessment. The Netherlands approach uses an audit team which may include various subject matter experts as appropriate, while FSIS generally uses a single EIAO officer who may solicit technical assistance from other program areas when necessary. The general focus of the audit is the design and validation of the plant's HACCP program.
2. "From and For the Practice – Lesions in Slaughtered Animals."  
 This paper is a brief summary of antemortem and postmortem findings in cattle and swine with endocarditis. The paper has little relevance to the current equivalence determination since FSIS does not routinely incise swine hearts.
3. W. Wouda, et. al. "Endocarditis and Meat Inspection in Pigs," (Parts 1 and 2).  
 This paper presents a discussion of clinical and microbiological findings in market swine with endocarditis and a rough cost-benefit analysis of routine incision of hearts at postmortem inspection. The conclusion is that routine incision of swine hearts may not be economically beneficial. The paper has little relevance to the current equivalence determination, since FSIS does not require routine incision of swine hearts.

Regards.

Scott

Scott Seebohm, DVM  
 Staff Officer  
 FSIS Technical Service Center  
 402-344-5000 / 800-233-3935

---

**From:** Mughal, Ghias  
**Sent:** Monday, November 27, 2006 6:11 AM  
**To:** White, Sally  
**Cc:** Smith, David; Seebohm, Scott; Goodwin, Nancy; McDermott, Steve; Proudie, Robin  
**Subject:** FW: visual inspection in the Netherlands: translated articles reg Q10 and ref for Q6 revised answer

The attached documents were sent to me by Dr. Hennecken last Thursday with a request to make them part of the NL responses previously sent to us.  
 I have not read these yet.  
 Ghias

*M. Ghias Mughal, DVM; M.S.; Ph.D.*  
 Senior Equivalence Officer,  
 Office of International Affairs  
 USDA, Food Safety and Inspection Service

FOIA\_NL&DEN00514

11/27/2006



1400 Independence Avenue, SW  
 Washington, DC 20250  
 Phone: 202 720-6400  
 Email: ghias.mughal@fsis.usda.gov

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

**From:** (b) (6) drs. (b) (6) [mailto:(b) (6)@minInv.nl]  
**Sent:** Thursday, November 23, 2006 8:50 AM  
**To:** Mughal, Ghias  
**Cc:** (b) (6) drs. (b) (6), dr. (b) (6)  
**Subject:** RE: visual inspection in the Netherlands: translated articles reg Q10 and ref for Q6 revised answer

Dear Dr. Mughal,

hereby you will receive the English translation of the last 4 reference documents that have to be included in the equivalence package for visual inspection in the Netherlands:

**Q10,ref1:** W. Wouda et. al., Endocarditis & Meat Inspection in pigs, part 1, Tijdschrift voor Diergeneeskunde, deel 112, afl. 21, 1987, p. 1226-1235

**Q10, ref3:** U. Narucka et. al., Lesions in slaughtered animals, Tijdschrift voor Diergeneeskunde, deel 110, afl. 19, 1985, p. 776-779

**Q10, ref4:** W. Wouda et. al. , Endocarditis & Meat Inspection in pigs, part 2, Tijdschrift voor diergeneeskunde, deel 112, afl. 21, 1987, p. 1236-1242.

**Q6 revised answer, ref1:** System Audit from Start to End

With these last documents the package is completed.  
 If you have further questions regarding this documentation please let me know.

Kind regards

Martin Hennecken

-----Oorspronkelijk bericht-----

**Van:** (b) (6) drs. (b) (6)  
**Verzonden:** dinsdag 14 november 2006 13:47  
**Aan:** 'Mughal, Ghias'  
**CC:** (b) (6) drs. (b) (6); (b) (6) dr. (b) (6)  
**Onderwerp:** FW: additional articles and revised answer Q6 reg. visual inspection

Dear Dr. Mughal,

hereby you will receive more additional documents/ articles as promised in my mail from 7 Nov.

**1. question 4, ref 4** (Wallace JM, Hannah JB. Mycobacterium avium complex infection in patients with the acquired immunodeficiency syndrome. A clinicopathologic study. Chest. 1988 May;93(5):926-32.)

**2. question 10, ref 5.**(R. Fries und J. Leps, Die Incision des Herzens beim Schwein, Fleischwirtschaft, vol 10, 2005, p. 116-119.):

At the moment the authors of this article are preparing an English version of this article for publication in a journal, (most probably Veterinary Quarterly). We have agreed to wait for that publication and not to disturb this proces by translating ourselves. Meanwhile I have found the English summary of the dissertation of the authors on which the article had been based (**J. Leps, Incision of the heart during meat inspection of pigs - A risk analysis approach, dissertation FU Berlin, 2003**) I have attached the summary (English summary starts on page 5) and a document (index) with the abstract and further details. Most probably you will find this summary suitable enough for your purposes. Please let me know if you still need the English article; we will send it as soon as it is published.



**3. question 6, revised answer** on verification procedures: as agreed during the last meeting.

This document refers to another VWA procedure document "**System Audit from Start 'til End**". This document is in the process of being translated and will be sent to you as soon as it is available.

Furthermore, as soon as Q10, ref 1,3 en 4 have been translated I will send them to you.

Kind regards

(b) (6)

-----Oorspronkelijk bericht-----

**Van:** (b) (6) drs. (b) (6)

**Verzonden:** dinsdag 7 november 2006 15:40

**Aan:** 'Mughal, Ghias'

**CC:** (b) (6) dr. (b) (6) (b) (6) drs. (b) (6) (b) (6) VD)

**Onderwerp:** Expert meeting with FSIS and the Netherlands reg. visual inspection

Dear Dr. Mughal,

on behalf of Dr Weijtens I will send you herewith a "package" of additional articles, which have been mentioned in our report as a reference.

Most of these articles are in English, but 4 articles (question 10) have to be translated first. Unfortunately this will take some time, so you will receive them as soon as the translation has been completed. 2 other documents (q4ref1 and q4ref4) will be sent later.

Beneath you find a list of the articles which you will receive today (with several e-mails due to the size of the attachments) and 4 articles as soon as possible after translation has been completed.

If you miss any reference article in this list that had been agreed to send to you please let me know. I will arrange that asap.

Regards

(b) (6)

**Drs.** (b) (6)

*Beleidsmedewerker vleeshygiëne*

*Directie Voedselkwaliteit en Diergezondheid*

Ministerie van Landbouw, Natuur en Voedselkwaliteit

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#### **Question 4:**

**Additional document:** Justification for sampling of *Mycobacterium avium* in pork with regard to supply chain meat inspection (06-11-06)

#### **References to additional document:**

\* New classification system for slaughter pig herds in the Danish surveillance- and-control program: L. Alban et.al., Prev.Vet. Med. 2002 (SDOC1268.pdf)

\* Trichinae certification in the United States Pork industry: D.G. Pyburn et.al., Vet. Parasitology, 2005 (SDOC1267.pdf)

#### **References Question 4:**

1) Inderlied CB, Kemper CA, Bermudez LE. The *Mycobacterium avium* complex. Clin Microbiol Rev. 1993 Jul;6(3):266-310. Review. **(will be sent later)**

- 2) Komijn, RE., PEW de Haas, ME Schneider, T Eger, JHM Nieuwenhuis, RJ van den Hoek, D. Bakker, FG van Zijderveld and D van Soolingen. Prevalence of *Mycobacterium avium* in Slaughter Pigs in The Netherlands and Comparison of IS1245 Restriction Fragment Length Polymorphism Patterns of Porcine and Human Isolates. *J of Clin Microb*, 1999, 37, 1254-1259
- 3) Komijn, RE., HJ. Wisselink, VMC. Rijsman, N. Stockhofe-Zurwieden, D. Bakker, FG. van Zijderveld, T. Eger, JA. Wagenaar, FF. Putirulan and BAP. Urlings, Prevalence of *Mycobacterium avium* subsp. *avium* in lymphnodes of slaughter pigs in The Netherlands. Accepted for publication in *Veterinary Microbiology* (2007)
- 4) Wallace JM, Hannah JB. *Mycobacterium avium* complex infection in patients with the acquired immunodeficiency syndrome. A clinicopathologic study. *Chest*. 1988 May;93(5):926-32. (will be sent later)
- 5) Wisselink, HM, C van Solt-Smits, N Stockhofe-Zurwieden, H Bergen-Buys, P. Overduin, M van Prehn, D van Soolingen and J Thole. Comparison of visual and bacteriological examination of mandibular and mesenteric lymphnodes in pigs, experimentally infected with *Mycobacterium avium* subsp. *Avium*. IPVS Conference Copenhagen 2007.

#### References question 10:

1. W. Wouda et. al. , Endocarditis en vleeskeuring bij slachtvarkens, *Tijdschrift voor Diergeneeskunde*, deel 112, afl. 21, 1987, p. 1226-1235 (will be translated and sent later)
2. Masanori Katsumi et. al, Bacterial Isolation from slaughtered pigs associated with endocarditis, especially the isolation of *Streptococcus suis*, *Journal of veterinary medical science*, vol. 59, 1997, p. 75-78
3. U. Narucka et. al., Afwijkingen bij slachtdieren, *Tijdschrift voor Diergeneeskunde*, deel 110, afl. 19, 1985, p. 776-779 (will be translated and sent later)
4. W. Wouda et. al. , Endocarditis en vleeskeuring bij slachtvarkens, *Tijdschrift voor diergeneeskunde*, deel 112, afl. 21, 1987, p. 1236-1242. (will be translated and sent later)
5. R. Fries und J. Leps, Die Incision des Herzens beim Schwein, *Fleischwirtschaft*, vol 10, 2005, p. 116-119. (will be translated and sent later)
6. C. Tarrads et. al., Identification of *Streptococcus suis* Isolated from Swine: Proposal for Biochemical Parameters, *journal of clinical microbiology*, vol. 32, 1994, p. 578-580
7. J.J. Staats et. al., *Streptococcus Suis*: past and present, *Veterinary research communications*, vol. 21, 1997, p. 381-407.
8. Yu-Tsung Huang et. al., *Streptococcus suis* infection, *Journal of Microbiol Immunol Infect*, vol. 38, 2005, p. 306-313.

#### References reg. Annex salmonella:

1. Petersen JV, Andersen JK, Sorensen F, Knudsen H. Food safety on the slaughterline: inspection of pig heads. *Vet Rec*. 2002 Jun 22;150(25):782-4. Review.
2. Swanenburg M, van der Wolf PJ, Urlings HA, Snijders JM, van Knapen F. *Salmonella* in slaughter pigs: the effect of logistic slaughter procedures of pigs on the prevalence of *Salmonella* in pork. *Int J Food Microbiol*. 2001 Nov 8;70(3):231-42.
3. Swanenburg M, Berends BR, Urlings HA, Snijders JM, van Knapen F. Epidemiological investigations into the sources of *Salmonella* contamination of pork. *Berl Munch Tierarztl Wochenschr*. 2001 Sep-Oct;114(9-10):356-9.

4. Berends BR, Van Knapen F, Snijders JM, Mossel DA. Identification and quantification of risk factors regarding Salmonella spp. on pork carcasses. *Int J Food Microbiol.* 1997 May 20;36(2-3):199-206.
5. Swanenburg M, Urlings HA, Snijders JM, Keuzenkamp DA, van Knapen F. Salmonella in slaughter pigs: prevalence, serotypes and critical control points during slaughter in two slaughterhouses. *Int J Food Microbiol.* 2001 Nov 8;70(3):243-54.
6. Swanenburg M, Urlings HA, Snijders JM, Keuzenkamp DA, van Knapen F. Salmonella in the lairage of pig slaughterhouses. *J Food Prot.* 2001 Jan;64(1):12-6..
7. "salmonella monitoring" report made during the pilot "supply chain inspection" 2005-2006 in Helmond, the Netherlands
8. Oosterom J, Dekker R, de Wilde GJ, van Kempen-de Troye F, Engels GB Prevalence of Campylobacter jejuni and Salmonella during pig slaughtering. *Vet. Quarterly* 7, 31-34.

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NOTES FROM THE CONFERENCE CALL WITH DR. TERRY SUTTON  
ON THE ELISA TEST USED BY NETHERLANDS' INSPECTION OFFICIALS

Date: March 5, 2007

Participants:

Dr. Terry Sutton, OPHS

Dr. David Smith, OIA

Dr. Ghias Mughal, OIA

This conference call took place as a follow up on Dr. Sutton's comments of March 3, 2007, relating to the Netherlands' ELISA testing of hog serum for the detection of *M. avium*.

Dr. Sutton concluded that:

- The ELISA test is sensitive enough to detect about 75% of the hogs infected with *M. avium subspecies avium* (MAA).
- The data submitted by the Netherlands did not address the specificity of this method. It did not show if there was a cross reactivity in sera of hogs infected with other strains of MAA, other non-TB group mycobacterium or organisms from the Mycobacterium-bovis group.
- Based on the Netherlands' data, the ELISA test, by itself, is not the most reliable test for the detection of MAA. However, the ELISA test, in combination with the following safeguards, can become a reliable test for the detection of MAA:
  - The production/slaughter of the market hogs is a vertically integrated operation,
  - There is a established frequency of follow-up testing for MAA,
  - No hogs, imported from any other country, are allowed in the program,
  - There is a TB testing program for the farm workers,
  - There is an environmental testing program for MAA, e.g., testing of bedding, house environment, etc., and
  - The participating companies have a control program for control of insects and other pests.

Dr. Sutton was further advised that in order for participating companies to be eligible for Visual Inspection, they must have a mandatory quality assurance (QA) program. The QA program is approved and verified by the Netherlands' inspection service on routine basis. The QA program must contain all six safeguards mentioned above.

MEMO: USE OF THE ELISA TEST BY NETHERLANDS' INSPECTION  
OFFICIALS

Date: March 12, 2007

References: Following additional references from Netherlands and FSIS were reviewed:

1. with *Mycobacterium avium subsp. avium*. Henk Wisselink, Conny van Solt-Smits, Norbert Stockhofe-Zurweiden, Herma Bergen-Buys, Jelle Thole (Unpublished report, 2007)
2. . Compariso of Pathological and bacteriological examination of mandibulary and mesenteric lymph nodes in pigs, experimentally infected with mycobacterium avium subsp. avium . HJ Wisselink, CB Van Solt-Smits, N Stockofe-Zurwieden, H Bergen-Buijs, VMC Rijsman, P Overduin, M Van Prehn, D Van Soelingen and JE Thole. Proc. 19<sup>th</sup> IPVS Congress, Copenhagen, Denmark, 2006, vol. 1.
3. Prevalence of *Mycobacterium avium* in Slaughter Pigs in The Netherlands and Comparison of IS1245 Restriction Fragment Length Polymorphism Patterns of Porcine and Human Isolates. Komijn, RE., PEW de Haas, ME Schneider, T Eger, JHM Nieuwenhuis, RJ van den Hoek, D. Bakker, FG van Zijderveld and D van Soelingen. J of Clin Microb, 1999, 37, 1254-1259.
4. Evaluation of Five Antibody Detection Tests for Diagnosis of Bovine Paratuberculosis. Michael T. Collins, Scott J. Wells, Kristine R. Peterini, James E. Collins, Ronald Schultz, and Robert Whitlock. Clinical and Diagnostic Laboratory Immunology, June 2005, p. 685-692.

FSIS Documents:

1. Multi-species Disposition Basics with a Public Health Focus. Public Health Veterinarian Training – USDA FSIS Canter for Learning, April 2004.

Following conclusions were drawn from review of the above literature:

- FSIS does not appear to consider tuberculosis as a food borne disease of public health significance.
- FSIS' routine post mortem inspection procedures have an unknown level of detection for *M. avium*. Dispositions are based on visual inspection after palpation and observation of certain lymph nodes and organs and 100 per cent detection of lesions is not always possible.
- Presence of tuberculosis in the Netherlands not higher than the United States.
- ELISA test used by the Netherlands inspection service shows a high level of sensitivity at the slaughter age of 20-20 weeks, although results show a sensitivity of about 75 per cent in hogs infected and tested at earlier age.

- The data submitted by the Netherlands did not address the specificity of this method. They only used one strain of *M. avium*- MAA serotype 4, strain 17404 during the experiment. They did not show if there was a cross reactivity in sera of hogs infected with other strains of MAA, other non-TB group mycobacterium or organisms from the Mycobacterium-bovis group.
- Based on the Netherlands' data, the ELISA test, by itself, is not the most reliable test for the detection of MAA. However, the ELISA test, in combination with the following safeguards, can become a reliable test for the detection of MAA:
  - The production/slaughter of the market hogs is a vertically integrated operation,
  - There is a established frequency of follow-up testing for MAA,
  - No hogs, imported from any other country, are allowed in the program,
  - There is a TB testing program for the farm workers,
  - There is an environmental testing program for MAA, e.g., testing of bedding, house environment, etc., and
  - The participating companies have a control program for control of insects and other pests.

It was explained to Dr. Sutton that in order for participating companies to be eligible for Visual Inspection, they must have a mandatory quality assurance (QA) program. The QA program is approved and verified by the Netherlands' inspection service on routine basis. The QA program must contain all six safeguards mentioned above and she agreed that with all these safeguards the ELISA test is a step forward and provides added level of assurance for detection of TB in market hogs.

Participants:

Dr. Terry Sutton, OPHS

Dr. David Smith, OIA

Dr. Ghias Mughal, OIA

Dr. Raymond,

During our recent briefing to you regarding the Netherlands' equivalence request for post-mortem visual inspection of market hogs, you requested that we contact APHIS to determine whether visual inspection would fail to detect the swine diseases it had declared as being present in the Netherlands. We contacted APHIS and explained to them the difference between FSIS traditional post-mortem inspection and the Netherlands' visual inspection of the head, viscera, and carcass. APHIS advised us that visual inspection would have no impact on the ability to detect the four swine diseases of concern (Foot and Mouth Disease, Classical Swine Fever, African Swine Fever, and Swine Vesicular Disease) because the symptoms related to these diseases would be evident throughout the carcass and organs.

4/16/07

MEMO: USE OF THE ELISA TEST BY NETHERLANDS' INSPECTION  
OFFICIALS

Date: March 12, 2007

References: Following additional references from Netherlands and FSIS were reviewed:

1. with *Mycobacterium avium subsp. avium*. Henk Wisselink, Conny van Solt-Smits, Norbert Stockhofe-Zurweiden, Herma Bergen-Buys, Jelle Thole (Unpublished report, 2007)
2. . Compariso of Pathological and bacteriological examination of mandibulary and mesenteric lymph nodes in pigs, experimentally infected with mycobacterium avium subsp. avium . HJ Wisselink, CB Van Solt-Smits, N Stockofe-Zurwieden, H Bergen-Buijs, VMC Rijsman, P Overduin, M Van Prehn, D Van Soelingen and JE Thole. Proc. 19<sup>th</sup> IPVS Congress, Copenhagen, Denmark, 2006, vol. 1.
3. Prevalence of *Mycobacterium avium* in Slaughter Pigs in The Netherlands and Comparison of IS1245 Restriction Fragment Length Polymorphism Patterns of Porcine and Human Isolates. Komijn, RE., PEW de Haas, ME Schneider, T Eger, JHM Nieuwenhuis, RJ van den Hoek, D. Bakker, FG van Zijderveld and D van Soelingen. J of Clin Microb, 1999, 37, 1254-1259.
4. Evaluation of Five Antibody Detection Tests for Diagnosis of Bovine Paratuberculosis. Michael T. Collins, Scott J. Wells, Kristine R. Peterini, James E. Collins, Ronald Schultz, and Robert Whitlock. Clinical and Diagnostic Laboratory Immunology, June 2005, p. 685-692.

FSIS Documents:

1. Multi-species Disposition Basics with a Public Health Focus. Public Health Veterinarian Training – USDA FSIS Canter for Learning, April 2004.

Following conclusions were drawn from review of the above literature:

- FSIS does not appear to consider tuberculosis as a food borne disease of public health significance.
- FSIS' routine post mortem inspection procedures have an unknown level of detection for *M. avium*. Dispositions are based on visual inspection after palpation and observation of certain lymph nodes and organs and 100 per cent detection of lesions is not always possible.
- Presence of tuberculosis in the Netherlands not higher than the United States.
- ELISA test used by the Netherlands inspection service shows a high level of sensitivity at the slaughter age of 20-20 weeks, although results show a sensitivity of about 75 per cent in hogs infected and tested at earlier age.



April 19, 2007

Seller's

Dr. (b) (6)  
Chief Veterinary Officer  
Ministry of Agriculture, Nature and Food Quality  
PO Box 19506  
2500 CM, The Hague  
Netherlands

Dear (b) (6):

This reaffirms my earlier notification to you on October 12, 2006, that meat products produced under visual inspection is not currently eligible for export to the United States. In that October 12 letter, I stated that the use of visual post-mortem inspection in establishments certified for export to the United States cannot commence until the Food Safety and Inspection Service (FSIS) completes the equivalence determination process.

It is our understanding that some of the swine slaughter establishments certified for export to the United States have been operating under visual inspection and is storing pork products with the expectancy to export to the United States following FSIS' equivalence approval of visual inspection. If this is occurring, it is important to understand that this product is not eligible for export to the United States now or following an acceptable equivalence determination by FSIS of the visual inspection. The date upon which FSIS notifies the Netherlands' government that it has determined the visual post-mortem inspection program to be equivalent will become the effective date that Netherlands' certified establishments can begin producing pork products for export to the United States under visual inspection.

If you have any questions regarding this matter, please contact me at telephone number (202) 720-3781, fax number (202) 690-4040, or electronic mail address: [sally.white@fsis.usda.gov](mailto:sally.white@fsis.usda.gov).

Sincerely,

Sally White  
Director  
International Equivalence Staff  
Office of International Affairs

cc.

(b) (6), Counselor, US Embassy, The Hague

(b) (6), Netherlands Embassy, Wash DC

(b) (6), Agric. / Consumer Affairs, EU Mission to the U.S., Wash DC

(b) (6), Acting Director, Directorate E, European Commission, Brussels

(b) (6), Minister-Counselor, US Mission to the EU in Brussels

Robert Macke, Assistant Deputy Administrator, OSTA, FAS

Dave Young, FAS Area Director

(b) (6), State Department

David Goldman, Acting Administrator, FSIS

Karen Stuck, Assistant Administrator, OIA, FSIS

William James, Deputy Assistant Administrator, OIA, FSIS

Donald Smart, Director, International Audit Staff, OIA, FSIS

Clark Danford, Director, IEPS, OIA, FSIS

Sally White, Director, IES, OIA, FSIS

Barbara McNiff, Director, FSIS CODEX

Mary Stanley, Director, IID, OIA, FSIS

Ghias Mughal, IES, OIA, FSIS

Country File

FSIS:OIA:IES:SMCDERMOTT:4-19-2007

**Adams, Susan**

---

**From:** White, Sally  
**Sent:** Tuesday, May 06, 2008 12:14 PM  
**To:** Adams, Susan  
**Cc:** Smith, David  
**Subject:** Fw: Supplementary information chain inspection  
  
**Attachments:** Suppl info ketenkeuring 6-5-08.doc

Please print off and log

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Sent from my BlackBerry Wireless Device

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

**From:** Smith, David  
**To:** White, Sally  
**Sent:** Tue May 06 12:11:05 2008  
**Subject:** FW: Supplementary information chain inspection



Suppl info  
etenkeuring 6-5-08.

Frits in ended to send this to you as well, but he got the wrong Sally.

David Smith, DVM, MS, BS  
Office of International Affairs  
International Equivalence Staff  
USDA, Food Safety and Inspection Service Room 3843 South Bldg.  
1400 Independence Ave, SW  
Washington DC 20250  
Phone: (202) 720-3395  
Email: david.smith@fsis.usda.gov

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

**From:** Thissen, Frits [mailto:frits.thissen@minbuza.nl]  
**Sent:** Tuesday, May 06, 2008 12:07 PM  
**To:** sally.smith@fsis.usda.gov; Smith, David  
**Cc:** Furey, Todd; (b) (6); (b) (6); (b) (6); (b) (6) @minInv.nl;  
(b) (6) @minInv.nl  
**Subject:** Supplementary information chain inspection

Dear Sally and David,

I would like to forward to you a note with supplementary information on the system of chain inspection as promised. I would like you to handle this information with the utmost confidentiality, because there are issues of intellectual property rights as well as commercial interests involved.

IES  
320  
5/06/08  
Aea

I hope this information will satisfy your needs in terms of the scientific underpinning of the MAA testing method.

All in all I hope this information will help you overcome the last obstacles in providing Undersecretary Dr Richard Raymond with a positive briefing on the chain inspection system and addressing his specific concerns.

Kind regards,

(b) (6)

Counselor for Agriculture,  
Nature and Food Quality  
Embassy of the Kingdom of the Netherlands

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## ADDITIONAL INFORMATION ON PORK SUPPLY CHAIN INFORMATION

This document contains additional information on:

1. *Mycobacterium avium* spp *avium* (MAA) serological test characteristics;
2. Results of MAA control program within pork supply chain inspection, and
3. Summary of MAA control within pork supply chain inspection.

The scientific research laboratory wants to preserve its abilities to file intellectual property rights with respect to MAA serological testing. The data presented in this document are to be kept confidential.

### *Mycobacterium avium* spp *avium* (MAA) serological test characteristics.

In order to demonstrate the presence of antibodies against MAA in pigs, an ELISA test has been developed. The antigen, cleared glycopeptide, used in this test is harvested from polar lipids of MAA bacteria. The bacterial MAA strain that is used originated from a slaughter pig in The Netherlands and is of the MAA hominissuis type. Glycopeptides are part of the polar lipids and originate from a genetically well-preserved area of MAA bacteria. Using a genetically well-preserved area of a bacterium provides the best ability to have cross-reactivity with different field strains of MAA.

When calculating the specifications of the MAA-Elisa, the bacteriological examination is used as the gold standard.

When an individual pig, or a pig herd, is suspected of an MAA infection at slaughter, there will be successive investigations in order to clear the case. Specific signs in these are: elevated serological results, specific liver abnormalities, and, or specific lymph node lesions. The examination of suspected herds consists of:

- Tuberculation of pigs at the herds of origin;
- When tuberculation reveals positive results, blood serum and lymph nodes of pigs at slaughter will be collected; and
- Serological, pathological and bacteriological examination of serum and lymph nodes at the veterinary research laboratory.

Additionally it needs to be noted that a Specialist Veterinary Pathologist carries out pathological examination.

Based on the above protocol, until 28 April, 2008, two pig farms confirmed positive on MAA have been detected in The Netherlands (since beginning 2006, the onset of supply chain inspection). A third suspected pig farm has been sampled extensively on 22 April, 2008, but the results are not yet available. Of the two confirmed positive pig farms, one farmer refused to cooperate with the scientific part of the research, so unfortunately only field data of one farm are available.

Table 1: Results validation MAA-ELISA. Numbers of pigs (%). Pathological examination was carried out on lnn of mandibular and mesenteric area. Serological result negative if PP% < 10, dubious if 10 < PP% > 20, positive if PP% > 20.

Experimental infection				
Examination	Negative	Positive	Dubious	Total (n)
Bacteriological	0 (0)	32 (100)		32
Pathological (lnn)	22 (69)	10 (31)		32
Serological	10 (31)	17 (53)	5 (16)	32
Field infection farm A				
Examination	Negative	Positive	Dubious	Total (n)
Bacteriological	90 (46)	104 (54)		186
Pathological	128 (68)	59 (32)		187
Serological	153 (78)	8 (4)	34 (18)	195

Table 2: Test characteristics MAA-ELISA, using bacteriology as the golden standard.

	Pathology		Serology	
	Specificity	Sensitivity	Specificity	Sensitivity
Experimental infection	100	31	100	69
Field infection farm A	73	35	79	22

According to Fisher's exact test the sensitivity of serology compared to pathology during the experimental infection is significantly different ( $p=0.0003$ ). The sensitivity of serology compared to pathology at farm A is not significantly different ( $p=0.132$ ). Specificity of the tests at farm A is not significantly different ( $p=0.273$ ).

For tuberculosis and paratuberculosis it is concluded that the ELISA is a suitable test for herd diagnostics. Mycobacterial Elisa's are utilized with this purpose in a lot of countries.

Important for this conclusion is the fact that for MAA it is obvious that risks for introduction will apply to the whole farm of origin (for example bedding material), thus resulting in a population at risk.

The numbers of pigs to be tested to estimate the MAA status of a farm is based on epidemiological calculations. In these calculations the sensitivity, specificity and prevalence of MAA within the farm are taken into account. Given a number of tests, the probability of testing at least one animal positive can be calculated, as shown in the table 3. Even with a low sensitivity and high specificity (worst case calculation) the probability is over 95% to test a farm positive with 36 samples to estimate a definite MAA status. Based on literature, prevalence at farm within the herd could be expected to be over 40% when herds are infected by sawdust or peat.

Table 3: Statistical evaluation of the effect of the number of samples on the reliability of the herd risk estimation.

Number of samples tested	Prevalence MAA within farm	Specificity of serology	Sensitivity of serology	Probability of testing at least one positive
18	40%	100%	20%	0.999544
36	40%	100%	20%	1
18	20%	100%	20%	0.962439
36	20%	100%	20%	0.998589
18	10%	100%	20%	0.784079
36	10%	100%	20%	0.953378

*According to Merchevsky et al. 1989, cited by Micheal Trustfield in: Veterinary Epidemiology, second ed. 1995. Blackwell Science Ltd.*

#### **Results of MAA control program within pork supply chain inspection.**

In previous documents exchanged with the USDA/FSIS we have already elaborated about the ongoing research on MAA in The Netherlands. In a study in 1996 it was shown that a low prevalence of MAA was present in Dutch slaughter pigs (Komijn et al 1999). After the implementation of additional control measures at farm level within the farm code of practice (IKB), a study of 2004 showed that MAA could not be detected anymore in Dutch slaughter pigs (Komijn et al, 2007).

- Since the start of pork supply chain inspection more than 300,000 blood samples of pigs have been analyzed for the presence of antibodies against MAA.

Table 4: Classification of pig farms, August 2007.

	N	%
Low risk farms	3303	80,66
Neutral risk farms	744	18,17
High risk farms <sup>1</sup>	48	1,17
Total farms	4095	100

<sup>1</sup> Farms classified as high-risk are not allowed to deliver pigs for pork supply chain inspection and are part of the MAA specific control program.

- Until April 2008, 78 farms have been visited because of elevated levels of antibodies, or specific lesions observed during post-mortem inspection. These farms have strengthened their biosecurity control measures, especially with respect to the control of MAA.
- Several of the 78 farms visited have taken part in tuberculation testing at farm level. Until now only two farms showed positive results in tuberculation tests.

- Two farms have been observed to be bacteriologically positive for MAA. A third farm is still under investigation.
- The farms that showed bacteriologically positive results have taken effective measures to eliminate the MAA infection on the farm. Elimination of MAA at farm level is only practiced in pig farms that participate in the pork supply chain inspection program. Traditional inspection does not prescribe additional measures to control MAA at farm level.

### **Summary of MAA control within pork supply chain inspection.**

Control of MAA in pork produced according to the supply chain inspection procedures consists of several control points within the pork supply chain.

1. All pig farms that supply pigs that are inspected according to the pork supply chain procedures need to produce according to the IKB code of practice at the farm level. On top of that the farm is not allowed to use wood shavings, peat or related MAA risk materials as bedding material. The IKB farm code of practice is audited and managed according to ISO 45011 rules.
2. A pig farm can only supply pigs that are to be inspected according to the pork supply chain procedures after at least 18 consecutive negative results of serological testing against MAA antigens. The procedure of calculating risk levels of individual farms with the respective sample sizes has already been reported to USDA/FSIS.
3. During the post-mortem inspection of carcasses and organs all pathological signs and morphological non-conformities are to be checked more in-depth at the re-assessment platform by the competent authorities. Specific pathological conditions, such as granulomatous lesions in lymph nodes and livers will be further evaluated.
4. Farms that show elevated serological test results, and, or specific pathological lesions will be visited. During the visit a re-assessment of the control points with respect to MAA will be carried out.
5. When the farm visit, or other slaughtering of pigs, shows increased risk of the presence of MAA, additional examination of the pigs and the farm of origin will occur. This examination consists of tuberculation of individual animals at the farm, and/or slaughtering and sampling of individual pigs for in-depth pathological, serological and bacteriological examination.

Based on the above information and the information that has been communicated before, it can be concluded that the control of MAA in pork supply chain inspection provides at least the same level of control as the procedures of the traditional post-mortem inspection. It is also obvious that none of the MAA control instruments alone provide a 100% control of MAA, nor does the traditional post-mortem inspection. The strength of the pork supply chain inspection is that it effectively combines MAA control measures at different parts of the supply chain. On top of that, refraining from cutting the lymph nodes in the mandibular area has demonstrated to reduce the level of cross-contamination with salmonella on pork substantially, thus resulting in safer pork.

05.06.2008



## **Minutes of Meeting**

**COUNTRY:** Netherlands

**SUBJECT:** Information regarding the public health significance of Mycobacterium avium.

**DATE:** May 29, 2008

**FSIS REPRESENTATIVES:**

Dr. William James, OIA

Sally White, OIA, IES

Dr. David Smith, IES, OIA

Dr. Robert Ragland, OPPD

Maritza Colon-Pullano, OPPD

**SUMMARY:** The meeting focused on the public health significance of Mycobacterium avium as it relates to food-borne transmission. In this meeting Dr. James discussed an email that was sent by Dr. Ragland. Dr. James described his understanding of Dr. Ragland's email as being that Mycobacterium avium is of minimal significance from the standpoint of public health as a zoonotic food-borne organism. Dr. Ragland agreed that was the message he was conveying in his email.

## Smith, David

---

**From:** Thaler, Alice  
**Sent:** Monday, June 02, 2008 2:41 PM  
**To:** Smith, David  
**Subject:** RE: FSIS position on Tuberculosis

The FSIS program addresses bovine TB to support APHIS in its eradication program. TB is primarily spread by aerosol (cow to cow) (or man to cow) or consumption of milk (cow to man) from infected animals. Extra-pulmonary TB is not considered a source of infection – hence occupational health issues for our inspectors is very low.

I am not sure if FSIS has looked recently at *Mycobacterium avium* and immunosuppressed people (AIDS)

Ref: Pan American Health Organization – Zoonoses and Communicable Diseases Common to Animals and Man.

Alice M. Thaler, DVM, DACVPM  
Senior Director for Program Services  
Office of Public Health Science  
202-690-2687  
Fax 202-720-8213  
alice.thaler@fsis.usda.gov

---

**From:** Smith, David  
**Sent:** Monday, June 02, 2008 1:31 PM  
**To:** Thaler, Alice  
**Subject:** FSIS position on Tuberculosis

Hi Dr. Thaler, (b) (5)

[REDACTED] I have found a PHV training manual from 2004 (link below) that says TB is not considered of public health significance. (b) (5)

[http://www.fsis.usda.gov/PDF/PHVt-Multi\\_Species\\_Disposition.pdf](http://www.fsis.usda.gov/PDF/PHVt-Multi_Species_Disposition.pdf)

Thanks,

*David Smith, DVM, MS, BS*  
*Office of International Affairs*  
*International Equivalence Staff*  
*USDA, Food Safety and Inspection Service Room 3843 South Bldg.*  
*1400 Independence Ave, SW*  
*Washington DC 20250*  
*Phone: (202) 720-3395*  
*Email: david.smith@fsis.usda.gov*

**Smith, David**

---

**From:** Ragland, Robert  
**Sent:** Friday, June 06, 2008 12:47 PM  
**To:** Smith, David  
**Subject:** RE: Comments on Netherlands/M. avium

To my knowledge, FSIS does not test serologically or type TB organism in any TB like lesions. There is a program for submitting all suspected TB lesions found in cattle to the APHIS lab not FSIS lab. There is not such a program for TB lesions found in swine. In the past APHIS did type for bovine and human TB organisms..

In addition, if a sample of cattle pathology submitted to a FSIS lab contains lesions or organisms suggestive of TB and a sample was not sent to the APHIS lab by the FSIS inspector the FSIS lab may sent some of the sample to the APHIS lab for testing for TB.

Robert D. Ragland, DVM  
Senior Staff Officer  
Risk Management Division, OPPD  
USDA, FSIS -- Rm 3549-S  
1400 Independence Ave. SW  
Washington, DC 20250-3700

Phone: 202-720-9063  
Fax: 202-720-0582  
Email: [robert.ragland@fsis.usda.gov](mailto:robert.ragland@fsis.usda.gov)

---

**From:** Smith, David  
**Sent:** Wednesday, June 04, 2008 4:24 PM  
**To:** Ragland, Robert  
**Subject:** RE: Comments on Netherlands/M. avium

Hi Bob thanks for the comments. (b) (5)

Are you aware of any usage of serology testing for Mycobacteria spp. by FSIS?

Thanks,

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](mailto:david.smith@fsis.usda.gov)

---

**From:** Ragland, Robert  
**Sent:** Wednesday, June 04, 2008 7:24 AM  
**To:** Smith, David  
**Cc:** Derfler, Philip; Hicks, John; Linville, John; Bowman Blackwell, Quita

**Subject:** Comments on Netherlands/*M. avium*

Specific Responses to the two questions in Dr. Smith's Monday June 02 email are listed below after some comments.

(b) (5)

and definitely cannot make such a statement regarding some of the other *Micobacteria*.

The primary issue appears to be is whether visual inspection of market hogs is equivalent to traditional FSIS inspection. Testing designed to show error rates, sensitivity, and specificity of each system on the same population of market hogs can be conducted to demonstrate equivalence or non-equivalency. FSIS did this in the late 1980s to show that FSIS's traditional inspection was equivalent to EEC inspection. (b) (5)

? (b) (5)

?"

(b) (5)

In addition, meat-born public health concerns regarding *M. avium* (b) (5)

Also, some literature suggest that visual inspection reduces the public health risk of some other condition when compared to FSIS traditional inspection procedures.

**Question1:** Does FSIS have any real concerns regarding *Mycobacterium avium* or any of the *Mycobacterium* as a food-borne public health concern.

**Response:** (b) (5)

I am not aware of a risk assessment related to *M. avium* in swine and human disease. However, FSIS/USDA in October 1986 publish *Mycobacterioses in Swine and Their Significance to Public Health*, Bibliographies and Literature of Agriculture, Number 46, National Agriculture Library, author Dey B. P. The conclusion in the paper was:

"All available evidence indicates that swine are not incidental host, but rather occasional host, and that MAIS [*M. avium*, *M. intracellulare*, *M. scrofulaceum*] complex infection of humans does not originate from swine. In a majority of cases, the organisms responsible for the lesions in swine are serotypically different from those encountered in human disease. Apparently, both swine and humans are constantly exposed to this group of organisms, abundantly present in the environment. In some people, with certain predisposition, organisms from this source may cause infection and disease."

*M. avium* is the leading cause of tuberculosis in swine. The disease in swine is self-limiting with lesions usually found in the lymph nodes. Serotypes of *M. avium* isolated from humans are usually different from those isolated from chickens. In areas where the disease is common in chickens, the occurrence of avian tubercle bacillus infection is rare, indicating that humans are resistant to the disease.<sup>1</sup> Although, both man and animals can acquire the disease it does not appear to be transmissible from animal to man.<sup>2</sup>

1. Handbook of Zoonosis, Viral. Ed. George W. Beran. Boca Raton: CRC, 1994

2. Thoen, C.O. and Karlson, A.G. Avian Tuberculosis.

However, the importance of mycobacterial infections caused by strains of *Mycobacterium avium* complex (MAC) in animals and humans is continuously increasing (3, 4). In the human population, the condition is aggravated by the spread of human immunodeficiency virus (HIV) infection. In AIDS patients, the incidence of disseminated mycobacterial infection caused by MAC strains can reach up to 55% (5, 6)

(b) (5)

In addition, if *Mycobacterium tuberculosis* and *M. avium* subspecies *paratuberculosis* are considered, (b) (5)

The causative agent for Johne's disease in cattle is *Mycobacterium avium* subspecies *paratuberculosis* (MAP), and some clinical research reports that this bacterium may be associated with Crohn's disease in humans. Beef consumption may be a potential route of MAP transmission to humans

**Question 2:** Is FSIS PHV training manual statement "Tuberculosis is not a disease of public health concern." consistent with current FSIS thinking. **Response:** The current PVH training manual 12/07/07 list tuberculosis in Section II Diseases and Condition not of Public Health Significance. (b) (5)

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## **TELECONFERENCE SUMMARY**

**COUNTRY:** Netherlands

**SUBJECT:** Submission of information regarding visual inspection project of market hogs

**DATE:** June 25, 2008

**FSIS REPRESENTATIVES:**

Dr. David Smith, IES, OIA

Dr. Terrie Sutton, OPHS

Dr. Scott Hafner, OPHS

**SUMMARY:** The teleconference focused on further information provided by the government of Netherlands that was received on June 16, 2008.

- Review of the information provided by Netherlands showed that FSIS' questions and concerns from the previous review were addressed. Netherlands is working to further develop their serological testing.
- When viewed as a whole, the proposed program appears to provide adequate food safety control.

**Answers on questions asked by USDA FSIS on June 5, 2008.**

The questions are based on the additional information sent on May 6, 2008 concerning Supply Chain Inspection of Pork.

**Question 1) In table 1 there is a comparison between an experimental infection study and a field infection farm A study. The conditions of the farm A study are not explained. Were the pigs infected or exposed to MAA?**

Answer 1) On farm A, pigs had a natural MAA-infection.

**Question 2) In the same table, there are columns labeled as negative, positive, and dubious. What is meant by dubious? It is unclear how the results in this column are to be interpreted without an understanding of what dubious means.**

Answer 2) To discriminate in the MAA-ELISA between positive and negative serum samples, cut-off values were calculated (n=153). For this the ELISA results were used, obtained on sera of pigs bacteriologically negative for MAA. Cut-off values in percentage positivity (PP) were determined at specificities of 0.90, 0.95, 0.975 en 0.99. At a specificity of 0.95 the cut off value appeared to be 7.5 PP with a confidential interval of 5.1-14.4 PP. At a specificity of 0.99 the cut off value appeared to be 12.3 PP. Based on these results a cut-off of 10 PP was used. However, we decided to determine a transition range from negative to positive. Below 10 PP all serum samples were negative and above 20 PP the serum samples were positive. The range from 10-20 PP was classified as dubious, in other words, as intermediary between a negative and positive result.

**Question 3) In the same table, for field examination farm A, on the row that gives results for bacteriological testing ? It is stated that 90 were negative, 104 were positive, but the total (n) is stated as being 186. How was this number calculated?**

Answer 3) This is a failure in calculating. We are sorry for this. Indeed 90 were negative and 104 were positive, the total number of samples, examined bacteriologically was 194 and not 186.

**Question 4) In table 2, the sensitivity of the serology for field infection A is stated as being 22. It appears as though this number was achieved by adding the positive percentage from field infection in table 1, which was 4, and the dubious results, which were 18. It's unclear what dubious means. If sensitivity is based on true positives then it appears that the sensitivity should be 4.**

Answer 4) The calculation of the sensitivity is based on the sum of positive and dubious-positive results. As described in question 2, a value of 10 PP was calculated as cut-off between negative and positive.

**Question 5) Is there any work on improving the sensitivity of this test?**

Answer 5) Yes. We are working on an improved version of the serological test.

Firstly we need to find more MAA-positive herds. We identified two Dutch farms with an MAA-infection. The earlier to FSIS reported study of Komijn et al (2007), revealed already that the prevalence of MAA infected herds in The Netherlands is very low. This seems to be one of the reasons that we have such a low number of positive herds. However we have now a third farm (foreign farm) that is suspected of MAA and under further investigation. Three naturally infected farms are still a low number to base the test specifications on. We need positive farms to further prove that we are able to detect MAA infections under the field conditions. Secondly research goes on in order to improve the serological test. Identification of the antigens of MAA is part of that. We focus especially on purification of lipid antigens from the current preparation which we are using in the ELISA. We expect that purification leads to a higher sensitivity with at least the same or a higher specificity.

**Question 6) If a carcass is determined to have granulomas that may be from tuberculosis, is the entire carcass condemned or is there any criteria for salvaging parts of a carcass? FSIS has regulations which address this situation and I am attaching them below.**

Answer 6) If the inspection of the carcass and/or organs shows malformation of the product or any sign of a generalized (disseminated) process, the carcass and pluck (including spleen) are being taken off line to undergo further inspection, which includes additional palpation and incisions, and the intestines are condemned. Generalized lesions (multiple granulomas, different organs affected) will result in condemnation

of the entire carcass and all its organs. If the carcass or pluck is only locally affected and the infectious process is confined to one primary site of infection, this affected part is being removed and condemned. The unaffected parts can be passed for human consumption without restriction. This is the regime of the EU-legislation.

#### **Literature**

Ruud E. Komijn, Henk J. Wisselink, Vincent M.C. Rijsman, Norbert Stockhofe-Zurwieden, Douwe Bakker, Fred G. van Zijderveld, Tony Eger, Jaap A. Wagenaar, Frans F. Putirulan, Bert A.P. Urlings, 2007: Granulomatous lesions in lymph nodes of slaughter pigs bacteriologically negative for *Mycobacterium avium* subsp. *avium* and positive for *Rhodococcus equi*. *Veterinary Microbiology* 120 (2007) 352–357.



**Smith, David**

---

**From:** (b) (6) [(b) (6)]@minbuza.nl]  
**Sent:** Monday, June 16, 2008 2:51 PM  
**To:** Smith, David  
**Cc:** (b) (6); (b) (6)  
**Subject:** Visual inspection -Q&A's  
**Importance:** High  
**Attachments:** 08-06-10-USDA-FSIS-PorkSupplyChain.doc

Hi David,

As discussed, please find attached the answers to your questions regarding the Netherlands chain inspection system. I know you had mentioned to have a telephone conference to discuss these Q&As, please let me know if you would still would like to have this to take place.

Thank you,

Caroline

(b) (6)  
Agricultural Trade Officer  
Netherlands Embassy  
4200 Linnean Avenue, NW  
Washington, D.C. 20008  
Ph:202-274-2719  
Fax: 202-244-3325

---

**From:** Smith, David [mailto:David.Smith@fsis.usda.gov]  
**Sent:** maandag 16 juni 2008 14:05  
**To:** (b) (6)  
**Cc:** (b) (6); (b) (6)  
**Subject:** RE: Visual inspection

Hi (b) (6),

Thanks for the help, I will try to get the call set up for one day the week of the 22nd. I will be in touch with you next week to refine the details.

Thanks,

David

Hi David,

Your questions have been forwarded to the Netherlands and our ministry is currently working on them. We anticipate that the written response will come soon. Due to travel commitments from the NL side, the first opportunity for a possible follow-up teleconference would be in the week

of June 22. I hope you have good trip!

Best regards,

(b) (6)  
Agricultural Trade Officer  
Netherlands Embassy  
4200 Linnean Avenue, NW  
Washington, D.C. 20008  
Ph: 202-274-2719  
Fax: 202-244-3325

---

From: Smith, David [<mailto:David.Smith@fsis.usda.gov>]  
Sent: donderdag 5 juni 2008 13:43  
To: (b) (6)  
Subject: FW: Visual inspection

Hi (b) (6), I sent this earlier to (b) (6) but I understand that he is out of the office until next week. Could you please follow up with the Ministry? Also, I sent an email to (b) (6) proposing a teleconference with Netherlands to discuss the information below. We would like to try for one day during the week of June 16. Possibly Wednesday?

I am out of the office tomorrow, and next week, but I'll have my blackberry so I can respond to emails.

Thank you,

David Smith, DVM, MS, BS

Office of International Affairs

International Equivalence Staff

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1400 Independence Ave, SW

Washington DC 20250

Phone: (202) 720-3395

Email: [david.smith@fsis.usda.gov](mailto:david.smith@fsis.usda.gov)  
<<mailto:david.smith@fsis.usda.gov>>

---

From: Smith, David  
Sent: Thursday, June 05, 2008 8:32 AM  
To: (b) (6) @minbuza.nl

Subject: Visual inspection

Hi (b) (6), after reviewing the most recent information that was provided to us with some of my colleagues we have the following questions:

<<Suppl info ketenkeuring 6-5-08.doc>>

1) In table 1 there is a comparison between an experimental infection study and a field infection farm A study. The conditions of the farm A study are not explained. Were the pigs infected or exposed to MAA?

2) In the same table, there are columns labeled as negative, positive, and dubious. What is meant by dubious? It is unclear how the results in this column are to be interpreted without an understanding of what dubious means.

3) In the same table, for field examination farm A, on the row that gives results for bacteriological testing - it is stated that 90 were negative, 104 were positive, but the total (n) is stated as being 186. How was this number calculated?

4) In table 2, the sensitivity of the serology for field infection A is stated as being 22. It appears as though this number was achieved by adding the positive percentage from field infection in table 1, which was 4, and the dubious results, which were 18. It's unclear what dubious means. If sensitivity is based on true positives then it appears that the sensitivity should be 4.

5) Is there any work on improving the sensitivity of this test?

6) If a carcass is determined to have granulomas that may be from tuberculosis, is the entire carcass condemned or is there any criteria for salvaging parts of a carcass? FSIS has regulations which address this situation and I am attaching them below.

[http://edocket.access.gpo.gov/cfr\\_2008/janqtr/pdf/9cfr311.2.pdf](http://edocket.access.gpo.gov/cfr_2008/janqtr/pdf/9cfr311.2.pdf)  
<[http://edocket.access.gpo.gov/cfr\\_2008/janqtr/pdf/9cfr311.2.pdf](http://edocket.access.gpo.gov/cfr_2008/janqtr/pdf/9cfr311.2.pdf)>

Thank you,

David Smith, DVM, MS, BS

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van welke aard ook, die verband houdt met risico's verbonden aan het elektronisch verzenden van berichten.

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## TELECONFERENCE SUMMARY

COUNTRY: Netherlands

SUBJECT: Submission of information regarding supply chain inspection project of market hogs

DATE: June 26, 2008

FSIS REPRESENTATIVES:

Dr. David Smith, IES, OIA

### NETHERLANDS REPRESENTATIVES

(b) (6), Embassy of Netherlands  
(b) (6), Deputy CVO  
(b) (6), (b) (4)  
(b) (6), Senior Veterinary Officer, VWA

SUMMARY: The teleconference focused on further information requested of the Netherlands regarding supply chain inspection.

- Discussed briefly the upcoming trip by FSIS to the Netherlands.
- Discussed the questions which were asked of the Netherlands on June 23, 2008.
  - After a farm achieves a low risk categorization what is the ongoing sampling program to show that the farm is maintaining a low risk status? How many samples are collected per herd? Is it serology only, or is intra-dermal testing performed as well?
    - The low risk category of a farm is monitored by collecting 2 samples/herd when they arrive at the slaughter establishment. These samples are serological only. If 1 sample returns a positive result which exceeds the dubious positive cutoff then the status becomes neutral. If both exceed the cutoff then the status becomes high.
  - Why does Netherlands perform intra-dermal testing as well as pathological testing on top of serology?
    - Intradermal testing is performed on the farms by a veterinarian employed by (b) (4). This testing is done as follow up testing for farms which are having their status re-evaluated. Also, intradermal testing has been used for collecting comparison data for the research on the serology test.
  - Is the IKB Pigs Scheme exclusive to supply chain inspection or does it apply to traditional as well?
    - The IKB Scheme is not exclusive to supply chain inspection, and not all pig farms participate in IKB. IKB is a program which makes allows access to a greater amount of information about the pig farms that do participate. There are farms whose pigs are subjected to traditional inspection which are participating in IKB, and there are farms whose pigs are subjected to traditional inspection which are not participating in IKB. However, all farms whose pigs go through supply chain inspection must participate in IKB.
  - How long does it take to receive the results of the serological testing?
    - Results are received in approximately 1 week.

**Smith, David**

---

**From:** (b) (6) (b) (6) @minbuza.nl]  
**Sent:** Monday, June 23, 2008 3:18 PM  
**To:** Smith, David  
**Cc:** (b) (6)  
**Subject:** RE: questions for Netherlands Inspection

Hi David,

Thank you! I will let you know tomorrow who will be at the teleconference on Thursday and the phone numbers.

Best,

(b) (6)

---

**From:** Smith, David [mailto:David.Smith@fsis.usda.gov]  
**Sent:** maandag 23 juni 2008 14:23  
**To:** (b) (6)  
**Subject:** questions for Netherlands Inspection

Hi (b) (6), these are questions that we would like to discuss during the conference call Thursday.

1. After a farm achieves a low risk categorization what is the ongoing sampling program to show that the farm is maintaining a low risk status? How many samples are collected per herd? Is it serology only, or is intra-dermal testing performed as well?
2. Why does Netherlands perform intra-dermal testing as well as pathological testing on top of serology?
3. Is the IKB Pigs Scheme exclusive to visual inspection or does it apply to traditional as well?

Thank you,

*David Smith, DVM, MS, BS*

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# FSIS Documents



## Comparison Table: Swine Inspection

<b>FSIS Swine Inspection Procedures (traditional):</b> <ul style="list-style-type: none"> <li>Authority: 21 USC 604 (FMIA), 9 CFR 310.1</li> <li>Procedures: Slaughter Inspection Training Materials (1/14/2005)</li> </ul>	<b>FSIS Swine Inspection Procedures for Plants Operating Under HIMP:</b> <ul style="list-style-type: none"> <li>Authority: 21 USC 604 (FMIA), 9 CFR 303.2</li> </ul>	<b>Netherlands Swine Inspection Procedures for Plants Operating Under Visual Inspection:</b> <ul style="list-style-type: none"> <li>Authority: EC 854/2004</li> <li>Procedures: "The New Organization of the Red Meat Inspection System in the Netherlands (2006)"</li> </ul>	<b>EU Swine Inspection Procedures (traditional):</b> <ul style="list-style-type: none"> <li>Authority: EC 854/2004</li> <li>Procedures: Annex I; Sec IV; Chap IV: Domestic Swine, B.—Post mortem Inspection</li> </ul>
<b>General:</b> <ul style="list-style-type: none"> <li>For all swine</li> </ul>	<ul style="list-style-type: none"> <li>For market hogs slaughtered in plants operating under the HACCP-based Inspection Models Project (HIMP).</li> <li>Carcasses must be presented for inspection with the mandibular lymph nodes incised.</li> </ul>	<ul style="list-style-type: none"> <li>For fattening pigs housed under controlled housing in integrated production systems since weaning.</li> <li>At the discretion of the competent authority based on epidemiological or other data from the holding [farm].</li> <li>Data from the farm must include food chain information, results of testing for <i>M. avium</i>, and certain additional requirements to control hazards in the food supply chain.</li> </ul>	<ul style="list-style-type: none"> <li>For all swine except those identified under paragraph (2).</li> </ul>

<b>Head Inspection:</b> <ul style="list-style-type: none"> <li>• Observe head and cut surfaces – eyes, fat, cheek muscles, and other tissues for abnormalities.</li> <li>• Incise and observe mandibular lymph nodes.</li> </ul>	<ul style="list-style-type: none"> <li>• Visual inspection of the head and throat.</li> <li>• Visual inspection of the incised mandibular lymph nodes.</li> <li>• Visual inspection of mouth, fauces, tongue.</li> </ul>	<ul style="list-style-type: none"> <li>• Visual inspection of the head and throat, including the mandibular lymph nodes.</li> <li>• Visual inspection of mouth, fauces, tongue.</li> </ul>	<ul style="list-style-type: none"> <li>• Visual inspection of the head and throat.</li> <li>• Incision and examination of the submaxillary lymph nodes (Lnn mandibulares).</li> <li>• Visual inspection of the mouth, fauces and tongue.</li> </ul>
<b>Viscera Inspection:</b> <ul style="list-style-type: none"> <li>• Observe eviscerated carcass, viscera and parietal (top) surface of spleen.</li> <li>• Observe and palpate mesenteric lymph nodes.</li> <li>• Palpate portal lymph nodes.</li> <li>• Observe dorsal (curved) surface of lungs.</li> <li>• Palpate bronchial lymph nodes.</li> <li>• Observe mediastinal lymph nodes.</li> <li>• Turn lungs over and observe ventral (flat) surfaces.</li> <li>• Observe heart.</li> <li>• Observe dorsal (curved) surface of liver.</li> <li>• Turn liver over and observe ventral (flat) surface.</li> </ul>	<ul style="list-style-type: none"> <li>• Visual inspection of the lungs, trachea, and oesophagus.</li> <li>• Visual inspection of the pericardium and heart.</li> <li>• Visual inspection of the liver and hepatic and pancreatic (portal) lymph nodes.</li> <li>• Visual inspection of the gastro-intestinal tract, mesentery, gastric and mesenteric lymph nodes.</li> <li>• Visual inspection of the spleen.</li> </ul>	<ul style="list-style-type: none"> <li>• Visual inspection of the lungs, trachea, and oesophagus.</li> <li>• Visual inspection of the pericardium and heart.</li> <li>• Visual inspection of the liver and hepatic and pancreatic (portal) lymph nodes.</li> <li>• Visual inspection of the gastro-intestinal tract, mesentery, gastric and mesenteric lymph nodes.</li> <li>• Visual inspection of the spleen.</li> <li>• Visual inspection of genital organs.</li> </ul>	<ul style="list-style-type: none"> <li>• Visual inspection of the lungs, trachea and oesophagus.</li> <li>• Palpation of the lungs and the bronchial and mediastinal lymph nodes (Lnn. bifurcationes, eparteriales and mediastinales).</li> <li>• 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.</li> <li>• Visual inspection of the liver and the hepatic and pancreatic lymph nodes, (Lnn portales).</li> <li>• Palpation of the liver and its lymph nodes.</li> <li>• Visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (Lnn gastrici, mesenterici, craniales and caudales).</li> <li>• Palpation and, if necessary,</li> </ul>

			incision of the gastric and mesenteric lymph nodes. <ul style="list-style-type: none"> <li>• Visual inspection and, if necessary, palpation of the spleen.</li> </ul>
<b>Carcass Inspection:</b>			
<ul style="list-style-type: none"> <li>• Observe back of carcass (turn carcass or use mirror).</li> <li>• Observe front and inside of carcass, including               <ul style="list-style-type: none"> <li>○ Cut surfaces,</li> <li>○ All body cavities,</li> <li>○ Lumbar region,</li> <li>○ Neck region.</li> </ul> </li> <li>• Grasp, turn, and observe the kidneys.</li> </ul>	<ul style="list-style-type: none"> <li>• Visual inspection of the carcass.</li> <li>• Visual inspection of the pleura and peritoneum [lining of chest and abdominal cavities].</li> <li>• Visual inspection of the kidneys.</li> <li>• Visual inspection of the diaphragm.</li> <li>• Visual inspection of the udder and its lymph nodes.</li> <li>• Visual inspection of the umbilical region and joints of young animals.</li> </ul>	<ul style="list-style-type: none"> <li>• Visual inspection of the carcass.</li> <li>• Visual inspection of the pleura and peritoneum [lining of chest and abdominal cavities].</li> <li>• Visual inspection of the kidneys.</li> <li>• Visual inspection of the diaphragm.</li> <li>• Visual inspection of the udder and its lymph nodes.</li> <li>• Visual inspection of the umbilical region and joints of young animals.</li> </ul>	<ul style="list-style-type: none"> <li>• Visual inspection of the carcass.</li> <li>• Visual inspection of the pleura and peritoneum.</li> <li>• Visual inspection of the kidneys.</li> <li>• Incision, if necessary, of the kidneys and the renal lymph nodes (Lnn. renales).</li> <li>• Visual inspection of the diaphragm.</li> <li>• Visual inspection of the udder and its lymph nodes (Lnn. supramammarii).</li> <li>• Incision of the supramammary lymph nodes in sows.</li> <li>• Visual inspection and palpation of the umbilical region and joints of young animals.</li> <li>• In the event of doubt, the umbilical region must be incised and the joints opened.</li> </ul>

DRAFT

# MARKET HOGS



# HIMP

(HACCP-BASED INSPECTION  
MODELS PROJECT)

## **HIMP MARKET HOG INSPECTION**

### **Background**

FSIS collected data to determine the current food safety and other consumer protection achievements of the traditional inspection system in five market hog slaughter plants. The data were used to develop performance standards that volunteer plants in the HACCP-based Inspection Models Project (HIMP) must meet. The performance standards were published in a Federal Register Notice on November 2, 2000. A total of six performance standards were developed: three Food Safety categories (FS 1-3) and three Other Consumer Protection categories (OCP 1-3). The performance standards for the Food Safety categories (FS-1-3) were set at zero. The performance standards for the Other Consumer Protection categories (OCP 1-3) were based on the 75<sup>th</sup> percentile of the ranges of baseline data. (See Attachment 1)

### **Types of Inspection Activities**

The Market Hog HIMP pilot consists of three types of inspection activities: system inspection, carcass inspection, and verification inspection. System inspection involves the evaluation of in-plant inspection findings and determines the effectiveness of the overall design and execution of all establishment slaughter processes under the HACCP and process control plans. Carcass inspection involves the examination of each carcass and its parts to determine that they are unadulterated. Verification inspection involves the evaluation of the effectiveness of the establishment's HACCP and Process Control plan in meeting the relevant performance standards. These three types of inspection are discussed in further detail below.

**System Inspection** - The System Inspector (SI) is either the Inspector in Charge (IIC) or the Supervisory Veterinary Medical Officer (SVMO). The SI has overall responsibility to assure that the plant and inspection personnel effectively conduct the required activities under the HIMP, as designed. The SI sends verification data to headquarters and provides overall feedback on how the project is working. Specifically, the SI:

- Determines (or assigns to the verification inspector (VI))\* the daily random sampling schedule and provides the schedule to the VI.
- Monitors and determines the effectiveness of ante-mortem verification inspection.
- Monitors and determines the effectiveness of the establishment ante-mortem sorting.
- Determines final disposition of animals designated by the VI as "suspects" at ante-mortem.
- Monitors and determines the effectiveness of the establishment's post-mortem sorting and disposition.
- Determines final disposition on carcasses retained by the carcass inspector (CI) or VI on post-mortem.\*
- Records FS-1 and FS-3 nonconformance findings on the appropriate HIMP form.
- Determines if the establishment is meeting relevant performance standards.
- Assesses the overall design and execution of the establishment's HACCP and process control procedures.
- Assures that all adulterated products are condemned in accordance with applicable regulations.
- Determines when unscheduled verification sampling is warranted.

- Maintains communication with the VI and CIs to facilitate coordination of all ante-mortem and post-mortem findings.

**Carcass Inspection** - The Carcass Inspectors (CI) are stationed at up to 3 fixed locations on the post-mortem line to determine whether a product is adulterated or unadulterated. They inspect each carcass and part on the line, as well as evaluate the on-going effectiveness of the establishment's food safety and other consumer protection processes. Specifically, the CIs:

- Determine whether each carcass and its parts are adulterated or unadulterated.
- Take appropriate action to prevent adulterated product from entering into human food channels.
- Notify the establishment personnel, VI and/or SI of carcass and/or parts defect findings.
- Examine sample sets when notified by the VI and verbally inform the VI during sampling when defects are found.
- Contact the SI if there are any concerns about process control.
- Retain carcasses and parts for further disposition by the SI if food safety and other conditions are identified that could result in condemnation.
- Maintain communication with the VI and SI to facilitate coordination of all post-mortem findings.

**Verification Inspection** - The Verification Inspector (VI) does not have a fixed position on the line, and can move freely. Specifically, the VI:

- Observes and evaluates the effectiveness of the establishment's HACCP and process control plans, including the examination of records, to determine whether the establishment is in compliance with applicable regulatory requirements.
- Conducts ante-mortem inspection of all animals at rest and 5-10 percent of animals in motion.
- Retains animals for further disposition by the SI, if the animal is suspected of having a condition that could result in condemnation.
- Documents ante-mortem findings on HIMP FORM 9.
- Takes verification samples to determine if establishment is complying with relevant performance standards, including scheduled and unscheduled sampling.
- Records all findings of noncompliance with applicable performance standards.
- Notifies the CI when verification samples are required and records the findings in each sample set during post-mortem. Evaluates the noncompliance findings and records in the appropriate category on HIMP form 7.
- Investigates potential process control problems.
- Notifies SI if the process control plan is not being met or if performance standards have been exceeded.
- Retains carcasses and parts for further disposition by the SI if food safety and other conditions are identified that could result in condemnation.
- Maintains communication with the CI and SI.

## MARKET HOG INSPECTION STATION

### Facilities required at each inspection station include:

1. The conveyor and/or rail shall be level for the entire length of the inspection station.
2. Floor space shall be adequate along the conveyor and rail.
3. Conveyor and rail stop/start switches shall be readily accessible.
4. A minimum of 50 foot-candles of shadow-free lighting shall exist at each inspection station.

### Inspection Stations will be established at up to 3 locations:

FSIS personnel are responsible for inspecting each head, viscera, and carcass. These locations will be:

1. After the mandibular lymph node incision step and before the head removal step for the Head Inspection Station.
2. After the establishment's viscera sorting step and before the viscera harvesting step for the Viscera Inspection Station.
3. After the final trim and sorting step and before the carcass wash step for the Carcass Inspection Station.

Inspection locations may be combined if carcass and/or parts (head and viscera) can be inspected at a single location. (Example: combining the viscera with carcass inspection if they can be inspected at one location.). Proposals for less than three inspector locations must be presented to the HIMP Project Manager.

## DOCUMENTATION

The forms used for the HIMP Market Hog project are:

- HIMP FORM-7, Postmortem Verification Inspection Activities
- HIMP FORM 8-1 OCP-1 25 Day Results
- HIMP FORM 8-2 OCP-2 25 Day Results
- HIMP FORM 8-3OCP-3 25 Day Results
- HIMP FORM-9 Ante-Mortem Verification Inspection Activities
- HIMP FORM-10 HIMP Verification/Corrective Action Log
- FSIS Form 5400-4 Noncompliance Record (NR)
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### **FS-1 and FS-3 nonconformance documentation -**

- The SI makes the final disposition on carcasses retained by inspection personnel on FS-1 and FS-3 categories and documents the FS-1 and FS-3 nonconformance on a NR as ISP code 03J01.
- If the SI finds additional noncompliance for **this specific slaughter production lot**, the SI will document the findings on separate NR's.

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  - All findings must be taken into consideration after the NR is written. The SI also checks the plant's corrective actions. All findings and plant's corrective actions are to be documented on the NR.
- The 03J02 procedure is considered to be complete when inspection personnel have verified the establishment's pre-shipment review.
- The SI will inform the VI to document FS-1 non-conformances on the daily HIMP Form 7
- The SI will document FS-3 non-conformances on the HIMP form 9.

### **FS-2 nonconformance documentation -**

- An FS-2 nonconformance is documented when feces, ingesta or milk are identified during verification activities.(according to the identification guidelines in FSIS Directive 6420.2).\*
- The CI at the final carcass inspection station will follow FSIS Directive 6420.2 *Livestock Post-Mortem Inspection Activities-Enforcing the Zero Tolerances for Fecal Material, Ingesta, and Milk* Section II. B. 1 as it pertains to the final rail inspector.\*
- The VI, when performing FS-2 verification, will document an FS-2 nonconformance on a NR as ISP code 03J01.
- If the VI finds additional noncompliance **for this specific slaughter production lot**, the VI will document their findings on additional NR's.
- All findings must be taken into consideration by the VI that found the noncompliance or another VI. The VI also checks the plant's corrective actions. All findings and plant's corrective actions are to be documented on the NR.
- The 03J02 procedure is considered to be complete when the VI has verified the establishment's pre-shipment review.
- The FS-2 nonconformance is also to be documented by the VI on HIMP FORM-7.



**OCP nonconformance documentation –**

The VI or SI will document the OCP nonconformance findings during the shift on Draft HIMP form 7.

- If the establishment exceeds the daily maximum limit (See Table 1) for a specific OCP category, the VI will notify the SI.
- At the end of each shift, the SI will document the number of defects and pass/fail for each OCP category on HIMP FORMS 8- 1 through 8-3.

## VERIFICATION PROCEDURES

FSIS conducts verification inspection to assure that plants are meeting the performance standards. Verification inspection occurs in ante-mortem and post-mortem.

### ANTE-MORTEM

- Establishment ante-mortem records for the FS-3 category are to be reviewed by the VI or SI.
- The VI or the SI will inspect 100% of live animals at rest that are presented by the establishment for slaughter.
- The SI (or assigns to VI) randomly selects ante-mortem sampling times throughout the shift. Ante-mortem sampling times can be scheduled if the entire kill is available prior to start of shift. Usually live animals continue to be shipped to the establishment throughout the day and it is not possible to schedule the times for random sampling. Therefore, it is left to the discretion of the SI to determine randomness of sampling throughout the shift when live animals are available.
- The VI or SI will inspect 5-10% of the live animals in motion randomly throughout the shift after establishment sorting for slaughter.
- The VI or SI will assess sorting activities and humane handling practices.
- The SI will assess plant activities at the suspect pen.
- The VI will retain as suspect for SI disposition any animal that could result in condemnation.
- FS-3 deficiency determined by the SI will be documented by the SI on a NR and the establishment follows HACCP procedures in 9 CFR 417.3.
- The SI will document or notify the VI to document any FS-3 deficiency on HIMP Form 9.
- Other deficiencies found on ante-mortem sampling by the VI will be reported to establishment and the SI (such as humane handling).
- A NR is to be documented for humane handling violation. The ISP procedure code for violations related to humane handling and slaughter is **04C02**. \*

### POST-MORTEM

The verification sampling procedures for both food safety and other consumer protection performance standards will be conducted on 24 randomly selected samples for each shift. This procedure can be conducted either off-line or on-line. If conducted on-line, the VI will identify the samples and have the CI's examine each part and carcass, starting with the head inspection station. The VI will follow the samples through the entire process and record all defects found during the CI examination. The VI will record a maximum of one defect in each performance standard category per sample unit (e.g., a sample having bile and a bruise on the carcass would be identified as 1 OCP-3 defect. A sample having arthritis and fecal contamination of the viscera would be identified as 1 OCP-1 and 1 OCP-2).

In addition, the VI or SI will review establishment post-mortem records for FS-1. The SI and/or VI will review other establishment post-mortem records.

## 1) General

- A sample consists of a carcass with corresponding head and viscera.
- The SI or the VI will notify the on-line CI when to inspect verification samples during the shift.
- The CI, when notified by the VI, will inspect the verification samples of the carcass with corresponding viscera and head per shift and verbally inform the VI of their findings during sampling.
- The 24 unit samples per shift may be taken in subsets.
  - Sample subsets may be randomly taken in one of the following manners:
    - 3 samples 8 times per shift.
    - 4 samples 6 times per shift.
    - 6 samples 4 times per shift.
    - 8 samples 3 times per shift.
- Any OCP defects, which are identified at the inspection stations, should be identified to the establishment but not scored toward plant performance unless it is part of a scheduled or unscheduled sample subset.
- Sample times and sample subsets are to be selected randomly prior to the start of the shift.
- The VI or SI will record findings on DRAFT HIMP Form-7. It is not necessary to record a specific condition within a performance standard category (i.e., localized lung or heart conditions would be recorded as a noncompliance of the OCP-1 performance standard category).
- If the establishment is engaged in product/process action at the time the random sample is to be taken, the VI will suspend random sampling until the establishment has completed its actions.

## 2. FS1 and FS 2

- Establishment post-mortem records for FS-1 and FS-2 categories are to be reviewed by the VI or SI in accordance with 9 CFR 417.8.
  - The CI, when notified by the VI, will examine the sample subsets for indications of FS-1 and FS-2 defects and verbally relay the information to the VI.
    - 1) FS-2 defects are recorded at the post-mortem rail inspection station.
    - 2) The CI will retain carcasses with potential FS-1 defects for final disposition by the SI. If the VI/SI finds additional non-compliance for this slaughter production lot, the VI/SI will document each additional FS-2 defect findings on separate NR's. \*
    - 3) The CI at the Pre-Wash Verification Location Inspection Station will identify potential FS-1 and FS-2 defects. The CI will retain the carcass for final disposition by the SI. The CI will identify FS-2 defects and take the appropriate action consistent with established HACCP procedures. The VI/SI will document the FS-2 defect that was found by the CI on a NR. If the VI/SI finds additional non-compliance for this slaughter production lot, the VI/SI will document each additional FS-2 defect findings on separate NR's. \*
- No carcasses are allowed to exhibit FS-2 defects at the post-mortem rail inspection station. The CI will follow instructions for "on-line inspection personnel" in FSIS Directive 6420.2. The CI will have the defect removed either by railing the carcass out or having it trimmed on-line. Notify the SI/VI for possible unscheduled verification sampling. \*
- The SI will write a NR for FS-1 noncompliance.
- The VI will write a NR for FS-2 noncompliance observed during verification sampling in accordance with FSIS Directive 6420.2.\*

### 3. OCP

- The CI or VI will retain a carcass for final disposition by the SI when OCP defects are found that could result in condemnation.
- If the VI or SI determines that defects in an OCP category exceed the performance standard as stated in Table 1, the VI or SI will check the establishment's process control records for the same time frame. If the establishment results show a potential or actual loss of control as defined in the establishment's process control plan (PCP), the VI or SI will check the establishment's records to determine whether corrective actions described in the PCP were taken.

**TABLE 1: OCP Maximum defects allowed Per Shift**

<b>SAMPLE SIZE</b>	<b>24 SAMPLES (Head, Viscera, carcass)</b>	<b>UNSCHEDULED 27 SAMPLES</b>	<b>UNSCHEDULED 30 SAMPLES</b>	<b>UNSCHEDULED 33 SAMPLES</b>
<b>OCP-1</b>	2	2	2	2
<b>OCP-2</b>	3	3	3	3
<b>OCP-3</b>	7	7	8	9

- If the establishment failed to take proper corrective action according to their PCP, the establishment should detail what new corrective and preventive action will be implemented to prevent recurrence. Any samples that exhibit defects in any of the OCP performance standard categories should be pointed out to establishment personnel.

### Unscheduled Verification Inspection

When the SI determines that an unscheduled inspection should occur, the SI will notify the VI to conduct the inspection. Each unscheduled verification inspection will be three carcasses with corresponding viscera and head.

- Unscheduled verification sampling done at the direction of the SI will also be recorded on Draft HIMP Form 7.
- Unscheduled verification sampling will count toward the establishment's performance evaluation (See Table 1).
- The SI may call for unscheduled verification inspection because a CI has identified a potential problem.
- The SI may call for unscheduled verification inspection after the establishment has had sufficient opportunity to correct an establishment identified problem. This would confirm that the problem has been corrected.
- The establishment is notified of unscheduled verification inspection.
- The SI and/or VI will notify the establishment of the results of unscheduled verification sampling and establishment record examinations.

## EXAMINATION OF PLANT SAMPLING RECORDS FOR OCP'S

- In addition to the 24 OCP samples, VI will review establishment's records for OCP sampling results at least three times per day.
- Examples of plant records evaluation may also include observations of the plant selecting samples and data recording procedures.
- The VI or SI should record the results on the Draft HIMP Form 10.
- The VI will notify the SI of any discrepancies in the record examination.

### SI evaluation of OCP 1 through 3 for 25 day performance

- To evaluate whether the establishment maintains process control, the SI will track the performance of OCP 1 through 3 for a 25-day period using Draft HIMP Form 8-1 through 8-3 and Table 1.
- Each OCP will be tracked each shift and referenced to the Table 1 values.
- The SI will record that the plant passed or failed each of the 3 OCP categories on the appropriate HIMP form 8 and notify the plant of their findings.
- For an entire 25-day period, the maximum number of days on which the Table 1 performance standards can be exceeded is given in Table 2.

**TABLE 2: Maximum Days (OCP's)  
(Number of Days Above maximum defects  
allowed Per 25-Day Period)**

<b>OCP-1</b>	<b>2 days</b>
<b>OCP-2</b>	<b>4 days</b>
<b>OCP-3</b>	<b>3 days</b>

- If the plant exceeds the maximum days for any OCP category listed in table 2 for a 25-day period, at any point during the 25 days, the SI will write a NR coded 04C01. The plant should detail what new corrective and preventive actions are implemented to prevent recurrence. The plant will provide this information to the SI.

Note: A 25 day period will end at a full 25 days provided that the Table 2 Maximum Number of Days are not exceeded. If the Table 2 Maximum Number of Days are exceeded before 25 days are completed, e.g. on the 13th day, the period stops then while the plant responds as described above. A new 25-day period will begin when those conditions are satisfied.

## Correlation

The SI and/or VI will meet regularly with plant management to conduct correlation activities during the transition period. Regular correlation will aid FSIS and the plant in establishing a common basis for both FS and OCP determinations.

## Attachment 1

**Model Performance Standards for Market Hogs Plants**

<b><u>Performance Standard Categories</u></b>	<b><u>Plant Performance Standards</u></b>
<b>FS-1—Condition – Infectious</b> (for example: septicemia/toxemia, pyemia, cysticercus)	<b>Zero</b>
<b>FS-2 – Condition – Digestive Content/Milk</b> (for example: fecal material, ingesta, milk)	<b>Zero</b>
<b>FS-3 – Ante-mortem Suspect</b> (for example: neurologic conditions, moribund, pyrexia, severe lameness)	<b>Zero</b>
<b>OCP-1 – Carcass- Pathology*</b> (for example: arthritis, emaciation,, erysipelas, localized abscess, mastitis, metritis, mycobacteriosis [M Avium], neoplasms, pericarditis, pleuritis, pneumonia, uremia)	<b>4.1%</b>
<b>OCP-2 – Visceral Pathology*</b> (for example: cystic kidneys, enteritis/gastritis, fecal contamination of viscera, nephritis/ pyelonephritis, parasites—other than Cysticercus, peritonitis)	<b>7.2%</b>
<b>OCP-3 – Miscellaneous</b> (for example: anemia, bile, bruise, edema, external mutilation, fractures, icterus, odor, skin lesions, scabs, toenails not removed)	<b>20.5%</b>

**\*Conditions exhibiting a septicemia or toxemia are considered food safety hazards**

## PLANT PERFORMANCE

### Ante-mortem Verification Inspection Activities (FS-3)

Shift: 1 2      Est. number: \_\_\_\_\_      Date: \_\_\_\_\_

Inspection Activity	1			2		
	Deficiency	FS-3	NR	Deficiency	FS-3	NR
Inspect 100% of hogs at rest						
Inspect 5-10% of hogs in motion, passed by plant for slaughter (at or after CCP location)						
Inspect suspects, as required (done by SI )						
Observe humane slaughter practices						
Examine Ante-mortem records						
Additional Comments:						

1. Circle Shift
2. Enter Establishment #
3. Enter Date
4. For each of the **Inspection Activities** listed, indicate if a **deficiency** is found. Also, indicate if the deficiency constitutes a FS-3 and/or an NR by writing a **yes** or **no** in the space provided.

## PLANT PERFORMANCE

### Postmortem Verification Inspection Activities – FS and OCP Conditions

Date	Shift 1 2	Est #	Est. Name	Unscheduled Verifications				
Performance Standard Categories			Scheduled Verification	Total	Set 1	Set 2	Set 3	Total
<b>FS-1 Condition – Infectious (SI ONLY)</b> (for example: septicemia/toxemia, pyemia, cysticercosis) <div style="text-align: right;">Max 0</div>			1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24					
<b>FS-2 Condition – Digestive Content/Milk (Carcass only)</b> (for example: fecal material, ingesta, milk) <div style="text-align: right;">Max 0</div>			1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24					
<b>OCP-1 Carcass – Pathology*</b> (for example: arthritis, erysipelas, localized abscess, mastitis, metritis, mycobacteriosis, [M avium] neoplasms, pericarditis, pleuritis, pneumonia, (SI only emaciation, uremia) <div style="text-align: right;">Max 2</div>			1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24					
<b>OCP-2 Visceral – Pathology* (Head and Viscera)</b> (for example: cystic kidneys, enteritis/gastritis, fecal contamination of viscera, nephritis/pyelonephritis, parasites - other than cysticercus, peritonitis) <div style="text-align: right;">Max 3</div>			1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24					
<b>OCP-3 Miscellaneous</b> (for example: Anemia/Pale Soft Exudative pork, bile, bruise, edema, external mutilation, fractures, icterus, odor, skin lesions, scabs, toenails not removed) <div style="text-align: right;">Max 7</div>			1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24					

\* Conditions exhibiting a septicemia or toxemia are considered food safety hazards.



DRAFT 7 HIMP FORM 7 5/24/01  
MARKET HOGS

1. Enter **Date**
2. Enter **Shift**
3. Enter **Establishment # and name**
4. For **FS** and **OCP** deficiencies, circle the number corresponding to the sample with the defect (condition). Enclose in brackets the sample subset (i.e. a three sample subset would be bracketed as [1 2 3] [4 5 6]...  
A 4 sample subset may also be taken 6 times per shift, or 6 a sample subset 4 times per shift, or a 8 sample subset 3 times per shift.  
Sample times and sample subsets are to be selected randomly **prior** to the start of the shift.

**TABLE 1: OCP Maximum defects allowed Per Shift**

<b>SAMPLE SIZE</b>	<b>24 SAMPLES (Head, Viscera, carcass)</b>	<b>UNSCHEDULED 27 SAMPLES</b>	<b>UNSCHEDULED 30 SAMPLES</b>	<b>UNSCHEDULED 33 SAMPLES</b>
<b>OCP-1</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>2</b>
<b>OCP-2</b>	<b>3</b>	<b>3</b>	<b>3</b>	<b>3</b>
<b>OCP-3</b>	<b>7</b>	<b>7</b>	<b>8</b>	<b>9</b>

EST. # \_\_\_\_\_

**MARKET HOGS****DRAFT HIMP FORM 8-1**

5/10/01

**OCP-1****25 Day Results**

Directions: Using the data from DRAFT HIMP Form 7 for OCP-1, determine plant performance per shift using Table 1. Record No. of Hogs with defects and indicate Pass or Fail for OCP-1 for each shift. The Maximum number of days on which this performance standard can be exceeded per 25 day window is given in Table 2.

Date of Collection	OCP-1	Date of Collection	OCP-1	Date of Collection	OCP-1
1		1		1	
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	
7		7		7	
8		8		8	
9		9		9	
10		10		10	
11		11		11	
12		12		12	
13		13		13	
14		14		14	
15		15		15	
16		16		16	
17		17		17	
18		18		18	
19		19		19	
20		20		20	
21		21		21	
22		22		22	
23		23		23	
24		24		24	
25		25		25	
TOTAL # PASSED		TOTAL # PASSED		TOTAL # PASSED	
TOTAL # FAILED		TOTAL # FAILED		TOTAL # FAILED	

**TABLE 1: OCP-1 Performance Standard Per Shift (24 head, carcass, & viscera samples)**

CONDITION	MAXIMUM DEFECTS ALLOWED
OCP-1	2

**TABLE 2: Maximum # of Days OCP-1 is Allowed Above Performance Standard (Per 25-Day Period)**

CONDITION	MAX. # DAYS PER 25 DAY PERIOD
OCP-1	2 days

EST. # \_\_\_\_\_

**MARKET HOGS****DRAFT HIMP FORM 8-2**

5/10/01

**OCP-2****25 Day Results**

Directions: Using the data from DRAFT HIMP Form 7 for OCP-2, determine plant performance per shift using Table 1. Record No. of Hogs with defects and indicate Pass or Fail for OCP-2 for each shift. The Maximum number of days on which this performance standard can be exceeded per 25 day window is given in Table 2.

Date of Collection	OCP-2	Date of Collection	OCP-2	Date of Collection	OCP-2
1		1		1	
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	
7		7		7	
8		8		8	
9		9		9	
10		10		10	
11		11		11	
12		12		12	
13		13		13	
14		14		14	
15		15		15	
16		16		16	
17		17		17	
18		18		18	
19		19		19	
20		20		20	
21		21		21	
22		22		22	
23		23		23	
24		24		24	
25		25		25	
TOTAL # PASSED		TOTAL # PASSED		TOTAL # PASSED	
TOTAL # FAILED		TOTAL # FAILED		TOTAL # FAILED	

**TABLE 1: OCP-2 Performance Standard Per Shift (24 head, & viscera samples)**

CONDITION	MAXIMUM DEFECTS ALLOWED
OCP-2	3

**TABLE 2: Maximum # of Days OCP-2 is Allowed Above Performance Standard (Per 25-Day Period)**

CONDITION	MAX. # DAYS PER 25 DAY PERIOD
OCP-2	4 days

EST. # \_\_\_\_\_

**MARKET HOGS****DRAFT HIMP FORM 8-3**

5/10/01

**OCP-3****25 Day Results**

Directions: Using the data from DRAFT HIMP Form 7 for OCP-3, determine plant performance per shift using Table 1. Record No. of Hogs with defects and indicate Pass or Fail for OCP-3 for each shift. The Maximum number of days on which this performance standard can be exceeded per 25 day window is given in Table 2.

Date of Collection	OCP-3	Date of Collection	OCP-3	Date of Collection	OCP-3
1		1		1	
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	
7		7		7	
8		8		8	
9		9		9	
10		10		10	
11		11		11	
12		12		12	
13		13		13	
14		14		14	
15		15		15	
16		16		16	
17		17		17	
18		18		18	
19		19		19	
20		20		20	
21		21		21	
22		22		22	
23		23		23	
24		24		24	
25		25		25	
TOTAL # PASSED		TOTAL # PASSED		TOTAL # PASSED	
TOTAL # FAILED		TOTAL # FAILED		TOTAL # FAILED	

**TABLE 1: OCP-3 Performance Standard Per Shift (24 head, carcass, & viscera samples)**

CONDITION	MAXIMUM DEFECTS ALLOWED
OCP-3	7

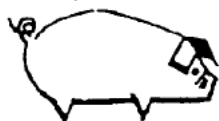
**TABLE 2: Maximum # of Days OCP-3 is Allowed Above Performance Standard (Per 25-Day Period)**

CONDITION	MAX. # DAYS PER 25 DAY PERIOD
OCP-3	3 days

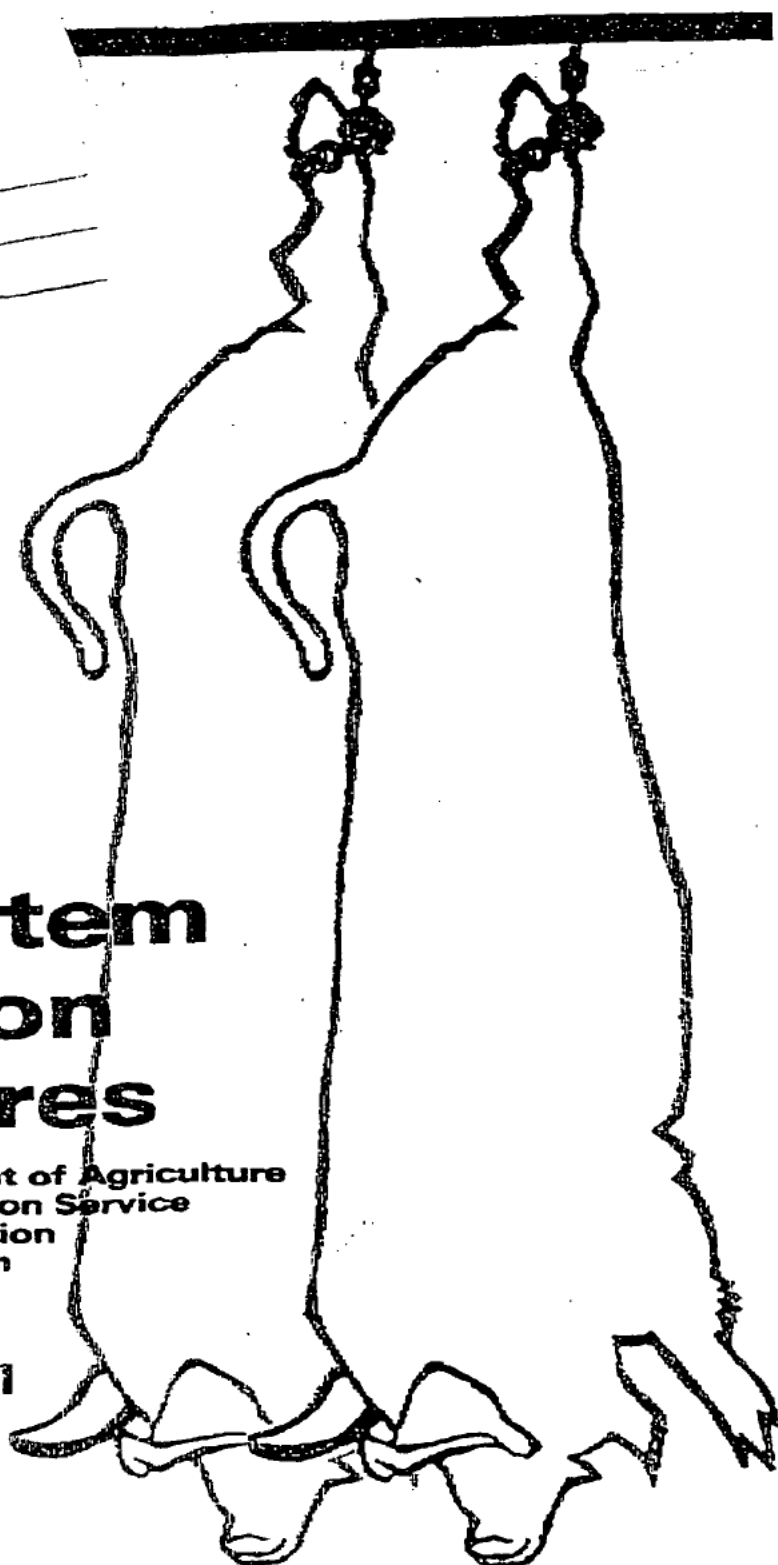


# Revised Swine Postmortem Inspection Procedures

United States Department of Agriculture  
Food Safety and Inspection Service  
Meat and Poultry Inspection  
Program Training Division



July 1981



HEAD

- STEP 1 OBSERVE HEAD AND CUT SURFACES. Observe the leading side of the head as the carcass approaches. The trailing side is observed after you have incised the mandibular nodes and observed the cut surfaces and as the carcass moves away from you.



- STEP 2 INCISE AND OBSERVE MANDIBULAR LYMPH NODES -- LEFT AND RIGHT. Use a wrist rolling motion to lay the slices open for greater exposure.

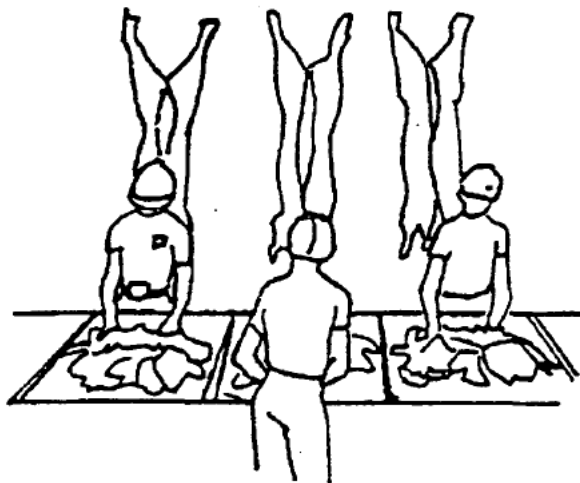


- STEP 3 OBSERVE/RETAIN CARCASS, WHEN REQUIRED. Normally it is not required to observe the carcass during head inspection. However while examining the head and cut surfaces you may see signs (such as abnormal color in the tissues) that may indicate a systemic condition. When this happens you should observe the carcass to determine if it should be retained for veterinary disposition.

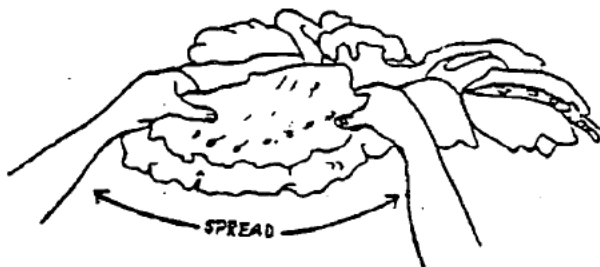


VISCERA

- 1 OBSERVE EVISCERATED CARCASS, VISCERA, AND PARIETAL (TOP) SURFACE OF SPLEEN. Viscera must be properly presented - mesentery toward you, spleen exposed, liver, and lungs dorsal surface up. The inspectors that face the carcasses should observe all of the eviscerated carcasses.

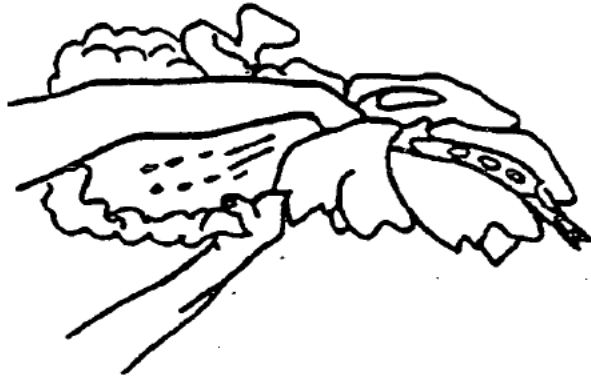


- 2 OBSERVE AND PALPATE MESENTERIC LYMPH NODES. Grasp and palpate the nodes in the center of the mesenteric lymph node chain with the thumb and fingers of both hands. Then palpate the remaining nodes in the chain by moving the hands away from the center toward the ends of chain. After this step is completed continue to grasp the end of the chain with your right hand. This will hold the viscera in place for the next step.



VISCERA (cont'd)

- STEP 3 PALPATE PORTAL LYMPH NODES. Grasp and palpate the portal nodes with the thumb and fingers of the left hand. Keep the left hand in this position to steady the viscera for the remaining steps.



- 4 OBSERVE DORSAL (CURVED) SURFACES OF LUNGS. Observe lungs while moving right hand into position over tracheobronchial (bronchial) nodes.





VISCERA (cont'd)PALPATE

~~THE~~ BRONCHIAL LYMPH NODES --  
AND LEFT. Palpate the right ~~and~~  
(left tracheobronchial nodes ~~USING~~  
the thumb and first 3 fingers of  
The right hand. (Use the ~~Thumb~~  
and index finger to ~~PALPATE~~  
~~the~~ the right node and the ~~MIDDLE~~  
~~and~~ and ring fingers to palpate  
left.)

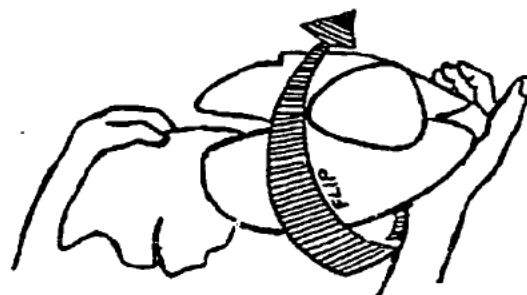
OBSERVE

~~THE~~ MEDIASTINAL LYMPH NODES.  
ight amount of pressure  
ted by the right hand will  
e the mediastinal space  
so the mediastinal nodes  
be easily observed.

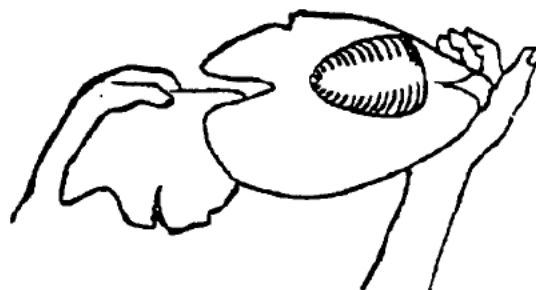


VISCERA (cont'd)

5. ) 7 TURN LUNGS OVER AND OBSERVE VENTRAL (FLAT) SURFACES. With a turn of the wrist and forearm of the right hand turn the lungs over so the lung's ventral surfaces may be observed.



- STEP 8 OBSERVE HEART. While observing the heart release the hold you have with your right hand and begin moving the hand toward the liver.

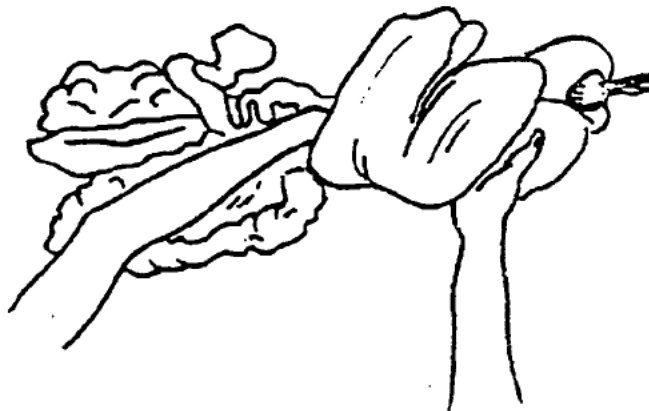


VISCERA (cont'd)

- EP 9 OBSERVE DORSAL (CURVED) SURFACE OF THE LIVER. As you observe the dorsal surface of the liver pass your right hand under the liver.

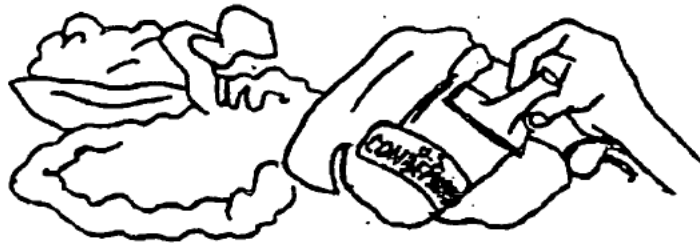


- EP 10 TURN LIVER OVER AND OBSERVE VENTRAL (FLAT) SURFACE. With a sweeping motion of the right hand lift the liver and turn it over allowing it to fall away from your grasp. Release your left hand from its hold on the portal nodes.



VISCERA (cont'd)

- EP 11 CONDEMN VISCERA OR PARTS WHEN REQUIRED. Identify as condemned those visceral organs or parts that require condemnation.



- EP 12 RETAIN CARCASS, VISCERA, AND PARTS WHEN REQUIRED. When veterinary disposition is required tag the viscera and retain the carcass and all parts, including the head.



①

CARCASS

STEP 1 LOOK IN MIRROR AND OBSERVE BACK OF CARCASS. The establishment is required to install a mirror at the carcass station so the back (dorsal) surfaces of the carcass may be observed without turning the carcass. Look for melanosis, abscesses, injection lesions, etc.



STEP 2 OBSERVE FRONT PARTS AND INSIDE OF CARCASS. This step includes observing those portions of the carcass not seen while looking at the carcass in the mirror. Such portions as the flank and neck regions of the carcass, the joints and axillary spaces, the entire front (ventral) surfaces of the carcass, as well as the cut surfaces and body cavities must be observed during this step.

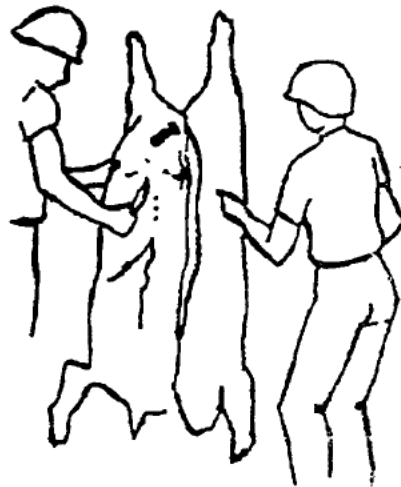


CARASSES (Cont.)

- 3 GRASP, TURN, AND OBSERVE KIDNEYS (BOTH SIDES). Turn the kidneys so that both sides may be observed.



- 4 DIRECT TRIM, REMOVE RETAIN TAGS, OR RETAIN CARCASS WHEN REQUIRED. When dressing defects or other abnormalities are observed take the required action.



**SWINE POST-MORTEM INSPECTION V****HEAD****STEP**

- 1 Observe head and cut surfaces.
- 2 Incise and observe mandibular lymph nodes.
- 3 Observe/retain carcass, when required.

**VISCERA****STEP**

- 1 Observe eviscerated carcass, viscera, and parietal (top) surface of spleen.
- 2 Observe and palpate mesenteric lymph nodes.
- 3 Palpate portal lymph nodes.
- 4 Observe dorsal surfaces of lungs.
- 5 Palpate bronchial lymph nodes.
- 6 Observe mediastinal lymph nodes.
- 7 Turn lungs over and observe ventral surfaces.
- 8 Observe heart.
- 9 Observe dorsal surface of liver.
- 10 Turn floor over and observe ventral surface.
- 11 Condemn viscera or parts when required.
- 12 Retain carcass, viscera, and parts when required.

**CARCASS****STEP**

- 1 Look in mirror and observe back of carcass.
- 2 Observe front parts and inside of carcass.
- 3 Grasp, turn, and observe kidneys (both sides).
- 4 Direct trim, remove retain tags, or retain carcass when required.

*// Inspectors must examine carcasses, organs, and parts for  
lesions, abnormalities, and diseases.*

*Leave back*

## SWINE POST-MORTEM INSPECTION 2

## STEP

## HEAD

- 1 Observe head and ear surfaces.
- 2 Inspect and observe mandibular lymph nodes.
- 3 Observe/trachea carcass, when required.

## STEP

## VISCERA

- 1 Observe external carcass, viscera, and gutted (top) surface of spleen.
- 2 Observe and palpate mesenteric lymph nodes.
- 3 Palpate parotid lymph nodes.
- 4 Observe dorsal surfaces of lungs.
- 5 Palpate bronchial lymph nodes.
- 6 Observe mediastinal lymph nodes.
- 7 Turn lungs over and observe ventral surfaces.
- 8 Observe heart.
- 9 Observe dorsal surface of liver.
- 10 Turn liver over and observe ventral surface.
- 11 Condition viscera or parts when required.
- 12 Retain carcass, viscera, and parts when required.

## STEP

## CARCASS

- 1 Look in mirror and observe back of carcass. 2/
- 2 Observe front parts and inside of carcass.
- 3 Grasp, turn, and observe kidneys (back side).
- 4 Direct trim, remove retain tags, or retain carcass when required.

1. d // Inspect and examine carcass, organs, and parts for  
 4261-255 (500) *muscle, abnormality, condition*

2. bony back



### Part 310 Post Mortem Inspection

310.1 Extent and time of post-mortem inspection; post-mortem inspection staffing standards.

310.1(b)(1) The staffing standards on the basis of the number of carcasses to be inspected per hour are outlined in the following tables. Standards for multiple inspector lines are based on inspectors rotating through the different types of inspection stations during each shift to equalize the workload.

**The inspector in charge shall have the authority to require the establishment to reduce slaughter line speeds where, in his judgment, the inspection procedure cannot be adequately performed at the current line speed because of particular deficiencies in carcass preparation and presentation by the plant at the higher speed, or because the health condition of the particular animals indicates a need for more extensive inspection.**



**Food Safety and Inspection Service**  
**United States Department of Agriculture**  
 Washington, D.C. 20250-3700

# Pathogen Reduction/HACCP & HACCP Implementation

October 4, 1999

## Role of Inspectors under Traditional Inspection and HACCP-based Models Project

Traditional Inspection	Models Project
Every carcass receives inspection	Every carcass receives inspection
Inspector has authority to stop line, as appropriate	Inspector has authority to stop line, as appropriate
Inspector has authority to retain adulterated product	Inspector has authority to retain adulterated product
Inspector has authority to withhold marks of inspection	Inspector has authority to withhold marks of inspection
Inspector can take action on insanitary conditions	Inspector can take action on insanitary conditions
Inspector sorts carcasses and directs plant to remove animals and birds before slaughter, and carcasses and parts after slaughter, that are unsafe for human consumption or unwholesome	Plant removes animals and birds before slaughter, and carcasses and parts after slaughter, to meet FSIS standards. Inspector oversees and verifies this process
Inspector located at fixed point on slaughter line	<i>2013 Fixed location</i> Inspector is free to move—at assignment by inspector-in-charge (IIC)—to any point on slaughter line needing oversight
Inspector defines corrective actions	Inspector oversees and verifies plant's corrective actions
Inspector identifies and directs plant to remove defects	Inspector oversees and verifies plant's identification and removal of defects; verifies that products meets FSIS standards
Inspector solves production control problems	Inspector oversees plant's solutions to production

	control problems
Inspector takes samples of products for analysis, using scientific and technical methods as determined by statistical design and IIC	Inspector takes samples of products for analysis, using scientific and technical methods as determined by statistical design and IIC
	Inspector conducts in-depth reviews of selected plant records, as determined by statistical design and IIC

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[Pathogen Reduction/HACCP Page](#) | [FSIS Home Page](#) | [USDA Home Page](#)

DRAFT  
**MARKET HOGS**



**HIMP**  
**(HACCP-BASED INSPECTION  
MODELS PROJECT)**

## **HIMP MARKET HOG INSPECTION**

### **Background**

FSIS collected data to determine the current food safety and other consumer protection achievements of the traditional inspection system in five market hog slaughter plants. The data were used to develop performance standards that volunteer plants in the HACCP-based Inspection Models Project (HIMP) must meet. The performance standards were published in a Federal Register Notice on November 2, 2000. A total of six performance standards were developed: three Food Safety categories (FS 1-3) and three Other Consumer Protection categories (OCP 1-3). The performance standards for the Food Safety categories (FS-1-3) were set at zero. The performance standards for the Other Consumer Protection categories (OCP 1-3) were based on the 75<sup>th</sup> percentile of the ranges of baseline data. (See Attachment 1)

### **Types of Inspection Activities**

The Market Hog HIMP pilot consists of three types of inspection activities: system inspection, carcass inspection, and verification inspection. System inspection involves the evaluation of in-plant inspection findings and determines the effectiveness of the overall design and execution of all establishment slaughter processes under the HACCP and process control plans. Carcass inspection involves the examination of each carcass and its parts to determine that they are unadulterated. Verification inspection involves the evaluation of the effectiveness of the establishment's HACCP and Process Control plan in meeting the relevant performance standards. These three types of inspection are discussed in further detail below.

**System Inspection** - The System Inspector (SI) is either the Inspector in Charge (IIC) or the Supervisory Veterinary Medical Officer (SVMO). The SI has overall responsibility to assure that the plant and inspection personnel effectively conduct the required activities under the HIMP, as designed. The SI sends verification data to headquarters and provides overall feedback on how the project is working. Specifically, the SI:

- Determines (or assigns to the verification inspector (VI))\* the daily random sampling schedule and provides the schedule to the VI.
- Monitors and determines the effectiveness of ante-mortem verification inspection.
- Monitors and determines the effectiveness of the establishment ante-mortem sorting.
- Determines final disposition of animals designated by the VI as "suspects" at ante-mortem.
- Monitors and determines the effectiveness of the establishment's post-mortem sorting and disposition.
- Determines final disposition on carcasses retained by the carcass inspector (CI) or VI on post-mortem.\*
- Records FS-1 and FS-3 nonconformance findings on the appropriate HIMP form.
- Determines if the establishment is meeting relevant performance standards.
- Assesses the overall design and execution of the establishment's HACCP and process control procedures.
- Assures that all adulterated products are condemned in accordance with applicable regulations.
- Determines when unscheduled verification sampling is warranted.

- Maintains communication with the VI and CIs to facilitate coordination of all ante-mortem and post-mortem findings.

**Carcass Inspection** - The Carcass Inspectors (CI) are stationed at up to 3 fixed locations on the post-mortem line to determine whether a product is adulterated or unadulterated. They inspect each carcass and part on the line, as well as evaluate the on-going effectiveness of the establishment's food safety and other consumer protection processes. Specifically, the CIs:

- Determine whether each carcass and its parts are adulterated or unadulterated.
- Take appropriate action to prevent adulterated product from entering into human food channels.
- Notify the establishment personnel, VI and/or SI of carcass and/or parts defect findings.
- Examine sample sets when notified by the VI and verbally inform the VI during sampling when defects are found.
- Contact the SI if there are any concerns about process control.
- Retain carcasses and parts for further disposition by the SI if food safety and other conditions are identified that could result in condemnation.
- Maintain communication with the VI and SI to facilitate coordination of all post-mortem findings.

**Verification Inspection** - The Verification Inspector (VI) does not have a fixed position on the line, and can move freely. Specifically, the VI:

- Observes and evaluates the effectiveness of the establishment's HACCP and process control plans, including the examination of records, to determine whether the establishment is in compliance with applicable regulatory requirements.
- Conducts ante-mortem inspection of all animals at rest and 5-10 percent of animals in motion.
- Retains animals for further disposition by the SI, if the animal is suspected of having a condition that could result in condemnation.
- Documents ante-mortem findings on HIMP FORM 9.
- Takes verification samples to determine if establishment is complying with relevant performance standards, including scheduled and unscheduled sampling.
- Records all findings of noncompliance with applicable performance standards.
- Notifies the CI when verification samples are required and records the findings in each sample set during post-mortem. Evaluates the noncompliance findings and records in the appropriate category on HIMP form 7.
- Investigates potential process control problems.
- Notifies SI if the process control plan is not being met or if performance standards have been exceeded.
- Retains carcasses and parts for further disposition by the SI if food safety and other conditions are identified that could result in condemnation.
- Maintains communication with the CI and SI.

## **MARKET HOG INSPECTION STATION**

### Facilities required at each inspection station include:

1. The conveyor and/or rail shall be level for the entire length of the inspection station.
2. Floor space shall be adequate along the conveyor and rail.
3. Conveyor and rail stop/start switches shall be readily accessible.
4. A minimum of 50 foot-candles of shadow-free lighting shall exist at each inspection station.

### Inspection Stations will be established at up to 3 locations:

FSIS personnel are responsible for inspecting each head, viscera, and carcass. These locations will be:

1. After the mandibular lymph node incision step and before the head removal step for the Head Inspection Station.
2. After the establishment's viscera sorting step and before the viscera harvesting step for the Viscera Inspection Station.
3. After the final trim and sorting step and before the carcass wash step for the Carcass Inspection Station.

Inspection locations may be combined if carcass and/or parts (head and viscera) can be inspected at a single location. (Example: combining the viscera with carcass inspection if they can be inspected at one location.). Proposals for less than three inspector locations must be presented to the HIMP Project Manager.

## DOCUMENTATION

The forms used for the HIMP Market Hog project are:

- HIMP FORM-7, Postmortem Verification Inspection Activities
- HIMP FORM 8-1 OCP-1 25 Day Results
- HIMP FORM 8-2 OCP-2 25 Day Results
- HIMP FORM 8-3OCP-3 25 Day Results
- HIMP FORM-9 Ante-Mortem Verification Inspection Activities
- HIMP FORM-10 HIMP Verification/Corrective Action Log
- FSIS Form 5400-4 Noncompliance Record (NR)

### **FS-1 and FS-3 nonconformance documentation -**

- The SI makes the final disposition on carcasses retained by inspection personnel on FS-1 and FS-3 categories and documents the FS-1 and FS-3 nonconformance on a NR as ISP code 03J01.
- If the SI finds additional noncompliance for **this specific slaughter production lot**, the SI will document the findings on separate NR's.
  - All findings must be taken into consideration after the NR is written. The SI also checks the plant's corrective actions. All findings and plant's corrective actions are to be documented on the NR.
- The 03J02 procedure is considered to be complete when inspection personnel have verified the establishment's pre-shipment review.
- The SI will inform the VI to document FS-1 non-conformances on the daily HIMP Form 7
- The SI will document FS-3 non-conformances on the HIMP form 9.

### **FS-2 nonconformance documentation -**

- An FS-2 nonconformance is documented when feces, ingesta or milk are identified during verification activities.(according to the identification guidelines in FSIS Directive 6420.2).\*
- The CI at the final carcass inspection station will follow FSIS Directive 6420.2 *Livestock Post-Mortem Inspection Activities-Enforcing the Zero Tolerances for Fecal Material, Ingesta, and Milk* Section II. B. 1 as it pertains to the final rail inspector.\*
- The VI, when performing FS-2 verification, will document an FS-2 nonconformance on a NR as ISP code 03J01.
- If the VI finds additional noncompliance **for this specific slaughter production lot**, the VI will document their findings on additional NR's.
- All findings must be taken into consideration by the VI that found the noncompliance or another VI. The VI also checks the plant's corrective actions. All findings and plant's corrective actions are to be documented on the NR.
- The 03J02 procedure is considered to be complete when the VI has verified the establishment's pre-shipment review.
- The FS-2 nonconformance is also to be documented by the VI on HIMP FORM-7.



**OCP nonconformance documentation –**

The VI or SI will document the OCP nonconformance findings during the shift on Draft HIMP form 7.

- If the establishment exceeds the daily maximum limit (See Table 1) for a specific OCP category, the VI will notify the SI.
- At the end of each shift, the SI will document the number of defects and pass/fail for each OCP category on HIMP FORMS 8- 1 through 8-3.

## **VERIFICATION PROCEDURES**

FSIS conducts verification inspection to assure that plants are meeting the performance standards. Verification inspection occurs in ante-mortem and post-mortem.

### **ANTE-MORTEM**

- Establishment ante-mortem records for the FS-3 category are to be reviewed by the VI or SI.
- The VI or the SI will inspect 100% of live animals at rest that are presented by the establishment for slaughter.
- The SI (or assigns to VI) randomly selects ante-mortem sampling times throughout the shift. Ante-mortem sampling times can be scheduled if the entire kill is available prior to start of shift. Usually live animals continue to be shipped to the establishment throughout the day and it is not possible to schedule the times for random sampling. Therefore, it is left to the discretion of the SI to determine randomness of sampling throughout the shift when live animals are available.
- The VI or SI will inspect 5-10% of the live animals in motion randomly throughout the shift after establishment sorting for slaughter.
- The VI or SI will assess sorting activities and humane handling practices.
- The SI will assess plant activities at the suspect pen.
- The VI will retain as suspect for SI disposition any animal that could result in condemnation.
- FS-3 deficiency determined by the SI will be documented by the SI on a NR and the establishment follows HACCP procedures in 9 CFR 417.3.
- The SI will document or notify the VI to document any FS-3 deficiency on HIMP Form 9.
- Other deficiencies found on ante-mortem sampling by the VI will be reported to establishment and the SI (such as humane handling).
- A NR is to be documented for humane handling violation. The ISP procedure code for violations related to humane handling and slaughter is **04C02**. \*

### **POST-MORTEM**

The verification sampling procedures for both food safety and other consumer protection performance standards will be conducted on 24 randomly selected samples for each shift. This procedure can be conducted either off-line or on-line. If conducted on-line, the VI will identify the samples and have the CI's examine each part and carcass, starting with the head inspection station. The VI will follow the samples through the entire process and record all defects found during the CI examination. The VI will record a maximum of one defect in each performance standard category per sample unit (e.g., a sample having bile and a bruise on the carcass would be identified as 1 OCP-3 defect. A sample having arthritis and fecal contamination of the viscera would be identified as 1 OCP-1 and 1 OCP-2).

In addition, the VI or SI will review establishment post-mortem records for FS-1. The SI and/or VI will review other establishment post-mortem records.

## 1) General

- A sample consists of a carcass with corresponding head and viscera.
- The SI or the VI will notify the on-line CI when to inspect verification samples during the shift.
- The CI, when notified by the VI, will inspect the verification samples of the carcass with corresponding viscera and head per shift and verbally inform the VI of their findings during sampling.
- The 24 unit samples per shift may be taken in subsets.
  - Sample subsets may be randomly taken in one of the following manners:
    - 3 samples 8 times per shift.
    - 4 samples 6 times per shift.
    - 6 samples 4 times per shift.
    - 8 samples 3 times per shift.
- Any OCP defects, which are identified at the inspection stations, should be identified to the establishment but not scored toward plant performance unless it is part of a scheduled or unscheduled sample subset.
- Sample times and sample subsets are to be selected randomly prior to the start of the shift.
- The VI or SI will record findings on DRAFT HIMP Form-7. It is not necessary to record a specific condition within a performance standard category (i.e., localized lung or heart conditions would be recorded as a noncompliance of the OCP-1 performance standard category).
- If the establishment is engaged in product/process action at the time the random sample is to be taken, the VI will suspend random sampling until the establishment has completed its actions.

## 2. FS1 and FS 2

- Establishment post-mortem records for FS-1 and FS-2 categories are to be reviewed by the VI or SI in accordance with 9 CFR 417.8.
  - The CI, when notified by the VI, will examine the sample subsets for indications of FS-1 and FS-2 defects and verbally relay the information to the VI.
    - 1) FS-2 defects are recorded at the post-mortem rail inspection station.
    - 2) The CI will retain carcasses with potential FS-1 defects for final disposition by the SI. If the VI/SI finds additional non-compliance for this slaughter production lot, the VI/SI will document each additional FS-2 defect findings on separate NR's. \*
    - 3) The CI at the Pre-Wash Verification Location Inspection Station will identify potential FS-1 and FS-2 defects. The CI will retain the carcass for final disposition by the SI. The CI will identify FS-2 defects and take the appropriate action consistent with established HACCP procedures. The VI/SI will document the FS-2 defect that was found by the CI on a NR. If the VI/SI finds additional non-compliance for this slaughter production lot, the VI/SI will document each additional FS-2 defect findings on separate NR's. \*
- No carcasses are allowed to exhibit FS-2 defects at the post-mortem rail inspection station. The CI will follow instructions for "on-line inspection personnel" in FSIS Directive 6420.2. The CI will have the defect removed either by railing the carcass out or having it trimmed on-line. Notify the SI/VI for possible unscheduled verification sampling. \*
- The SI will write a NR for FS-1 noncompliance.
- The VI will write a NR for FS-2 noncompliance observed during verification sampling in accordance with FSIS Directive 6420.2.\*

### 3. OCP

- The CI or VI will retain a carcass for final disposition by the SI when OCP defects are found that could result in condemnation.
- If the VI or SI determines that defects in an OCP category exceed the performance standard as stated in Table 1, the VI or SI will check the establishment's process control records for the same time frame. If the establishment results show a potential or actual loss of control as defined in the establishment's process control plan (PCP), the VI or SI will check the establishment's records to determine whether corrective actions described in the PCP were taken.

**TABLE 1: OCP Maximum defects allowed Per Shift**

<b>SAMPLE SIZE</b>	<b>24 SAMPLES (Head, Viscera, carcass)</b>	<b>UNSCHEDULED 27 SAMPLES</b>	<b>UNSCHEDULED 30 SAMPLES</b>	<b>UNSCHEDULED 33 SAMPLES</b>
<b>OCP-1</b>	2	2	2	2
<b>OCP-2</b>	3	3	3	3
<b>OCP-3</b>	7	7	8	9

- If the establishment failed to take proper corrective action according to their PCP, the establishment should detail what new corrective and preventive action will be implemented to prevent recurrence. Any samples that exhibit defects in any of the OCP performance standard categories should be pointed out to establishment personnel.

### Unscheduled Verification Inspection

When the SI determines that an unscheduled inspection should occur, the SI will notify the VI to conduct the inspection. Each unscheduled verification inspection will be three carcasses with corresponding viscera and head.

- Unscheduled verification sampling done at the direction of the SI will also be recorded on Draft HIMP Form 7.
- Unscheduled verification sampling will count toward the establishment's performance evaluation (See Table 1).
- The SI may call for unscheduled verification inspection because a CI has identified a potential problem.
- The SI may call for unscheduled verification inspection after the establishment has had sufficient opportunity to correct an establishment identified problem. This would confirm that the problem has been corrected.
- The establishment is notified of unscheduled verification inspection.
- The SI and/or VI will notify the establishment of the results of unscheduled verification sampling and establishment record examinations.

## EXAMINATION OF PLANT SAMPLING RECORDS FOR OCP'S

- In addition to the 24 OCP samples, VI will review establishment's records for OCP sampling results at least three times per day.
- Examples of plant records evaluation may also include observations of the plant selecting samples and data recording procedures.
- The VI or SI should record the results on the Draft HIMP Form 10.
- The VI will notify the SI of any discrepancies in the record examination.

HIMP 7  
 1/2 Post.

### SI evaluation of OCP 1 through 3 for 25 day performance

- To evaluate whether the establishment maintains process control, the SI will track the performance of OCP 1 through 3 for a 25-day period using Draft HIMP Form 8-1 through 8-3 and Table 1.
- Each OCP will be tracked each shift and referenced to the Table 1 values.
- The SI will record that the plant passed or failed each of the 3 OCP categories on the appropriate HIMP form 8 and notify the plant of their findings.
- For an entire 25-day period, the maximum number of days on which the Table 1 performance standards can be exceeded is given in Table 2.

**TABLE 2: Maximum Days (OCP's)  
 (Number of Days Above maximum defects  
 allowed Per 25-Day Period)**

OCP-1	2 days
OCP-2	4 days
OCP-3	3 days

- If the plant exceeds the maximum days for any OCP category listed in table 2 for a 25-day period, at any point during the 25 days, the SI will write a NR coded 04C01. The plant should detail what new corrective and preventive actions are implemented to prevent recurrence. The plant will provide this information to the SI.

Note: A 25 day period will end at a full 25 days provided that the Table 2 Maximum Number of Days are not exceeded. If the Table 2 Maximum Number of Days are exceeded before 25 days are completed, e.g. on the 13th day, the period stops then while the plant responds as described above. A new 25-day period will begin when those conditions are satisfied.

## Correlation

The SI and/or VI will meet regularly with plant management to conduct correlation activities during the transition period. Regular correlation will aid FSIS and the plant in establishing a common basis for both FS and OCP determinations.

Am - CCF - 10/10/05  
 - 10/10/05  
 P/L - 10/10/05  
 FS - 10/10/05  
 10/10/05  
 10/10/05

**Attachment 1****Model Performance Standards for Market Hogs Plants**

<b><u>Performance Standard Categories</u></b>	<b><u>Plant Performance Standards</u></b>
<b>FS-1—Condition – Infectious</b> (for example: septicemia/toxemia, pyemia, cysticercus)	<b>Zero</b>
<b>FS-2 – Condition – Digestive Content/Milk</b> (for example: fecal material, ingesta, milk)	<b>Zero</b>
<b>FS-3 – Ante-mortem Suspect</b> (for example: neurologic conditions, moribund, pyrexia, severe lameness)	<b>Zero</b>
<b>OCP-1 – Carcass- Pathology*</b> (for example: arthritis, emaciation,, erysipelas, localized abscess, mastitis, metritis, mycobacteriosis [M Avium], neoplasms, pericarditis, pleuritis, pneumonia, uremia)	<b>4.1%</b>
<b>OCP-2 – Visceral Pathology*</b> (for example: cystic kidneys, enteritis/gastritis, fecal contamination of viscera, nephritis/pyelonephritis, parasites—other than Cysticercus, peritonitis)	<b>7.2%</b>
<b>OCP-3 – Miscellaneous</b> (for example: anemia, bile, bruise, edema, external mutilation, fractures, icterus, odor, skin lesions, scabs, toenails not removed)	<b>20.5%</b>

**\*Conditions exhibiting a septicemia or toxemia are considered food safety hazards**





Food Safety and Inspection Service  
United States Department of Agriculture  
Washington, D.C. 20250-3700



Pathogen Reduction/HACCP & HACCP Implementation

July 22, 1998

## HACCP-Based Inspection Models Project: Diseases and Conditions Observable in Meat and Poultry

### Background

In a June 10, 1997, Federal Register notice, the Food Safety and Inspection Service (FSIS) requested public comments on the design and development of new inspection models for slaughter and processing in a Hazard Analysis and Critical Control Point (HACCP) environment (62 FR 31553). In a section discussing the need to reform the meat and poultry inspection program, the notice summarized recommendations by the National Academy of Sciences and the General Accounting Office that FSIS reduce its reliance on organoleptic inspection, shift to prevention-oriented inspection systems based on risk assessment, and redeploy its resources in a manner that better protects the public from foodborne diseases. FSIS will study how to bring about such inspection changes and resource redeployments during its HACCP-Based Inspection Models project. A June 24-25, 1997, public meeting, which the notice announced, provided a forum for dialogue between FSIS and all parties interested in the project. The project has been discussed in meetings of the National Advisory Committee on Meat and Poultry Inspection and in other forums.

Establishments volunteering to participate in the HACCP-Based Inspection Models project will carry out activities relating to food safety and other consumer-protection matters. FSIS will conduct activities aimed at improving inspection-system compatibility with the Pathogen Reduction/HACCP regulations. FSIS will develop inspection models in which slaughter process control is an industry responsibility under FSIS oversight and verification.

One step in the development of these inspection models is that of distinguishing, at post-mortem, animal diseases and conditions that are food-safety hazards from diseases and conditions that are objectionable for other reasons. This document reflects the current FSIS view of that distinction. In the course of the inspection models project, the volunteer establishments will decide how best to verify the removal from the food supply of carcasses or parts affected by these diseases and conditions and FSIS will decide how best to verify their removal. These decisions will depend partially on a consideration of this document.

Please submit written comments on this document to Ms. Patricia Stolfa, Assistant Deputy Administrator, Office of Policy, Program Development and Evaluation, Room 402 Cotton Annex, 300 12<sup>th</sup> Street SW, Washington, DC 20250-3700. Comments may also be provided by facsimile (202-401-1760).

### HACCP-Based Inspection Models Project: Food-Safety-Related and Other Diseases and Conditions Observable at Post-Mortem

Volunteer establishments will conduct a pathological and anatomical examination of each carcass while FSIS oversees and verifies the establishments' process controls. Livestock and poultry diseases and conditions identified at post-mortem are categorized according to their food-safety or other consumer-protection significance. Diseases and conditions likely to present a meat- or poultry-borne hazard to public health are considered food-safety hazards. Diseases and conditions having other consumer-protection significance are defects that rarely or never present a direct public health risk, but that are unacceptable components of meat and poultry products. Diseases and conditions in both categories are to be removed from the human food supply. Establishments will consider food-safety-related diseases and conditions for inclusion in their HACCP plans.

2 (vet.) Am - USDA  
CCP 2  
CCP 2

10 Carcasses, viscera/pho  
for PS Condition  
10 Carcasses, viscera & Tura  
day shift for CCP



**Part I -- Diseases and Conditions that Affect Food Safety****Food Safety Hazards**

FSIS has identified two general post-mortem food-safety categories: (1) Infectious Conditions and (2) Contamination. Food-safety-related infectious conditions and contamination are identified organoleptically, that is, by using the senses, and are presumed to contain infectious agents (bacteria, virus, rickettsia, fungus, protozoa or helminth organisms) that may cause a food to be unsafe for human consumption *and* that are likely to be transmitted through meat and poultry. Examples of diseases and conditions in each category are listed below.

**(1) Infectious Conditions that Affect Food Safety**

- (i) localized – remove lesion(s) and pass unaffected carcass portions
- (ii) generalized – condemn or treat to render non-infective

**Examples:**

- Abscess: A localized collection of pus.
- *Cysticercus bovis* \* : The larval form of *Taenia saginata*. Any single cysticercus indicates generalized infection.
- *Cysticercus cellulosae* \* : The larval form of *Taenia solium*. Any single cysticercus indicates generalized infection.
- *Mycobacterium bovis* (included to support eradication surveillance).
- Pyemia: Septicemia associated with multiple abscesses arising from vascular dissemination of pyogenic organisms.
- Septicemia: Systemic disease associated with the presence and persistence of pathogenic organisms in the bloodstream.
- Toxemia: Systemic disease associated with bacterial products (toxins) in the bloodstream.

**(2) Contamination – prevent or remove in accordance with establishment HACCP plan**

\* Dependent on other elements in the HACCP plan. On-farm production records demonstrating no cysticercosis in a herd may obviate the need for cysticercosis in the slaughter component of the HACCP Plan.

**Examples:**

- Fecal material
- Milk (livestock)
- Ingesta (livestock)

**Part II -- Diseases and Conditions with Consumer-Protection Implications Not Related to Food Safety**

FSIS has identified four general categories of diseases and conditions that affect consumer protection because they adulterate products but that are not food-safety hazards. The categories and examples of diseases and conditions are listed below.

**(1) Animal infectious conditions. Animal infectious conditions contain infectious agents that do not render foods unsafe to humans or are unlikely to be transmitted to humans.**

- (i) localized – remove lesion(s) and pass unaffected carcass portions
- (ii) generalized – condemn or treat to render non-infective

**Examples:**



- Actinomycosis
- Actinobacillosis
- Airsacculitis
- Arthritis – infectious ✓
- Ascariasis
- Caseous lymphadenitis
- Coccidioidal granuloma
- *Cysticercus ovis*
- *Cysticercus tenuicollis*
- Erysipelas
- Fascioliasis
- Infectious process
- Mastitis
- Metritis
- *Mycobacterium avium*
- Nephritis, pyelitis
- Osteomyelitis
- Pericarditis
- Peritonitis
- Pleuritis
- Pneumonia
- Synovitis

## (2) Neoplasia (tumors)

- (i) localized –remove localized lesion(s) and pass unaffected carcass portions
- (ii) metastatic – condemn

### Examples:

- Carcinoma
- Epithelioma
- Lymphoma
- Sarcoma

## (3) Pigmentary, metabolic, degenerative conditions

- (i) localized –remove localized lesion(s) and pass unaffected carcass portions
- (ii) generalized – condemn

### Examples:

- Anasarca
- Anemia
- Arthritis – degenerative
- Ascites
- Emaciation
- Eosinophilic myositis
- Icterus
- Melanosis
- Sawdust liver
- Telangiectasia
- Uremia

- Xanthosis

#### (4) Miscellaneous

- (i) localized –remove localized lesion(s) and pass unaffected carcass portions
- (ii) generalized – condemn

#### Examples:

- Bruises
- Cadaver -- always considered generalized
- Fetus -- always condemned
- Fractures
- Overscald

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Food Safety and Inspection Service  
United States Department of Agriculture  
Washington, D.C. 20250-3700

## Key Facts

December 1998

# Slaughter Inspection Under the HACCP-Based Inspection Models Project- -Oversight and Verification

## Introduction

FSIS is developing new models for slaughter inspection to be used in pilot plants that are extending their Hazard Analysis and Critical Control Point (HACCP) systems to cover additional parts of their slaughter operations. Only plants that slaughter young, healthy, uniform animals are being accepted as volunteers for this project.

The HACCP-Based Inspection Models Project is designed to test whether new government slaughter inspection procedures, applied in conjunction with extended plant HACCP controls, can improve food safety and increase consumer protection. Implementing HACCP alone does not fully accomplish this objective because FSIS continues to use its slaughter inspection workforce in traditional ways. This means that, during the slaughter process, FSIS inspectors have assumed responsibility for identifying and removing defects, defining corrective actions to prevent problems, and solving production control problems. This is in direct contrast with how FSIS inspection personnel now function with respect to other plant process control systems--HACCP and Standard Operating Procedures for sanitation. Here, plants assume their proper responsibilities for process control, and FSIS verifies that they are meeting regulatory requirements.

As part of the model development process, FSIS is further describing the procedures—oversight inspection and verification inspection—that inspectors will perform in slaughter plants participating in the project. FSIS will test different staffing arrangements in order to determine the most effective means of carrying out its inspection responsibilities. All existing statutory responsibilities will be met under the new inspection procedures.

Success of the new slaughter inspection models will permit FSIS to better use its resources and focus more aggressively on improving food safety and addressing public health concerns such as microbial pathogens. For example, FSIS already has set pathogen reduction performance standards for *Salmonella* and intends to set standards for *Campylobacter*. FSIS will also be able to move forward more quickly on implementation of its farm-to-table strategy by redeploying inspection resources made available through the models to carry out activities in-distribution.

## Volunteer Plants

Baseline data collection has been completed in an initial group of volunteer plants that slaughter certain market classes of young, healthy, and uniform animals. These first five plants slaughter young poultry and market hogs. They are: Jennie-O Foods, Inc., Wilmar, MN, a turkey plant; Hatfield, Inc., Hatfield, PA, a swine plant; Rocco Farm Foods, Edinburg, VA, a poultry plant; Quality Pork Processors, Austin, MN, a swine plant; and Goldkist Inc., Guntersville, AL., a poultry plant. (Claxton Poultry Farms, Claxton, GA, a poultry plant, has deferred participation in the project until next year.) FSIS expects to expand the pilot project to involve more plants.

These plants will extend their HACCP plans to include food safety hazards that may occur beginning when live animals or birds enter the facility. In addition, the volunteer plants will design and implement process control plans that address other consumer protection matters, such as removing bruises and other quality defects. When volunteer plants take on these process control responsibilities, the FSIS inspection team will be able to implement and evaluate the new slaughter inspection procedures.

## Oversight Inspection and Verification Inspection

In the pilot plants, slaughter inspection will consist of two types of procedures: oversight inspection and verification inspection. Only government inspectors will perform these procedures, and all government inspectors in the plant will be trained and expected to perform both types of procedures. The number of inspectors needed to perform these inspection procedures will vary according to factors such as plant size and complexity of its operations. The inspector-in-charge (IIC)--a veterinarian or other professional with a scientific background--will determine how to allocate inspection resources in the plant.

### Oversight inspection

Under oversight inspection, FSIS inspectors make expert and informed observations of the company's HACCP and process control systems and immediately communicate process variations to the inspector-in-charge (IIC). HACCP systems address food safety concerns, and process control systems address other consumer protection concerns. *Every carcass will receive oversight inspection.* Whenever the plant is slaughtering, oversight inspection will occur.

Unlike the current system, where slaughter inspectors are assigned to fixed points along the slaughter line, under the models, inspectors may be assigned to perform oversight inspection at any point in the slaughter process. Inspectors may perform oversight inspection at places where plant employees are monitoring critical control points, at points where critical equipment such as poultry eviscerators are operating, or at the location where live animals and birds are arriving at the plant. In addition to performing oversight inspection at varied locations, inspectors will rotate through oversight inspection assignments. Under the current system, individual inspectors often spend long periods of time at one location, looking at carcasses that are highly uniform. Under the models, the IIC will determine where oversight inspection will be conducted and will assign a large portion of oversight inspection resources to sanitary dressing operations--removing inedible portions and making sure the edible portions are suitable for human consumption.

Inspectors conducting oversight inspection will be equipped with modern technology to immediately report to the IIC any observations of process variation beyond normal variation at their assigned locations. Food production processes are expected to vary throughout the day, and process control systems are designed to define normal variation and respond to it. At the time an oversight inspector observes a variation, he or she may not know if, down the line, the system catches and responds suitably to that variation. For example, the eviscerating equipment in a poultry plant may not be perfectly aligned for the size birds that have arrived that morning--as a result, an unusual portion of carcasses may be contaminated. The oversight inspector will immediately communicate this information to the IIC, who will decide how to respond.

### Verification inspection

Verification is the other type of slaughter inspection under the new system. It consists of inspectors taking samples of products and plant records and carefully examining them. In examining these samples, verification inspectors will use a variety of scientific and technical methods to make sure that regulatory requirements have been met by the plant's control systems.

The frequency with which verification inspections will be conducted will be driven by two factors. There will be a routine or steady-state frequency designed to confirm successful performance. If successful, eventually this frequency will be incorporated into the agency's Performance Based Inspection System (PBIS)--the automated system through which inspection assignments are communicated and results reported. In addition, the IIC may choose to assign extra verification inspection procedures in response to oversight inspection findings reported to him or her. This strategic assignment of extra verification inspections will enhance the capacity of the regulatory system to hold establishments accountable for the continuous successful operation of their HACCP and other process control systems.

Verification inspection procedures will be carried out by inspectors after the company's process control systems have been completed. The slaughter process is generally considered to be complete after final washing and before carcasses enter the process for reducing temperatures. Thus, in poultry establishments, for example, samples taken after the final

wash but before carcasses enter the chiller will be carefully examined for a variety of food safety and other consumer protection defects that should be removed by this point.

## Daffing Implications

The Agency has no plans to reduce its workforce. FSIS does, however, expect that its new slaughter inspection procedures will result in a need for fewer in-plant inspectors. Initially, in these five plants, FSIS will have one inspector per line for oversight, one or more inspectors per plant for verification, and one veterinarian per plant. Inspectors not needed in these plants will be used to cover existing vacancies as well as to perform in-distribution activities.

## Regulatory Action by Inspection Personnel

Under the models, plants are required to take corrective action if their process control systems are not producing products meeting Federal standards. The authority of inspection personnel to take action in plants will be the same as in plants operating under traditional inspection. Inspectors have the authority to stop the line as appropriate, retain product that they believe is adulterated or misbranded, to withhold the marks of inspection, and to reject facilities, equipment, or any parts of the plant they determine are not in compliance with the regulations.

## For Additional Information

General inquiries on the models project:

- Patricia Stolfa, leader, Steering Committee on the HACCP-based Inspection Models Project, (202) 205-0699
- Michael Grasso, special assistant, Office of Policy, Program Development, and Evaluation, (202) 205-0010

IS Steering committee on the HACCP-based Inspection Models Project:

- John McCutcheon, Office of Field Operations, (202) 720-5190
- William James, Office of Public Health and Science, (202) 501-7321
- Marlin Waller, Office of Management, (202) 720-4828
- Cheryl Hicks, Food Safety Executive Management and Coordination Staff, (202) 690-3881
- Danielle Schor, Congressional and Public Affairs Staff, (202) 690-0997.

Media Inquiries: (202) 720-9113

Congressional Inquiries: (202) 720-3897

Constituent Inquiries: (202) 720-8594

Consumer Inquiries: Call USDA's Meat and Poultry Hotline at 1-800-535-4555. In the Washington, DC, area, call (202) 720-3333. The TTY number is 1-800-256-7072.

FSIS Web site: <http://www.fsis.usda.gov>

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### For Further Information Contact:

FSIS Congressional and Public Affairs Staff

Phone: (202) 720-3897

Fax: (202) 720-5704

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<http://www.fsis.usda.gov/OA/background/keyover.htm>

2/13/2006



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, D.C.  
20250

OCT 2 2006

Dr. (b) (6)  
Chief Veterinary Officer  
Ministry of Agriculture, Nature and Food Quality  
PO Box 19506  
2500 CM, the Hague  
Netherlands

Dear Dr. (b) (6):

This letter is in response to the July 14, 2006, letter from Dr. (b) (6), Deputy Chief Veterinary Officer, in which he provided results of the pilot project on visual post-mortem inspection of swine and provided information on the reorganization of the meat inspection system in the Netherlands, and requested a follow-up meeting to further discuss the following two issues:

1. Use of visual post-mortem inspection for swine carcasses in establishments certified to export to the United States. In the letter, Dr. (b) (6) indicates that visual post-mortem inspection has become a normal inspection procedure in certain slaughter establishments that are certified for export to the United States.
2. Use of auxiliaries to conduct certain post-mortem inspection activities in establishments certified to export to the United States. The letter is not clear as to whether auxiliaries are currently being used to conduct these post-mortem activities. We understand that the use of auxiliaries is based on provisions contained in EC 852/2004 and EC 854/2004.

We would be pleased to discuss these issues further in a teleconference and are working to arrange such a call. However, we want to make it clear that when a Netherlands establishment is producing product destined for the United States, neither of these proposed changes can be used until FSIS completes an equivalence determination. If the changes have already been instituted in U.S.-certified establishments, and cannot be reversed, these establishments should suspend exports to the United States.

If you have questions regarding this matter, you may reach me by telephone at 202-720-3187, by facsimile at 202-690-4040 or electronic mail at [sally.white@fsis.usda.gov](mailto:sally.white@fsis.usda.gov).

Sincerely,

Sally White  
Director  
International Equivalence Staff  
Office of International Affairs

**Mughal, Ghias**

---

**From:** Seebohm, Scott  
**Sent:** Friday, November 17, 2006 9:30 AM  
**To:** Mughal, Ghias  
**Cc:** Smith, David  
**Subject:** RE: additional articles and revised answer Q6 reg. visual inspection

Ghias,

Comments on the additional references:

1. Wallace and Hannah, "Mycobacterium avium Complex Infection in Patients with the Acquired Immunodeficiency Syndrome." This paper describes findings related to MAC infections in AIDS individuals. It has little relevance to the present equivalence determination.
2. "Summary of thesis: Incision of heart during meat inspection of pigs: a risk analysis approach." This paper finds that heart incision has little importance for public health. The issue is not relevant to the current equivalence determination since the US doesn't incise swine hearts at inspection.
3. "Audit and verification procedures regarding supply chain meat inspection." This is a written summary of the information provided during the meeting regarding verification activities, including slaughterhouse and on-farm verification activities.

Scott Seebohm, DVM  
 Staff Officer  
 FSIS Technical Service Center  
 402-344-5000 / 800-233-3935

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**From:** Mughal, Ghias  
**Sent:** Wednesday, November 15, 2006 3:59 PM  
**To:** Seebohm, Scott  
**Subject:** FW: additional articles and revised answer Q6 reg. visual inspection

Scott, you were absolutely correct. I forgot to send you these and other set that came in this week. Here is one set. I will send the other set separately.  
 Thanks

*M. Ghias Mughal, DVM; M.S; Ph.D.*  
 Senior Equivalence Officer,  
 Office of International Affairs  
 USDA, Food Safety and Inspection Service  
 1400 Independence Avenue, SW  
 Washington, DC 20250  
 Phone: 202 720-6400  
 Email: ghias.mughal@fsis.usda.gov

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

**From:** Mughal, Ghias  
**Sent:** Tuesday, November 14, 2006 1:17 PM  
**To:** Proudie, Robin  
**Cc:** White, Sally; Smith, David; Goodwin, Nancy  
 FOIA\_NL&DEN00603

11/17/2006



**Subject:** FW: additional articles and revised answer Q6 reg. visual inspect ion

Robin,  
These documents just came in from NL. Please make copies and log these also.

David/Scott,  
Please review these also and send me your comments ASAP.

*M. Ghias Mughal, DVM;M.S; Ph.D.*  
Senior Equivalence Officer,  
Office of International Affairs  
USDA, Food Safety and Inspection Service  
1400 Independence Avenue, SW  
Washington, DC 20250  
Phone: 202 720-6400  
Email: ghias.mughal@fsis.usda.gov

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

**From:** (b) (6), drs. (b) (6) [mailto:(b) (6)@minInv.nl]  
**Sent:** Tuesday, November 14, 2006 7:47 AM  
**To:** Mughal, Ghias  
**Cc:** (b) (6) drs. (b) (6) (b) (6) dr. (b) (6)  
**Subject:** FW: additional articles and revised answer Q6 reg. visual inspect ion

Dear Dr. Mughal,

hereby you will receive more additional documents/ articles as promised in my mail from 7 Nov.

**1. question 4, ref 4** (Wallace JM, Hannah JB. Mycobacterium avium complex infection in patients with the acquired immunodeficiency syndrome. A clinicopathologic study. Chest. 1988 May;93(5):926-32.)

**2. question 10, ref 5.**(R. Fries und J. Leps, Die Incision des Herzens beim Schwein, Fleischwirtschaft, vol 10, 2005, p. 116-119.):  
At the moment the authors of this article are preparing an English version of this article for publication in a journal, (most probably Veterinary Quarterly). We have agreed to wait for that publication and not to disturb this proces by translating ourselves. Meanwhile I have found the English summary of the dissertation of the authors on which the article had been based (**J. Leps, Incision of the heart during meat inspection of pigs - A risk analysis approach, dissertation FU Berlin, 2003**) I have attached the summary (English summary starts on page 5) and a document (index) with the abstract and further details. Most propably you will find this summary suitable enough for your purposes. Please let me know if you still need the English article; we will send it as soon as it is published.

**3. question 6, revised answer** on verification procedures: as agreed during the last meeting.  
This document refers to another VWA procedure document "**System Audit from Start 'til End**". This document is in the process of being translated and will be sent to you as soon as it is available.

Furthermore, as soon as Q10, ref 1,3 en 4 have been translated I will send them to you.

Kind regards

(b) (6)

-----Oorspronkelijk bericht-----

**Van:** (b) (6), drs. (b) (6)  
**Verzonden:** dinsdag 7 november 2006 15:40  
**Aan:** 'Mughal, Ghias'  
FOIA\_NL&DEN00604

11/17/2006

CC: (b) (6), dr. (b) (6) (b) (6) drs. (b) (6) (b) (6) (VD)  
**Onderwerp:** Expert meeting with FSIS and the Netherlands reg. visual inspection

Dear Dr. Mughal,

on behalf of Dr (b) (6) I will send you herewith a "package" of additional articles, which have been mentioned in our report as a reference.

Most of these articles are in English, but 4 articles (question 10) have to be translated first. Unfortunately this will take some time, so you will receive them as soon as the translation has been completed. 2 other documents (q4ref1 and q4ref4) will be sent later.

Beneath you find a list of the articles which you will receive today (with several e-mails due to the size of the attachments) and 4 articles as soon as possible after translation has been completed.

If you miss any reference article in this list that had been agreed to send to you please let me know. I will arrange that asap.

Regards

(b) (6)

**Drs. (b) (6)**

*Beleidsmedewerker vleeshygiëne*

*Directie Voedselkwaliteit en Diergezondheid*

Ministerie van Landbouw, Natuur en Voedselkwaliteit

Adres: Bezuidenhoutseweg 73

Postbus: 20401, 2500 EK Den Haag

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Telefoon: 070-3784289

Telefax: 070-3786389

#### **Question 4:**

**Additional document:** Justification for sampling of *Mycobacterium avium* in pork with regard to supply chain meat inspection (06-11-06)

#### **References to additional document:**

\* New classification system for slaughter pig herds in the Danish surveillance- and-control program: L. Alban et.al., *Prev. Vet. Med.* 2002 (SDOC1268.pdf)

\* *Trichinae* certification in the United States Pork industry: D.G. Pyburn et.al., *Vet. Parasitology*, 2005 (SDOC1267.pdf)

#### **References Question 4:**

1) Inderlied CB, Kemper CA, Bermudez LE. The *Mycobacterium avium* complex. *Clin Microbiol Rev.* 1993 Jul;6(3):266-310. Review. **(will be sent later)**

2) Komijn, RE., PEW de Haas, ME Schneider, T Eger, JHM Nieuwenhuis, RJ van den Hoek, D. Bakker, FG van Zijderveld and D van Soelingen. Prevalence of *Mycobacterium avium* in Slaughter Pigs in The Netherlands and Comparison of IS1245 Restriction Fragment Length Polymorphism Patterns of Porcine and Human Isolates. *J of Clin Microb*, 1999, 37, 1254-1259

3) Komijn, RE., HJ. Wisselink, VMC. Rijsman, N. Stockhofe-Zurwieden, D. Bakker, FG. van Zijderveld, T. Eger, JA. Wagenaar, FF. Putirulan and BAP. Urlings, Prevalence of *Mycobacterium avium* subsp. *avium* in lymphnodes of slaughter pigs in The Netherlands. Accepted for publication in *Veterinary Microbiology* (2007)

4) Wallace JM, Hannah JB. *Mycobacterium avium* complex infection in patients with the acquired immunodeficiency syndrome. A clinicopathologic study. *Chest.* 1988 May;93 (5):926-32. **(will be sent later)**

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## Mughal, Ghias

---

**From:** Mughal, Ghias  
**Sent:** Tuesday, February 20, 2007 2:07 PM  
**To:** White, Sally  
**Cc:** James, William; Smith, David  
**Subject:** RE: Dr. Raymond's questions with answers on NL- Visual-

Sally,  
I have forwarded this e-mail to David Smith also. Dr. Smith and I are getting together in next few minutes to go over Dr. Sutton's response and I will send you our comments shortly. Thanks. Ghias

M. Ghias Mughal, DVM;M.S; Ph.D.  
Senior Equivalence Officer,  
Office of International Affairs  
USDA, Food Safety and Inspection Service  
1400 Independence Avenue, SW  
Washington, DC 20250  
Phone: 202 720-6400  
Email: ghias.mughal@fsis.usda.gov

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

From: White, Sally  
Sent: Tuesday, February 20, 2007 1:54 PM  
To: Mughal, Ghias  
Cc: James, William  
Subject: Fw: Dr. Raymond's questions with answers on NL- Visual-

This is your top priority. Please cc me on your response...also Bill.

-----  
Sent from my BlackBerry Wireless Handheld

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

From: Dey, Bhabani <Bhabani.Dey@fsis.usda.gov>  
To: White, Sally <Sally.White@fsis.usda.gov>  
CC: Thaler, Alice <Alice.Thaler@fsis.usda.gov>; Sutton, Mary <Mary.Sutton@fsis.usda.gov>  
Sent: Tue Feb 20 13:49:32 2007  
Subject: FW: Dr. Raymond's questions with answers on NL- Visual-

Mrs. White:

Here is the response from Dr. Sutton.  
Bhabani

Alice, here is what I have in general terms. Whether the test is reliable or how specific and sensitive it is will rely on how well the ELISA has been designed for use in hogs. If you have any specifics on the serological test they are using or where I could look at their peer review on the study validating the test, please let me know.

<<Serological Testing of Hogs for Mycobacterium avium.doc>>

B.P.Dey, DVM, MS, MPH, PhD.  
Room 341 Aerospace Bldg.  
Washington, DC 20250  
ph - 202-690-2676  
fx - 202-720-8213  
email: bhabani.dey@fsis.usda.gov

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

From: Thaler, Alice  
Sent: Friday, February 16, 2007 9:44 AM  
To: White, Sally  
Cc: Sutton, Mary; Dey, Bhabani  
Subject: Dr. Raymond's questions with answers on NL- Visual-

Terri Sutton/pathologist FSIS Eastern Lab has agreed to handle this request for information. Incoming is attached.

<<Further clarification on Dr. Raymond's Q..doc>>

Alice M. Thaler, DVM, DACVPM  
Senior Director for Program Services  
Office of Public Health Science  
202-690-2687  
Fax 202-720-8213  
alice.thaler@fsis.usda.gov

**Tracking:**

**Recipient**

White, Sally  
James, William  
Smith, David

**Read**

Read: 2/20/2007 2:24 PM

## Mughal, Ghias

**From:** White, Sally  
**Sent:** Tuesday, February 20, 2007 1:54 PM  
**To:** Mughal, Ghias  
**Cc:** James, William  
**Subject:** Fw: Dr. Raymond's questions with answers on NL- Visual-

This is your top priority. Please cc me on your response...also Bill.

-----  
Sent from my BlackBerry Wireless Handheld

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

**From:** Dey, Bhabani <Bhabani.Dey@fsis.usda.gov>  
**To:** White, Sally <Sally.White@fsis.usda.gov>  
**CC:** Thaler, Alice <Alice.Thaler@fsis.usda.gov>; Sutton, Mary <Mary.Sutton@fsis.usda.gov>  
**Sent:** Tue Feb 20 13:49:32 2007  
**Subject:** FW: Dr. Raymond's questions with answers on NL- Visual-

Mrs. White:

Here is the response from Dr. Sutton.  
Bhabani

Alice, here is what I have in general terms. Whether the test is reliable or how specific and sensitive it is will rely on how well the ELISA has been designed for use in hogs. If you have any specifics on the serological test they are using or where I could look at their peer review on the study validating the test, please let me know.



Serological Testing  
of Hogs fo...

<<Serological Test ng of Hogs for Mycobacterium avium.doc>>

B.P.Dey, DVM, MS, MPH, PhD.  
Room 341 Aerospace Bldg.  
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email: bhabani.dey@fsis.usda.gov

*Sutton*  
*Rec - info*  
*① → what you need for*  
*② →*

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

**From:** Thaler, Alice  
**Sent:** Friday, February 16, 2007 9:44 AM  
**To:** White, Sally  
**Cc:** Sutton, Mary; Dey, Bhabani  
**Subject:** Dr. Raymond's questions with answers on NL- Visual-

Terri Sutton/pathologist FSIS Eastern Lab has agreed to handle this request for



Further clarification  
on Dr. R...

information. In oming is attached.

<<Further clarification on Dr. Raymond's Q..doc>>

Alice M. Thaler, DVM, DACVPM

Senior Director for Program Services  
Office of Public Health Science  
202-690-2687  
Fax 202-720-8213  
alice.thaler@fsis.usda.gov



## Serological Testing of Hogs for Mycobacterium avium

Alice, I am going to give you a preliminary response to the question posed by Drs. Raymond and Mann. In order to really give an accurate response, we would need to know what kind of serological test the Netherlands is using and find out what the sensitivity and specificity of the test in hogs from their data. I am assuming that the Netherlands is using an ELISA since their website indicates that, "recently an ELISA assay for the serological detection of antibodies against MAA in pigs has become available. However, the test characteristics of this ELISA assay are not established yet." I assume that the ELISA detects LAM-A (derived from Mycobacterium avium) or other cell wall component. I had read that the Pasteur Institute in Bucharest had developed an ELISA using LAM-A (derived from Mycobacterium avium spp. avium); although I have no evidence that this is the test that is being done in hogs in the Netherlands. I am still looking for a peer reviewed article about that method.

Many ELISAs used to detect Mycobacterium detect a component of the mycobacterial cell wall, like lipoarabinomannin (LAM). One of the hardest problems to correct with these analyses is that although they are fairly sensitive, there is a cross reaction problem with other mycobacterial organisms (lack of specificity). To correct this problem, many of the tests absorb their sera against other strains of mycobacteria (for example M. phlei). By doing this, and by using LAM derived from the strain of organisms that they wish to detect, they have reduced the cross reactivity due to other strains of Mycobacterium.

In general, the reliability of an ELISA to detect mycobacterium varies widely with the species of mycobacterium one is trying to detect and the species of animal that is being tested. For example, in detecting human TB, ELISA based tests are still of limited use, although the ELISA based tests are improving. One study I remember indicated that a specific ELISA test detected 76% of active tuberculosis infections in patients – where the time honored sputum test detection of active cases was lower, sometimes around 50%.

On the other hand, ELISA tests are the most sensitive and specific test for the detection of paratuberculosis (caused by Mycobacterium avium spp. paratuberculosis) in cattle. Sensitivity is comparable to complement fixation (CF) in clinical cases, but better than CF in subclinically infected carriers. Cross reactions with other strains of Mycobacterium (like M. avium) have been decreased by absorption of sera against M. phlei. In cattle, one kit was found to have sensitivity in clinical cases of 88.3% and a specificity of 99.8%; in sheep a sensitivity of 35-54% and specificity of 98.2-98.5% was reported. Although there are several commercially available ELISA tests for the detection of paratuberculosis in cattle, the sensitivity in ruminants (other than bovids) is generally much lower than in cattle.

If you have any information on the specific ELISA the Dutch are using please forward it to me. I will keep looking through available sources until I hear from you.

I did check with the TB group of APHIS (NVSL, Ames, IA) about the commercial availability of an ELISA for Mycobacterium avium in hogs. They indicated that they

were unaware of any commercially available ELISA for use in hogs and that they didn't know of anyone in the US researching such a product.

Thank you.

Question 1 What other diseases were detected in the 2,116,536 swine study in the Netherlands? **(Dr. Raymond)**

ANS:

This study was done from Jan 2004 to August 2004 and focused only on the prevalence of granulomatous lesions found in the sub-maxillary (mandibular) lymph nodes.

- This study describes analysis of granulomatous lesions from mandibular lesions selected from farms with a high prevalence of mandibular lymph node lesions.
- It was a focused research study on the prevalence of *M. avium*. No data on prevalence on any other diseases was collected
- The researchers were unable to isolate *M. avium* from any lesions, but isolated *Rhodococcus equi* from many of the affected lymph nodes.
- The study was used as a support to show that incidence of *M. avium* was low in swine herds in the Netherlands..
  
- **Reference:** Wisselink HJ, Rijsman VMC, Stockhofe-Zurweiden N, Bakker D, van Zijderveld FG, Eger T, Wagenaar JA, Putirulan FF, Urlings B. Granulomatous lesions in lymph nodes of slaughter pigs bacteriologically negative for *Mycobacterium avium* subsp. *avium* and positive for *Rhodococcus equi*. Accepted for publication 2007).

Q. 2. What diseases were found in during the pilot study done on 174,250 swine in the Netherlands? **(Dr. Raymond and Dr. Mann)**

ANS:

- Focus of the study was diseases related to Food safety and public health. Lesions associated with the following three zoonotic diseases were observed on post-mortem examination during the pilot.
  1. Endocarditis in swine due to *E rhusiopathiae* (causes local dermatitis in humans)
  2. Infections due to *Rhodococcus equi*- granulomatous lesions in the lymph nodes of swine- ( can cause pneumonia in HIV patients)
  3. *M. avium* infections- granulomatous lesion in the lymph nodes of swine ( can cause respiratory tract infections in HIV patients)
  
- Inspectors who performed visual inspection missed lesions in nine carcasses. These carcasses were in rejected by the inspectors who performed traditional inspection. Following is detail of the lesions found:

- |  |   |
|--|---|
| 1. infected legs/ abscesses in legs----- | 3 |
| 2. Endocarditis-----                     | 1 |
| 3. Jaundice---                           | 1 |
| 4. Osteomyelitis -----                   | 1 |
| 5. Tail abscesses-----                   | 3 |

Total carcasses rejected during the traditional inspection: 9

**Reference:** Draft report of the pilot on Visual Inspection and the Netherlands answers to FSIS questions, 2006.

- Q. 3. a) Is the tuberculin testing a surveillance tools in these hog farms?  
 b) Is serological testing a reliable test ( **Dr. Mann**)

ANS:

Both serological testing and Tuberculin testing was performed.

From each lot of pigs sent to slaughter house, 2 - 6 blood samples are taken for blood testing. A farm can only be qualified to participate in the visual inspection program only when 18 subsequent blood samples are found negative by ELISA test.

When lot from a farm repeated serologically tested positive for *M. avium*, these farms were visited by the (b) (4) (Producer) and the accredited veterinarian for additional tests. These tests consist of tuberculin testing and further evaluation of the farm. Lymph nodes from the tested hogs are sent to lab and analyzed for the presence of *M. avium*.

**Reference:** Draft report of the pilot on Visual Inspection and the Netherlands answers to FSIS questions, 2006.

**Notes:**

OIA had a follow-up meeting (on 1-25-07)

Dr. James collecting further information on the following would help in clarifying answers:

1. Information on other zoonotic diseases found the Netherlands. I contacted Dr. Kristin Holt (FSIS liaison at the CDC). She responded to me on 2/5/07 that Netherlands participates in a surveillance system similar to CDC (European **Centre for Disease Prevention and Control**). – I have not had a chance to follow up on this lead thus far. I will do it immediately on return to the office.

2. I was asked to contact Dr. Alice Thaler to get more information on Dr. Mann's question relating to the reliability of serological test for *M. avium*. – I sent an E-mail to Dr. Thaler on 1-26-07 requesting name of a person I could contact to discuss the issue and I have not seen a response.

**Mughal, Ghias**

---

**From:** Sutton, Mary  
**Sent:** Friday, March 02, 2007 6:22 PM  
**To:** Mughal, Ghias  
**Subject:** RE: Visual Inspection: Need more information

Dr. Mughal,

In this email, I have limited myself to evaluating the ELISA as a way reliable way to detect MAA infected hogs, not whether it is or could be equivalent to incision/ palpation of lymph nodes. The information in the article from the Netherlands has raised more questions than it has answered for me. The ELISA that they developed was able to detect about 70 - 75% of the Mycobacterium avium subspecies avium (MAA) experimentally infected hogs (32 hogs infected experimentally). This level of detection corresponds to some of the ELISA methods developed to detect M. tuberculosis - bovis infections in people (these detect about 3/4 of the people with active M. TB lesions). About 50% of the experimentally infected hogs had granulomatous lesions in the mandibular and/or mesenteric lymph nodes. From the data summarized in the article, I would say that the ELISA was sensitive enough to detect about 3/4 of the hogs infected with MAA serotype 4 strain 17404.

The data doesn't give me any real good grasp of the specificity of this ELISA method. The hogs were infected with the same strain of MAA that the ELISA antigen was isolated from. There is no data addressing whether there is cross reactivity in sera from hogs infected with other strains of MAA, other non-TB group mycobacterium or organisms from the Mycobacterium TB-bovis group. Nor is there any survey data comparing serological results using the experimental ELISA to the presence of granulomatous lesions in the mandibular and/or mesenteric lymph nodes and the culture results from slaughter hogs. Information from both of these types studies would be important to determine how this ELISA method compares to physical examination of mandibular and mesenteric lymph nodes to detect active infection with MAA.

The data presented about the MAA serotype 4 strain 17404 ELISA is an encouraging step forward, but doesn't give me the information needed to evaluate how good a test it will be to detect MAA infected herds.

Mary T. Sutton, DVM, MS  
Chief, Pathology Branch  
Eastern Laboratory, OPHS, FSIS, USDA  
Russell Research Center  
950 College Station Road  
Athens, GA 0605  
PH: 706-546-3556 FAX: 706-546-3589

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

**From:** Mughal, Ghias  
**Sent:** Thursday, March 01, 2007 3:40 PM  
**To:** Sutton, Mary  
**Subject:** RE: Visual Inspection: Need more information

That is great. You can let her read the material.

M. Ghias Mughal, DVM;M.S; Ph.D.  
Senior Equivalence Officer,  
Office of International Affairs  
USDA, Food Safety and Inspection Service  
1400 Independence Avenue, SW  
Washington, DC 20250  
Phone: 202 720-6400  
Email: ghias.mughal@fsis.usda.gov

- The data submitted by the Netherlands did not address the specificity of this method. They only used one strain of *M. avium*- MAA serotype 4, strain 17404 during the experiment. They did not show if there was a cross reactivity in sera of hogs infected with other strains of MAA, other non-TB group mycobacterium or organisms from the Mycobacterium-bovis group.
- Based on the Netherlands' data, the ELISA test, by itself, is not the most reliable test for the detection of MAA. However, the ELISA test, in combination with the following safeguards, can become a reliable test for the detection of MAA:
  - The production/slaughter of the market hogs is a vertically integrated operation,
  - There is a established frequency of follow-up testing <sup>by</sup> for MAA,
  - No hogs, imported from any other country, are allowed in the program,
  - There is a TB testing program for the farm workers,
  - There is an environmental testing program for MAA, e.g., testing of bedding, house environment, etc., and
  - The participating companies have a control program for control of insects and other pests.

It was explained to Dr. Sutton that in order for participating companies to be eligible for Visual Inspection, they must have a mandatory quality assurance (QA) program. The QA program is approved and verified by the Netherlands' inspection service on routine basis. The QA program must contain all six safeguards mentioned above and she agreed that with all these safeguards the ELISA test is a step forward and provides added level of assurance for detection of TB in market hogs.

Participants:

Dr. Terry Sutton, OPHS

Dr. David Smith, OIA

Dr. Ghias Mughal, OIA

Mughal, Ghias

---

From: (b) (6) [REDACTED]@hotmail.com]  
Sent: Sunday, April 15, 2007 2:37 PM  
To: Mughal, Ghias  
Cc: McDermott, Steve  
Subject: Netherlands Serological Testing for Mycobacterium

Ghias

See if you agree with the following summary and we can discuss in the morning.

FSIS did receive information from the Netherlands regarding serological testing for Mycobacterium. This information was discussed with Dr. Terry Sutton, pathologist at FSIS Eastern Laboratory. Dr. Sutton had the following comments:

The ELISA (serological) test used by the Netherlands is sensitive enough to detect about 75% of the hogs infected with M. avium subspecies avium (MAA). The data submitted by the Netherlands did not address the specificity of the ELISA method. They only used one strain of M. avium, i.e., the MAA serotype 4, strain. The data did not show if there was a cross reactivity in sera of hogs infected with other strains of MAA, other non-TB group mycobacterium or organisms from the Mycobacterium-bovis group. Based on the Netherlands' data, the ELISA test, by itself, is not the most reliable test for the detection of MAA. However, the ELISA test can become a reliable test for the detection of MAA if it is combined with the following safeguards proposed by the Netherlands:

- o The production/slaughter of the market hogs is a vertically integrated operation,
- o There is a established frequency of follow-up testing for MAA,
- o No hogs, imported from any other country, are allowed in the program,
- o There is a TB testing program for the farm workers,
- o There is an environmental testing program for MAA, e.g., testing of bedding, house environment, etc., and
- o The participating companies have a program for controlling insects and other pests.

It is also important to note that FSIS no longer considers TB as a food borne disease of public health significance caused by the consumption of meat. This is based on a decision made by FSIS in April 2004 with regard to changing the curriculum for its public health veterinarian training.

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*Added Report.*  
Brief of NL *Tues*



8-7-07

Steve,

Yesterday afternoon ( 8-6-07), I called APHIS- VS office in Maryland to check if APHIS would have any concerns about missing a disease(s) in market hogs of Netherlands going through visual post mortem inspection. I posed this question to Drs. Christopher Robinson and Lynette Williams after I explained to them FSIS traditional inspection procedures for market hogs and Netherlands visual inspection procedures and pointed out the differences between these procedures. I also inquired about list of the diseases of market hogs in Netherlands that APHIS considers to be important. They gave me the following list

- Food and Mouth Disease (FMD)
- Classical Swine Fever
- African Swine Fever
- Swine Vesicular Disease

Both of them said APHIS regulations refer to only one disease on Ante-mortem - FMD

Both stated that visual inspection would not impact on detection of any of the above diseases.

*M. Ghias Mughal, DVM;M.S; Ph.D.*

Senior Equivalence Officer,  
Office of International Affairs  
USDA, Food Safety and Inspection Service  
1400 Independence Avenue, SW  
Washington, DC 20250  
Phone: 202 720-6400  
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## ISSUE ALERT: FSIS Determines Netherlands' Alternate Post-Mortem Inspection Procedure for Market Hogs is Equivalent

**ISSUE:** FSIS has conducted an equivalence review of the Netherlands' request to use an alternate post-mortem inspection procedure for market hogs slaughtered for export to the United States. The alternate procedure – visual inspection of the carcass and viscera – would occur in lieu of traditional post-mortem inspection procedures of incising the mandibular lymph nodes, palpating the mesenteric, portal and bronchial lymph nodes, turning the lungs and liver, and grasping and turning the kidneys.

**BACKGROUND:** A team of FSIS experts from OPPED and OIA reviewed the Netherlands' visual inspection procedures, scientific studies, and other supporting documents and information presented by Netherlands government officials during an FSIS-Netherlands bilateral meeting held November 1-2, 2006, in Washington, DC. The team evaluated the Netherlands' visual post-mortem inspection procedures against the two FSIS post-mortem inspection procedures [Traditional Inspection and HACCP-Based Inspection Models Project (HIMP)] currently conducted for market hogs slaughtered in the United States.

The basis of the Netherlands' alternative procedure is its use of pre-slaughter data collection and post-mortem inspection verification to ensure the identification and removal of sick animals and adulterated carcasses and parts from the food supply, and that the prevalence of *Mycobacterium avium*, the primary cause of Tuberculosis in swine, is very low. Pre-slaughter data collection is accomplished through a system called "Supply Chain Inspection," which is an integrated quality assurance program with comprehensive controls over the production chain requirements for feed, hygiene, the use of veterinary drugs, transport of animals, and animal welfare. The Netherlands' inspection system has legal jurisdiction over on-farm production. Market hogs processed under this program will continue to receive ante-mortem inspection, and visual post-mortem inspection will be conducted on the head, viscera, and carcass of all carcasses. If any abnormalities are discovered during visual inspection, the carcass will undergo traditional post-mortem inspection. In addition, all market hogs slaughtered for export to the United States must be born and raised in the Netherlands, and the farms must qualify as a neutral or low risk farm based on ongoing serological surveillance for *Mycobacterium avium*.

FSIS' traditional post-mortem inspection procedures for market hogs include incision, observation, and palpation, as applicable, of the head, viscera, and carcass. FSIS' HIMP post-mortem inspection procedures are very similar to the Netherlands' visual inspection procedure in that the FSIS inspector performs only a visual inspection, with no palpations or incisions. In both cases, the FSIS inspection procedures are intended to identify and remove unwholesome and adulterated carcasses and parts thereof from the food supply.

This equivalence decision is significant because other EU Member States are expected to request a similar equivalence determination for market hogs slaughtered for export to the United States.

**TRADE IMPACT:** The United States imported 7,762,202 pounds of pork products from the Netherlands from January 1 through November 30, 2006.

NEXT STEPS: FSIS will send a letter to the Netherlands informing meat inspection officials of its equivalence decision, and will observe the program in-practice during the next on-site audit of the Netherlands meat inspection system to verify implementation standards.

FSIS-OIA-Dec. 13, 2006

## BRIEFING NOTES – NETHERLANDS

### Equivalence Submission

- The Netherlands' Ministry of Agriculture, Nature and Food Quality submitted a request in 2006 to the Food Safety and Inspection Service (FSIS) to use an alternative inspection system in Netherlands' establishments slaughtering market hogs for export to the United States.
- The Netherlands' equivalence request is specific to using visual inspection procedures during post-mortem inspection of market hogs.
- Visual inspection is the examination of parts of the slaughtered hog (head, viscera, and carcass) without incising or palpating for identifying and removing adulterated carcasses and parts from the food supply chain.
- (b) (4) a supporter of post-mortem visual inspection, currently has (b) (4) slaughter and processing establishments certified to export to the United States,
- FSIS is still in the evaluation process of the Netherlands' equivalence submission.
- Mr. (b) (6), Agricultural Counselor of the Netherlands' Embassy in Washington, DC, has met with FSIS on several occasions regarding this equivalence submission.

### FSIS Audit of the Netherlands' Meat Inspection System

- FSIS recently completed an audit of the Netherlands' meat inspection system in March 2007.
- During this audit, the FSIS official identified that a slaughter establishment, a (b) (4) slaughter facility, was operating under visual inspection. Since FSIS has not determined visual inspection to be equivalent to the U.S. inspection system, product produced in this establishment would not be eligible for export to the United States.

USDA-FSIS-OIA-April 12, 2007

## Mughal, Ghias

---

**From:** White, Sally  
**Sent:** Monday, April 16, 2007 7:28 PM  
**To:** Stuck, Karen; James, William  
**Cc:** Mughal, Ghias; McDermott, Steve  
**Subject:** Fw: Netherlands data

Karen and Bill,  
Please see attached a note drafted by Steve and Ghias from me to you. We hope this is helpful. Sally

-----  
Sent from my BlackBerry Wireless Handheld

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

**From:** McDermott, Steve <Steve.McDermott@fsis.usda.gov>  
**To:** White, Sally <Sally.White@fsis.usda.gov>  
**CC:** Mughal, Ghias <Ghias.Mughal@fsis.usda.gov>  
**Sent:** Mon Apr 16 15:58:28 2007  
**Subject:** Netherlands data



Netherlands - MGM  
-Brief on EI...

<<Netherland - MGM -Brief on EILSA Testi for TB in Hogs1.doc>>  
I have reviewed Ghias' summary of information. See if you are ok with this. The attachment is written as a memo to Karen and Bill from you.

Steven A. McDermott  
Deputy Director, International Equivalence Staff  
Office of International Affairs  
USDA, Food Safety and Inspection Service  
Washington, DC  
202-690-0297

Karen / Bill,

We did receive data from the Netherlands regarding serological testing for *Mycobacterium avium* and Ghias discussed this information with Dr. Terry Sutton, Chief of Pathology Section at FSIS Eastern Laboratory. Dr. Alice Thaler recommended that we discuss the Netherlands' data with Dr. Sutton.

Dr. Sutton had the following comments:

- The Netherlands' study indicates that for hogs infected with *M. avium* subspecies *avium* (MAA), the sensitivity of the ELISA (serological) test was 75% for hogs tested between 4 and 22 weeks of age.
- The data submitted by the Netherlands did not address the specificity of the ELISA method because only one strain of *M. avium* (MAA serotype 4) was used in the study.
- Based on the Netherlands' data, the ELISA test, by itself, is not the most reliable test for the detection of MAA. However, the ELISA test can become a dependable test for the detection of MAA if it is combined with the safeguards proposed by the Netherlands as part of its equivalence request. These safeguards are:
  - The production/slaughter of the market hogs is a vertically integrated operation,
  - There is an established frequency of follow-up testing for MAA,
  - Only hogs born and raised in Netherlands are allowed in the program,
  - There is a TB testing program for the farm workers,
  - There is an environmental testing program for MAA, e.g., testing of bedding, house environment, etc., and
  - The participating companies have a program for controlling insects and other pests.

It is also important to note the following:

- FSIS no longer considers TB as a food borne disease of public health significance caused by the consumption of meat. This is based on a the current FSIS' Training document (2004) used in the curriculum for its public health veterinarian training.
- FSIS' routine post-mortem inspection procedures have an unknown level of detection for *M. avium*. Dispositions are based on visual inspection after palpation and observation of certain lymph nodes and organs and 100% detection of lesions is not always possible.
- In regard to Dr. Sutton's comments about 75% sensitivity results, I understand that Bill and Ghias also reviewed the Netherlands' data and it showed that the sensitivity increased to about 90% in hogs tested between 20 and 22 weeks of age, which is the slaughter age of market hogs.
- Also, we believe we have found the research paper by J. F. T. Griffin of New Zealand that was mentioned by Dr. Mann. The article is entitled, "Immunoglobulin GI

Enzyme-Linked Immunosorbent Assay for the Diagnosis of Johne's Disease in Red Deer, by J. T. F. Griffin, Evelyn Spittle, Christiie R. Rodgers, Simon Liggett, Marc Cooper, Douwe Bakker, and John P. Bannantine. Published in Clinical and Diagnostic Laboratory Immunology, December, 2005, pages 1401 – 1409.

This study was designed to develop a customized enzyme-linked immunosorbent assay (ELISA) for the serodiagnosis of Johne's disease in farm deer. Two antigens were selected on the basis of their superior diagnostic readouts. Sensitivity estimates and test parameters were established using 102 *Mycobacterium paratuberculosis*-infected animals from more than 10 deer herds and specificity estimates were determined using 508 unaffected animals from 5 known disease-free herds. There was 99.5% specificity and sensitivities of 84% and 88% between the two antigens.

The Netherlands also submitted a 2005 study conducted by the University of Wisconsin regarding an evaluation of five ELISA methods used for diagnosis of bovine TB caused by *Mycobacterium avium* subsp. *Paratuberculosis* in dairy cattle in support of their proposal. The results of this study show that the specificity of the three of the five ELISA methods was equal or above 99.8%. Specificity of the other two methods was 84.7% and 94.9%.

- The Netherlands' inspection service has implemented a government verification program to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects. In the Netherlands, verification of visual inspection takes place on a daily basis (minimum once a day) and is carried out by the official veterinarian.

#### Definitions:

Sensitivity: An operating characteristic of a diagnostic test that measures the ability of a test to detect a disease (or condition) when it is truly present. Sensitivity is the proportion of all diseased patients for whom there is a positive test, determined as the number of true positives divided by the sum of true positives + false negatives. (Contrast with specificity.)

Specificity: An operating characteristic of a diagnostic test that measures the ability of a test to exclude the presence of a disease (or condition) when it is truly not present. Specificity is the proportion of nondiseased patients for whom there is a correctly negative test, expressed as the number of true negatives divided by the sum of true negatives + false positives. (Contrast with sensitivity.)

## Mughal, Ghias

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**From:** James, William  
**Sent:** Sunday, April 15, 2007 1:32 PM  
**To:** Stuck, Karen; McDermott, Steve; White, Sally; Mughal, Ghias  
**Subject:** Re: Roger will call you about Dutch spareribs

IES has that. They can summarize it for Dr R on Monday.

Bill James  
International Affairs

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

**From:** Stuck, Karen <Karen.Stuck@fsis.usda.gov>  
**To:** James, William <William.James@fsis.usda.gov>; McDermott, Steve <Steve.McDermott@fsis.usda.gov>  
**Sent:** Sat Apr 14 17:11:16 2007  
**Subject:** Fw: Roger will call you about Dutch spareribs

I thought we gave this to Dr. Raymond??

Karen Stuck  
FSIS  
-----

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

**From:** Dick.Raymond@usda.gov <Dick.Raymond@usda.gov>  
**To:** Curt.Mann@usda.gov <Curt.Mann@usda.gov>; Garner, Arriell -USDA <Arriell.Garner@usda.gov>; Myers, Jean -USDA <jean.myers@usda.gov>; Stuck, Karen <Karen.Stuck@fsis.usda.gov>; Goldman, David <David.Goldman@fsis.usda.gov>; Quick, Bryce <Bryce.Quick@fsis.usda.gov>; Derfler, Philip <Philip.Derfler@fsis.usda.gov>; Mughal, Ghias <Ghias.Mughal@fsis.usda.gov>; McDermott, Steve <Steve.McDermott@fsis.usda.gov>; Goodwin, Nancy <Nancy.Goodwin@fsis.usda.gov>; White, Sally <Sally.White@fsis.usda.gov>; McNiff, Barbara <Barbara.McNiff@fsis.usda.gov>; James, William <William.James@fsis.usda.gov>; Danford, Clark <Clark.Danford@fsis.usda.gov>; Smart, Donald <Donald.Smart@fsis.usda.gov>; Stanley, Mary <Mary.Stanley@fsis.usda.gov>  
**Sent:** Sat Apr 14 15:48:40 2007  
**Subject:** RE: Roger will call you about Dutch spareribs

I had requested information from them regarding serological testing for Mycobacterium. Did we ever get that information from them?

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

**From:** Stuck, Karen -FSISE2K3  
**To:** Raymond, Dick; Mann, Curt; Garner, Arriell; Myers, Jean; Goldman, David -FSISE2K3; Quick, Bryce -FSISE2K3; Derfler, Philip -FSISE2K3; Mughal, Ghias -FSISE2K3; McDermott, Steve -FSISE2K3; Goodwin, Nancy -FSISE2K3; White, Sally -FSISE2K3; McNiff, Barbara -FSISE2K3; James, William -FSISE2K3; Danford, Clark -FSISE2K3; Smart, Donald -FSISE2K3; Stanley, Mary -FSISE2K3  
**Sent:** 4/13/2007 2:45 PM  
**Subject:** FW: Roger will call you about Dutch spareribs

Dr. Raymond: You may be getting a call from the U.S. Ambassador to the Netherlands on the request from the Dutch for equivalence of their visual inspection system for market hogs.

Karen Stuck  
Assistant Administrator  
Office of International Affairs  
FSIS, U.S. Department of Agriculture  
Phone 202-720-3473  
Fax: 202-690-3856



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

From: Mughal, Ghias  
Sent: Friday, April 13, 2007 2:21 PM  
To: James, William; Stuck, Karen  
Cc: White, Sally; Goodwin, Nancy; McDermott, Steve  
Subject: RE: Roger will call you about Dutch spareribs

Dr. James,  
Attached is the revised Netherlands-Issue Brief which incorporates the requested statement. Thanks. Ghias

M. Ghias Mughal, DVM;M.S; Ph.D.  
Senior Equivalence Officer,  
Office of International Affairs  
USDA, Food Safety and Inspection Service  
1400 Independence Avenue, SW  
Washington, DC 20250  
Phone: 202 720-6400  
Email: ghias.mughal@fsis.usda.gov

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

From: James, William  
Sent: Friday, April 13, 2007 12:48 PM  
To: Mughal, Ghias; Stuck, Karen  
Cc: White, Sally; Goodwin, Nancy; McDermott, Steve  
Subject: RE: Roger will call you about Dutch spareribs

I think we need a sentence that says we have (or will) tell the Netherlands that product produced under the newly approved system (if approved) will be eligible only if produced after the approval date.

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

From: Mughal, Ghias  
Sent: Friday, April 13, 2007 12:45 PM  
To: Stuck, Karen  
Cc: White, Sally; Goodwin, Nancy; James, William; McDermott, Steve  
Subject: RE: Roger will call you about Dutch spareribs

Karen, attached is a short brief focusing on the meeting with the US Ambassador as you requested.  
Thank you,  
Ghias

M. Ghias Mughal, DVM;M.S; Ph.D.  
Senior Equivalence Officer,  
Office of International Affairs  
USDA, Food Safety and Inspection Service  
1400 Independence Avenue, SW  
Washington, DC 20250  
Phone: 202 720-6400  
Email: ghias.mughal@fsis.usda.gov

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

From: Stuck, Karen  
Sent: Friday, April 13, 2007 8:57 AM  
To: McDermott, Steve  
Cc: White, Sally; Mughal, Ghias; Goodwin, Nancy; James, William

Subject: Re: Roger will call you about Dutch spareribs

Steve: please prepare a short issue brief on this focusing on the meeting with the US ambassador and impending call to Dr. Raymond. Please get this to me today.

Karen Stuck  
FSIS  
-----

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

From: McDermott, Steve <Steve.McDermott@fsis.usda.gov>  
To: Stuck, Karen <Karen.Stuck@fsis.usda.gov>  
CC: White, Sally <Sally.White@fsis.usda.gov>; Mughal, Ghias <Ghias.Mughal@fsis.usda.gov>; Goodwin, Nancy <Nancy.Goodwin@fsis.usda.gov>  
Sent: Fri Apr 13 07:50:17 2007  
Subject: Fw: Roger will call you about Dutch spareribs

FYI  
-----

Sent from my BlackBerry Wireless Handheld

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

From: Bob.Flach@USDA.GOV <Bob.Flach@USDA.GOV>  
To: McDermott, Steve <Steve.McDermott@fsis.usda.gov>  
CC: Roger.Wentzel@USDA.GOV <Roger.Wentzel@USDA.GOV>; (b) (6) @hotmail.com  
(b) (6) @hotmail.com>; Marcel.Pinckaers@USDA.GOV <Marcel.Pinckaers@USDA.GOV>  
Sent: Fri Apr 13 05:56:07 2007  
Subject: Roger will call you about Dutch spareribs

Dear Steve,

It is a few years ago since we met during one of your audits in the Netherlands. I am writing you this mail because of the following:

The Director General of the Dutch MinAg, Mr (b) (6), contacted our office yesterday. He requested a meeting with our Ambassador, Mr Arnall, to discuss the Dutch system of visual inspection of slaughterhogs. This morning, (b) (6) met with Mr Arnall. Because Roger is on holidays this week (he is back in the office on Monday) I was present at the meeting. To summarize the meeting:

(b) (6) wanted to gently remind the U.S. Government how important a timely approval of the visual inspection of slaughterhogs is for the (b) (4). On the Ambassador's question on how long they could wait, he answered a month or so. At the moment, (b) (4) reportedly stores the shipments destined for the U.S. market in a cold storage. (b) (6) advocated the visual inspection system. I am sure FSIS has this information readily available, so I do need to summarize this for you.

At the moment we are preparing a memo for the Ambassador. This memo will contain the contact info of Richard Raymond as the person for the Ambassador to contact. So, Mr Arnall might call Mr Raymond regarding this matter. We will give this memo to the Ambassador on Monday.

Today Roger (he is in Paris right now) will try to contact you regarding this matter.

Kindest regards, bob

Bob Flach (Agricultural Specialist)  
United States Department of Agriculture, Foreign Agricultural Service U.S. Embassy, Lange Voorhout 102, 2514 EJ The Hague, The Netherlands  
Phone: ++31 (0)70 3102 303 Fax: ++31 (0)70 3657 681 <http://www.fas.usda.gov>

<<NETHERLANDS arnell-oostra mtg 4-13-07.doc>>

NETHERLANDS—Issue Brief

Meeting between US Ambassador Arnell and Mr. (b) (6), Director General, Ministry of Agriculture, Nature and Food Quality for the Netherlands

- On April 13, US Ambassador Arnell met with the Director General for the Ministry of Agriculture, Nature and Food Quality, Mr. (b) (6) at the request of Mr. (b) (6).
- The discussions centered on a pending equivalence determination from the Food Safety and Inspection Service regarding the Netherlands' request for the use of visual-only inspection of market age hogs.
- FAS, The Hague, reported that Mr. (b) (6) diplomatically reminded Ambassador Arnell that timely approval of the request is important for the Netherlands and that it was hoped that a decision could be reached and relayed to him within the next 30 days.
- FAS, The Hague, also reported that product produced under visual inspection is being stored in warehouses for eventual export to the United States.
- Ambassador Arnell was advised that Dr. Raymond is the contact point for further information. FAS reported that the Ambassador may call Dr. Raymond to discuss the situation.

## **BRIEFING NOTES**

Meeting with (b) (6)  
(Director General Ministry of Agriculture, Nature and Food Quality)  
Concerning Netherlands' Visual Meat Inspection  
On April 13, 2007

Dear Ambassador Arnall,

Please find the answers on your questions regarding your meeting with (b) (6) in this memo. The answers are based on my conversation with (b) (6) Deputy Chief Veterinary Officer of the Dutch Ministry of Agriculture, Nature and Food Quality.

**When did the (b) (4) started with the visual inspection procedures during post-mortem inspection of market hogs?**

In September 2005, the (b) (4) started a pilot project. In March 2006, they fully implemented the visual inspection procedures.

**When did the European Commission (EC) approve the visual inspection of market hogs?**

-The EC didn't approve the visual inspection procedures. The procedures don't need to be approved by the EC to be legally applied because they are conforming EC Regulation EC/854/2004. This Regulation is laying down specific rules for the organization of official controls on products of animal origin intended for human consumption.

-In February 2006, the European Food and Veterinary Office (FVO) inspected the Netherlands' meat inspection system. As part of their visit the FVO audited the execution of the visual inspection procedures in practice.

-The official report of the FVO regarding this visit is not yet public, and therefore not yet official. The content of the report is reportedly positive towards the implementation of the Dutch visual inspection procedures.

**What is the percentage of hogs undergoing visual inspection on the total number of hogs slaughtered in the EU?**

-Martijn Weijtens estimated the percentage at five percent. The (b) (4) is the only company applying visual inspection. The (b) (4) is the second largest hog slaughterer in Europe and owns slaughterhouses in the Netherlands and Germany.

**Who is the best person in the USDA to contact?**

Dr. Richard Raymond  
Under Secretary for Food Safety  
U.S. Department of Agriculture  
227-E Jamie Whitten Building  
Washington, DC 20250  
Phone: (202) 720-0350  
Fax: (202) 690-0820  
Dick.Raymond@usda.gov

## **BRIEFING NOTES**

For Meeting with Ate Oostra  
(Director General Ministry of Agriculture, Nature and Food Quality)  
Concerning Netherlands' Visual Meat Inspection  
April 13, 2007

### Equivalence Submission

- The Netherlands' Ministry of Agriculture, Nature and Food Quality submitted a request in 2006 to the Food Safety and Inspection Service (FSIS) to use an alternative inspection system in Netherlands' establishments slaughtering market hogs for export to the United States.
- The Netherlands' equivalence request is specific to using visual inspection procedures during post-mortem inspection of market hogs.
- Visual inspection is the examination of parts of the slaughtered hog (head, viscera, and carcass) without incising or palpating for identifying and removing adulterated carcasses and parts from the food supply chain.
- (b) (4) a supporter of post-mortem visual inspection, currently has six slaughter and processing establishments certified to export to the United States,
- FSIS is still in the evaluation process of the Netherlands' equivalence submission.
- Mr. Wim Tacken, Agricultural Counselor of the Netherlands' Embassy in Washington, DC, has met with FSIS on several occasions regarding this equivalence submission.

### FSIS Audit of the Netherlands' Meat Inspection System

- FSIS recently completed an audit of the Netherlands' meat inspection system in March 2007.
- During this audit, the FSIS official identified that a slaughter establishment, a (b) (4) slaughter facility, was operating under visual inspection. Since FSIS has not determined visual inspection to be equivalent to the U.S. inspection system, product produced in this establishment would not be eligible for export to the United States.

USDA-FSIS-OIA-April 12, 2007

**Mughal, Ghias**

---

**From:** McDermott, Steve  
**Sent:** Tuesday, April 17, 2007 7:34 AM  
**To:** Stuck, Karen; James, William  
**Cc:** White, Sally; Mughal, Ghias  
**Subject:** FW: Memo To Ambassador Arnall - Netherlands Visual Inspection

As the result of U.S. Ambassador Arnall's meeting with Director General's (Netherlands Agriculture Dept) last Friday, the Ambassador had a few follow-up questions, of which FAS provided the attached response.

Steven A. McDermott  
Deputy Director, International Equivalence Staff  
Office of International Affairs  
USDA, Food Safety and Inspection Service  
Washington, DC  
202-690-0297

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

**From:** Patricia.VanGeemen@USDA.GOV [mailto:Patricia.VanGeemen@USDA.GOV]  
**Sent:** Tuesday, April 17, 2007 6:38 AM  
**To:** McDermott, Steve  
**Cc:** Bob.Flach@USDA.GOV; Roger.Wentzel@USDA.GOV  
**Subject:** Memo To Ambassador Arnall

Dear Mr. McDermott,

Roger Wentzel asked me to forward the attached memo to you, delivered to our Ambassador this morning.

With regards,

**Patricia van Geemen**  
Secretary FAS  
Tel.: +31-(0)70-310-2299  
Fax: +31-(0)70-365-7681  
E-mail: [patricia.vangeemen@usda.gov](mailto:patricia.vangeemen@usda.gov)  
[agthehague@fas.usda.gov](mailto:agthehague@fas.usda.gov)  
[vgeemenp@state.gov](mailto:vgeemenp@state.gov)

April 16, 2007

## Memorandum

**To:** The Ambassador

**Through:** Roger Wentzel, Agricultural Counselor

**From:** Bob Flach, Agricultural Specialist

**Subject:** Follow-up To Your Meeting With Ate Oostra (Director General, Dutch Ministry of Agriculture) on April 13, 2007

You had a number of questions following your meeting with Ate Oostra, which are answered below. The answers are based on my telephone conversation with Martijn Weijtens, Deputy Chief Veterinary Officer of the Dutch Ministry of Agriculture.

**When did the (b) (4) begin using the visual inspection procedures during post-mortem inspection of market hogs?**

In September 2005, the (b) (4) started a pilot project. In March 2006, they fully implemented the visual inspection procedures.

**When did the European Commission (EC) approve the visual inspection of market hogs?**

-The EC didn't approve the visual inspection procedures. The procedures don't need to be approved by the EC to be legally applied because they are conforming EC Regulation EC/854/2004. This Regulation lays down specific rules for the organization of official controls on products of animal origin intended for human consumption.

-In February 2006, the European Food and Veterinary Office (FVO) inspected the Netherlands' meat inspection system. As part of their visit, the FVO audited the visual inspection procedures in practice.

-The official report of the FVO regarding this visit is not yet public, and therefore not yet official. The content of the report is reportedly positive towards the implementation of the Dutch visual inspection procedures.



**What is the percentage of hogs slaughtered in the EU undergoing visual inspection ?**

-Martijn Weijtens estimated the percentage at five percent. The (b) (4) is the only company applying visual inspection. The (b) (4) is the second largest hog slaughterer in Europe and owns slaughterhouses in the Netherlands and Germany.

**Who is the best person in the USDA to contact?**

Dr. Richard Raymond  
Under Secretary for Food Safety  
U.S. Department of Agriculture  
227-E Jamie Whitten Building  
Washington, DC 20250  
Phone: (202) 720-0350  
Fax: (202) 690-0820  
Dick.Raymond@usda.gov

April 16, 2007

## Memorandum

**To:** The Ambassador

**Through:** Roger Wentzel, Agricultural Counselor

**From:** Bob Flach, Agricultural Specialist

**Subject:** Follow-up To Your Meeting With Ate Oostra (Director General, Dutch Ministry of Agriculture) on April 13, 2007

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-The EC didn't approve the visual inspection procedures. The procedures don't need to be approved by the EC to be legally applied because they are conforming EC Regulation EC/854/2004. This Regulation lays down specific rules for the organization of official controls on products of animal origin intended for human consumption.

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-The official report of the FVO regarding this visit is not yet public, and therefore not yet official. The content of the report is reportedly positive towards the implementation of the Dutch visual inspection procedures.

**What is the percentage of hogs slaughtered in the EU undergoing visual inspection ?**

-Martijn Weijtens estimated the percentage at five percent. The Vion Food Group is the only company applying visual inspection. The Vion Food Group is the second largest hog slaughterer in Europe and owns slaughterhouses in the Netherlands and Germany.

**Who is the best person in the USDA to contact?**

Dr. Richard Raymond  
Under Secretary for Food Safety  
U.S. Department of Agriculture  
227-E Jamie Whitten Building  
Washington, DC 20250  
Phone: (202) 720-0350  
Fax: (202) 690-0820  
Dick.Raymond@usda.gov

## ISSUE ALERT: Equivalence Request for Netherlands' Visual Inspection

Issue: The government of Netherlands is requesting to use an alternative post-mortem inspection procedure for market hogs intended for export to the United States. The alternative procedure is visual inspection of the head, carcass and viscera, without incising or palpating, to identify and remove adulterated carcasses and parts.

Latest Development: July 2007: Dr. Ate Oostra, Director General for International Affairs of Netherlands Ministry of Agriculture, Nature and Food Quality, has requested a visit with the Office of the Under Secretary for Food Safety. The primary purpose of Dr. Oostra's visit is to ask about the status of FSIS' equivalence decision regarding Netherlands' visual inspection. Current FSIS import data show that U.S. imports of fresh and canned pork products from the Netherlands have decreased significantly from 2005 (10.3 million pounds) to 2007 (217,529 pounds – January through July). The Dutch Product Board states that this decrease is directly due to Netherlands' slaughter establishments owned by (b) (4) producing under visual inspection and, therefore, ineligible to export to the United States directly (fresh product) or indirectly (supplier to canning establishments).

### Background:

- In July 2006, FSIS received a request from the Netherlands to use an alternative post-mortem inspection procedure for market hogs—visual inspection of the head, carcass and viscera. The procedure does not require incising of the mandibular lymph nodes, palpation of the mesenteric, portal and bronchial lymph nodes, turning of lungs and liver, or grasping and turning of the kidneys, which are required under FSIS traditional post-mortem inspection procedures. The Netherlands' alternative post-mortem procedures under visual inspection are further explained in Attachment 1.

The basis of the Netherlands' provision for visual inspection is dependent on the implementation of an integrated quality control program by Netherlands' market hog producers coupled with a system of government verification for checking the accuracy of visually inspected carcasses and organs to ensure that passed carcasses and parts thereof are wholesome and not adulterated.

- On November 1 and 2, 2006, a team of Netherlands' inspection officials met with FSIS to provide further information regarding its request for visual inspection.
- During late 2006 and early 2007, Mr. Wim Tacken, Agricultural Counselor of the Netherlands' Embassy in Washington, DC, met with FSIS on several occasions regarding this equivalence submission. [*Mr. Tacken has since retired and has been replaced by Mr. Fritz Thissen.*]
- On January 22, 2007, FSIS/OIA briefed Drs. Raymond and Mann on the outcome of the equivalence review. At that time, Drs. Raymond and Mann requested additional information on the serological testing method used by the Netherlands for testing of *Mycobacterium avium* (*M. avium*) during the pilot phase of visual inspection. The purpose of the additional information was to determine the dependability of serological testing as an indicator for the detection of Tuberculosis (TB) in market hogs. FSIS/OIA received the additional information from the Netherlands' Chief Veterinary Officer and concluded that serological testing was a viable test under certain conditions. Further explanation is found in Attachment 2 and this information was sent to the Office of the Under Secretary for Food Safety on June 18, 2007.

- On April 13, 2007, Dr. Oostra met with the U.S. Ambassador to the Netherlands, Roland Arnall, concerning the status of FSIS' equivalence decision on visual inspection.
- On April 23, 2007, FSIS sent a letter to the Netherlands Ministry of Agriculture, Nature and Food Quality reaffirming FSIS' October 2006 communication that the Netherlands' establishments cannot produce pork products under visual inspection for export to the United States until FSIS determines that the alternative procedure is equivalent. The April letter was initiated after learning that Netherlands' slaughter establishments owned by (b) (4) had implemented visual inspection. FSIS received a response dated May 29, 2007, from the Ministry of Agriculture, Nature and Food Quality stating that Netherlands' establishments are not producing for export to the United States while operating under visual inspection.

#### Other Interest in Visual Inspection

- (b) (4) the largest pork producer in the Netherlands and a supporter of post-mortem visual inspection, currently has six slaughter and processing establishments certified to export to the United States. However, since early 2007, the (b) (4) slaughter establishments have been producing under visual inspection and thus, product has not been eligible for export to the United States. This has caused a significant decrease in the amount of pork imports into the United States from the Netherlands.
- Denmark has shown interest in requesting a similar equivalence determination for market hogs slaughtered for export to the United States although it has not submitted a formal equivalence request to FSIS. Other EU Member States are expected to request a similar equivalence determination.

FSIS/OIA Recommendation: FSIS/OIA has completed its equivalence review and determined that the Netherlands' alternative post-mortem inspection procedure of visual inspection is equivalent and, therefore, recommends granting the government of the Netherlands approval to implement this procedure for market hogs produced for export to the United States.

FSIS/OIA August 3, 2007

## **NETHERLANDS' VISUAL INSPECTION**

Netherlands uses a combination of pre-slaughter data collection and post-mortem inspection verification to ensure the identification and removal of unhealthy animals, adulterated carcasses and parts and resulting products from the food supply. Pre-slaughter data collection is conducted through a system of "Supply Chain Inspection" called the IKB Varkens (IKB) program, which is an integrated quality assurance program with comprehensive controls over the production chain in addition to national and EU requirements for feed, hygiene, the use of veterinary drugs, transport of animals, and animal welfare. The IKB requires transfer of animal health records from the farm to both the establishment and inspection officials to provide greater assurance that only wholesome meat products are produced. All market hogs receive ante-mortem and post-mortem visual inspection of the head, viscera, and carcass. Only market hogs born and raised in the Netherlands and under the IKB program are eligible for visual inspection.

In addition, the Netherlands has implemented a government verification program to check the accuracy of the inspection tasks for the removal of both food safety and non-food safety defects (other consumer protection defects). The verification activities occur on a daily basis (minimum once a day), carried out by the official government veterinarian, and split into two basic standards: (1) standards for inspection procedures and (2) standards for inspection decisions. The government inspectors are required to perform inspection procedures correctly and completely. The government veterinarian verifies appropriate performance of inspection procedures by observing inspectors.

### **ANTE-MORTEM INSPECTION**

Ante-mortem inspection on all market hogs is performed by the official government veterinarian using traditional inspection procedures, which are equivalent to FSIS' traditional inspection procedures.

### **POST-MORTEM INSPECTION**

Visual post-mortem inspection of each head, viscera and carcass is performed by official government auxiliaries (contract inspectors) located at three fixed inspection stations. The procedures are as follows:

#### **Head Inspection**

- Visual inspection of the head and throat, including the mandibular lymph nodes
- Visual inspection of the mouth, fauces, and tongue

#### **Viscera Inspection**

- Visual inspection of the lungs, trachea, and esophagus
- Visual inspection of the pericardium and heart
- Visual inspection of the liver and hepatic and pancreatic (portal) lymph nodes
- Visual inspection of the gastro-intestinal tract, mesentery, gastric and mesenteric lymph nodes
- Visual inspection of the spleen
- Visual inspection of the genital organs

(Attachment 1 continue)

**Carcass Inspection**

- Visual inspection of the carcass
- Visual inspection of the pleura and peritoneum (linings of chest and abdominal cavities)
- Visual inspection of the kidneys
- Visual inspection of the diaphragm
- Visual inspection of the udder and its lymph nodes
- Visual inspection of the umbilical region and joints of young animals

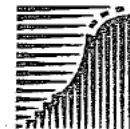
**Additional Information Requested by Drs. Raymond and Mann  
(Serological (ELISA) Testing for *M. avium*)**

- Sensitivity of ELISA (serological) test used by the Netherlands was about 75% of the hogs infected with *M. avium* subspecies *avium* (MAA) and tested at younger age. The data submitted by the Netherlands did not address the specificity of the ELISA method. They only used one strain of *M. avium*, i.e., the MAA serotype 4, strain. The data did not show if there was a cross reactivity in sera of hogs infected with other strains of MAA, other non-TB group mycobacterium or organisms from the Mycobacterium-bovis group. However, a 2006 study on the evaluation of five antibody detection tests for diagnosis of bovine tuberculosis caused by the *Mycobacterium avium* subsp. *paratuberculosis* shows that specificity of the three ELISA methods was equal or above 99.8 percent. Specificity of the other two methods was 84.7 percent and 94.9 percent. Four of the five tests produced similar sensitivity in detecting fecal culture positive cattle.
- Based on Netherlands' data, the ELISA test, by itself, is not the most reliable test for the detection of MAA. However, when the ELISA test is used as a component with the other on-farm measures listed below, the combined safeguards provide a dependable level of assurance that the market hogs slaughtered in Netherlands establishments undergoing visual inspection are free of TB.
  - The production/slaughter of the market hogs is a vertically integrated operation,
  - There is a established frequency of follow-up testing for MAA,
  - Only hogs born and raised in Netherlands are allowed in the program,
  - There is a TB testing program for the farm workers, and
  - There is an environmental testing program for MAA, e.g., testing of bedding, house environment, etc.
- During review of the proposal, FSIS technical experts also took note of the following:
  - FSIS no longer considers TB as a food borne disease of public health significance caused by the consumption of meat. This is based on the current FSIS' training document (2004) used in the curriculum for its public health veterinarian training.
  - A recent European Food Safety Authority publication on human Mycobacterium *bovis* states that transmission of tuberculosis to humans through the consumption of meat has not been documented as a public health risk during surveillance for TB in many countries over many decades. (Rua-Domenech, 2006). Additionally, the European Food Safety Authority's two most recent reports (2005, 2006) titled, "Trends and Sources of Zoonoses, Zoonotic Agents, Antimicrobial Resistance and Foodborne Outbreaks in the European Union" do not list any outbreaks of TB (from *M. bovis* or *M. avium*).
  - No reference could be found in the scientific literature specifically relating to *M. avium* transmission to humans from eating meat.



- During the past five years (August 1, 2002 to August 1, 2007), over 3.4 million market hogs were slaughtered in the United States and, of these, 2,566 were condemned for TB. The condemnation rate is 0.74 per 100,000 slaughtered.

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Food Safety and Inspection Service  
International Equivalence Staff  
Ms Sally White  
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landbouw, natuur en  
voedselkwaliteit

Your letter of	your reference	our reference	date
Feb. 24, 2006		VD 06.1018/IH	31-3-2006
re:		extension no.	enclosures
2006 audit preparation		+31-70-3785435	2

Dear Ms. White,

Your letter dated February 24, 2006, to the European Commission informing them of the dates of the upcoming annual audit of the Netherlands meat inspection system (April 19 through May 18, 2006) has been brought to my attention and I am happy to confirm these dates to you. The details of the audit and the itinerary to be followed are currently being worked out by our services.

As agreed during my visit of December 8, 2005, I take pleasure in providing you with additional information about recent changes in our meat inspection system, which I believe will be of benefit for your auditor in the preparation of his visit. These changes are in part resulting from the introduction of the new EU Hygiene Regulations on January 1, 2006, which cover the entire spectrum of food safety, including meat and meat products. This new legislation was discussed between FSIS and the European Commission at the recent Joint Management Committee meeting in October 2005. On January 12, 2006, the European Commission sent you a complete set of the acts and related implementing measures.

In our letter of February 14, 2006, we elaborated on the information provided by the Commission, by informing all CVO's in our foreign markets of the new and old legislation and certain other changes, which might have an effect on the text of our veterinary health certificates.

There are two aspects of our meat inspection system that I would like to specifically address in this letter, i.e. the option of visual post mortem inspection offered under the new legislation, and the delegation of certain elements of the post mortem meat inspection from the official veterinarian to official auxiliaries employed by an independent organization, which is permitted under both old and current EU legislation.

#### A. Visual post mortem inspection

During my visit on December 8, 2005, we discussed developments in the philosophy of meat inspection in the EU and certain comparable developments in the US (i.e. HIMP Market Hogs). We agreed that this topic was of mutual interest and that an exchange of

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information by U.S. and Dutch experts could take place during a conference call. Unfortunately, a mutually convenient date for this conference call has not been found yet, but we remain keenly interested in setting this up, preferably before the next audit.

The hygiene regulations EC 852/2004, EC 853/2004 and EC 854/2004 offer the possibility for fattening pigs, housed under controlled conditions in integrated production systems since weaning, to be subject to a visual inspection before and after slaughter. This visual inspection is part of a risk-based inspection system. Application of this inspection system requires the availability of food chain information and epidemiological data. Every enterprise has the option to either stick to the "old" system or to implement a visual inspection system. The legal basis of visual inspection is to be found in Appendix 1, Section IV, B post-mortem inspection of EU Regulation 854/2004.

The (b) (4) Company, the major pork producer in the Netherlands, looked into the merits of this type of inspection and consulted with the competent authority, the Food and Consumer Product Safety Authority (VWA), on how to proceed. In order to get official approval for the new inspection system, (b) (4) had to demonstrate to VWA that the produced pork would at least meet the EU set levels of food safety and would fulfill the mandatory EU hygiene regulations provisions.

For your information I would like to refer you to the enclosed final evaluation of (b) (4) pilot project, which was carried out in one of the slaughter plants of that company. As you will remember, a company report on this pilot project was submitted to you during our meeting on December 8, 2005.

VWA investigated the content of the chain management system in order to be convinced that the official requirements laid down in regulation (EC) 853/2004 have been met and that the submitted Food Chain Information was sufficient to realize - at least - a similar level of food safety by means of the applied visual inspection, in comparison to the current procedures for meat inspection. These two prerequisites constitute the basis for official certification. Based on their positive findings, VWA gave (b) (4) the green light to implement the visual inspection system. You will find the VWA final report 'Pilot Chain Management (b) (4) enclosed.

In February 2006 the Food and Veterinary Office of the European Commission visited the pilot slaughterhouse during an inspection mission on the official controls related to food safety of animal products and took note of the applied visual inspection system. FVO found the slaughterhouse in compliance with EU legislation.

With both the VWA approval and the positive FVO report, (b) (4) intends to now fully implement this inspection system in their Helmond facility. This will enable your auditor to personally observe the way in which the system works, when he visits this establishment, which I believe is planned at the end of the program.

I would like to underline that it is a company's decision to apply for a food chain management and visual inspection system. Whether other Dutch pork producers will try to implement such a system is unknown. If they will, every implementation will be evaluated by VWA.

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**B. New organization of the red meat inspection system**

During our meeting on December 8, 2005, the delegation of certain aspects of the post mortem meat inspection from the VWA to an independent organization was also raised, and you indicated that this topic had been brought to your attention before. At your request, a formal document explaining the details of this delegation has been drawn up, and I take pleasure in sending you this report as an enclosure. The report focuses on meat slaughterhouses under permanent supervision of the VWA.

I hope that the above information on the new EU legislation and the modernization of meat inspection will provide a good basis for discussion during the upcoming audit. I am looking forward to your response with great interest, especially on my suggestion to hold a conference call on visual post mortem meat inspection on short notice.

Yours sincerely,

CHIEF VETERINARY OFFICER,



dr. P.W. de Leeuw

cc:

Ms. Karen Stuck, Assistant Administrator, USDA/FSIS  
Mr. William James, Deputy Assistant Administrator, USDA/FSIS  
Mr. Steven McDermott, Deputy Director International Equivalence Staff, USDA/FSIS  
Mr. Ghias Mughal, Senior Equivalence Officer, USDA/FSIS  
Ms. Anita Manka, Senior Food Technologist, USDA/FSIS  
DG Sanco, Mr. Paul van Geldorp & Mr. Lorenzo Terzi  
Food and Consumer Product Safety Authority (VWA)  
Agricultural Counselor Washington, DC

# **The new organisation of the red meat inspection system in the Netherlands (2006)**

## **Introduction**

The Dutch government has decided to modernize the organisation of the red meat inspection system. The so-called post mortem inspection in red meat slaughter facilities was carried out so far by inspectors employed by the Food and Consumer Product Safety Authority (VWA). EU legislation allows the inspection to be carried out by official auxiliaries employed by an independent organisation. The VWA remains responsible for the official control and the verification of compliance. The official auxiliaries are independent of the slaughter facilities. On January 1, 2006, the official auxiliaries, who were up to then employed by the Dutch government, entered the service of an organisation based on civil law, the B.V. Kwaliteitskeuring Dierlijke Sector (KDS). For the purpose of this document, the independent organisation will be referred to as KDS.

## **Definitions**

### Competent authority

Competent authority means the central authority of a Member State competent to carry out veterinary checks or any authority to which it has delegated that competence.

### Official veterinarian

Official veterinarian means a veterinarian qualified, in accordance with Regulation (EC) 854/2004, to act in such a capacity and appointed by the competent authority.

### Official auxiliary

Official auxiliary means a person qualified, in accordance with Regulation (EC) 854/2004, to act in such a capacity, appointed by the competent authority and working under the authority and responsibility of an official veterinarian.

### Red meat inspection

Inspection of meat from domestic bovine (including Bubalus and Bison species), porcine, ovine and caprine animals, and domestic solipeds

### Inspection procedures

Inspection procedures as meant by Regulation (EC) 854/2004, Annex I, Section IV.

### Protocol

Protocol as meant in section I, annex 27 of the Supervision Protocol which is drawn up by the official veterinarian of the VWA for each slaughter facility and which contains the arrangements which have been agreed upon between the VWA and the operator of the slaughter facility.

## **Philosophy**

Practical experience and further analyses showed that if the way in which the official auxiliaries and the procedures concerning the red meat inspection (post mortem inspection) were structured, this could lead to certain advantages. These advantages were most visible if the official auxiliaries were placed in an organisational unit based on civil law independent of the slaughter facility concerned, of course with regard to the European Community legislation which states that the final responsibility for the inspection lies with the official veterinarian. These advantages can be found in aspects such as efficiency, lower labor cost and a reduction in overhead.

## **Legal basis**

- Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (in force as of January 1, 2006, and in part replacing Directive 64/433/EEC). In this Regulation it has been decided that under certain conditions the official auxiliaries may assist the official veterinarian as regards certain inspection procedures.
- Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal

health and animal welfare rules (in force as of January 1, 2006, and in part replacing Directive 64/433/EEC).

- Agreement on the organisation of red meat inspection (post mortem) in the Netherlands dated June 6, 2004.
- Implementation contract between VWA and KDS dated November 29, 2005 (including the supervision protocol)

#### **Parties involved**

In order to safeguard animal and public health, the Dutch government is responsible for an adequate organisation of meat inspection, based on European Community legislation. An agreement between the government and the meat sector on the organisation of the red meat inspection (post mortem) in the Netherlands has been reached (the "Covenant"). The objective of this agreement is to make binding and enforceable commitments between the parties in the framework of the modernization of the meat inspection system, which should have as a result that effective January 1, 2006, the inspection procedures laid down in this agreement should transfer from the VWA to an independent organisation based on civil law, which is independent of the Dutch slaughter facilities. In the pilot phase which will run through the end of December 2007, the relevant meat inspection procedures will be assigned to the B.V. Kwaliteitskeuring Dierlijke Sector in a way which ensures that these activities are carried out independently of the slaughter facilities, but under the supervision and responsibility of the official veterinarians i.a., so that the requirements of the European legislation are met.

#### **Parties involved:**

- Ministry of Agriculture, Nature and Food Quality (LNV)
- Ministry of Public Health, Welfare and Sport (VWS)
- Food and Consumer Product Safety Authority (VWA)
- Commodity Board for Livestock and Meat (PVV)
- Central Organisation of the Meat Sector (COV)

#### **B.V. Kwaliteitskeuring Dierlijke Sector (KDS)**

KDS is an organisation based on civil law linked to the Foundation Central Bureau Services for Slaughter Animals (Stichting Centraal Bureau Diensten aan Slachtdieren). The government parties must be satisfied that this organisation operates independently from the slaughter facilities. As a minimum requirement, the organisation has to be accredited as an independent agency. KDS' independence is assured as follows:

- The majority of the board consists of independent persons, including the chairman.
- Accreditation by the Council on Accreditation according to the NEN EN 45004 (ISO/IEC 17020) norm.
- Requirements for training and education, and registration of the official auxiliaries.
- Requirements for bribery and conflict of interest situations included in the implementation contract (art. 31)

The transfer of inspection to KDS is a pilot for the duration of 2005, 2006 and 2007. KDS has been charged with the inspection of red meat until the end of 2007. Other organisations could in the future also be certified to perform these tasks.

#### **Relationship between VWA and KDS**

The relationship between the VWA and KDS has been laid down in an implementation contract, which has been drawn up between both parties. This contract includes the requirements for the inspection and the requirements for the official auxiliaries. It also describes the respective responsibilities of the VWA and KDS. Article 2 of the contract provides a basic outline of the content of the agreement:

1. The inspection procedures will be carried out by KDS effective January 1, 2006. KDS must assume an independent position vis-à-vis the Dutch slaughter facilities.
2. Official auxiliaries carry out the inspection procedures referred to under # 1.
3. The VWA supervises the implementation of the inspection procedures referred to under # 1 by KDS, in order to meet the requirements of relevant European legislation.
4. KDS guarantees that the inspection procedures carried out by her, or on her behalf, will meet the requirements laid down in the contract.
5. KDS guarantees that the inspection procedures carried out by her, or on her behalf, will be executed in a professional way.

Moreover, an application for meat inspection must be submitted by the operator of the slaughter facility to the VWA. The VWA issues written orders to KDS for each application of a slaughter facility. On these orders it is indicated when the inspection procedures have to be done.

Annexes to this implementation contract include the

- Quality Manual put together by KDS (Annex III to the implementation contract), which contains the policy of the organisation, its objectives, the relationships and the work procedures; and the
- Supervision Protocol (Annex II to the implementation contract), which contains a detailed description of the way in which the VWA supervises KDS per type of slaughter facility.

The final responsibility of the official veterinarian (VWA) is of great importance. The official veterinarian measures the quality level of the post mortem inspection and of the post mortem inspection procedures (outlined in enclosure 2) carried out by the official auxiliaries of KDS based on standards described in the Supervision Protocol (including standards for the quality of the red meat inspection, the number of staff required for supervision of the post mortem inspection, the number of official auxiliaries of KDS that should be present, the VWA staff requirements, a location (establishment level) protocol, auditing, and sanctions). These standards have been described in enclosure 1.

#### **Financial structure**

The VWA has to reimburse KDS for the time spent by the official auxiliaries for the inspection procedures (increments of 15 minutes). KDS needs to submit to VWA annually no later than July 1 an estimate of the cost and a proposal for a rate. The VWA converts these costs into tariffs, which are then officially fixed by the Ministry of Agriculture, Nature and Food Quality based on relevant legislation and rulemaking. VWA does the actual billing to the slaughter facility, while the Ministry of Agriculture, Nature and Food Quality has final responsibility for collection of payment.

#### **Qualifications and education official auxiliaries**

1. Education requirements laid down in Regulation EC/854/2004 (Annex I, Section III, Chapter IV)
2. VWA evaluates whether the training meets the requirements of the Regulation. VWA also determines the rules for examination for the training.
3. The official auxiliaries must be registered with VWA.
4. The official auxiliaries must maintain their knowledge through ongoing education and professional literature and need to keep informed of new developments. The content of the ongoing education is part of the Quality Manual of KDS.
5. VWA maintains a register of the official auxiliaries, checks annually whether they are still employed by KDS and whether they take part in the ongoing education.

## **Bibliography**

1. Regulation (EC) 854/2004: Organisation of Official Controls on Products of Animal Origin Intended for Human Consumption
2. Agreement on the organisation of red meat inspection (post mortem) in the Netherlands
3. Implementation contract VWA-KDS
4. Supervision protocol (Annex II to the implementation contract)
5. Normstelling en normen roodvlees en *pluimveevlees* Slachthuizen, *uitsnijderijen* en koel- en vrieshuizen



## **Enclosure 1**

### **Standards for meat slaughterhouses under permanent VWA supervision**

#### **Introduction**

The standards and norms are divided into four elements:

1. Quality standards for meat inspection
2. Standard for the amount of staff required for supervision of the post mortem inspection and other supervisory tasks
3. Quality standards for auditing
4. Regulation of corrective measures

There is a division of responsibility between the official veterinarian and KDS. Both carry out their tasks following this division of responsibility as described in Regulation (EC) 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption. The official veterinarian is and remains ultimately responsible. Under the division of responsibility, the employees of KDS are qualified official auxiliaries, who carry out inspection procedures under full responsibility of the official veterinarian. The official veterinarian measures the quality level of the post mortem inspection and of the post mortem inspection procedures by the official auxiliaries of KDS based on the standards and norms described below.

#### **1. Quality standards for meat inspection**

In order to set criteria by which the official veterinarian can measure the post mortem inspection performance of KDS, several sources were consulted. One of these sources was the experience gained over the years in New Zealand with the implementation of meat inspection by an independent organisation and with clear standards for the quality of the meat inspection under the responsibility of the government. The New Zealand standards have been used as the main source in order to develop the standards in the Dutch system.

The standards can be distinguished into two basic elements, i.e. standards for inspection procedures and standards for inspection decisions:

##### **1. Inspection procedures**

The starting point is that inspection procedures have to be carried out in compliance with Regulation (EC) 854/2004. Verification of the execution of official controls has to be done on the inspection station. The standard for the number of procedures is fixed at 5% per inspection position. By this standard is meant the maximum number of deviations of the number of inspection procedures. The size of the random sample is determined at  $\sqrt{n}$  ( $n$ =number of animals in a one-day production cycle) over two batches. A summary of the inspection procedures can be found in enclosure 2.

##### **2. Inspection decisions**

The verification of the correct execution of the inspection decisions distinguishes two parts, i.e. pathological abnormalities and hygienic slaughtering. The verification of pathological abnormalities takes place on the inspection station, as long as the carcass and the organs are running synchronically. The verification of hygienic slaughtering takes place between the trimming station and the end of the slaughtering line.

##### **Pathological abnormalities**

Regulation (EC) 854/2004, annex 1, section II, chapter V describes which pathological abnormalities are reason to declare meat unfit for human and/or animal consumption. The standard for missed pathological abnormalities is determined at 6% cumulative and is in fact a check on wrongly approved material. This standard consists of a 2% standard for the carcass, 2% for the pluck, and 2% for the organs. This cumulative standard is based on the fact that this was found to be very realistic in New Zealand. New Zealand is the only country that has experience in this area with meat.

The size of the random sample per inspection position to test the standard of 6% cumulative is fixed at  $\sqrt{n}$  ( $n$ =number of animals in a one-day-production cycle) over two batches. If the result of  $\sqrt{n}$  exceeds 50, these batches will be traced to two batches of a minimum of 25 carcasses per inspection position. The cumulative standard of 6% for missed pathological abnormalities is a guidance standard for the assessment of the post mortem inspection quality. Together with the size of the random sample, a statistically justifiable picture of the post mortem inspection quality is created.

### **Hygienic slaughtering**

In the first place it needs to be clear that faecal contamination has to be a Critical Control Point in the HACCP-system (EC Decision 2001/471). The slaughterhouse is responsible for the guaranteeing of this CCP.

In addition, slaughter animals with deviations as a result of errors in the slaughtering hygiene are offered for inspection, which require an inspection decision. The standard per carcass for contamination because of slaughtering errors is fixed at 2% total contamination and 0% faecal contamination. The faecal contamination will always have to be 0% at the end of the slaughtering line! The size of the random sample to test the standards of 2% and 0% is fixed at  $2\sqrt{n}$  ( $n$ =number of animals in a one-day-production cycle) over four batches. If the result of  $\sqrt{n}$  exceeds 50, these batches will be traced to four batches of a minimum of 25 carcasses.

### **Assessment of other aspects in relation to the post mortem inspection**

- Check on the synchronized running of the belts in relation to carcass and organs
- The official veterinarian will have to carry out the inspection of the carcasses which are to be examined further
- Supervision on the release of carcasses from the trimming station by KDS. The carcasses, which have to be transported to a trimming station, e.g. as a result of the implementation of the HACCP-system, will have to be cleaned up by employees of the slaughterhouse. Each slaughterhouse will have to arrange its processes this way. The release from the trimming station takes place under responsibility of KDS. KDS in turn operates under the responsibility of the official veterinarian.

## **2. Standard for the amount of staff required for supervision of the post mortem inspection and other supervisory tasks**

The supervision on the execution of the post mortem inspection (belt inspection) consists of the following elements:

- a) The Food and Consumer Product Safety Authority (VWA), Implementation Division, regularly audits externally for the compliance of the execution of the Quality Manual of KDS. The frequency of the audit varies between 1 to 4 times a year and will be based on a bonus/malus system.
- b) The official veterinarian verifies in each participating slaughterhouse the execution and compliance of the Quality Manual of KDS. This verification is aimed at veterinary procedures/training/refresher courses in the Quality Manual. The frequency of this verification will be based on a bonus/malus system.
- c) KDS will have to take care of sufficient availability of official auxiliaries. The VWA will not fill in "empty spots" for the post mortem inspection at the belt. No execution of the inspection means no slaughtering. The official veterinarian supervises the execution of the post mortem inspection carried out by official auxiliaries of KDS.
- d) The quality of the execution of the post mortem inspection will have to be verified regularly by the official veterinarian (in principle daily, but for small-sized meat slaughterhouses a different frequency can be used). The set standards and checklists will be used.

The other supervisory activities in a meat plant are contained in the hygiene regulations ((EC) 852/2004, 853/2004, 854/2004 and 882/2004) and other European regulations, and consists of the following elements:

- a) Supervision/execution ante mortem inspection (live inspection)
- b) Verification of hygiene plan on the basis of HACCP/hygiene codes/microbiological controls
- c) Verification of technical construction and equipment of the establishment; verification of various managerial aspects in an establishment, such as water management, pest control, health attestations of employees, register of incoming and outgoing material and general tracking and tracing, verification of the removal of animal by-products (category 1-, 2- and 3-material as meant in Regulation (EC) 1774/2002).
- d) Daily verification of hygiene, both before the start of the slaughtering and during the slaughtering
- e) Periodic sampling for residues, such as the National Plan and in case of suspected prohibited materials and in case of a suspicion of a contagious animal disease.
- f) With the implementation of Regulation (EC) 854/2004 on January 1, 2006, supervision will be directed more towards process control based on a complete HACCP integration and the evaluation of food chain information prior to slaughter.

The standard for the number of VWA staff required for the supervisory tasks listed above will be dependent on the situation of the slaughterhouse. This means that the number of official veterinarians and the number of assistants to supervisory veterinarians have to be determined.

### **3. Quality standards for auditing**

The official veterinarian has to have auditing qualifications in line with Regulation (EC) 854/2004.

### **4. Regulation of corrective measures**

KDS has to set up a system of guarantees and corrective measures based on the quality standards for post mortem inspection. This system will be part of the Quality Manual of KDS and will be tested by the VWA.

In case of insufficient performance of KDS, the official veterinarian may have to decide to withdraw inspection or to adapt the speed of the belt. Before taking such a measure, KDS will be offered the opportunity to take steps to guarantee the quality of the post mortem inspection procedures. If the steps taken by KDS do not guarantee the post mortem inspection quality, then it is up to the official veterinarian to take corrective measures.

### **5. Standard for the number of KDS official auxiliaries that need to be present**

Regulation (EC) 854/2004, Article 5, Part 4 states the following. Official auxiliaries may assist the official veterinarian with the official controls carried out in accordance with Sections I and II of Annex I with the frequency specified in Section III, Chapter I. In line with the implementation contract between VWA and KDS, the standard for the number of KDS official auxiliaries is determined as follows:

- a) VWA determines the number of official auxiliaries that perform inspection tasks and need to be present at the slaughter line of a slaughtering facility. This is in line with article 5, paragraph 5, part a of Regulation (EC) 854/2004 and based on a risk-based approach. The number of official auxiliaries is dependent on the type of slaughter facility and is fixed in the protocol in such a way that all requirement of Regulation (EC) 854/2004 are met.
- b) KDS may submit a proposal to change this number of official auxiliaries per slaughter line and slaughter facility. This proposal based on a risk-based approach per slaughter line and per slaughter facility, where the inspection takes place. KDS may request information from the official veterinarian about this risk-based approach.
- c) KDS will clarify this approach and will in consultation with the official veterinarian of the slaughter facility concerned submit a proposal to VWA on how the determined number of official auxiliaries should be changed.
- d) VWA will evaluate the KDS proposal and will proceed to determine the number of official auxiliaries that perform inspection tasks per slaughter line and per slaughter facility. VWA will then confirm this new number in the protocol of the slaughter facility concerned.
- e) VWA has the authority to change the number of official auxiliaries mentioned under a) and d), if the risk-based approach mentioned under a) and b) calls for it. If the number of determined official auxiliaries needs to be changed, VWA and KDS will consult together in order to guarantee the quality of the inspection procedures. In case of a change, the procedure listed under d) will be followed.
- f) KDS has to ensure that the number of required official auxiliaries determined under a) and d) is present at the slaughter line and in the slaughter facility concerned during the planned activities. KDS needs to take measures if the determined amount of official auxiliaries is not present to perform the inspection tasks. These measures are listed in the Quality Manual.

### **6. Standards for VWA staff**

For the supervision in a EU approved meat slaughter facility, the daily supervision consists of:

- Verification of control before the slaughtering begins
- Control on the hygienic procedures of the establishment
- A verification of the post mortem inspection
- Sampling of animals to be tested/National Plan
- Conclude extensive testing
- General supervision, such as BSE/Trichinella and category 1-, 2-, 3- material as meant under Regulation (EC) 1774/2002
- Administrative tasks

To carry out these supervisory duties, it was concluded that at least one official veterinarian would be required, together with a maximum of one assistant supervisory veterinarian in meat slaughter facilities under permanent VWA supervision.

Under this standard, the additional supervisory tasks that have to be carried out have not been taken into account. These are tasks such as:

- UBA/ISI<sup>1</sup> reporting, for which there is a separate frequency, depending on the degree in which the establishment meets the approval requirements
- HACCP-audit twice a year and a weekly verification of an effective implementation of the HACCP-system. The audit of the HACCP-system has to be done by an official veterinarian, because this is prescribed in Regulation (EC) 854/2004. A system auditor may assist.
- Audit for USA approval or other obligations of the establishment resulting from exports to a third country
- Assessment of protocols for BSE/TSE/third country canalisation requirements
- Export certification for third countries

The ante mortem inspection will also have to be done by the official veterinarian. For this the presence of at least one official veterinarian in a large meat slaughter facility is necessary. The policy to make use of official veterinarians for the ante mortem inspection, which was started a number of years ago, will thus remain unchanged.

## **7. Protocol**

For each slaughter facility a protocol needs to be set up, in which the number of official auxiliaries at the belt will be determined on an individual slaughterhouse level (see 5). Also the standard for the VWA activities need to be incorporated. This will result in a customized belt staffing and supervision. The protocol also needs to contain the agreements made, for instance for the processing of BSE, TSE, Trichinella results, permanent VWA supervision, and ritual slaughtering.

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<sup>1</sup> UBA and ISI are data registration systems

Enclosure 2

**Post mortem inspection procedures of the official auxiliaries for domestic porcines**

- 1) Carcasses and offal of pigs other than those referred to in paragraph 2 are to undergo the following post mortem inspection procedures:
  - a) Visual inspection of the head and throat; incision and examination of the submaxillary lymph nodes (Lnn. mandibulares); visual inspection of the mouth, fauces and tongue;
  - b) Visual inspection of the lungs, trachea and oesophagus; palpation of the lungs and the bronchial and mediastinal lymph nodes (Lnn. bifurcationes, eparteriales and mediastinales). The trachea and the main branches of the bronchi must be opened lengthwise and the lungs must be incised in their posterior third, perpendicular to their main axes; these incisions are not necessary where the lungs are excluded from human consumption;
  - c) Visual inspection of the pericardium and heart, the latter being incised lengthwise so as to open the ventricles and cut through the interventricular septum;
  - d) Visual inspection of the diaphragm;
  - e) Visual inspection of the liver and the hepatic and pancreatic lymph nodes (Lnn. Portales); palpation of the liver and its lymph nodes;
  - f) Visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (Lnn. gastrici, mesenterici, craniales and caudales); palpation and, if necessary, incision of the gastric and mesenteric lymph nodes;
  - g) Visual inspection and, if necessary, palpation of the spleen;
  - h) Visual inspection of the kidneys; incision, if necessary, of the kidneys and the renal lymph nodes (Lnn. renales);
  - i) Visual inspection of the pleura and the peritoneum;
  - j) Visual inspection of the genital organs (except for the penis, if already discarded);
  - k) Visual inspection of the udder and its lymph nodes (Lnn. supramammarii); incision of the supramammary lymph nodes in sows;
  - l) Visual inspection and palpation of the umbilical region and joints of young animals; in the event of doubt, the umbilical region must be incised and the joints opened.
- 2) The competent authority may decide, on the basis of epidemiological or other data from the holding, that fattening pigs housed under controlled housing conditions in integrated production systems since weaning need, in some or all of the cases referred to in paragraph 1, only undergo visual inspection).

Apart from the inspection procedures mentioned above, the VWA may indicate that other inspection procedures need to be done by the official auxiliaries. These may differ between slaughter facilities, but they are in all cases related to the post mortem inspection of red meat. Examples are sampling under the National Plan and for Trichinella testing.

## **Mughal, Ghias**

---

**From:** Feitel, Caroline [caroline.feitel@minbuza.nl]  
**Sent:** Thursday, May 18, 2006 12:29 PM  
**To:** McDermott, Steve  
**Cc:** Mughal, Ghias; WAS-LNV; White, Sally; Tacken, Wim  
**Subject:** Visitor from the Netherlands-May 26th-risk assessment

Dear Steve,

A representative of the Netherlands Food and Consumer product Safety Authority (VWA), Dr. Benno ter Kuile will give a presentation on risk management in the Netherlands, the interaction with the European Food Safety Authority and consequences for international trade, during the 106th General Meeting of the American Society for Microbiology. After this meeting, which will take place May 21-25 in Orlando Florida, Dr. Ter Kuile will be visiting Washington, DC on Friday May 26th. Dr. Ter Kuile would be very interested to discuss risk management with FSIS representatives and could give his powerpoint presentation on risk assessment, which he gave in Florida, to interested FSIS parties on the (morning of) the 26th. Afterwards there could be an informative exchange of views between professionals in the field of risk assessment. Would you be able to find out if there is interest within FSIS for a presentation by Dr. Ter Kuile? I would accompany him to FSIS. To make his presentation valuable he would prefer to give his actual powerpoint presentation.

Alternatively, FSIS is also invited to come to our Embassy, where Dr. Ter Kuile could also give his presentation that morning. Whatever would work best.

Thank you very much for your help. I very much look forward to hearing from you.

Yours truly,

Caroline Feitel

Caroline Feitel  
Agricultural Trade Officer  
Royal Netherlands Embassy  
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## memo

To  
Steering group visual inspection

Subject  
Final Report 'Pilot Chain Management' (b) (4)

Deleted:

datum  
24 januari 2006  
ons kenmerk

### Introduction

With the implementation of the hygiene regulations EC 852/2004, EC 853/2004 & EC 854/2004 the possibility was created for the application under certain conditions of a differentiated inspection regime for fattening pigs by which one or more incisions can be omitted (henceforward to be referred to as "visual inspection"). The verbatim text is as follows:

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behandeld door  
R. Lesuis  
telefoon (0575) 58 81 00  
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*'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.'*<sup>1</sup>

The condition 'epidemiological or other data' included above will be in addition to the providing of food chain information, which has also become mandatory on January 1, 2006.<sup>2</sup>

Based on this new legislation, the Food and Consumer Safety Authority (VWA) together with (b) (4) started a pilot in 2005 where a regime of visual inspection was applied in one slaughtering facility (Helmond). Under 2005 legislation (EC directive 609/433) incisions were still mandatory. Therefore, the pilot was a combination of visual inspection and traditional inspection.

The objective of the pilot was to gain answers to three questions, i.e.:

- Does the system of visual inspection guarantee that the right food chain information is provided in the right manner? If not, which adaptations are necessary.

<sup>1</sup> EC regulation 854/2004, Annex I, section IV, chapter IV, B Post-mortem inspection, paragraph 2

<sup>2</sup> Meanwhile, a phased implementation within the EU has been agreed on.

- Does the system safeguard that at least the same level of food safety is guaranteed.
- Is the selected supervision arrangement adequate, both in a quantitative sense as in the qualitative sense.

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24 januari 2006  
ons kenmerk

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In order to translate these questions into verifiable working procedures, three procedures were draughted in the initial phase, i.e.

- Procedure Control of Mycobacterium Avium in pork
- Procedure Food chain information
- Procedure Visual inspection

This report will describe the answers to the first two questions. The third question will not be answered in this report but will be dealt with in a different context.

### Material and methods

Both the (b) (4) and the VWA did research and collected data to provide answers to the questions that were formulated. The following types of data were collected:

By the VWA:

- A numeric comparison of historical VWA-inspection data with those of the pilot
- Results of checks performed by the official veterinarian during the pilot
- Results of risk-based research into antibiotics residues where food chain information played a role
- Specific rejection data (particularly endocarditis and results of bacteriological research)
- Supplementary literature data in relation to the categories mentioned above. In addition, literature data were collected in relation to:
  - The potential food safety risk of *Rhodococcus equi* in fattening pigs.
  - The potential food safety risk of *Mycobacterium Avium* in fattening pigs.
- Results of VWA-audits on the correct implementation of the three procedures mentioned above.

By (b) (4) Food:

- A serological testing method for Mycobacterium avium was developed and tested
- A system for the supplying of food chain information was developed and tested



### Procedural results

As mentioned in the introduction, specific procedures were developed for the pilot. In order to evaluate the content of the collected data on the pilot it is important to establish whether these procedures were followed. For this purpose the following information sources can be used:

- Audit reports: the audits did not show any serious shortcomings. The main findings were some necessary text adaptations in the procedures.
- Checks by the official veterinarian. During these checks it was found:
  - That the drawing of blood during slaughter took place lege artis and that the traceability of the samples was safeguarded.
  - That with the exception of the information on the M. avium status in the initial phase, the described food chain information has been correctly supplied in a minimum of 90 % of the cases.
- **(b) (4)** own checks on the completeness of the supplied food chain information (see *Results Food Chain Information (FCI) in the pilot 'Visual inspection'*): in the vast majority of the cases the FCI had been supplied in conformity with the procedure. At the start of the pilot the lack of information on group treatments was the main quantitative shortcoming. In the second phase it concerned mainly the information about the origin of the feed.

### Evaluation food safety balance

The project team determined in advance that visual inspection couldn't be introduced until at least the same level of food safety can be guaranteed as in the case of traditional inspection. Based on the collected data the following semi-quantitative balance can be provided per defined data source:

1. A numeric comparison of historical VWA-inspection data with those of the pilot (see also the Preliminary final report of the data analysis "pilot visual inspection", 5.1)

Initially a comparison was made between the inspection data from the historical summary and the inspection data during the pilot. It turned out that the total number of rejections with the historical data differed significantly in comparison with the data of the pilot. Because a traditional inspection also always took place during the pilot, which in principle did not differ from the inspection during the historical summary, this difference was unexpected. This difference could be explained by the fact that the supply of fattening pigs from the historical data did not match with the supply during the pilot. On the basis of possible bias, no further comparison of these two types of data was done.

During the pilot it turned out that a number of deviations, which were reason for rejection, and which were detected during the traditional inspection, were not detected

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## voedsel en waren autoriteit

during visual inspection. This happened in nine cases out of a total of 174250. In one case the testing for antibiotics was positive, in a number of cases the bacteriological testing was positive.

It should be mentioned, however, that there were also logistical factors, which could partly explain the difference between visual inspection and traditional inspection.<sup>3</sup>

The meaning of the pathogen agents which lead to a positive bacteriological testing will be explained later.

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Based on the data mentioned above it can be concluded that there is minimal loss of food safety.

2. Results of risk-based research into antibiotics residues where food chain information played a role (see also Preliminary final report of the data analysis " pilot visual inspection", 5.3 & (b) (4)4 contribution  
Detecting antibiotic residues in pork)

Based on earlier slaughtering data (increased number of lung-pleura deviations in four previous weeks), targeted testing for antibiotics was done. During the first screening a significant number of animals tested positive for antibiotics<sup>4</sup>. In two cases the MRL was exceeded which was a reason for rejection.

The conclusion that a – limited – gain in food safety was reached seems justified.

3. Specific rejection data (particularly endocarditis and results of bacteriological research) (see also Preliminary final report of the data analysis " pilot visual inspection", enclosure 2)

It was expected that the elimination of incisions in the heart muscle could result in the missing of a number of cases of endocarditis. It should be noted however that the prevalence of endocarditis is very low. (During the pilot 0,0034 %; range comparable historical data 0,005%<sup>5</sup> - 0,036%<sup>6</sup>).

Of the total number of six cases of endocarditis, two were detected during visual inspection. Only one of the six found endocardites turned out to be positive at bacteriological testing. This is lower than the percentage of positive endocarditides in

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<sup>3</sup> The comparison with the historical data showed, however, that the total number of rejections (the sum of visual inspection and traditional inspection) was significantly lower. This strongly suggests that the findings from historical data was not 100% comparable to the findings during the pilot.

<sup>4</sup> Reference: results of samples taken under the National Residues Plan at the slaughter facility in Helmond

<sup>5</sup> Slaughter establishment (b) (4) 2004

<sup>6</sup> W.Wouda et al. Endocarditis and meat inspection of slaughter pigs. Journal of Animal Medicine, part 112, edition 21, 1987, p. 1226-1235. The percentage mentioned concerns data of 1982.

2004 at slaughter facility (b) (4) but in view of the low numbers it is difficult to draw hard conclusions from this.

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From VWA's own data, but also from literature data, it turns out that in a number of cases (10,5-16,7%) a pathogen agent (*A. pyogenes*) is concerned of which the significance for public health is considered negligible. In a number of other cases it is not always possible to make a direct connection with food safety.

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The conclusion is that the possible missing of endocarditides could mean a limited to very limited loss of food safety, especially if the pathogenicity of the pathogen agents found is incorporated.

4. Data surface contamination *Salmonella* spp. Head area before and after incision of the mandibular lymph nodes (see *Vion Food -contribution Salmonella monitoring*)

It has turned out that the incision of the mandibular lymph nodes greatly increases the chance for surface contamination with *Salmonella*. From a pathophysiological point of view, this is explainable because the mandibular lymph nodes are a predilection location for the presence of *Salmonella*. In a small number of cases there is a reversed effect, namely that is no longer possible to demonstrate the presence of *Salmonella* after the incision. This could be explained by values that are close to the detection limit of the analysis.

Based on these data, the demonstrated over-all positive effect of no incision and other literature data, the (b) (4) contribution shows that the omission of the incision can play a clear role in the prevention of *Salmonella* caused food infections originating from contaminated pork..

The conclusion is that omitting the incision of the mandibular lymph nodes in relation to the risk of *Salmonella*-contamination leads to considerable gains in food safety.

5. Literature data collected in relation to the potential food safety risk of *Rhodococcus equi* in the mandibular lymph nodes of fattening pigs. (See also Preliminary final report of the data analysis "pilot visual inspection", enclosure 1)

The reason for including this pathogen agent in the research was the fact that this pathogen agent has been found fairly regularly in lymph nodes with purulent lesions of pigs. The lesion is comparable to the lesion that can be caused by *M. Avium*. In humans with immunodeficiencies (HIV/AIDS patients) the pathogen agent can a.o. cause pneumonia, with fatal results. A clear etiological connection has not been demonstrated, however. Moreover, it can be argued that the incision of the lymph nodes could have a

contraproductive effect. In addition, it is known from literature that the macroscopic detection of *Rhodococcus equi* infections using purulent infection focuses has its limitations.

An important difference with *M. avium* (see below) is that the presence of *Rhodococcus equi* in fattening pigs is almost always limited to the head lymph nodes. *M. avium* can also systemically spread in pigs.

The conclusion is that there are, for the time being, not enough data available to determine either a gain or a loss in food safety.

6. Literature data in relation to the potential food safety risk of *Mycobacterium Avium* in fattening pigs. (See also the Preliminary final report of the data analysis "pilot visual inspection", enclosure 3)

It has turned out that the presence of purulent lesions in lymph nodes is not always an indication of the presence of *M. Avium*. Inversely *M. Avium* can also be found in lymph nodes without such lesions. No distinct conclusion can be drawn over the zoonotic character. Just like in the case of *Rhodococcus equi* this pathogen agent especially plays a role in immunodeficient humans and in children. As mentioned above, this pathogen agent could spread systemically in fattening pigs. In the analysis *Risk Assessment System Meat Production Chain – phase 1* a panel of experts has concluded that with respect to the significance of *M. avium* for food safety there are gaps in knowledge, but that there could be an element of priority.<sup>7</sup>

The conclusion is that :

- The significance of *M. Avium* in fattening pigs for food safety is largely unknown, but should not be considered a negligible risk either
- The incision of lymph nodes as a means of detection has limited significance

7. The results of serological monitoring for *M. Avium* (see *Results monitoring Mycobacterium avium*<sup>8</sup> and *A serological approach of the control of Mycobacterium avium spp avium in the fattening pigs production chain: a descriptive analysis of the pilot data of the* (b) (4) (4) *and Animal Sciences Group*<sup>9</sup>)

In the course of the pilot, a considerable number of samples have been taken (22461). Because new pigs farms joined in the course of the pilot, it was not possible to determine the *Mycobacterium avium* status for all farms conform the procedure for the minimum number of samples. Nevertheless, it was possible to take more than 10

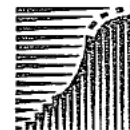
<sup>7</sup> Risk Assessment System Meat Production Chain– Report phase 1, Final draft 11 August 2004.

<sup>8</sup> Draft version

<sup>9</sup> Concept version



U.S. Department of Agriculture  
Food Safety and Inspection Service  
International Equivalence Staff  
Ms Sally White  
Director  
South Building, room 4434  
Washington, D.C. 20250



landbouw, natuur en  
voedselkwaliteit

U.S.A.

Your letter of	your reference	our reference	date
Feb. 24, 2006		VD 06.1018/IH	31-3-2006
re:		extension no.	enclosures
2006 audit preparation		+31-70-3785435	2

\_\_\_\_\_ Dear Ms. White,

|

Your letter dated February 24, 2006, to the European Commission informing them of the dates of the upcoming annual audit of the Netherlands meat inspection system (April 19 through May 18, 2006) has been brought to my attention and I am happy to confirm these dates to you. The details of the audit and the itinerary to be followed are currently being worked out by our services.

As agreed during my visit of December 8, 2005, I take pleasure in providing you with additional information about recent changes in our meat inspection system, which I believe will be of benefit for your auditor in the preparation of his visit. These changes are in part resulting from the introduction of the new EU Hygiene Regulations on January 1, 2006, which cover the entire spectrum of food safety, including meat and meat products. This new legislation was discussed between FSIS and the European Commission at the

Ministry of Agriculture,  
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Food Quality and Animal  
Health  
Cluster International  
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recent Joint Management Committee meeting in October 2005. On January 12, 2006, the European Commission sent you a complete set of the acts and related implementing measures.

In our letter of February 14, 2006, we elaborated on the information provided by the Commission, by informing all CVO's in our foreign markets of the new and old legislation and certain other changes, which might have an effect on the text of our veterinary health certificates.



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There are two aspects of our meat inspection system that I would like to specifically address in this letter, i.e. the option of visual post mortem inspection offered under the new legislation, and the delegation of certain elements of the post mortem meat inspection from the official veterinarian to official auxiliaries employed by an independent organization, which is permitted under both old and current EU legislation.

#### **A. Visual post mortem inspection**

During my visit on December 8, 2005, we discussed developments in the philosophy of meat inspection in the EU and certain comparable developments in the US (i.e. HIMP Market Hogs). We agreed that this topic was of mutual interest and that an exchange of

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information by U.S. and Dutch experts could take place during a conference call. Unfortunately, a mutually convenient date for this conference call has not been found yet, but we remain keenly interested in setting this up, preferably before the next audit. The hygiene regulations EC 852/2004, EC 853/2004 and EC 854/2004 offer the possibility for fattening pigs, housed under controlled conditions in integrated production systems since weaning, to be subject to a visual inspection before and after slaughter. This visual inspection is part of a risk-based inspection system. Application of this inspection system requires the availability of food chain information and epidemiological data. Every enterprise has the option to either stick to the "old" system or to implement a visual inspection system. The legal basis of visual inspection is to be found in Appendix 1, Section IV, B post-mortem inspection of EU Regulation 854/2004.

The (b) (4) Company, the major pork producer in the Netherlands, looked into the merits of this type of inspection and consulted with the competent authority, the Food and Consumer Product Safety Authority (VWA), on how to proceed. In order to get official approval for the new inspection system, (b) (4) had to demonstrate to VWA that the produced pork would at least meet the EU set levels of food safety and would fulfill the

mandatory EU hygiene regulations provisions.

For your information I would like to refer you to the enclosed final evaluation of (b) (4) pilot project, which was carried out in one of the slaughter plants of that company. As you will remember, a company report on this pilot project was submitted to you during our meeting on December 8, 2005.

VWA investigated the content of the chain management system in order to be convinced that the official requirements laid down in regulation (EC) 853/2004 have been met and that the submitted Food Chain Information was sufficient to realize - at least - a similar level of food safety by means of the applied visual inspection, in comparison to the current procedures for meat inspection. These two prerequisites constitute the basis for official certification. Based on their positive findings, VWA gave VION the green light to

implement the visual inspection system. You will find the VWA final report 'Pilot Chain Management' (b) (4) enclosed.

In February 2006 the Food and Veterinary Office of the European Commission visited the pilot slaughterhouse during an inspection mission on the official controls related to food safety of animal products and took note of the applied visual inspection system. FVO found the slaughterhouse in compliance with EU legislation.

With both the VWA approval and the positive FVO report, (b) (4) intends to now fully implement this inspection system in their Helmond facility. This will enable your auditor to personally observe the way in which the system works, when he visits this establishment, which I believe is planned at the end of the program.

I would like to underline that it is a company's decision to apply for a food chain management and visual inspection system. Whether other Dutch pork producers will try to implement such a system is unknown. If they will, every implementation will be evaluated by VWA.



Date  
31-3-2006

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VD 06.1018/IH

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**B. New organization of the red meat inspection system**

During our meeting on December 8, 2005, the delegation of certain aspects of the post mortem meat inspection from the VWA to an independent organization was also raised, and you indicated that this topic had been brought to your attention before. At your request, a formal document explaining the details of this delegation has been drawn up, and I take pleasure in sending you this report as an enclosure. The report focuses on meat slaughterhouses under permanent supervision of the VWA.

I hope that the above information on the new EU legislation and the modernization of meat inspection will provide a good basis for discussion during the upcoming audit. I am looking forward to your response with great interest, especially on my suggestion to hold a conference call on visual post mortem meat inspection on short notice.

Yours sincerely,  
CHIEF VETERINARY OFFICER,

(b) (6)

cc:

Ms. Karen Stuck, Assistant Administrator, USDA/FSIS

Mr. William James, Deputy Assistant Administrator, USDA/FSIS

Mr. Steven McDermott, Deputy Director International Equivalence Staff, USDA/FSIS

Mr. Ghias Mughal, Senior Equivalence Officer, USDA/FSIS

Ms. Anita Manka, Senior Food Technologist, USDA/FSIS

(b) (6)

Food and Consumer Product Safety Authority (VWA)

Agricultural Counselor Washington, DC

**(Draft)**

## **Results Food Chain Information (FCI) in the pilot 'Visual Inspection'**

### **Summary**

During the pilot, Food Chain Information (FCI) is made available by the supply chain for the visual inspection of slaughter pigs. On average, 98% of the delivered herds arrived at the slaughter plant with the correct FCI. While on average for 99% of the delivered herds the information is available just before slaughtering the pigs. Lack of information about the origin of feed is the main reason for not being accepted to 'visual inspection'. The FCI is also used to decide whether a farm is part of the residue monitoring program. This program is risk based and resulted in average on 14% of the farms that were selected for residue monitoring. The serological results of MA monitoring is not yet part of the Food Chain Information, while the monitoring started during the pilot.

### **Methods**

During the pilot, FCI is provided through the supply chain for the visual inspection of slaughter pigs. All groups of pigs presented for inspection must comply with the following information:

- Pigs from farms meeting the requirements laid down in the Code of Practice of the IKB-scheme or equivalent quality assurance schemes;
- Individual pigs of IKB status;
- Pigs from farms providing data on origin of feed;
- Pigs from farms providing data on group treatment of pigs covering a minimum period of two months prior to slaughter.
- Pigs from farms with a neutral to low Farm Risk Profile (FRP) with respect to *Mycobacterium avium* (This was not yet implemented in the pilot).
- When percentages of lung lesion and pleurisy in the previous 4 weeks, are higher than twice the slaughterhouse average, additional checks for antibiotic residues will occur. A risk-based monitoring is performed regarding a higher risk of group treatments.

The farmer supplies the information on group treatment and IKB status of the pigs, the other information is supplied through (b) (4) Farming. The slaughterhouse checks the IKB status of every batch of pigs presented for slaughter (verification with the aid of Verin's database and IKB-2004). IKB audits verify the delivery of GMP+ approved feed. Data on delivery forms are checked against data on feed supply documents. When in doubt, calculations can be made on the basis of the stated quantity of feed and the number of pigs presented for slaughter.

In the future, the official veterinarian decides on basis of this information, whether the carcasses of pigs will be subjected to a visual or a traditional post mortem inspection. In the pilot, all the carcasses are is subjected to visual and traditional post mortem inspection.

An employee at the slaughterhouse checks if all the required Food Chain Information is available. The employee checks the IKB status, group medicine information, percentage of lung lesions and/or pleurisy and origin of feed. Incomplete information for one of these items is recorded per farm.

Pigs not complying with IKB are separated by means of canalisation. From each herd with lung lesions and/or pleurisy higher than twice the slaughterhouse average an additional check on antibiotic residues is carried out.

### **Results**

Figure 1 and 2 show the % farms which are accepted for 'visual inspection' at respectively arrival at the slaughterhouse and just before the actual slaughtering, in the period of 15 September 2005 till 5 January 2006.

The information needed for the visual inspection of slaughter pigs is not always complete at arrival at the slaughterhouse. On average, 98% of the delivered herds provide the correct information at arrival at the slaughter plant, while for 99% of the delivered herds the information is available just before slaughtering the pigs.

Figure 1 % Farms accepted to 'visual inspection' at arrival slaughterhouse (except for *M. avium*)

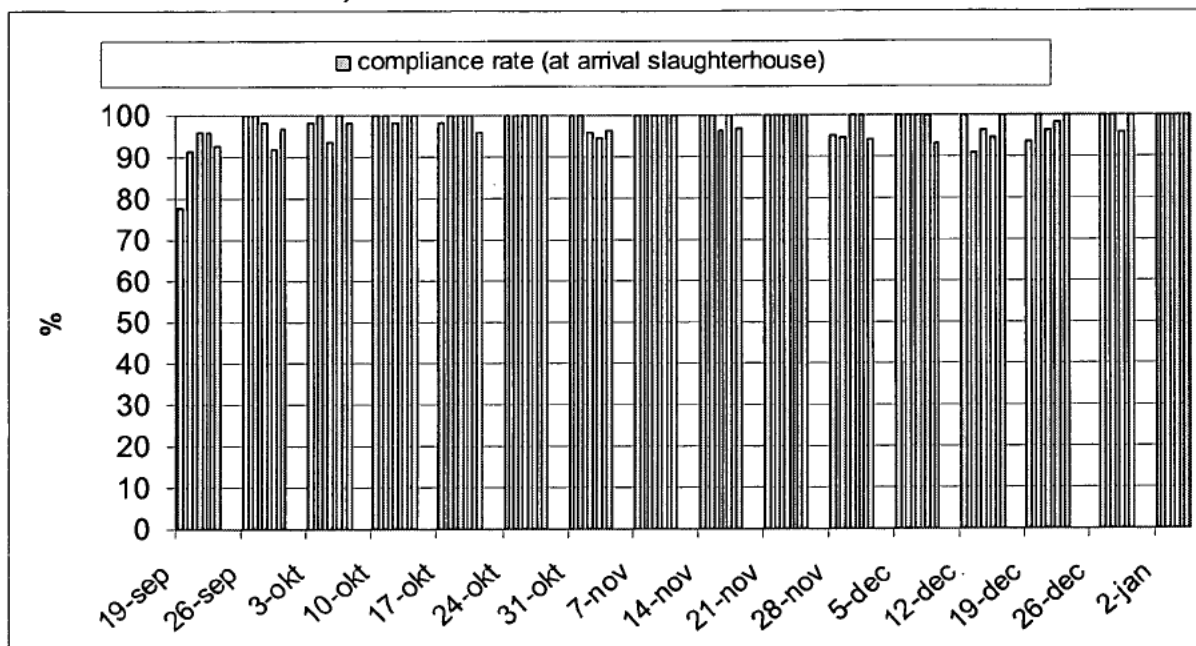


Figure 2 % Farms accepted to 'visual inspection' at start slaughtering pigs (except for *M. avium*)

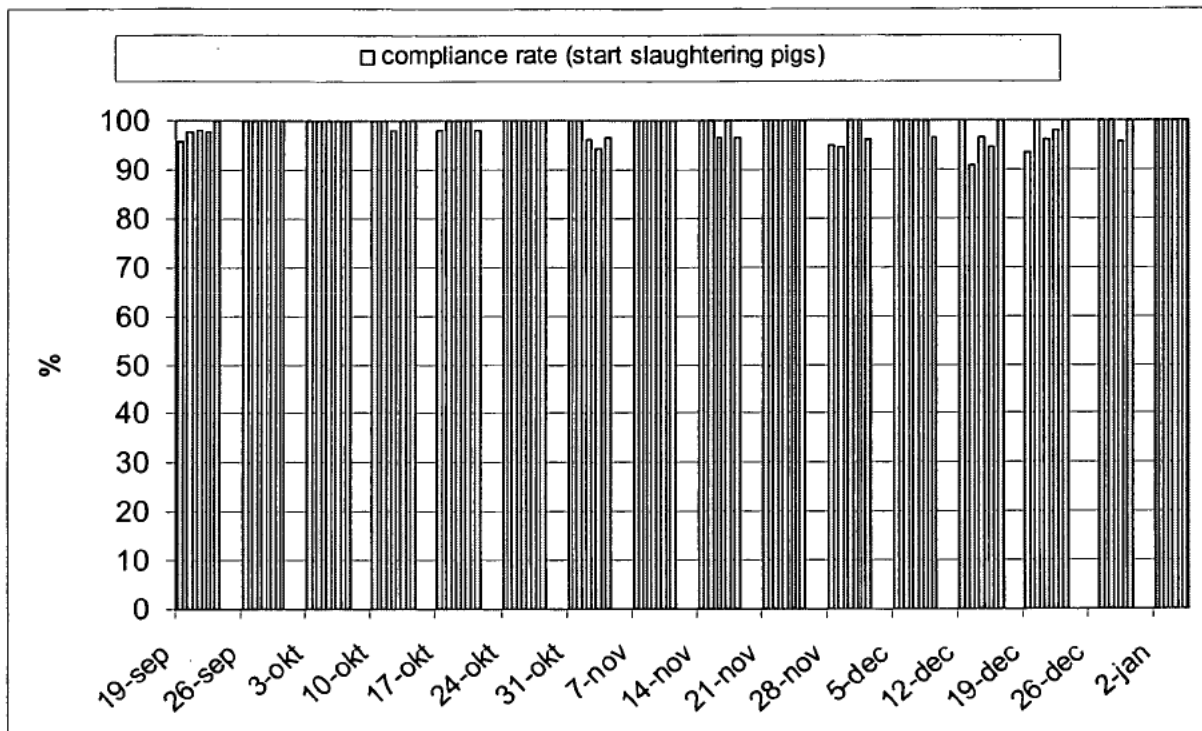
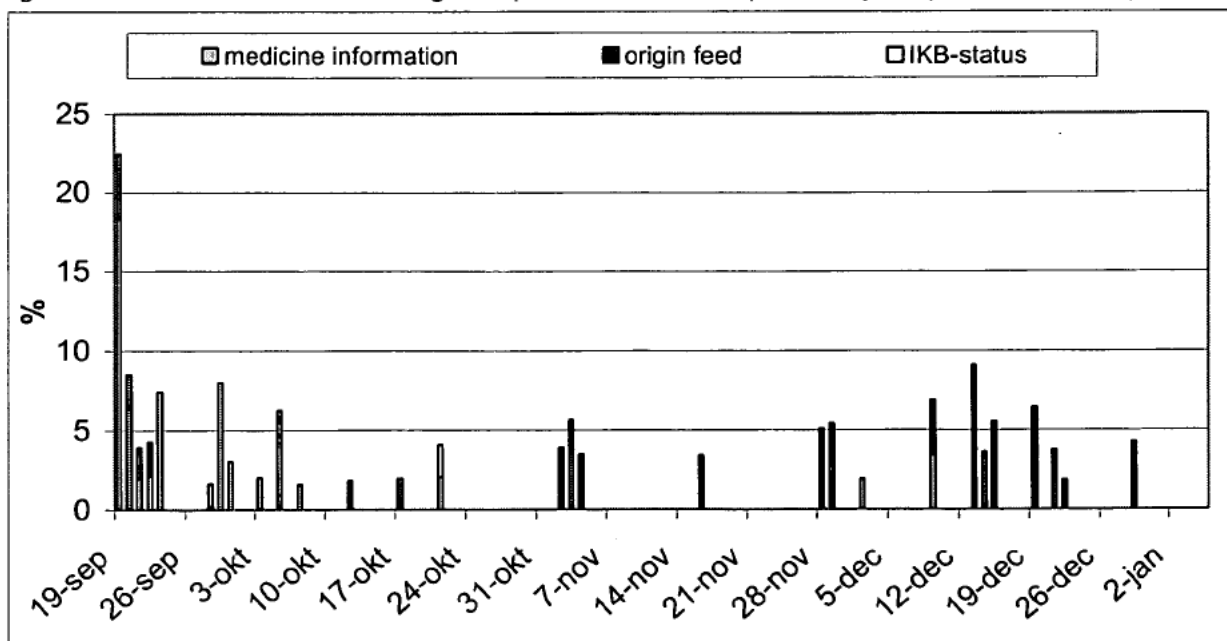


Figure 3 shows the reasons for not being accepted for 'visual inspection'. The Farm Risk Profile for M. Avium is not yet included in this figure. In the beginning of the pilot the absence of the information concerning group treatment was the main reason for a herd of pigs not being accepted for 'visual inspection' (see figure 3). The farmers had to adjust to the new procedure to provide this information on the transport document.

(b) (4) Farming records the origin of feed per farm. Figure 3 shows that this record is not 100% complete yet and is during the pilot the main reason for not being accepted to 'visual inspection'.

Figure 3 Reason for not being accepted for 'visual inspection' (except for M. Avium)

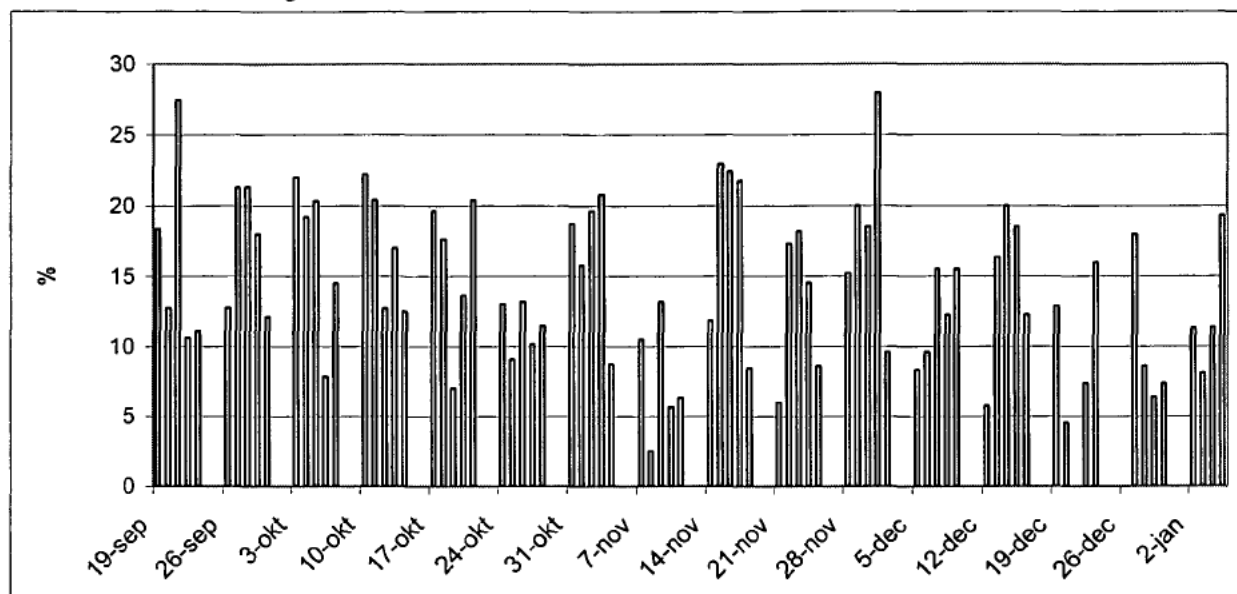


When percentages of lung and liver lesion and pleurisy in the previous 4 weeks, are



higher than twice the slaughterhouse average, additional checks for antibiotic residues will occur. A risk-based control is performed regarding a higher risk of group treatments.

Figure 4      % farms with % lung lesion and/or pleurisy more than twice the average of the slaughterhouse



On average 14% of all farms, had in the previous 4 weeks an average percentage of lung and/or pleurisy lesions, higher than twice the slaughterhouse average. From each farm of that group, an additional check for antibiotic residues was required.

## Pork Supply Chain Meat Inspection

Ate Jelsma  
Food and Consumer Product Safety Authority (VWA)  
Directorate of Inspection and Communication  
The Netherlands

EU seminar Lyon 2008

Ate Jelsma, the Netherlands

1



### Subjects:

- (small) overview relevant EU legislation
- project visual inspection pigs and results in NL 2005/2006
- continuation project and results until 2008

EU seminar Lyon 2008

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## EU-Food safety legislation

- General Food law – Regulation 178/2002
- H 1 - hygiene of foodstuffs – Regulation 852/2004
- H 2 - hygiene rules for food of animal origin – Regulation 853/2004
- H 3 - official controls (meat inspection) – Regulation 854/2004
- H 4 – 2002/99/EC (animal health)
- H 5 - repealing 17 directives
- Official Feed & Food Controls – Regulation 882/2004

EU seminar Lyon 2008

Ate Jelsma, the Netherlands

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## Pilot project pork supply chain meat inspection in the Netherlands

Hygiene Package, Regulation 854/2004, ANNEX I, section IV, Chapter IV, point B 2:

"the competent authority may decide, on the basis of epidemiological or other data from the holding, that fattening pigs housed under controlled housing conditions in integrated production systems since weaning need, in some or all of the cases referred to in paragraph 1, only undergo visual inspection"

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## Pilot project

### Procedures:

- Procedure Food Chain Information (FCI)
- Procedure control of *Mycobacterium avium*
- Procedure visual p.m. inspection
- Inspection arrangement VWA
- Investigation on Salmonella in throat area before and after incision of lymph nodes of the head

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## FCI

Based on the IKB system of the industry:

- FCI: items of Regulation 853/2004, Annex II, Section III, point 3, a) till h)
- Water, pest control
- Animal health and animal movements
- Additional on top of IKB:
- Feed origin
- Outdoor management
- Control on compost (not used)
- History of treatment with antibiotics last two months before slaughtering
- Historical data of previous pathological findings at slaughter (pleurisy, pneumonia, liver and skin disorders).

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## Procedure FCI

Allowed to visual p.m. inspection:

- IKB status/FCI format + additional requirements
- Selection of pigs from farmers with more than the average of deviations of lungs/pleura for further investigation on antibiotics (VWA)
- Only fattening pigs
- Comply with *M. Avium* procedure

## Procedure *M. Avium*

Procedure *M. Avium* :

- Blood sera for verification on *M. avium*
- Registration of all the results gives a Risk Profile at farm level (BRP)
- Three categories BRP:
  - Neutral, low and high with different decisions
- Supervision of control is based on:
  - Samples are taken under supervision of competent authority
  - Audit by the competent authority of the procedures

## Procedure visual p.m. inspection pigs

Visual inspection based on:

- FCI information available in the slaughterhouse, 24 hours before slaughtering
- BRP *M. Avium* is neutral or low
- Visual inspection, and for all non-conformities followed by "traditional" inspection with incisions of heart, lung and lymph nodes of the head

## Procedure inspection arrangement

VWA audits and verification

- Audit on procedures FCI and *M. Avium*
  - Audit on delivering FCI at slaughterhouse level
  - Audit on implementation of FCI
- Verification at slaughterhouse level: FCI, *M. Avium* and visual inspection (see next slide)
- Verification at farm level

## Procedure inspection arrangement

Verification by official veterinarian of the VWA at slaughterhouse level

- Check on FCI
- Check on *M. Avium* status with Risk Profile level (BRP)
- Check on program of blood-sera and traceability of samples
- Check on decisions made by visual p.m. inspectors

## Supervision on p.m. in Pork Supply Chain Meat Inspection

Supervision based on two pillars:

1. Regular supervision by the OV of the work of the OA
    - Inspection tasks
    - Inspection decisions (pathological defects and hygienic slaughtering)
  2. Monitoring of the plant operators on slaughter defects and pathological observations just before cooling:
    - 4 times a day 40 carcasses
    - 2 times a day 40 plucks
- This performance of the whole process of pm inspection and rework should be below 2% defects.
- The OV verifies 2x /day also 40 carcasses to check the quality of the monitoring of the plant.

## Literature aspects

Three aspects in literature

- Hazard analysis for food safety of *Rhodococcus equi*
- Risk assessment for food safety of endocarditis
- Hazard analysis for food safety of *M. avium*

## Testing during pilot

During pilot tests have been done for:

- Comparison inspection results visual and traditional p.m. inspection
- Selection of pigs from farmers with more than the average of deviations of lungs/pleura for further investigation on antibiotics
- Literature
- Serological verification system for *M. avium*
- Investigation on Salmonella in throat area

## Result Comparison inspection results

Comparison inspection results visual p.m. inspection with historical results:

- Report with analysis of the data from pilot and historical data
- During the pilot 174,250 pigs were inspected

## Result Comparison inspection results

- 174,250 were inspected
- 9 carcasses were not detected by visual inspectors and were condemned by traditional inspection
  - 1 positive for antibiotic examination
  - 4 positive by bacteriological examination (3 *A. pyogenes*)
  - 4 other reasons

## Result Comparison inspection results

- Low amount of not detected carcasses
- Maybe logistic reasons for not detecting some carcasses
- Literature of *A. pyogenes*: low risk for food safety

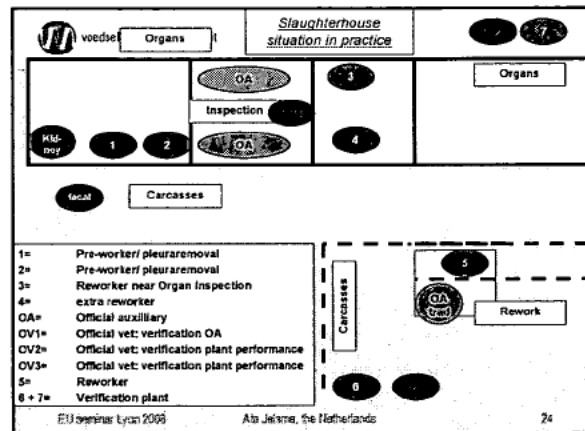
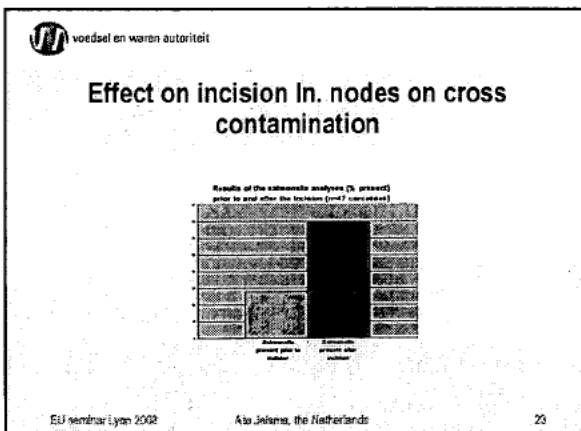
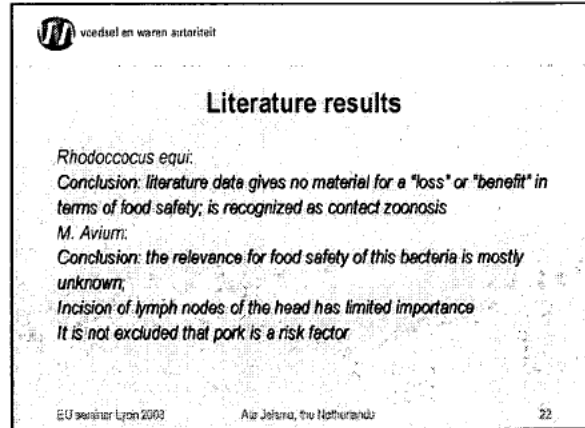
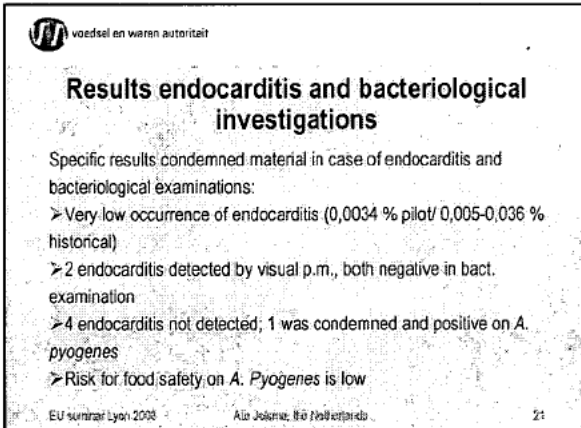
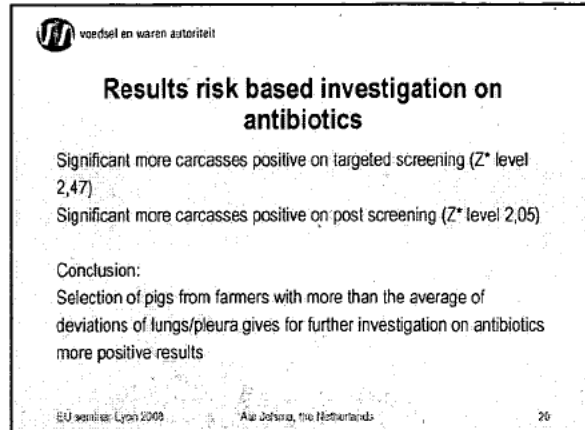
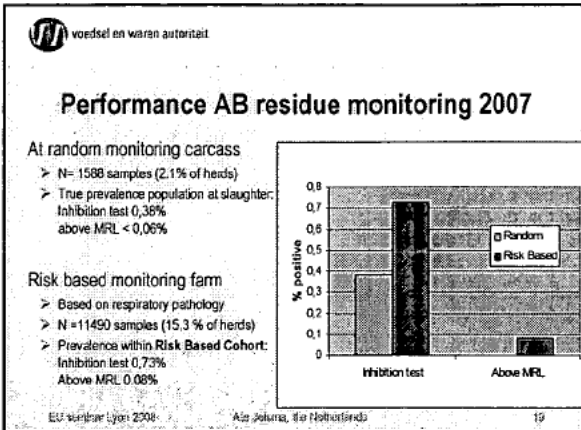
## Results audits and controls of official veterinarian

Audits:

- no major remarks

Verification by Official Veterinarian:

- Verification on program of blood-sera and traceability of samples: no remarks
- After "start" problems: delivering FCI correct for > 90 %



## Standard visual inspection

- > Same standard as used for traditional inspection
  - > Inspection tasks
  - > Inspection decisions (pathological defects and hygienic slaughtering)

Results of check on performing the p.m inspection in traditional and visual inspection (pork supply chain meat inspection) during and after pilot: no difference in results and both systems fulfil the standard (inspection task: 5% and path. defects and hyg. slaughtering: both below 2%)

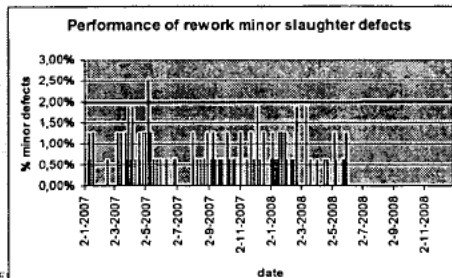
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## Reporting process performance 2007-2008

Target level is below 2% daily. Non conformance with this target is followed by increased inspection by the competent authority.



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## Risk profiling farms for MAA

- High risk farms
- >> traditional inspection
  - >> control program at farm
  - >> access to supply chain inspection after repeated negative testing

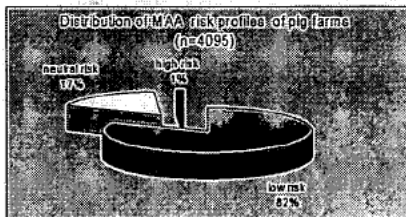


Figure: Distribution of MAA risk profiles of pig farms (n=4095) August 2007.

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## Does the system safeguard that at least the same level of food safety is guaranteed?

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## Level of food safety

- > Number of condemnations
  - > Pilot: visual + traditional: 0,0247 %
  - > Pilot: visual: 0,0195 %
  - > Pilot: visual not detected and condemned by traditional: 0.0052 %;
- > Endocarditis: two out of six cases detected with visual inspection;
- > Risk-based testing against residues of antibiotics: significant more carcasses positive on (post) screening;
- > Omitting of incision of the mandibular lymphnodes showed a substantial reduction in the cross contamination of salmonella in that region;
- > Implementation of *M. Avium* farm control system with the monitoring of antibodies as a verification procedure and defining a herd status

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## Level of food safety

The introduction of a hands off system by visual inspection during the pilot has shown that this system has an advantage in terms of food safety!

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## Key terms

- FCI from farmer level to the slaughterhouse is basic
- Serological monitoring system: Risk profil farmer (M. Avium)
- Information on slaughterhouse level used for testing residues related to farmer level
- OV in charge for auditing the system



voedsel en waren autoriteit

**memo**

To  
Steering group visual inspection

Subject  
Final Report 'Pilot Chain Management' (b) (4)

Deleted:

datum  
24 januari 2006  
ons kenmerk

**Introduction**

With the implementation of the hygiene regulations EC 852/2004, EC 853/2004 & EC 854/2004 the possibility was created for the application under certain conditions of a differentiated inspection regime for fattening pigs by which one or more incisions can be omitted (henceforward to be referred to as "visual inspection"). The verbatim text is as follows:

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behandeld door  
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telefoon (0575) 58 81 00  
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*'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.'*<sup>1</sup>

The condition 'epidemiological or other data' included above will be in addition to the providing of food chain information, which has also become mandatory on January 1, 2006.<sup>2</sup>

Based on this new legislation, the Food and Consumer Safety Authority (VWA) together with (b) (4) started a pilot in 2005 where a regime of visual inspection was applied in one slaughtering facility (Helmond). Under 2005 legislation (EC directive 64/433) incisions were still mandatory. Therefore, the pilot was a combination of visual inspection and traditional inspection.

The objective of the pilot was to gain answers to three questions, i.e.:

- Does the system of visual inspection guarantee that the right food chain information is provided in the right manner? If not, which adaptations are necessary.

<sup>1</sup> EC regulation 854/2004, Annex I, section IV, chapter IV, B Post-mortem inspection, paragraph 2

<sup>2</sup> Meanwhile, a phased implementation within the EU has been agreed on.



- Does the system safeguard that at least the same level of food safety is guaranteed.
- Is the selected supervision arrangement adequate, both in a quantitative sense as in the qualitative sense.

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In order to translate these questions into verifiable working procedures, three procedures were draughted in the initial phase, i.e.

- Procedure Control of Mycobacterium Avium in pork
- Procedure Food chain information
- Procedure Visual inspection

This report will describe the answers to the first two questions. The third question will not be answered in this report but will be dealt with in a different context.

### Material and methods

Both the (b) (4) and the VWA did research and collected data to provide answers to the questions that were formulated. The following types of data were collected:

By the VWA:

- A numeric comparison of historical VWA-inspection data with those of the pilot
- Results of checks performed by the official veterinarian during the pilot
- Results of risk-based research into antibiotics residues where food chain information played a role
- Specific rejection data (particularly endocarditis and results of bacteriological research)
- Supplementary literature data in relation to the categories mentioned above. In addition, literature data were collected in relation to:
  - The potential food safety risk of *Rhodococcus equi* in fattening pigs.
  - The potential food safety risk of *Mycobacterium Avium* in fattening pigs.
- Results of VWA-audits on the correct implementation of the three procedures mentioned above.

By (b) (4) Food:

- A serological testing method for Mycobacterium avium was developed and tested
- A system for the supplying of food chain information was developed and tested

### Procedural results

As mentioned in the introduction, specific procedures were developed for the pilot. In order to evaluate the content of the collected data on the pilot it is important to establish whether these procedures were followed. For this purpose the following information sources can be used:

- Audit reports: the audits did not show any serious shortcomings. The main findings were some necessary text adaptations in the procedures.
- Checks by the official veterinarian. During these checks it was found:
  - That the drawing of blood during slaughter took place lege artis and that the traceability of the samples was safeguarded.
  - That with the exception of the information on the M. avium status in the initial phase, the described food chain information has been correctly supplied in a minimum of 90 % of the cases.
- (b) (4) own checks on the completeness of the supplied food chain information (see *Results Food Chain Information (FCI) in the pilot 'Visual inspection'*): in the vast majority of the cases the FCI had been supplied in conformity with the procedure. At the start of the pilot the lack of information on group treatments was the main quantitative shortcoming. In the second phase it concerned mainly the information about the origin of the feed.

### Evaluation food safety balance

The project team determined in advance that visual inspection couldn't be introduced until at least the same level of food safety can be guaranteed as in the case of traditional inspection. Based on the collected data the following semi-quantitative balance can be provided per defined data source:

1. A numeric comparison of historical VWA-inspection data with those of the pilot (see also the Preliminary final report of the data analysis "pilot visual inspection", 5.1)

Initially a comparison was made between the inspection data from the historical summary and the inspection data during the pilot. It turned out that the total number of rejections with the historical data differed significantly in comparison with the data of the pilot. Because a traditional inspection also always took place during the pilot, which in principle did not differ from the inspection during the historical summary, this difference was unexpected. This difference could be explained by the fact that the supply of fattening pigs from the historical data did not match with the supply during the pilot. On the basis of possible bias, no further comparison of these two types of data was done.

During the pilot it turned out that a number of deviations, which were reason for rejection, and which were detected during the traditional inspection, were not detected

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during visual inspection. This happened in nine cases out of a total of 174250. In one case the testing for antibiotics was positive, in a number of cases the bacteriological testing was positive.

It should be mentioned, however, that there were also logistical factors, which could partly explain the difference between visual inspection and traditional inspection.<sup>3</sup> The meaning of the pathogen agents which lead to a positive bacteriological testing will be explained later.

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Based on the data mentioned above it can be concluded that there is minimal loss of food safety.

2. Results of risk-based research into antibiotics residues where food chain information played a role (see also Preliminary final report of the data analysis " pilot visual inspection", 5.3 & (b) (4) contribution  
Detecting antibiotic residues in pork)

Based on earlier slaughtering data (increased number of lung-pleura deviations in four previous weeks), targeted testing for antibiotics was done. During the first screening a significant number of animals tested positive for antibiotics<sup>4</sup>. In two cases the MRL was exceeded which was a reason for rejection.

The conclusion that a – limited – gain in food safety was reached seems justified.

3. Specific rejection data (particularly endocarditis and results of bacteriological research) (see also Preliminary final report of the data analysis " pilot visual inspection", enclosure 2)

It was expected that the elimination of incisions in the heart muscle could result in the missing of a number of cases of endocarditis. It should be noted however that the prevalence of endocarditis is very low. (During the pilot 0,0034 %; range comparable historical data 0,005%<sup>5</sup> - 0,036%<sup>6</sup>).

Of the total number of six cases of endocarditis, two were detected during visual inspection. Only one of the six found endocardites turned out to be positive at bacteriological testing. This is lower than the percentage of positive endocarditides in

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<sup>3</sup> The comparison with the historical data showed, however, that the total number of rejections (the sum of visual inspection and traditional inspection) was significantly lower. This strongly suggests that the findings from historical data was not 100% comparable to the findings during the pilot.

<sup>4</sup> Reference: results of samples taken under the National Residues Plan at the slaughter facility in Helmond

<sup>5</sup> Slaughter establishment (b) (4) 2004

<sup>6</sup> W.Wouda et al. Endocarditis and meat inspection of slaughter pigs. Journal of Animal Medicine, part 112, edition 21, 1987, p. 1226-1235. The percentage mentioned concerns data of 1982.

2004 at slaughter facility (b) (4) but in view of the low numbers it is difficult to draw hard conclusions from this.

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From VWA's own data, but also from literature data, it turns out that in a number of cases (10,5-16,7%) a pathogen agent (*A. pyogenes*) is concerned of which the significance for public health is considered negligible. In a number of other cases it is not always possible to make a direct connection with food safety.

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The conclusion is that the possible missing of endocarditides could mean a limited to very limited loss of food safety, especially if the pathogenicity of the pathogen agents found is incorporated.

4. Data surface contamination *Salmonella* spp. Head area before and after incision of the mandibular lymph nodes (see (b) (4) *Food -contribution Salmonella monitoring*)

It has turned out that the incision of the mandibular lymph nodes greatly increases the chance for surface contamination with *Salmonella*. From a pathophysiological point of view, this is explainable because the mandibular lymph nodes are a predilection location for the presence of *Salmonella*. In a small number of cases there is a reversed effect, namely that is no longer possible to demonstrate the presence of *Salmonella* after the incision. This could be explained by values that are close to the detection limit of the analysis.

Based on these data, the demonstrated over-all positive effect of no incision and other literature data, the (b) (4) contribution shows that the omission of the incision can play a clear role in the prevention of *Salmonella* caused food infections originating from contaminated pork..

The conclusion is that omitting the incision of the mandibular lymph nodes in relation to the risk of *Salmonella*-contamination leads to considerable gains in food safety.

5. Literature data collected in relation to the potential food safety risk of *Rhodococcus equi* in the mandibular lymph nodes of fattening pigs. (See also Preliminary final report of the data analysis "pilot visual inspection", enclosure 1)

The reason for including this pathogen agent in the research was the fact that this pathogen agent has been found fairly regularly in lymph nodes with purulent lesions of pigs. The lesion is comparable to the lesion that can be caused by *M. Avium*. In humans with immunodeficiencies (HIV/AIDS patients) the pathogen agent can a.o. cause pneumonia, with fatal results. A clear etiological connection has not been demonstrated, however. Moreover, it can be argued that the incision of the lymph nodes could have a

contraproductive effect. In addition, it is known from literature that the macroscopic detection of *Rhodococcus equi* infections using purulent infection focuses has its limitations.

An important difference with *M. avium* (see below) is that the presence of *Rhodococcus equi* in fattening pigs is almost always limited to the head lymph nodes. *M. avium* can also systemically spread in pigs.

The conclusion is that there are, for the time being, not enough data available to determine either a gain or a loss in food safety.

6. Literature data in relation to the potential food safety risk of *Mycobacterium Avium* in fattening pigs. (See also the Preliminary final report of the data analysis "pilot visual inspection", enclosure 3)

It has turned out that the presence of purulent lesions in lymph nodes is not always an indication of the presence of *M. Avium*. Inversely *M. Avium* can also be found in lymph nodes without such lesions. No distinct conclusion can be drawn over the zoonotic character. Just like in the case of *Rhodococcus equi* this pathogen agent especially plays a role in immunodeficient humans and in children. As mentioned above, this pathogen agent could spread systemically in fattening pigs. In the analysis *Risk Assessment System Meat Production Chain – phase 1* a panel of experts has concluded that with respect to the significance of *M. avium* for food safety there are gaps in knowledge, but that there could be an element of priority.<sup>7</sup>

The conclusion is that :

- The significance of *M. Avium* in fattening pigs for food safety is largely unknown, but should not be considered a negligible risk either
- The incision of lymph nodes as a means of detection has limited significance

7. The results of serological monitoring for *M. Avium* (see *Results monitoring Mycobacterium avium*<sup>8</sup> and *A serological approach of the control of Mycobacterium avium spp avium in the fattening pigs production chain: a descriptive analysis of the pilot data of the* (b) (4) *and Animal Sciences Group*<sup>9</sup>)

In the course of the pilot, a considerable number of samples have been taken (22461). Because new pig farms joined in the course of the pilot, it was not possible to determine the *Mycobacterium avium* status for all farms conform the procedure for the minimum number of samples. Nevertheless, it was possible to take more than 10

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<sup>7</sup> Risk Assessment System Meat Production Chain– Report phase 1, Final draft 11 August 2004.

<sup>8</sup> Draft version

<sup>9</sup> Concept version

**NETHERLANDS—****VISUAL INSPECTION OF SWINE****Questions and Concerns on the Draft Final Report titled “Pilot Pork Supply Chain Inspection (b) (4)”**

1. The pilot study concludes that visual inspection failed to reject 9 of 174,250 (.0052%) carcasses that were inspected. However, this also represents 9 of 43 (20.9%) carcasses rejected during the pilot study. Therefore visual inspection failed to detect a significant portion (21%) of carcasses affected with pathological conditions that warranted rejection. It appears that the Netherlands considers it acceptable to pass one fifth of all carcasses that should be condemned for pathology. Is this correct? Can human factors of visual-only inspection be an aggravating factor?
2. The paper mentions that pigs from farms meeting requirements laid down in the Code of Practice of the IKB Scheme or an equivalent quality assurance scheme were used. Further information on the scheme is needed. For example, what records are available related to ongoing disease surveillance, treatment records, production methods to reduce exposure to specific pathogens, etc?
3. The paper did not provide adequate historical data to support that there are enhancements of visual-only inspection over traditional inspection. It was stated that total number of condemnations during the previous year differed significantly in comparison with data of the pilot. It was concluded that this difference could be explained by the fact that the supply of fattening pigs during the previous year did not match the supply during the pilot. This suggests and does support that source has a significant impact on “risk.” More information is needed to support if such decisions can be maintained regularly and predictably in the future. It is difficult to make a comparison of inspection methods if the source animals are not from the same source.
4. The report indicates that decision making was made primarily on farm data and history. A serological test would need to be reliable as a predictor for evaluating the TB herd status. It was not clear if reliability and value of an antibody test for *M. avium* had been established. The report indicates that antibody testing should be, for the time being, be considered as the most sensible diagnostic tool. However, no specific data was presented supporting serological testing as an effective or practical herd monitoring tool for TB.
5. It is not clear if visual inspection would be used for non-market weight hogs, such as sows and boars. Since the basis for deciding not to incise lymph nodes is based on epidemiological data of pigs raised since weaning, and TB, if present, is more or less likely to be seen in older animals, detection in sows might be more important in evaluating the risk of TB. Are incisions to be performed in older animals (non-market hogs)?
6. It is not clear if/how the Farm Risk Profile considers previous slaughter results? What criteria will be used to determine whether a particular slaughter lot requires more intensive inspection procedures? How rapidly will those criteria be re-evaluated based on information from previous slaughter lots (or even the current slaughter lot)? Is the data real time?
7. How will scheduling of verification procedures occur to ensure that visual inspection continues to protect food safety? Verification procedures should be initiated based on random and biased factors. Verification lots of market hogs where abscess/granulomas

are observed in the mesenteric lymph nodes would be an excellent way to rule out *M. avium* lesions that might have been missed by not incising the mandibular lymph nodes.

8. How does the Farm Risk Profile factor impact *M. avium*, *Salmonella*, etc. without validated blood testing or historical slaughter data under traditional inspection? It is reasonable to factor seasonal changes in calculating risk of disease (pneumonia) and need for additional residue testing.
9. Will verification testing for residues be based on history of treatment? It is not clear what value the history of "group treatments" has on supporting visual-only inspection to rule out whether non-TB abscesses or drug residues are likely to be present.
10. A discussion on the impact of visual inspection on detection of endocarditis lesions and some of the causative agents has been provided in the draft report. Results indicate that inspectors will not be able to identify as many lesions as during traditional inspection. Although some possible reasons have been mentioned, further information and discussion on this issue are needed, especially discussion on *Strep. suis* and other microorganisms of zoonotic concern.
11. It is not clear if farm workers are subject to health testing. This may be of concern in cases where there is a high turnover rate and there are migrant workers from other EU countries and non EU countries that work on farms. What is the normal turnover rate for the work force at the farms. There could be a potential risk of farm or abattoir workers introducing TB, especially drug-resistant TB, to livestock or food products.
12. The report indicated that the supply of food chain information was at a high rate of compliance, but it did not indicate what information was provided. The report also indicated that visual inspection resulted in a minimal loss of food safety. Food safety improvements were based on increased risk based testing for residues (regardless of the new scheme). The claim that, omitting incision of mandibular lymph nodes reduced the spread of *Salmonella*, was not supported. The claim that the incision of mandibular lymph nodes to detect *M. avium* is "not very meaningful" is without support. Further information is needed.

\*\*\*\*\*



U.S. Department of Agriculture  
Food Safety and Inspection Service  
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Ms. Sally White  
South Building, room 4434  
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U.S.A.



landbouw, natuur en  
voedselkwaliteit

Your letter of	your reference	our reference	date
		VD 06.1985/IH	14-07-2006
re:		extension no.	enclosures
Pork Supply Chain Inspection System		+31-70-3785435	6

Dear Ms. White,

I should like to make reference to the conference call of June 19, 2006, with Mr. Steve McDermott and associates, during which we had an interesting exchange of information on new developments in meat inspection systems in both our countries. As a general remark, I feel that a further exploration of these issues would be useful and I would, therefore, like to repeat my suggestion for a follow-up scientific meeting, either in the Netherlands, or in the U.S.

In our letter of April 3, 2006, we provided information on the pilot on visual post-mortem inspection, which was conducted in one of the (b) (4) slaughter facilities, and we included the final report of the Food and Consumer Product Safety Authority (VWA) on this pilot. This report included a positive recommendation for the implementation of this type of inspection, if the industry chooses to do so. As I stated during the conference call, the supply chain inspection system has since then become the normal way of operation in the (b) (4) Helmond slaughter facility. I promised to send an update of the VWA Final Report including supplemental information on data analysis, the results of Food Chain Information, monitoring for Mycobacterium avium, detecting antibiotic residues in pork and Salmonella monitoring. This information has been enclosed with this letter. Although these papers are indicated as "drafts", they can be considered as final. The "draft" label merely indicates that the papers are pending publication in scientific journals.

On the topic of the reorganization of the meat inspection system, whereby certain post mortem inspection activities are carried out by official auxiliaries under the supervision and responsibility of the official veterinarian who is permanently present during the operating hours of the slaughter facility, I should like to draw your attention to the paper "The new organization of the red meat inspection system in the Netherlands (2006)", which was included with our letter of April 3, 2006. If you should need any further clarification on this paper, I would be most willing to provide that, possibly during a follow-up conference call at your convenience.

The issue of palpation of mesenteric lymph nodes was briefly discussed. I intend to send you updated information on this in the near future.

Date  
14-07-2006

Reference  
VD 06.1985/IH

Following page  
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On a final note, I have requested our Agricultural Counselor in Washington, D.C. to send you a copy of the Guidance Document on the implementation of procedures based on the HACCP principles, and facilitation of the implementation of the HACCP principles in certain food businesses, which was published by the European Commission to elaborate on the HACCP principles laid down in Regulation (EC) 852/2004 and which includes guidance particularly to small food businesses. This document might be helpful in the further development of the FSIS Strategic Implementation Plan for Strengthening Small and Very Small Plant Outreach, which we also discussed during the conference call. I trust that you have received this document in the meantime.

I have very much appreciated the opportunity for a useful exchange during the conference call and I am looking forward to your reaction with great interest.

Sincerely yours,

DEPUTY CHIEF VETERINARY OFFICER,

(b) (6)

Cc: Mr. Steven McDermott, OIA, FSIA; Mr. Ghias Mughal, OIA, FSIS; Mr. Rober Wentzel, FAS, The Hague; Dr. (b) (6), CVO; Mr. (b) (6), Agricultural Counselor Washington, D.C.

## Mughal, Ghias

From: (b) (6) drs. (b) (6) (b) (6) @minlnv.nl  
Sent: Thursday, October 05, 2006 6:05 AM  
To: Mughal, Ghias  
Cc: (b) (6) drs. (b) (6) ; (b) (6) , drs. (b) (6) (b) (6) drs. (b) (6) ; (b) (6) , dr. (b) (6) ; (b) (6) dr. (b) (6) ; (b) (6) mr. drs. (b) (6)  
Subject: RE: Netherlands request for visual inspection of mesenteric Lymph Nodes of young hogs

Dear Mr. Mughal,

I received your request for information and I hereby will try to answer your question below. If you need further detail information on specific points please do not hesitate to ask.

1. Regarding your specific question on verification of visual inspection of mesenteric Lymph Nodes I can inform you that we do not sample Lymph Nodes at random after visual inspection. Instead we have serological sampling at the slaughter line on batch/farm level on M.avium as a precondition to perform visual inspection. Only hogs from a farm that has minimal 18 consecutive negative results are allowed to be visually inspected. This will be verified before admission to slaughter.

2. Furthermore if visual inspection of mesenteric Lymph Nodes results in suspicion of pathological conditions both, organs and carcass will be railed out and inspected by the traditional way. Cutting of Lymph Nodes and focused sampling are possible actions. In protocols and instructions special attention is paid to good communication between (visual) inspectors of the intestines and inspectors of the carcass.

3. Please note that beside "systematic serological sampling on M.avium" as a precondition for visual inspection also specific rules at farm level have to be obeyed and specific food chain information (batch-specific) has to be available before slaughter can start. Based on this food chain information (e.g. disease history) the official vet can decide about focused surplus testing at the slaughter line.

The effectivity of this system had been tested with good results in a pilot that had been performed end of 2005/beginning 2006 (I presume you have received the report of that pilot). A system of verification of the performance/ accuracy of both, inspectors and the preconditions for visual inspection by the competent authority is in place.

As you can conclude from the above the risk of pathological conditions that cannot be found at visual inspection is secured by preconditions for visual inspection at farm level (food chain information) and a system of serological monitoring for M.avium at slaughter. Focused sampling and cutting of Lymph Nodes of suspected carcasses is always possible and laid down in protocols/ instructions. We think that our system secures the above mentioned risk in a different, but equivalent way.

Best regards

Drs. (b) (6)  
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Ministerie van Landbouw, Natuur en Voedselkwaliteit  
Adres: Bezuidenhoutseweg 73  
Postbus: 20401, 2500 EK Den Haag  
E-mail: (b) (6) @minlnv.nl  
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-----Original Message-----

From: Mughal, Ghias [mailto:Ghias.Mughal@fsis.usda.gov]  
Sent: woensdag 27 september 2006 14:19  
To: (b) (6)  
Cc: White, Sally  
Subject: RE: Netherlands request for visual inspection of mesenteric Lymph Nodes of young hogs



Good afternoon (b) (6) ,

I am in process of preparing final draft of FSIS' response to the Netherlands request for equivalence on the visual inspection of mesenteric lymph nodes of young swine. I need your help in getting one more piece of information, from Dr. (b) (6) office, as explained below.

Under HACCP-Based Inspection Model Project (HIMP), FSIS periodically verifies the accuracy of visual inspection by taking samples of the viscera and carcasses passed (by the on-line inspector performing visual inspection) at some point below his/her inspection station. This is done to ensure that no diseased carcass or parts are passed for human consumption. In reviewing the documents sent to us along with the request, I could not discern if any such of verification is done by your inspection service.

I would appreciate, if you could contact Dr. (b) (6) to get a clarification on the type of a carcass and parts verification system in place in swine establishments undergoing visual inspection of mesenteric lymph nodes.

Thank you very much,

Best Regards,  
Ghias Mughal

M. Ghias Mughal, DVM;M.S; Ph.D.  
Senior Equivalence Officer,  
Office of International Affairs  
USDA, Food Safety and Inspection Service  
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Washington, DC 20250  
Phone: 202 720-6400  
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-----Original Message-----

From: (b) (6) [mailto:(b) (6)@minbuza.nl]  
Sent: Wednesday, July 26, 2006 2:20 PM  
To: White, Sally  
Cc: McDermott, Steve; Mughal, Ghias; WAS-LNV; Tacken, Wim  
Subject: NL data on health status hogs-palpation

Dear Sally:

During the telephone conference between FSIS and the Netherlands on June 19th, 2006, the topic of equivalence determination for palpation of lymphnodes was discussed. During this discussing the Netherlands promised FSIS that additional information on this issue would be provided. With reference to the conference, please find attached a letter of Dr. Weijtens, the Netherlands Deputy CVO and updated information on the health status of hogs presented for slaughter in the Netherlands.

Once I receive the original hard copy version of Dr. (b) (6) letter and the document I will deliver it to your office.

This report, the DG Sanco paper sent on the 30th of June, and the information I sent to you earlier by email on July 17th are all the documents the Netherlands had promised to provide to FSIS during the teleconference on the 19th of June. Please let me know if you need additional information or if there are any questions.

Best regards,

(b) (6)  
Agricultural Trade Officer  
Royal Netherlands Embassy  
4200 Linnean Avenue, NW

Ministry of Agriculture, Nature and Food Quality

United States Department of Agriculture  
Food Safety and Inspection Service  
International Equivalence Staff  
Office of International Affairs  
Attn. Mrs. S. White  
Director  
US Department of Agriculture  
Room 2137, South Building  
Washington, DC 20250

landbouw, natuur  
voedselkwaliteit

Your letter  
October 2, 2006

your reference

our reference  
VD.06.2687.PL

Date  
October 6, 2006

Re:  
US certified establishments

extension no.  
+3170-3785037

enclosures

Dear Mrs. White,

Herewith I acknowledge the receipt of your email preceding an official letter regarding U.S. certified establishments in the Netherlands implementing visual post-mortem inspection and employing auxiliaries for the inspection. The mail was forwarded to me by Mr. (b) (6), Agricultural Counselor of the U.S. Embassy, The Hague, on October 3, 2006.

The email did surprise us, as we felt that we had been trying to be fully transparent, unfortunately additional clarification seems to be necessary. I would highly appreciate if you would be willing to receive a mission from the Netherlands, headed by my Deputy Dr. (b) (6), at your earliest convenience. I consulted the European Commission and they like Dr. (b) (6) from the EU representation in the US to take part in the discussion as well, in particular on the question of equivalence. Our Agricultural Counselor in Washington, Mr. (b) (6), will also be involved in the mission and will be the contact point with respect to the organization of the mission.

*Need  
to  
Plan*  
In the meantime we took your message seriously and we discussed it with our Food and Consumer Products Authority and the (b) (4) Company that owns the establishments involved. The company decided to wait for the outcome of the discussions that we are trying to arrange and for the time being not to ask for certification for the U.S., effective of Monday next.

I hope that this information suffices for now and that we can have the meeting as suggested already next week.

Our Agricultural Counselor in Washington informed me on your health. May I wish you a full and quick recovery.

If you have any questions regarding this letter, you can reach me by email: (b) (6)@minlnv.nl or even better on my mobile (011) (b) (6)

Sincerely,  
CHIEF VETERINARY OFFICER

Dr. (b) (6)

**Proudie, Robin**

---

**From:** White, Sally  
**Sent:** Wednesday, November 08, 2006 7:19 AM  
**To:** Proudie, Robin  
**Subject:** Fw: additional articles reg. visual inspection: q4ref1 Part a

Please log

-----  
Sent from my BlackBerry Wireless Handheld

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

**From:** Mughal, Ghias <Ghias.Mughal@fsis.usda.gov>  
**To:** White, Sally <Sally.White@fsis.usda.gov>  
**CC:** Seebohm, Scott <Scott.Seebohm@fsis.usda.gov>; Smith, David <David.Smith@fsis.usda.gov>; Goodwin, Nancy <Nancy.Goodwin@fsis.usda.gov>; McDermott, Steve <Steve.McDermott@fsis.usda.gov>  
**Sent:** Wed Nov 08 07:16:17 2006  
**Subject:** FW: additional articles reg. visual inspection: q4ref1 Part a



Q4Ref1a  
Inderlied.pdf (2 MB)

This is part one of an article on Mycobacterium avium complex that came in this morning.

M. Ghias Mughal, DVM;M.S; Ph.D.

Senior Equivalence Officer,

Office of International Affairs

USDA, Food Safety and Inspection Service

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

**From:** (b) (6) drs. (b) (6) [mailto:(b) (6)@minlnv.nl]  
**Sent:** Wednesday, November 08, 2006 3:00 AM  
**To:** Mughal, Ghias  
**Cc:** (b) (6) dr. (b) (6)  
**Subject:** RE: additional articles reg. visual inspection: q4ref1 Part a

dear Dr. Mughal,

IES-#416  
fp 2/1/07

herewith I send you ref 1 of question 4 (1) Inderlied CB, Kemper CA, Bermudez LE. The Mycobacterium avium complex. Clin Microbiol Rev. 1993 Jul;6(3):266-310. Review. ). Due to the big size of the article we had to split it into two parts (a en b sent by two mails).

best regards

(b) (6).

-----Oorspronkelijk bericht-----

Van: (b) (6) drs. (b) (6)

Verzonden: dinsdag 7 november 2006 15:40

Aan: 'Mughal, Ghias'

CC: (b) (6) dr. (b) (6); (b) (6) drs. (b) (6); (b) (6)

(VD)

Onderwerp: Expert meeting with FSIS and the Netherlands reg. visual inspection

Dear Dr. Mughal,

on behalf of Dr (b) (6) I will send you herewith a "package" of additional articles, which have been mentioned in our report as a reference.

Most of these articles are in English, but 4 articles (question 10) have to be translated first. Unfortunately this will take some time, so you will receive them as soon as the translation has been completed. 2 other documents (q4ref1 and q4ref4) will be sent later.

Beneath you find a list of the articles which you will receive today (with several e-mails due to the size of the attachments) and 4 articles as soon as possible after translation has been completed.

If you miss any reference article in this list that had been agreed to send to you please let me know. I will arrange that asap.

Regards

(b) (6)

Drs. (b) (6)

Beleidsmedewerker vleeshygiëne

Directie Voedselkwaliteit en Diergezondheid

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Question 4:

Additional document: Justification for sampling of Mycobacterium avium in pork with regard to supply chain meat inspection (06-11-06)

References to additional document:

\* New classification system for slaughter pig herds in the Danish surveillance- and-control program: L. Alban et.al., Prev.Vet. Med. 2002 (SDOC1268.pdf)

\* Trichinae certification in the United States Pork industry: D.G. Pyburn

References Question 4:

1) Inderlied CB, Kemper CA, Bermudez LE. The Mycobacterium avium complex. Clin Microbiol Rev. 1993 Jul;6(3):266-310. Review. (will be sent later)

2) Komijn, RE., PEW de Haas, ME Schneider, T Eger, JHM Nieuwenhuis, RJ van den Hoek, D. Bakker, FG van Zijderveld and D van Soolingen. Prevalence of Mycobacterium avium in Slaughter Pigs in The Netherlands and Comparison of IS1245 Restriction Fragment Length Polymorphism Patterns of Porcine and Human Isolates. J of Clin Microb, 1999, 37, 1254-1259

3) Komijn, RE., HJ. Wisselink, VMC. Rijsman, N. Stockhofe-Zurwieden, D. Bakker,

FG. van Zijderveld, T. Eger, JA. Wagenaar, FF. Putirulan and BAP. Urlings, Prevalence of Mycobacterium avium subsp. avium in lymphnodes of slaughter pigs in The Netherlands. Accepted for publication in Veterinary Microbiology (2007)

4) Wallace JM, Hannah JB. Mycobacterium avium complex infection in patients with the acquired immunodeficiency syndrome. A clinicopathologic study. Chest. 1988 May;93(5):926-32. (will be sent later)

5) Wisselink, HM, C van Solt-Smits, N Stockhofe-Zurwieden, H Bergen-Buys, P. Overduin, M van Prehn, D van Soolingen and J Thole. Comparison of visual and bacteriological examination of mandibular and mesenteric lymphnodes in pigs, experimentally infected with Mycobacterium avium subsp. Avium. IPVS Conference Copenhagen 2007.

References question 10:

1. W. Wouda et. al. , Endocarditis en vleeskeuring bij slachtvarkens, Tijdschrift voor Diergeneeskunde, deel 112, afl. 21, 1987, p. 1226-1235 (will be translated and sent later)

2. Masanori Katsumi et. al, Bacterial Isolation from slaughtered pigs associated with endocarditis, especially the isolation of Streptococcus suis, Journal of veterinary medical science, vol. 59, 1997, p. 75-78

3. U. Narucka et. al., Afwijkingen bij slachtdieren, Tijdschrift voor Diergeneeskunde, deel 110, afl. 19, 1985, p. 776-779 (will be translated and sent later)

4. W. Wouda et. al. , Endocarditis en vleeskeuring bij slachtvarkens, Tijdschrift voor diergeneeskunde, deel 112, afl. 21, 1987, p. 1236-1242. (will be translated and sent later)

5. R. Fries und J. Leps, Die Incision des Herzens beim Schwein, Fleischwirtschaft, vol 10, 2005, p. 116-119. (will be translated and sent later)

6. C. Tarrads et. al., Identification of Streptococcus suis Isolated from Swine: Proposal for Biochemical Parameters, journal of clinical microbiology, vol. 32, 1994, p. 578-580

7. J.J. Staats et. al., Streptococcus Suis: past and present,

8. Yu-Tsung Huang et. al., Streptococcus suis infection, Journal of Microbiol Immunol Infect, vol. 38, 2005, p. 306-313.

References reg. Annex salmonella:

1. Petersen JV, Andersen JK, Sorensen F, Knudsen H. Food safety on the slaughterline: inspection of pig heads.  
Vet Rec. 2002 Jun 22;150(25):782-4. Review.
2. Swanenburg M, van der Wolf PJ, Urlings HA, Snijders JM, van Knapen F. Salmonella in slaughter pigs: the effect of logistic slaughter procedures of pigs on the prevalence of Salmonella in pork. Int J Food Microbiol. 2001 Nov 8;70(3):231-42.
3. Swanenburg M, Berends BR, Urlings HA, Snijders JM, van Knapen F. Epidemiological investigations into the sources of Salmonella contamination of pork.  
Berl Munch Tierarztl Wochenschr. 2001 Sep-Oct;114(9-10):356-9.
4. Berends BR, Van Knapen F, Snijders JM, Mossel DA. Identification and quantification of risk factors regarding Salmonella spp. on pork carcasses.  
Int J Food Microbiol. 1997 May 20;36(2-3):199-206.
5. Swanenburg M, Urlings HA, Snijders JM, Keuzenkamp DA, van Knapen F. Salmonella in slaughter pigs: prevalence, serotypes and critical control points during slaughter in two slaughterhouses. Int J Food Microbiol. 2001 Nov 8;70(3):243-54.
6. Swanenburg M, Urlings HA, Snijders JM, Keuzenkamp DA, van Knapen F. Salmonella in the lairage of pig slaughterhouses.  
J Food Prot. 2001 Jan;64(1):12-6..
7. "salmonella monitoring" report made during the pilot "supply chain inspection" 2005-2006 in Helmond, the Netherlands
8. Oosterom J, Dekker R, de Wilde GJ, van Kempen-de Troye F, Engels GB. Prevalence of Campylobacter jejuni and Salmonella during pig slaughtering. Vet. Quarterly 7, 31-34.

Dit bericht kan informatie bevatten die niet voor u is bestemd. Indien u niet de geadresseerde bent of dit bericht abusievelijk aan u is gezonden, wordt u verzocht dat aan de afzender te melden en het bericht te verwijderen. De Staat aanvaardt geen aansprakelijkheid voor schade, van welke aard ook, die verband houdt met risico's verbonden aan het elektronisch verzenden van berichten.

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## The *Mycobacterium avium* Complex

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\* Corresponding author.



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## CLASSIFICATION

### Conventional Criteria.

Mycobacteria have been conventionally classified into four or five broad taxonomic groups on the basis of the following general criteria: pathogenicity for humans and animals, rate of growth at optimum temperatures, and effect of visible light on pigment production. These criteria have proven useful for the classification of mycobacteria since first developed by Runyon and others in the early 1950s (179, 408, 451); recent evidence from comparative 16S rRNA sequencing studies (437) has corroborated their taxonomic validity. Accordingly, mycobacteria included in the *Mycobacterium avium* complex (MAC) are classified as acid-fast, slowly growing bacilli that may produce a yellow pigment in the absence of light (exposure to light often intensifies pigment production). The MAC is composed of opportunistic pathogens capable of causing disease in both animals (448) and humans (253, 504). Tuberculosis, caused by mycobacteria in the *M. tuberculosis* complex, has been traditionally viewed as the "typical" mycobacterial disease; thus, other species of mycobacteria (with the exception of *M. leprae*) have been viewed by contrast as "atypical." Consequently, mycobacteria other than *M. tuberculosis* and *M. leprae* have been commonly referred to by the imprecise and taxonomically inappropriate term atypical mycobacteria. Other terms commonly applied to these mycobacteria are mycobacteria other than tuberculosis, or MOTT, and nontuberculous mycobacteria (NTM). Wayne and Sramek (474) recently reviewed the systematics of the mycobacteria and pointed out that the distinction among *M. tuberculosis*, *M. leprae*, and the other species of mycobacteria is not the ability to cause serious disease in humans but rather differences in natural habitats and contagiousness. Thus, they proposed the term potentially pathogenic environmental mycobacteria, or PPEM, a term which emphasizes the importance of environmental exposure to these mycobacteria since there is little or no contagiousness between humans associated with these microorganisms.

## Serotypes

The MAC is a serological complex of 28 serovars of two species, *M. avium* and *M. intracellulare*, which sometimes has been extended to include three additional serovars of a third species, *M. scrofulaceum*. Therefore, the mycobacteriology literature may include references to the complex as the *M. avium-M. intracellulare* complex or the *M. avium-M. intracellulare-M. scrofulaceum* intermediate complex. However, the inclusion of *M. scrofulaceum* is no longer appropriate given our current understanding of mycobacterial systematics (474). The distinction between *M. avium* and *M. intracellulare* is now well established, and Thorel et al. (450) have proposed three subspecies of *M. avium* on the basis of phenotypic properties and nucleic acid studies: *M. avium* subsp. *avium*, *M. avium* subsp. *paratuberculosis*, and *M. avium* subsp. *silvaticum*. The International Working Group on Mycobacterial Taxonomy has suggested, however, that there is taxonomic evidence for a third genospecies within the MAC (473).

Serovar distinctions within the MAC are based on a seroagglutination procedure originally described by Schaefer (419). Later, Brennan and coworkers (65-67) showed that the serovar antigens of the MAC have a common lipopeptidyl-*O*-methyl rhamnose linked to an oligosaccharide; i.e., serologic specificity was conferred by the specific oligosaccharide residues of the C-mycoside glycopeptidolipids (GPLs), which are integral constituents of the cell wall and envelope. On the basis of this more complete knowledge of the chemistry of the serovar antigens, strains now are serotyped by thin-layer chromatography (68, 454) and enzyme-linked immunosorbent assay (ELISA) analysis (498) of species- and type-specific glycolipids as well as by the conventional seroagglutination procedure. More recently, Rivoire et al. (399) described an ELISA system that used murine monoclonal antibodies to specific sugar epitopes of the MAC derived with either purified GPL antigens or synthetic neoantigens. The focus of the latter study was to generate monoclonal antibodies that were absolutely specific for each of the major serovars of the MAC. In achieving this objective, the oligosaccharide haptens were defined for the



most common serovars of the MAC isolated from patients with AIDS in the United States, i.e., serovars 1, 4, and 8 (399). Serovar and DNA relatedness studies have led to a consensus that serovars 1 through 6 and 8 through 11 are assigned to *M. avium* while serovars 7, 12 through 17, and 19, 20, and 25 are assigned to *M. intracellulare* (413).

#### Multilocus Enzyme Electrophoresis Types

Recently, Wasem et al. (470) examined 35 strains of the MAC and an additional 12 species or strains of other mycobacteria by multilocus enzyme electrophoretic typing, using 20 different enzymes. A total of 33 electrophoretic types (ETs) were identified, of which 24 types included the 35 MAC strains. Two distinct clusters were apparent in the resulting dendrogram of the 24 ETs: an *M. intracellulare* cluster and an *M. avium* cluster. The clustering agreed entirely with the species identity as determined by the GenProbe nucleic acid hybridization system. When the analysis was extended to include all 33 ETs, again two distinct clusters were observed, but with an *M. scrofulaceum* strain joined to the *M. intracellulare* cluster and an *M. paratuberculosis* strain joined to the *M. avium* cluster. All but one of the serovars separated into the *M. intracellulare* and *M. avium* clusters when ET types were compared with serovar classification. The common serovars, serovars 1, 4, 8 to 10, 14, and 16, could be subdivided into two to four ETs. Although the authors pointed out that serovar and ET designations are not interchangeable, it was of interest that serovars 1 to 4 and 8 to 10 appeared in the *M. avium* ET cluster and serovars 12, 14, 16, and 19 appeared in the *M. intracellulare* cluster. These results are in virtually complete agreement with earlier DNA-DNA relatedness studies or GenProbe DNA-rRNA hybridization and serovar studies. There are two DNA relatedness groups that make up the *M. avium-M. intracellulare* complex (a third group includes *M. scrofulaceum*) (400), and DNA relatedness studies first performed by Baess (13) and later confirmed by Yoshimura and Graham (500) showed that serovars 1 to 6 and 8 to 11 were *M. avium* whereas serovar 7 and serovars 13 to 28 were *M. intracellulare*. More recently, Saito et al. (413) used the GenProbe DNA-rRNA hybridization system to analyze the species distribution of serovars and concluded that serovar 21 is most likely *M. avium* and serovars 7, 12 to 20, and 25 are *M. intracellulare*; serovars 22 to 24 and 26 to 28 were too disordered to assign a species epithet.

#### Phage Types

Although phage typing has proven to be a useful tool for discriminating between strains of *M. tuberculosis* (434), there has been only a limited application of phage typing to the epidemiology of the MAC. Crawford et al. (111) described a technique of phage typing for the *M. avium-M. intracellulare-M. scrofulaceum* complex and applied the technique in a study of several hundred *M. avium-M. intracellulare-M. scrofulaceum* complex strains isolated from the environment, animals, and clinical specimens from geographically disperse humans (107). Only approximately one-third of the isolates and none of the environmental isolates were susceptible to the mycobacteriophages tested. Nevertheless, for susceptible strains, the phage-typing system appeared to be a reliable epidemiological tool, but the lack of phage susceptibility of the majority of strains is an important limitation. Crawford and Bates (107) pointed out that several factors can influence the susceptibility of myco-

bacteria to phage infection, including a requirement for accessible cell surface receptors, lysogenic immunity, the presence of a restriction-modification system, and plasmid interference. It is conceivable that all or any combination of these factors might influence the phage susceptibility of the MAC. Restriction-modification systems have been described in the MAC (110), and many MAC isolates carry plasmids (332). The lack of phage susceptibility may be an important complication to the otherwise exciting potential application of luciferase-phagemid systems to the direct detection and identification of the MAC in clinical specimens as well as susceptibility testing (15).

#### Plasmid Types

Plasmid typing may be similarly limited for epidemiology studies in that only 50% of clinical isolates and only 20% of environmental isolates carry plasmids (332); however, there is evidence that there may be an epidemiologically significant uneven distribution of MAC strains, both clinical and environmental, which carry plasmids. In a study of 26 MAC isolates from AIDS patients, Crawford and Bates (108) described three types of plasmids that were present in various configurations in all strains. Indeed, all strains carried plasmids that hybridized to recombinant molecules carrying fragments of a small plasmid (pLR7) derived from a serotype 4 strain of the MAC. However, this observation is somewhat at odds with other more recent studies that showed that only 5 of 16 MAC isolates from AIDS patients in Denmark carried plasmids (260) and that there was no difference in the rate of plasmid carriage in 128 strains from AIDS and non-AIDS patients in the United Kingdom (215). Morris et al. (344) determined the plasmid profiles of 12 separate *M. avium* isolates and identified multiple plasmids of <100 kb in 9 of 12 isolates. Although the pLR7 plasmid probe hybridized to DNA extracts from all plasmid-bearing strains, restriction analysis suggested that the plasmids were not identical. Morris et al. (344) concluded that plasmids may not be required for the development of disseminated MAC disease and the role of plasmids can be determined only by virulence transformation experiments. Meissner and Falkinham (332) showed that although on average only 19% of environmental isolates carried plasmids, 75% of isolates from aerosols carried plasmids. Also, the study by Hellyer et al. (215) concluded that plasmids were common in serovar 4 and 8 strains of the MAC and corroborated the observation of Crawford et al. (108) that these plasmids had DNA sequences homologous to that of the pLR7 plasmid. The role of plasmids in the biology and pathogenicity of the MAC may be important because of the association of plasmids with virulence factors (162, 382) and, in two studies, with antibiotic resistance (155, 339).

#### Large RFLP Types

Distinctions between MAC strains have been achieved by restriction fragment length polymorphism (RFLP) analysis of genomic DNA, using endonucleases with both frequent and infrequent restriction sites and separation of large DNA fragments. The application of the latter technique to mycobacteria takes into consideration that mycobacterial DNA contains a high percentage of guanine plus cytosine (62 to 70 mol%); therefore, restriction endonucleases with 6-base recognition sites that are rich in adenine and thymine are likely to cleave mycobacterial DNA into 30 or fewer fragments. The number of fragments can be predicted by a

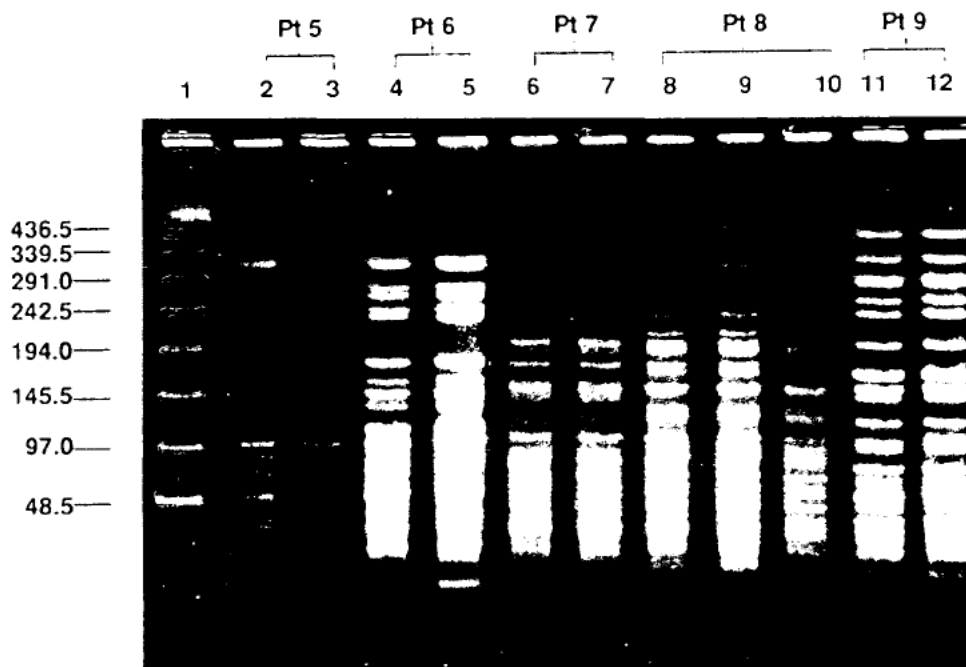


FIG. 1. Large RFLPs of two separate isolates of MAC from each of five patients, taken from Mazurek et al. (320). Mycobacterial DNA was restricted with *Xba*I, and fragments were separated by pulsed-field gel electrophoresis. For patients 6, 7, and 9, both isolates were from sputum, while for patients 5 and 8, the isolates were from different body sites. Reprinted with permission of the publisher.

nearest-neighbor analysis; however, as with other bacteria, in the few studies of the MAC that have been published, fewer fragments are generated than are predicted by such an analysis. Nevertheless, the number and size of fragments often approximate the total DNA content of the cell, and the resulting RFLP patterns most likely reflect the distribution of restriction sites within nearly the entire genome. Two endonucleases (with the corresponding restriction sites) that have proven useful in generating RFLP patterns with mycobacterial DNA are *Dra*I (AAATTT) and *Ssp*I (AATATT). These enzymes generate large restriction fragments that can be resolved only by field inversion gel electrophoresis or pulsed-field gel electrophoresis into fragments that range from 45 to >400 kb. Levy-Frebault et al. (299) examined various strains of mycobacteria by RFLP analysis by using *Dra*I and pulsed-field gel electrophoresis and showed that strains of *M. paratuberculosis* were identical to strains of mycobacteria isolated from patients with Crohn's disease, confirming the earlier observations of McFadden et al. (327). Furthermore, Levy-Frebault et al. (299) showed that wood pigeon mycobacteria could be distinguished from *M. paratuberculosis* and that *M. avium* isolates were readily distinguished from *M. intracellulare*. Coffin et al. (93) used *Ssp*I and pulsed-field gel electrophoresis to identify five RFLP groups in a study of 13 MAC strains. Their results showed that RFLP analysis allows one to readily distinguish between strains of *M. paratuberculosis* isolated from cattle. An *M. paratuberculosis* strain grouped with a serovar 8 MAC strain (the authors apparently mistakenly identified this serovar as *M. intracellulare*), which is consistent with the aforementioned conclusion that *M. paratuberculosis* is most likely a subspecies of *M. avium*. In a large recent study, Mazurek et al. (320, 321) analyzed 72 MAC isolates from 44 patients, including 16 patients with two to five isolates. RFLP patterns

generated with *Dra*I were unique for different patients, while multiple isolates from individual patients, including isolates from a variety of body sites, were identical; patterns of multiple isolates were identical over as long as 6 months between isolations (Fig. 1). Arbeit et al. (9) recently reported a similar study of 69 MAC isolates from 14 patients, using the restriction enzyme *Ase*I, but discovered 2 patients who were infected with more than one strain of MAC, suggesting that mixed infections may be common in certain patients or patient populations.

#### Colony Variant Types

Perhaps one of the most important, yet incompletely understood, features of the MAC is the occurrence of colony type variations. Three colony variants have been described: (i) a smooth, opaque, and domed type; (ii) a smooth, transparent, and flat type; and (iii) a rough type. Clinical isolates of the MAC usually appear as smooth transparent or smooth opaque types or as a mixture of the two. In our experience, MAC isolates from AIDS patients with disseminated disease are frequently exclusively of the smooth transparent type. Barrow and Brennan (16) showed that the rough colony type can be selected by promoting the growth of a pellicle in a broth medium, but once isolated, rough colony types are stable even when repeatedly subcultured on 7H11 agar. They showed that rough colony types lacked both polar and apolar GPLs, and when examined by electron microscopy, rough colony types lacked the sheath (capsule) of fibrillar filaments seen with smooth opaque colony-type cells. Although rough colony variants may occur naturally as an inapparent subpopulation of smooth-type cells, rough forms do not appear to be found in primary isolations from

clinical specimens, and their clinical significance is unknown.

In contrast, the translucent colony variants are reported to be more resistant to antimicrobial agents (391, 411, 486), and there is evidence based on both macrophage and animal studies that this variant is more virulent (116, 335, 407, 420). Stormer and Falkinham (442) isolated nonpigmented colony variants from both environmental sources and clinical material from AIDS patients and showed that these variants were significantly more resistant to antimicrobial agents than pigmented segregants of the same strains. Furthermore, pigmented segregants grew faster on agar media, leading to a concern that the less obvious nonpigmented variants could be overlooked when colonies were being selected for susceptibility testing. Thorel and David (449) showed that there are significant differences in the expression of cell surface antigens between transparent and opaque colony variants; however, such specific differences have not been related to functional differences such as antimicrobial resistance or pathogenicity.

Despite the apparent relationship between colony type and antimicrobial resistance, very little is known about the genetics and regulation of colony type variation. Woodley and David (486) showed that the rate of the transparent-to-opaque transition was dependent on temperature and thus is not a consequence of mutation. The same investigators also indicated that colony type transition was not linked to mutator effects (MAC is not unusually susceptible to UV-induced mutations) or the presence or absence of extrachromosomal genetic elements (124). The rate of transparent-to-opaque transition was  $4.6 \times 10^{-4}$ , while the rate of opaque-to-transparent transition was about  $10^{-6}$  per bacterium per generation (486).

## CELL WALL AND ENVELOPE

### Structure

One of the best-studied aspects of mycobacteria is the structure and function of the mycobacterial cell wall and envelope which confers upon these unusual bacteria their distinctive feature of acid fastness. The envelope is composed of a variety of soluble proteins, carbohydrates, and lipids and basically three insoluble macromolecular components: arabinogalactan, peptidoglycan, and mycolic acid (329). Together, the insoluble macromolecules constitute the mycoylarabinogalactanpeptidoglycan core of the cell wall, one of two lipopolysaccharides (LPS) common to all mycobacteria. The mycoylarabinogalactanpeptidoglycan appears as electron-dense and electron-transparent zones in thin sections of mycobacteria viewed by negative staining. However, the core is frequently surrounded by additional electron-dense layers at the surface of the cell. This electron-dense layer is made up, in part, of unique GPLs that are specific for the MAC. In addition, all mycobacteria possess a second LPS as a component of the cell envelope, more specifically, a lipoarabinomannan. The lipoarabinomannan is not covalently linked to the mycoylarabinogalactanpeptidoglycan core but most likely is anchored in the plasma membrane of the mycobacterial cell, with the polysaccharide extending to the exterior of the cell. The mycoylarabinogalactanpeptidoglycan, lipoarabinomannan, and GPLs of the MAC are strongly immunogenic, with properties similar to those of the LPS of other bacteria. In addition, certain

components of these complex macromolecules have proven to have diagnostic utility; e.g., tuberculostearic acid (10-methyloctadecanoate), which is a useful diagnostic marker for *M. tuberculosis*, occurs as a fatty acid in the lipoarabinomannan of this species. A cartoon of the cell wall structure of mycobacteria that displays the orientations and relationships between the various components of this complex structure is shown in Fig. 2.

McNeil and Brennan (329) discussed the possible relationships between the cell envelope structural features and the noted resistance of the MAC to antimicrobial agents. Clearly, the complex array of parallel hydrocarbon chains is the most likely source of the impermeability of mycobacteria. Camphausen et al. (75) also suggested that these unusual structures were consistent with the long-held conclusion of Rastogi et al. (391, 393) that the antimicrobial resistance of the MAC can be attributed to a lack of drug penetration. Although intrinsic drug resistance is likely to reflect the complex cell wall structure, at the same time these unique structures, amide-linked fatty acids, D-amino acids, and methylated 6-deoxyhexoses, and the corresponding biosynthetic enzymes are excellent potential targets for highly selective and nontoxic antimycobacterial agents.

The impermeability of the MAC cell wall and membrane has been the focus of attempts to potentiate the effect of antimicrobial agents by combining agents with a cell wall-active agent such as ethambutol or a detergent such as Tween 80. Rastogi et al. (392) showed that both ethambutol and an inhibitor of C-mycoside biosynthesis (*m*-fluorophenylalanine) enhanced the activity of other drugs, and Yamori and Tsukamura (496) demonstrated that the activities of rifampin and streptomycin increased in the presence of Tween 80; paradoxically, Tween 80 diminished the activities of ethambutol and sulfadimethoxine.

As mentioned previously, the MAC is a collection of serovars that are distinguished from one another on the basis of antigenic differences in the GPL oligosaccharides. The MAC GPLs, referred to previously as C-mycosides or Shaefer antigens, are alkali-stable molecules, a feature that has been exploited in their analysis, since alkali treatment reduces nonspecific serologic reactions and permits the analysis of whole lipid preparations by ELISAs. In addition, the antigens of other atypical mycobacteria such as *M. kansasii*, *M. xenopi*, and *M. szulgai* are lipo-oligosaccharides that are readily destroyed by alkali (498). *M. simiae* and *M. fortuitum* complex also have alkali-stable GPLs, but there is only limited cross-reaction between these GPLs and those of the MAC. In general, there is good agreement among seroagglutination, thin-layer chromatography, and ELISA; however, some strains remain intractable to analysis by any of these methods, including the monoclonal antibody-based assays. In addition, cross-reactions in the ELISAs are not uncommon and thin-layer chromatography patterns can be indistinct. The type-specific antigens for many of the *M. avium* serovars have been fully described; for example, the structures for serovars 2 and 4 are 2,3-di-O-methyl-fucopyranosyl-( $\alpha 1 \rightarrow 3$ )-L-rhamnopyranosyl-( $\alpha 1 \rightarrow 2$ )-6-deoxytalose and 4-O-methyl-L-rhamnopyranosyl-( $\alpha 1 \rightarrow 4$ )-2,3-di-O-methyl-fucopyranosyl-6-deoxytalose, respectively (66).

### Synthesis

Although McNeil and Brennan (329) have proposed a hypothetical biosynthetic pathway for the assembly of the

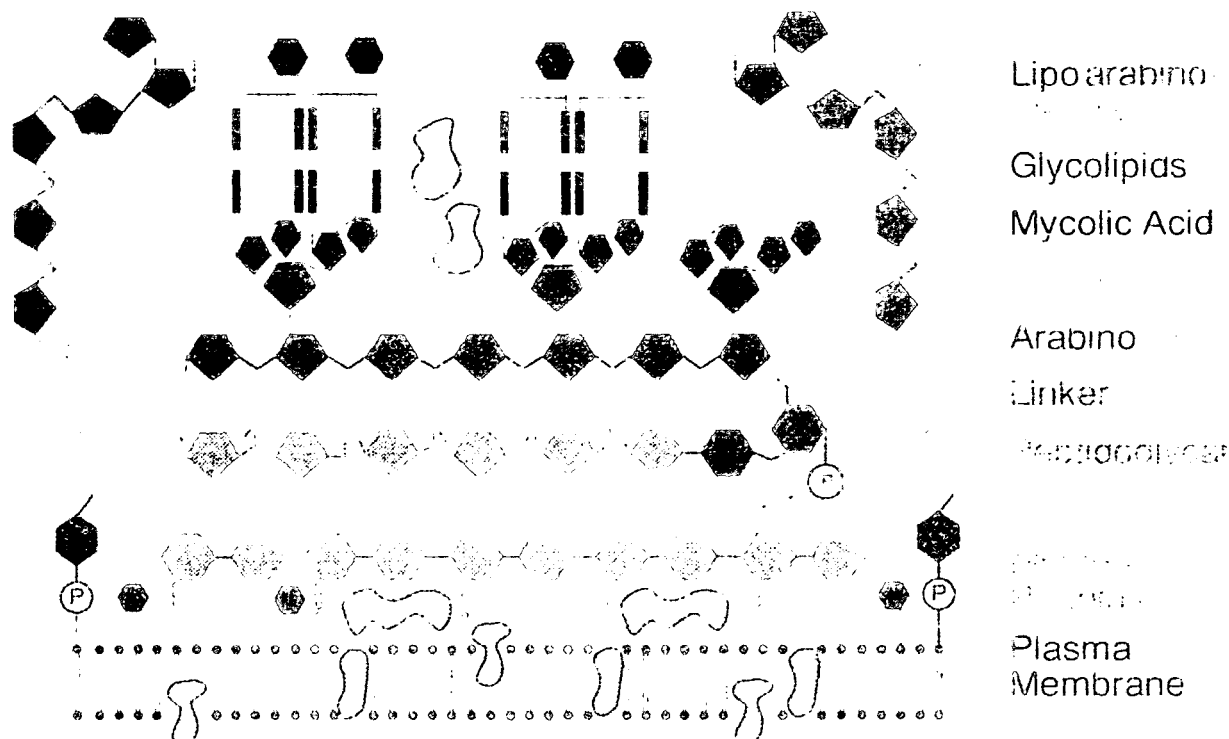


FIG. 2. Schematic representation of the mycobacterial cell wall, taken from McNeil and Brennan (329). MAC serovars are distinguished on the basis of differences in the oligosaccharide component of the glycolipid component. Tuberculostearic acid is a component of the lipoarabinomannan of *M. tuberculosis*. Reprinted with permission of the publisher.

arabinogalactan, including attachment to the peptidoglycan and mycolylation, there is no direct evidence for the biosynthetic enzymes and only a few of the intermediates have been isolated and identified from mycobacteria. Therefore, the recent publication of Belisle et al. (18) on the cloning of genes responsible for the synthesis of GPL antigens must be viewed as a landmark study in the efforts to understand the synthesis of the mycobacterial cell wall and envelope. By using a genomic library prepared from a serovar 2 strain of MAC, the gene cluster responsible for the synthesis of the serovar 2-specific GPL was cloned into *M. smegmatis* mc<sup>2</sup>155 with the pYUB18 shuttle cosmid (256). Clones were screened for expression of the serovar 2-specific GPL (antigen) by using a monoclonal antibody directed against this GPL (399). A cluster of genes, designated *ser2*, within a 22- to 27-kb continuous segment of genomic DNA was identified as responsible for the expression of the specific oligosaccharide; chemical analysis revealed that only the oligosaccharide segment arose from the cloned genes. Belisle et al. (18) pointed out that the cloned fragment was larger than necessary to encode the two or three transferases needed to synthesize the oligoglycosyl unit; thus, the fragment may contain multiple operons or other genes. Recently, the same group (130) identified the isomerase that converts ribulose-5-phosphate to arabinose-5-phosphate, which is incorporated into arabinofuranose; this may lead to a better understanding of the mechanism of action of ethambutol since ethambutol is known to disrupt the incorporation of arabinose-5-phosphate into cell wall arabinan.

## MICROBIAL PHYSIOLOGY AND GENETICS

### Physiology

Considerable basic information about the metabolism and physiology of the MAC is lacking; e.g., there is little or no information about anabolic or catabolic enzymatic pathways, energy metabolism, or carbon and nitrogen cycles. Furthermore, there have been no studies directed at understanding the regulation of macromolecular synthesis or gene expression in this increasingly important group of mycobacteria. As discussed earlier, although there is considerable information about the chemistry of important cell wall constituents, especially antigenic components, there is limited or no information about the biosynthetic pathways. Fundamental work on the growth and nutrition of the MAC, largely from Charlotte McCarthy's laboratory, revealed that the growth of these microorganisms is complex. By studying partially synchronized cultures, McCarthy and Ashbaugh (326) were able to show that the growth of MAC isolates, either transparent or opaque colony variants, occurs in three stages. During the first stage, cells elongate and there is a rapid uptake of fatty acids and an increase in protein and DNA, but without cell division. Binary fission occurs during the second stage of growth, with a generation time as short as 6 h. Protein synthesis continues during the second stage of growth, but at a diminished rate, and the uptake of fatty acids decreases and intracellular pools of triglycerides are catabolized to supply carbon and energy. At the end of the second stage, most cells are in the form of coccobacilli.

During the third stage of growth, which is most analogous to the conventional stationary phase, the morphology of the cells becomes quite heterogeneous, leading to a mixture of filaments, rods, and coccobacilli. McCarthy and her colleagues concluded that the opaque colony cells will increase during the third stage of growth since these cells are nutritionally less demanding than the cells of the transparent type. These observations have clear and compelling implications for antimicrobial resistance and possibly virulence, but to understand these relationships, additional information is needed about the regulation of the growth cycle and, perhaps especially, the mechanisms of differentiation.

Palmitic and oleic acids are important sources of carbon and energy for the MAC. McCarthy (322) showed that during the first stage of growth there was a rapid uptake of  $^{14}\text{C}$ -palmitic acid which ceased with the initiation of cell division or fragmentation. Cells of both the transparent and the opaque colony types exhibited similar responses to palmitic acid. Other carbon sources, such as glycerol and glucose, failed to support cell division. During the first part of the growth cycle, exogenous fatty acids are initially incorporated into the triglyceride fraction and then redistributed into other components. By the end of the fission stage of growth, exogenous fatty acid is incorporated into the polar fraction, primarily glycolipids. The triglyceride fraction is metabolized during the cell division phase as the uptake of exogenous fatty acids ceases. Curiously, smooth transparent-type cells produce large numbers of nonviable particles during all phases of growth, and these particles consist in large part of sulfolipids (323). McCarthy also showed that nitrogen metabolism varies depending on the stage of growth within the cell cycle. During elongation, cells were unable to use organic forms of nitrogen such as glutamic acid or glutamine, but they used these amino acids as well as sulfur during periods of rapid cell fission (324). More recently, McCarthy (325) showed that the MAC, including several clinical isolates, preferentially uses ammonia and nitrite and, with the exception of glutamine, does not use amino acids as a source of nitrogen.

### Genetics

In those mycobacteria that have been studied in detail, the genome has been found to consist of a single length of DNA in the form of a closed loop. The genome is not contained by a nuclear membrane, although the tightly packed DNA is recognizable on electron microscopy as a nuclear body. Genome size determinations revealed that mycobacteria, compared with most other prokaryotes, have large genomes, in the range of  $2.8 \times 10^9$  to  $4.5 \times 10^9$  bp (91). The DNAs of most mycobacteria have between 64 and 70 mol% guanine plus cytosine, and DNA from the *M. tuberculosis* complex exhibited 4 to 25% homology with DNA from members of the fast-growing mycobacterial groups. Extrachromosomal DNA in the form of self-replicating plasmids is common in the MAC (106, 108, 109), but attempts to clearly define the biologic significance of plasmids in *M. avium* strains have been unsuccessful so far. A recent study described an insertion sequence (IS901) found in pathogenic strains of *M. avium* but absent in *M. avium* isolates from patients with AIDS (291). The IS901 insertion element has a nucleotide sequence of 1,422 bp with one open reading frame (ORF1), which encodes a protein of 401 amino acids. It was also determined that the terminal ends and target sites of IS901 were similar to those of the IS900 insertion element of *M. paratuberculosis*, while the DNA sequence of both elements

exhibited only 60% homology. *M. avium* strains containing IS901 were found to be more virulent in mice than closely related strains lacking IS901. RFLP analyses suggest that *M. avium* A/I (which contains a single copy of IS901) and *M. paratuberculosis* (which contains multiple copies of IS900), both of which cause enteritis and disseminated infection in birds and ruminants, have evolved from an ancestral *M. avium* type A which lacks both insertion sequences (328). Interestingly, *M. avium* RFLP type A is the predominant strain isolated from AIDS patients with disseminated infection as well as from non-AIDS patients with focal disease, while *M. avium* type A/I is rarely isolated from either group.

### Genetics of Antimicrobial Resistance

The MAC is considered inherently resistant to most, if not all, traditional antimycobacterial agents (179, 341). As mentioned previously, the basis for this resistance has been largely ascribed to the complex structure of the cell wall and the resulting impermeability (391, 392). There is no evidence that the MAC produces aminoglycoside- and peptide-inactivating enzymes (341), but there is evidence of the production of  $\beta$ -lactamases (340). The role of the cell wall architecture in antimicrobial resistance is underscored by a variety of observations. (i) Targets of certain antimicrobial agents, such as the ribosomes, bind the respective agents, and their function is inhibited despite the fact that intact organisms are resistant to these agents (341). (ii) Reagents such as Tween 80 potentiate the effect of antimicrobial agents most likely as a result of the surfactant effect on the cell wall structure (316, 496). (iii) There is growing evidence that ethambutol potentiates the activity of other agents (220, 394, 494), and this influence is a consequence of an ethambutol effect on cell wall permeability as evidenced, for example, by microcalorimetric measurements (221).

The colony type has a strong relationship with antimicrobial susceptibility (329, 341, 391), and because colony type transition is not a mutational event, the conversion of antimicrobial resistance phenotypes that is linked to the colony type transition occurs at a relatively high frequency, i.e.,  $10^{-4}$  (transparent-resistant to opaque-susceptible) to  $10^{-6}$  (opaque-susceptible to transparent-resistant). Superimposed on this phenomenon is the mutation rate for resistance to specific drugs or heavy metals, which is in the range of  $10^{-5}$  to  $10^{-9}$  per bacterium per generation. The resistance associated with colony type may be considered a type of phenotypic or adaptive resistance and, as such, may be expressed to varying degrees. However, it has been difficult to assess the influence of colony type transitions on some of these measurements. In general, the nontuberculous mycobacteria and MAC, in particular, should be considered heterogeneous, with subpopulations of resistant microorganisms which may range in frequency from  $10^{-4}$  to 1 (125).

### EPIDEMIOLOGY

#### General

Human disease caused by the MAC reportedly occurs worldwide but is predominantly endemic in certain Northern temperate geographic areas, including the United States (180), Canada (170, 250), Great Britain (240), Europe (127, 331), The Netherlands (144), and Japan (338); disease also occurs in Australia (126) and South Africa (356).

Infections with NTM are not reportable in the United States; as a result, the true prevalence of NTM disease is not



known. While *M. gordonae* is the most frequent NTM species isolated from human specimens, MAC is most frequently associated with human disease (38.2 to 73.3% of all pathogenic isolates) (127, 180, 250). The incidence of laboratory isolation of MAC in the United States, based on a 1979 survey of 44 state public health laboratories, is estimated to be 3.2 cases per 100,000 population and was greatest for Hawaii (10.8 cases), Connecticut (8.9 cases), Florida (8.4 cases), Kansas (6.8 cases), North Carolina, Maryland, Rhode Island, and Arizona (180). Several authors have noted an apparent increase in the incidence of NTM infections in the United States and Europe, even when cases in patients with AIDS are excluded (7, 21, 103, 127, 136, 365). In at least two locations, however, the incidence of MAC in non-AIDS patients remained stable or decreased. The rate of isolation of MAC from respiratory specimens at the San Francisco General Hospital steadily increased from 1977 to 1989, but the rate of increase paralleled the increasing incidence of AIDS cases in that city, while the prevalence of MAC isolated in respiratory specimens from non-AIDS patients remained stable (approximately 0.3%) (354). Clinical and laboratory diagnoses of NTM infections actually declined in British Columbia from 1972 to 1981 (250).

Serovar analyses indicate that there are differences in the patterns of human disease-related strains between geographic areas. In the United States, 40 to 50% of the clinical MAC infections in non-AIDS patients are caused by *M. intracellulare*, whereas in western Germany, 81% of the human infections are due to *M. avium* and only 19% are due to *M. intracellulare* (331). In addition, serovar analyses suggest a shift in the proportion of human disease caused by *M. avium* relative to that caused by *M. intracellulare* in certain geographic areas. Meissner and Anz noted that while disease due to intermediate *M. avium* serovars (4 to 6 and 8 to 11) increased from 26 to 71%, the frequency of disease due to *M. intracellulare* decreased from 22 to 5% from 1965 to 1975 in western Germany (331). In Japan, of 661 isolates that caused pulmonary disease, biotype studies indicate a similar significant shift from *M. intracellulare* to *M. avium* in the period 1976 to 1986 (338).

MAC organisms are ubiquitous in nature and can be isolated from natural sources of water, pools, soil, plants and bedding material, and even house dust (158, 243, 396, 467). Surveys of skin test reactivity to antigens prepared from *M. intracellulare* (PPD-B) indicate that the frequency of exposure to this organism is high, particularly in the coastal regions of the southeastern United States and the Gulf, especially in rural areas (>70% in some counties) (140). Data suggest that environmental sources of water constitute the greatest risk of exposure for humans (77, 85, 137, 148, 184, 331, 376, 435, 477), but there are significant gaps in our understanding of the mode of acquisition and pathogenesis of this disease. Indeed, NTM have been isolated from the water supplies of some of the largest metropolitan areas in the United States, including the water supplies of hospitals (85, 138). Drinking water contaminated with MAC was found in 32 of 141 rainwater tanks in Queensland, Australia, but there was no relationship to human disease (458).

Organisms of the MAC may be isolated from both fresh- and saltwater sources (17 to 61% of samples), but recovery is more frequent from waters of moderate salinity ( $\leq 2$  g% NaCl) and from the Southeast (33%) compared with the Northeast (20%) (148, 190). Studies of soil samples taken from the flood plains of four major eastern rivers demonstrated higher rates of recovery from soil and water samples of relatively high acidity (pH 4.6 to 6.8) and at lower

altitudes (69). MAC, but not *M. scrofulaceum*, is found in aerosols in droplet sizes of 0.7 to 3.3  $\mu$ m above fresh water which is sufficiently small to reach the alveolar spaces after inhalation (477). These studies led the authors to estimate that as many as 18 organisms may be inspired by a human during a 1-h period of exposure. Although isolation from seawater is slightly less frequent than that from fresh water, *M. intracellulare* is highly concentrated within jet droplets released from the air-seawater interface (190). These findings may explain the greater frequency of isolation of *M. intracellulare* from respiratory specimens in some geographic areas.

Plasmids are more commonly found in isolates from surface layer aerosols (75%) compared with isolates identified in soil (5%), dust (7%), and water samples (25%), and the plasmid DNA profiles of aerosolized isolates closely resemble those most commonly isolated from humans (332). A comparison of clinical and environmental MAC isolates revealed that clinical isolates were better able to grow at 43°C without oleic acid-albumin-dextrose-catalase enrichment and more frequently expressed resistance to cadmium compared with environmental isolates, features that closely correlated with the presence of plasmids (158). Only environmental isolates identified in droplets above bodies of water shared those unique characteristics.

*M. avium* is an important cause of disease in poultry and swine and is commonly excreted in the feces of birds (but not cattle or swine), after which the bacilli can persist in the soil for long periods of time. Although the direct transmission of *M. avium* from animals to humans is thought to be exceedingly rare, epidemiologic analyses of infecting strains suggests that the avian-associated serovars 1 to 3 cause infections in areas where humans and fowl are in close proximity; swine and cattle are even less frequently implicated as the source of infection for humans (331). Additional studies indicate disparity between the serovars that commonly infect humans, poultry, and swine (92, 356). The results of skin test surveys of relatives and housemates of infected persons do not support human-to-human transmission as a significant risk factor (140).

Vaccination with *M. bovis* BCG results in some cross-protection from *M. avium* infection in animals and, possibly, humans. The rate of recovery of viable organisms is lower in BCG-vaccinated mice than in nonvaccinated mice aerogenically challenged with *M. avium* or *M. kansasii*, but not *M. intracellulare* (99, 371). This moderate degree of protection may explain an increase in NTM infections in children following the cessation of community-wide BCG vaccination programs (403).

#### Patients with AIDS

Since the advent of the AIDS epidemic, immune deficiency due to human immunodeficiency virus (HIV) infection has become the single most significant risk factor for MAC disease. On the basis of AIDS case reporting to the Centers for Disease Control through 1987, the incidence of disseminated MAC as the AIDS-defining illness was 5.5% (233). By December 1990, there were more than 12,000 cases of disseminated NTM infection among the 161,073 patients with AIDS reported to the Centers for Disease Control; of these, the vast majority (96 to 98%) were due to MAC (191, 225, 233). Progressive immunodeficiency due to HIV infection appears to be the single most significant risk factor for disseminated MAC disease (81, 199, 234, 358). The incidences of disseminated disease 1 and 2 years after a diagno-

sis of AIDS, as defined by at least one blood culture positive for MAC, were 21 and 43%, respectively (358). The incidence of disseminated MAC at 1 year was 39% for patients with CD4 counts of <10 per mm<sup>3</sup>, but it was only 3% for patients with CD4 counts of 100 to 200 per mm<sup>3</sup> (234). These data correspond to histopathologic evidence of MAC infection in 47 to 50% of patients at autopsy (10, 466). At any given level of immunity, however, the incidence of MAC disease is greater for patients with AIDS compared with those HIV-infected patients without AIDS and is linear over time, suggesting that disseminated MAC may be an inevitable outcome in all HIV-infected patients who do not die of other causes (83, 358).

While there is no apparent age discrimination, disseminated MAC infection is more frequent in Caucasians compared with Hispanic, Haitian, and African-Americans (58, 226, 233, 342, 385). In addition, in patients with HIV infection, disseminated NTM disease is somewhat more frequent in men than in women (9.4 versus 7.0%), in homosexual and bisexual men compared with persons in other HIV risk categories (9.5 versus 6.2%), and in adults compared with children (8.3 versus 5.7%) (226). In contrast, infection due to *M. tuberculosis* is more common in Hispanic, Haitian, and African-Americans compared with Caucasians (58, 226). Inner-city intravenous drug users and women are also more likely to be infected with tuberculosis compared with their homosexual, white male counterparts (151). For example, in a sample of HIV-infected patients with mycobacterial disease, 27 of 45 (60%) Haitian patients were infected with *M. tuberculosis* compared with only 1 of 37 non-Haitians (385).

Despite its emergence as an increasingly common infection in the United States and other developed countries (233), disseminated MAC infection is uncommon in AIDS patients in countries of Africa and other developing nations (58, 345). Serial blood cultures failed to reveal a significant incidence of disease in Ugandan patients with AIDS, even though *M. avium* can frequently be recovered from soil and water specimens in that country (345). This finding may be, in part, due to the significantly higher incidence of tuberculosis and toxoplasmosis in patients with AIDS from developing countries compared with those from developed countries (58). Whereas tuberculosis can occur at any level of immunity, disseminated MAC infection predominantly occurs in patients with profoundly compromised immunity (<50 CD4 cells per mm<sup>3</sup>). In geographic areas with inadequate health care and a high incidence of tuberculosis and tuberculosis-associated mortality, patients may not survive long enough to develop disseminated MAC infection.

Environmental strain-related differences also may account for different prevalence rates in various geographic areas. MAC strains isolated from patients with AIDS in the United States and Australia are predominantly serovars 1, 4, and 8 (108, 126, 282, 495). In Sweden, however, while the incidence of disseminated MAC disease is relatively low in patients with AIDS, serovar 6 is most commonly isolated from clinical specimens in that country (219). In Africa, the predominant human and environmental isolate, RFLP type H, does not correlate with any known strain isolated from Western or European AIDS patients (328).

Also, environmental exposure may differ between populations; whereas 98% of MAC infections in AIDS patients are due to *M. avium*, approximately 40% of MAC isolates recovered from patients without AIDS are *M. intracellulare* (191). In addition, *M. intracellulare* made up 13% of respiratory isolates in one large survey of patients with AIDS but

only 1.3% of blood isolates and none of the stool isolates (495). Based on RFLP analyses, 73% of the MAC strains recovered from individual patients with AIDS were found to be genetically indistinguishable (194). These intriguing observations suggest that the source of environmental exposure, the route of infection, and other complex host factors, independent of the nature of the infecting strain, may differ in patients with and without HIV infection.

In addition, certain strains of MAC may possess virulence factors that more readily lead to infection and dissemination in patients with HIV infection. In one small study, all 26 strains isolated from persons with AIDS carried plasmids (11 carried one small plasmid and 15 carried two), suggesting that plasmids may play a pathogenetic role in patients with AIDS (108). No data to confirm a role for plasmids in the pathogenicity of MAC are available. The predominant strains isolated from patients with AIDS are, however, serovars 4 and 8, which frequently contain small plasmids or portions of plasmids (215, 265, 344). These plasmids are similar to those identified in serovars 4 and 8 isolated from environmental specimens (265), suggesting that these plasmids may confer specific virulence.

Although MAC organisms can occasionally be isolated from the stools of healthy humans, most are not associated with disease. Furthermore, strains that are more frequently isolated from AIDS patients with disseminated disease are not commonly found in the stools of healthy individuals (194). This observation led investigators to suggest that MAC isolates that cause disease in AIDS patients are not simply gratuitous opportunists but possess specific genetic determinants that confer an ability to penetrate and multiply within macrophages and host cells and contribute to the existing immunodeficiency (194). Implicit in this postulate is the assumption that there are host immune defects, possibly unrelated to the underlying HIV infection, which predispose patients to disseminated infection (39, 54, 114, 115, 224, 352, 446, 457).

## PATHOGENESIS

### Pathogenesis and the Host

Despite the fact that disease caused by mycobacteria has been known since the time of Koch and that satisfactory therapy exists for most mycobacterial infections, very little is known about the mechanisms of pathogenesis of the most common mycobacteria that cause disease, including *M. tuberculosis*, *M. leprae*, the MAC, and *M. kansasii*.

While humans are highly susceptible to *M. tuberculosis* and *M. leprae* infection, most people who are exposed to these bacteria never develop clinical disease, indicating that the normal immune system can control these microorganisms (86, 483). This observation is even more applicable to exposure to MAC organisms because, despite evidence of exposure rates as high as 70%, the incidence of clinical disease is remarkably low (<10 cases per 100,000 population). Before the AIDS epidemic, pulmonary infection was the principal, albeit infrequent, manifestation of disease. Dissemination of infection was unusual and, with rare exception, occurred in persons with defects in cellular immunity. However, even in severely immunocompromised individuals, such as those with hairy cell leukemia who seem to be predisposed to MAC infection (21, 64, 318, 397, 440, 476, 481), the incidence of MAC infection is only 5%. In contrast, *M. avium* appears to have a particular predilection for infecting and disseminating within HIV-infected patients.

### Routes of Infection

The most likely route of penetration of opportunistic mycobacteria into tissue is across the bronchial or intestinal mucosa. Current evidence points to the intestinal tract as the primary route of *M. avium* infection in AIDS patients (186, 287, 342, 436, 466) and the respiratory tract as a secondary and significantly less frequent portal of entry (4, 231, 257, 388). Disseminated disease in AIDS patients is frequently preceded by gastrointestinal tract colonization (22, 87, 231, 388) as evidenced by the relatively high frequency of positive stool cultures (22, 120, 202, 231, 342, 436) and the high frequency of gastrointestinal involvement, with large numbers of mycobacteria infiltrating the intestinal mucosa and submucosa (120, 186, 287, 406). A study of AIDS patients by Damsker and Bottone (120) was one of the first to suggest that colonization of the intestinal tract preceded the development of bacteremia. Other work supports this concept and, indeed, colonization of the intestinal tract with *M. avium* in patients with AIDS was shown to precede the appearance of bacteremia and disseminated disease by 4 to 5 months (53). Massive Peyer's patch and mesenteric lymph node involvement is a common histopathologic finding in these patients, along with intestinal erosion and chronic diarrhea (120, 287, 405, 406, 484).

Although there is little direct evidence that *M. avium* disseminates from the lung, one study showed that sputum cultures were twice as likely to be positive as stool cultures (66 versus 33%) (231). Progression to dissemination occurred with equal frequency (33%) in patients with positive respiratory or stool isolates during a mean observation period of 5 months. Recent data presented by Chin et al. (87) indicated that nearly 75% of patients develop mycobacteremia within 1 year (median duration time of 6 months) after the isolation of MAC organisms from respiratory secretions or stool. Nevertheless, of those patients who developed MAC bacteremia, only 25 and 36% had a preceding positive respiratory or stool culture, respectively. These data suggest that the methods available to screen for gastrointestinal tract colonization lack sufficient sensitivity, resulting in a poor negative predictive value.

Asymptomatic respiratory and intestinal colonization with *M. avium* can be seen in healthy individuals, but the development of focal or disseminated disease in them is rare. Ingestion of mycobacteria in water or food appears to lead to colonization of the intestinal tract (100, 309). Our studies with a beige (C57BL/6 *bg*+/*bg*+) mouse model of oral infection demonstrated that oral exposure of *M. avium* strains isolated from AIDS patients leads to intestinal colonization and subsequent dissemination of infection. Detailed studies of bacterial localization along the gastrointestinal tract showed that the great majority of the organisms are found in the terminal ileum and ascending colon (34). Concomitant ingestion of a mucosal irritant, such as ethanol, led to an increased colonization of the upper gastrointestinal tract, with a large number of bacteria being cultured from the stomach and mucosa and submucosa of the proximal intestines. Once in the intestinal lumen, the bacteria bind to enterocytes and probably M cells and quickly penetrate the intestinal epithelial cells before translocating into the lamina propria. The bacteria can colonize Peyer's patches and are eventually found localized in the liver and spleen as well as circulating in the blood.

It is possible that factors such as gastric achlorhydria and the use of oral antibiotics facilitate the colonization by *M. avium*. Studies in animals support this hypothesis, although

even closely related mycobacterial species can exhibit wide variations in mouse virulence when introduced by the oral route (34).

### Invasion of Mucosal Cells

We showed that AIDS-related *M. avium* strains can bind and invade HT-29 cells, a well-differentiated human intestinal epithelial cell line, in a manner that is likely to mimic the attachment and invasion of mycobacteria to the gastrointestinal tract of humans (41). Non-AIDS-related *M. avium* strains also bind and invade but are less efficient than AIDS-related strains. In addition, *M. avium* can bind and invade both human oropharyngeal cells and the HEP-2 oropharyngeal cell line (41). In more recent studies, we injected mycobacteria into the intestinal lumen of an isolated segment of the terminal ileum of C57BL *bg*+/*bg*+ mice being kept alive under anesthesia. Following different periods of exposure, we performed quantitative cultures on a 2-in. (ca. 5-cm) segment of the terminal ileum to measure the number of bacilli associated with mucosa and submucosa. In these experiments, we found that *M. avium* rapidly bound to and invaded the intestinal mucosa; however, this feature was strain specific. Strain MAC 101 colonized and invaded more rapidly than another AIDS-related strain (MAC 107, a serovar 8 strain) (236). Histopathological studies, in which hundreds to thousands of mycobacteria were observed in intestinal macrophages, clearly confirm that disease-associated strains of *M. avium* readily invade the intestinal mucosa and submucosa (236). Less virulent serovars of *M. avium* also possess the necessary cell wall adhesion but probably lack accessory virulence factors and do not survive within tissue macrophages.

Recent studies of *M. tuberculosis* demonstrated that the ability of tubercle bacilli to invade HeLa cells is encoded in a 3-kb genomic DNA fragment (11). In a parallel series of experiments, we used an *M. avium* library of chromosomal DNA to transform *Escherichia coli* K-12, which cannot invade cultured mammalian cells. *E. coli* transformants that had acquired a 2.7-kb fragment of chromosomal DNA and the ability to bind and invade human HT-29 and HEP-2 cells were isolated. Thus far, we have evidence for the presence of at least one adhesion protein in virulent strains of *M. avium*. Specific antibody generated with a purified preparation of a 27-kDa putative adhesion protein blocked the binding of *M. avium* strains to both intestinal and oropharyngeal mucosal cells (236). However, it seems clear from our studies and studies of *Yersinia enterocolitica*, *Yersinia pseudotuberculosis*, and *Salmonella cholerae-suis* that the ability to penetrate epithelial mucosal cells can proceed by a number of pathways (154, 251). In the case of *Salmonella* sp., Finlay and Falkow (154) showed that a cluster of proteins is synthesized in response to contact with MDCK cells. A mutation that blocks the synthesis of these proteins interferes with the ability of salmonellae to bind and enter mammalian cells; by extrapolation, intestinal cells may play an active role in taking up *M. avium*. Indeed, a 47- to 50-kDa glycoprotein present on HT-29 cells and oropharyngeal cells binds to the putative 27-kDa *M. avium* adhesion protein and appears to be involved in the binding of several different *M. avium* strains. However, it must be emphasized that in AIDS patients a number of factors probably facilitate *M. avium* infection and invasion of the intestinal mucosa, including coinfections with cytomegalovirus and HIV type 1.



### Infection of Nonprofessional Phagocytes

Virulent MAC strains can invade and survive within cells other than mononuclear phagocytes and epithelial cells. This ability to infect a variety of cell types may be related to the persistence of infection in the immunocompromised host; e.g., Bermudez (26) demonstrated that MAC organisms can infect and grow within fibroblasts and, once inside the fibroblast, the mycobacteria are protected against nonspecific mechanisms of killing. Once the bacilli are intracellular, major histocompatibility class I-mediated or NK cell-mediated cytotoxicity is necessary to release the bacilli from the cells. Although it is difficult to assess the overall importance of the ability of MAC to infect "nonprofessional" phagocytes, it is plausible that in a setting of profoundly impaired cytotoxic response the ability to invade fibroblasts, endothelial cells, and other nonprofessional phagocytes contributes to persistence and dissemination.

### Interaction with Mononuclear Phagocytes

Intracellular pathogens typically reside within a niche of the host where the pathogen can multiply or survive the onslaughts of cellular and humoral defense mechanisms. Thus, the armamentarium of pathogens includes mechanisms that counteract both nonspecific and specific host defenses. Studies with *M. tuberculosis* (421) and *M. leprae* (422) demonstrated the importance of complement receptors (CR1 and CR3) for the binding and phagocytosis of mycobacteria. In addition, it is now clear that several species of mycobacteria including *M. leprae*, *M. tuberculosis*, and *M. bovis* bind to serum fibronectin by way of a 30-kDa receptor (1). Phagocytosis of the MAC by monocytes and macrophages occurs mainly via the CR3 receptors in both the presence and the absence of serum (47, 401). In addition, MAC organisms bind to serum fibronectin and the bacilli are internalized by macrophages by using the integrin fibronectin receptor. The use of an Fc receptor-independent pathway for uptake may offer significant advantages for the invading microorganism. For instance, a study by Wright and Silverstein (488) showed that phagocytosis with Fc receptors, but not complement receptors, is associated with superoxide anion production by phagocytic cells, and invasion by other mechanisms may influence the structure and function of the intracellular vacuole. Although the ability to multiply inside mononuclear phagocytes is not uniform among *M. avium* strains, AIDS-associated strains remain viable within human and murine macrophages (39, 116) and resist the respiratory burst-associated bactericidal mechanisms (42, 166). MAC as well as *M. tuberculosis* synthesize a 23-kDa superoxide dismutase that can inactivate macrophage-derived superoxide anion (319) and other proteins, such as the 65-kDa heat shock protein, which are powerful inhibitors of superoxide anion production (30). The origin of this activity is unknown, but the 65-kDa protein is released in large quantities in response to stress conditions such as high temperature, change in pH, and phagocytosis (30). The survival of pathogenic strains of *M. avium* within macrophages also is related in part to their capacity to inhibit fusion of the phagosome and lysosome, thus preventing contact with proteolytic enzymes (54, 115). In the absence of phagolysosome fusion, the intracellular environment of the macrophage remains neutral or alkaline, which may directly influence pathogen survival and the effectiveness of certain antimicrobial therapies. Studies by Frechel and colleagues (156) suggested a role for cell surface components, other than the C-mycro-

sides, in this phenomenon. Walker and Lowrie (465), using *M. microti*, proposed a role for cyclic AMP and prostaglandin E<sub>2</sub> in phagolysosome fusion.

## IMMUNE RESPONSE

### Cellular Immunity

Mycobacteria are considered the archetypical intracellular pathogens because of the capacity of these bacilli to invade and multiply within macrophages (39, 116); thus, the cellular immune response to mycobacterial infection has been a subject of considerable study. Phagocytosis and processing of antigens by macrophages or B lymphocytes trigger a specific cellular immune response, including the activation of T-helper cells, macrophages, T-cytotoxic cells, and NK cells. Antigen processing occurs after infection with mycobacteria and leads to a complex host response involving multiple arms of the immune system (427, 428). Although there is evidence that CD4<sup>+</sup> T cells, CD8<sup>+</sup> T cells, NK cells, and  $\gamma\delta$  T cells (197, 237, 348) are important factors in this response, there is surprisingly little information about the cellular immune response to NTM. For example, some strains of the MAC induce a chronic, lifelong lung infection in normal mice (102), while more virulent MAC strains cause a disseminated disease associated with high mortality (163). Most strains of *M. intracellulare* are less virulent and tend to induce chronic pulmonary infections in C57BL/6 or beige mice (370), but infection with these strains is exacerbated by the absence of T cells such as in congenitally athymic *nu/nu* mice (101). In mice, resistance to early growth of *M. bovis*, *M. lepraemurium*, *M. intracellulare*, and *M. avium* may be controlled by a single dominant autosomal gene, *Bcg* (424). Furthermore, phagocytosis- or ligand-induced respiratory burst activity is significantly greater in macrophages from resistant animals than in macrophages from susceptible mice (372), and the transfer of immune cells (T or NK cells) from resistant to susceptible mice is associated with an increased ability of the latter animals to control *M. avium* infection (31). However, these observations contradict the observation that peritoneal macrophages from MAC-resistant and MAC-susceptible mice have equal capacities to ingest and inhibit or kill MAC in vitro (31).

### Role of Cytokines

Both cultured mouse and human macrophages can be stimulated by cytokines to inhibit or kill intracellular *M. avium*. Bermudez and coworkers (45, 51) and Denis and Gregg (132) showed that recombinant tumor necrosis factor (TNF) and granulocyte-macrophage colony-stimulating factor (GM-CSF) induce mycobacteriostatic and/or mycobactericidal activity and that macrophages stimulated with TNF or GM-CSF respond differently than unstimulated macrophages. In stimulated macrophages, there is an increased release of superoxide anion and phagolysosome fusion occurs more frequently following uptake of mycobacteria (54). Although the mechanisms of inhibition and killing of intracellular MAC are not completely understood, the nonoxidative mechanisms of defense have an important role (27, 42). Bactericidal proteins purified from human macrophages increase the permeability of the mycobacterial cell, and this effect is ultimately bactericidal (40). Although the nitric oxide-dependent pathway of intracellular killing is associated with the nonoxidative killing of a number of intracellular pathogens such as *Taxoplasma gondii* (3) and *Leishmania*

major (187), there is controversy about the role of this pathway in the killing or inhibition of mycobacteria. Some studies suggest that this pathway is important in the killing of the MAC (131), *M. leprae* (2), and *M. tuberculosis* (84), while other studies show that this pathway is not important for the killing or inhibition of MAC growth (27).

The ability of cytokines to stimulate macrophages and inhibit growth of the MAC depends on the strain; e.g., gamma interferon (IFN- $\gamma$ ) stimulates inhibition or killing of certain non-AIDS strains of MAC (44), but not that of AIDS-related MAC strains (51). Paradoxically, the administration of recombinant TNF or GM-CSF was associated with increased killing of mycobacteria in the beige mouse model of disseminated MAC infection (32, 35), but macrophage monolayers infected with MAC organisms for longer than 48 h failed to respond to these cytokines even when the cytokines were administered 7 days after infection (44). The conclusion was that response to cytokine stimulation reflects the influence of MAC infection on the ability of macrophages to respond to cytokines. In addition, the MAC can interfere with other cytokine pathways by stimulating the production and release of suppressor molecules such as interleukin-6 (IL-6) and transforming growth factor  $\beta$  (TGF- $\beta$ ) or by directly influencing the mechanism of signal transduction within macrophages (28, 38). The release of inhibitory cytokines by MAC-infected macrophages occurs within a few days of infection, and infection with AIDS-related strains of the MAC stimulates the release of IL-6 and a suppression of macrophage function by down-regulating the expression of TNF receptors and decreasing TNF production (35, 57, 132). There is some evidence that IL-6 stimulates growth of the MAC (426); however, IL-6 binds not only to virulent MAC strains, but also to nonvirulent strains, *M. smegmatis*, *E. coli*, and *Pseudomonas aeruginosa*, raising the possibility that the influence of IL-6 binding is nonspecific (35).

*M. avium*-infected macrophages release TGF- $\beta$  soon after infection (28), and the 61- and 33-kDa cell surface proteins of MAC stimulate macrophages to release TGF- $\beta$  in culture (28). Furthermore, much of the TGF- $\beta$  released from infected macrophages is in the active form, whereas TGF- $\beta$  released from control macrophages is in the inactive form. Since TGF- $\beta$  is known to impair the ability of macrophages to respond to cytokines, the release of TGF- $\beta$  is likely to be responsible for the lack of response to IFN- $\gamma$  by MAC-infected macrophages. A specific amino acid sequence within the 33-kDa protein interferes with the regulation of transcription in macrophages, which in turn influences the response of macrophages to stimulation with TNF- $\alpha$  (29). Interference with cytokine-related signal transduction and transcription is probably an important mechanism of pathogenesis and contributes to the persistence of MAC within macrophages.

Thus far, the results of various studies directed at understanding the nature of the interaction between HIV type 1 and *M. avium* within macrophages are inconclusive. In some studies of coinfecting macrophages, HIV type 1 did not affect the *M. avium* infection, while others claim that *M. avium* grew significantly faster in HIV-infected macrophages (262, 267). Peripheral blood mononuclear phagocytes obtained from AIDS patients are not functionally impaired (334), since these phagocytes respond to stimulation with cytokines several days after being harvested from blood; however, phagocytic cells obtained from the peripheral blood may be significantly less impaired than heavily infected tissue macrophages.

Finally, a number of cofactors could contribute to the

impairment of macrophage function in AIDS patients. Alcohol ingestion is common in some at-risk population groups (315). Because of the relationship between alcohol consumption and pulmonary tuberculosis (70, 238), it is plausible that there is an association between alcohol consumption and *M. avium* infection in AIDS patients. Human macrophages exposed to serum-achievable concentrations of ethanol are more permissive to intracellular growth of *M. avium* than macrophages not treated with ethanol (46), and ethanol both impairs the ability of macrophages to respond to stimulation with TNF and GM-CSF (37) and may act as a mycobacterial stress factor (43). Other drugs of abuse impair macrophage function. Peterson et al. (381) demonstrated that treatment of macrophage monolayers with cocaine was associated with increased replication of HIV type 1; however, the relationship between this observation and infection of macrophages with MAC organisms is unknown.

### Role of Lymphocytes

Several studies have shown that T lymphocytes are important in the immune response to mycobacterial infections including the generation of a positive skin hypersensitivity response to intradermal administration of PPD. In the infected host, expression of class II molecules by infected macrophages results in the presentation of mycobacterial antigens to class II-restricted CD4<sup>+</sup> T lymphocytes of the helper/inducer type. Mice inoculated with a crude lysate of *M. tuberculosis* or *M. avium* will respond with a proliferation of T cells specific for mycobacterial antigens. In a limiting-dilution analysis, approximately 20% of the CD4<sup>+</sup> T lymphocytes that were reactive to mycobacterial antigens recognized the mycobacterial 60-kDa heat shock protein (272).

Little is known about the role of T cells in preventing the growth of *M. avium* in the tissues of immunocompetent hosts. While T-cell depletion enhances the severity of infections with some MAC strains, T-cell depletion does not affect the severity of infection with other strains (101). Depletion of the L3T4<sup>+</sup> or Lyt-2<sup>+</sup> T-cell subpopulation does not have any significant effect on the immune response to *M. avium* in mice, but depletion of both subsets ablates the immune response (237). However, it appears that the interaction of activated CD4<sup>+</sup> T cells with macrophages does not have the same effect with *M. avium* as with *M. tuberculosis* (271).

The antibody response of humans and mice to MAC infection, as judged by Western blots (immunoblots), is heterogeneous (36, 343), and blot profiles from different patients show distinct individual patterns with a few predominant common bands. Like *M. tuberculosis*, *M. avium* releases a 65-kDa protein in response to the stress of increased temperature or exposure to acid pH (39). The release of proteins in response to stress has been demonstrated in nonmycobacterial systems, and Young and Garbe (501) speculated that the 65-kDa protein of *M. tuberculosis* is an analog of the GroEL protein in *E. coli*. Other mycobacterial antigens, including the 71-, 65-, 38-, 33-, 30-, and 10-kDa proteins, can be released and recognized by CD4<sup>+</sup> and CD8<sup>+</sup> T lymphocytes. In addition, mycobacterial glycolipids can have an immunomodulatory effect (447) and certain GPLs from *M. avium* can interfere with the lymphoproliferative response (72). T cells bearing the  $\gamma\delta$  T-cell receptor appear to have a special role in the immune defense system and there is a strong correlation between infection with an intracellular pathogen and the accumulation of  $\gamma\delta$  T cells at

the sites of infection, including the skin and lung epithelium. The relationship between  $\gamma\delta$  T cells and invading microorganisms is central to the hypothesis of immunosurveillance and suggests that a primitive subset of T cells provides an initial line of immune defense by recognizing highly conserved molecules produced during environmental stress; i.e.,  $\gamma\delta$  T cells with a severely restricted receptor repertoire react to the release of highly conserved mycobacterial 60- and 70-kDa heat shock proteins. O'Brien et al. showed that  $\gamma\delta$  T cells proliferate in response to PPD and to a recombinant 65-kDa protein of *M. tuberculosis* (368), and our preliminary studies confirmed these findings and extended the observation to *M. avium*; i.e.,  $\gamma\delta$  T cells from four different donors lysed infected target cells in a major histocompatibility complex-independent manner after stimulation with *M. avium* (33).

The role of human  $\gamma\delta$  T cells in the first line of immune defense to mycobacterial infections also is strongly suggested by the accumulation of  $\gamma\delta$  T cells at the site of granulomatous responses to *M. leprae* (462) and in tuberculous lymphadenitis (258). Among the  $\gamma\delta$  T-cell subpopulations there is evidence that the response to pathogenic *M. tuberculosis*, *M. avium*-*M. intracellulare*, and *M. scrofulaceum* is mainly confined to the V $\delta$ 9 V $\delta$ 2 TCR-positive cells, and the selective triggering of these T cells may reflect a super-antigen-like effect of mycobacterial antigens or antigen-specific stimulation, possibly in response to the heat shock protein 60 (196, 367).

#### Role of NK Cells

The role of NK cells in the immune response to *M. tuberculosis* and *M. avium* has been well established in a variety of studies (50, 55, 270). More recent findings indicated that NK cells are cytotoxic in a nonrestricted manner and stimulate mycobacteriostatic and mycobactericidal activities in infected macrophages (50, 55, 270). The cytotoxicity of NK cells for infected macrophages appears to depend on binding via the LFA-1 glycoprotein receptor (56); however, the validity of this observation could be questioned since other recent studies showed that NK cells do not efficiently bind or lyse target cells expressing the class I major histocompatibility complex. It is of interest to note that Blanchard and colleagues (57) showed that NK cells exposed to *M. avium* release large amounts of IL-6, which may have an important influence on the host immune response.

The mechanism by which NK cells stimulate macrophages appears to be mediated by the release of cytokines. Gomez et al. (176) and Pohjda et al. (387) demonstrated the ability of activated NK cells to produce cytokines that activate macrophages, and studies of the role of NK cells in the inhibition and killing of MAC organisms are in agreement with these previous studies (50). TNF, IFN- $\gamma$ , and GM-CSF are secreted by activated NK cells and, theoretically, can influence macrophage activity. Anti-TNF antibody, but not anti-GM-CSF antibody, partially blocks the stimulatory effect of the supernatant fraction of activated NK cells but cannot block the effect of purified NK cells. This observation suggests that the effect of NK cells on macrophages occurs through direct cell-to-cell contact (50). Numerical and functional deficiencies of NK cells in patients with AIDS (61) may account for the ability of *M. avium* to invade and establish infection in tissues. This hypothesis is supported by a recent study that showed that C57BL/6 mice treated

with antibody to deplete NK cells developed a more severe form of disseminated disease than untreated mice (197).

### CLINICAL DISEASE IN PATIENTS WITHOUT AIDS

#### Pulmonary Disease

The first case of human disease due to *M. avium* was reported in 1943 in a middle-aged underground miner from the Mesabi Iron Range of Minnesota in what became a classic description of pulmonary disease due to this organism (152). During the next two decades, a number of cases of MAC pulmonary disease were reported (113, 300, 451), and until the emergence of AIDS, lung infection alone was the most common presentation of disease due to this organism.

Pulmonary disease due to *M. avium* predominantly involves white males 45 to 65 years of age with preexisting pulmonary disease (144, 145, 404, 468), but there is tremendous variation in the sex, age, and race of these patients. Predisposing conditions such as chronic obstructive pulmonary disease, bronchiectasis, chronic aspiration or recurrent pneumonia, inactive or active tuberculosis, pneumoconiosis, and bronchogenic carcinoma are present in 54 to 77% of patients with pulmonary MAC disease (144, 145). Also, MAC organisms are frequently recovered from adults with cystic fibrosis, particularly in the southeastern United States (283). Differentiation of infection from the coexistent pulmonary disease may be difficult, and the clinical and radiographic presentation may be indistinguishable from tuberculosis (373). A positive tuberculin skin test may be helpful in differentiating the two processes; however, coinfection with *M. tuberculosis* and *M. avium* has been demonstrated (456).

The symptoms are varied and nonspecific, commonly including chronic productive cough, dyspnea, sweats, malaise, fatigue, and, less commonly, hemoptysis. Fever and weight loss are not common but may occur. Approximately 75% of patients have evidence of cavitory infiltrate on chest roentgenograms, typically involving the apical and anterior segments of the upper lobes, but dense unilobular or multilobular infiltrates, diffuse interstitial or reticulonodular infiltrates, or a solitary pulmonary nodule may occur (89, 188, 310, 389). Cavities or infected bullae tend to be thin walled with less surrounding infiltrate than that associated with tuberculosis. Bilateral involvement is common and there may be a dense pleural reaction, but pleural effusions are unusual. The radiograph of a patient without AIDS and one of a patient with AIDS, both with pulmonary disease, are shown in Fig. 3 and Fig. 4 and may be compared.

MAC organisms may be isolated from the sputum in the absence of apparent disease, particularly in patients with chronic respiratory disorders; such low-grade infection or colonization is more common than true disease. These patients may have episodic excretion of organisms which frequently clears with good pulmonary toilet. Also, isolation of the organism may simply represent contamination of the specimen, and care must be exercised in interpreting the results of these cultures.

Guidelines have been suggested for distinguishing patients with NTM lung disease from patients who are simply colonized. NTM disease in patients with noncavitory infiltrates can be assumed to be present when (i) two or more sputum or bronchoalveolar wash specimens are smear positive and/or result in moderate to heavy growth in culture; (ii) sputum cultures fail to revert despite good pulmonary toilet or 2 weeks of antimycobacterial therapy; and (iii) reasonable attempts fail to identify other underlying causes of disease

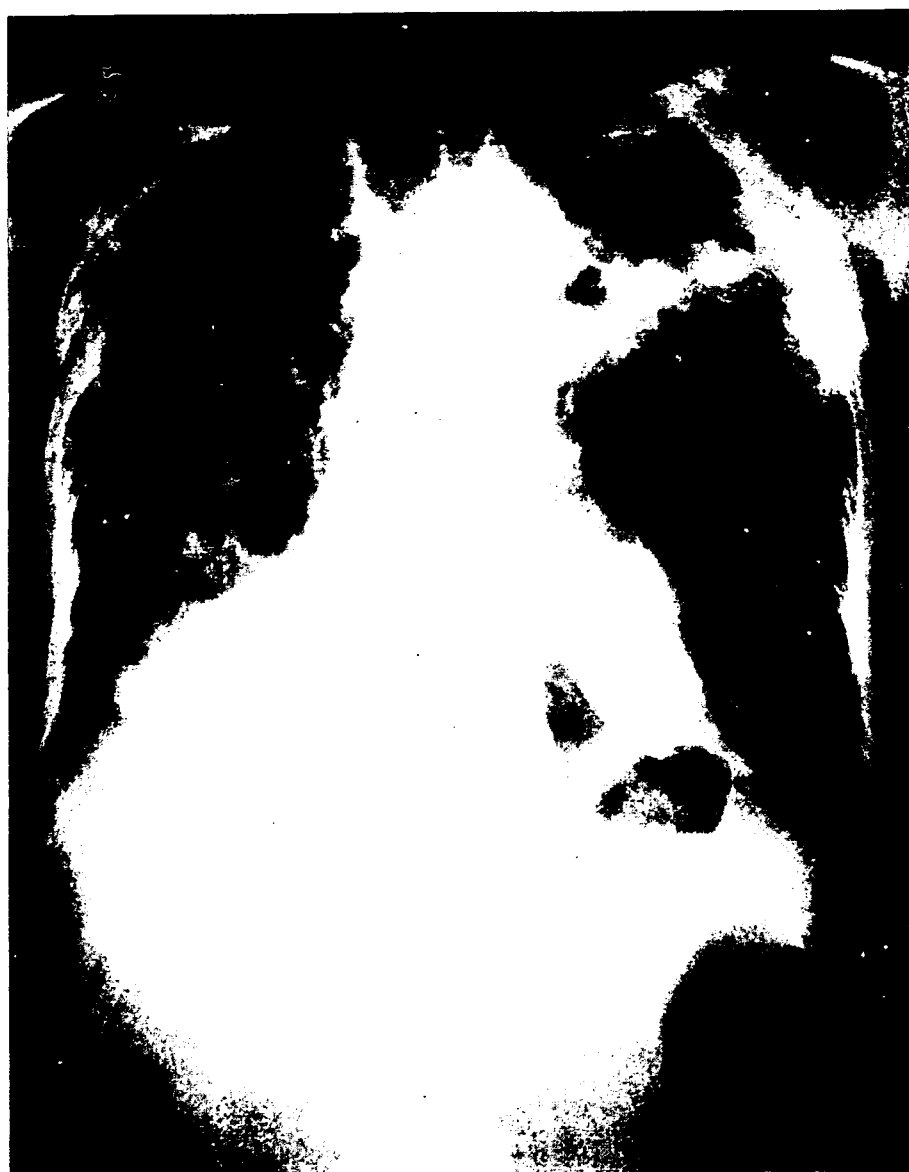


FIG. 3. Posterior-apical chest roentgenogram of a 48-year-old immunocompetent woman with severe bullous emphysema and extensive pulmonary disease due to MAC. Scattered infiltrates and a diffuse irregular pleural thickening are noted bilaterally.

(468). It is important to note that these guidelines may not apply to immunodeficient patients.

More individuals, especially women, in previously good health and without the usual predisposing conditions are being recognized with pulmonary MAC disease (252, 389, 395). Many of these patients were older women with indolent symptoms and atypical radiographic features (e.g., a solitary nodule), which frequently resulted in a delayed diagnosis. Six of 29 patients, all female, with *M. avium* pulmonary infection had isolated middle lobe or lingular involvement (395). The authors termed this the Lady Windermere's Syndrome, after Oscar Wilde's Victorian character, because many patients had a fastidious habit of cough suppression that the authors considered a potential predisposing factor. In another series, 4 of 21 patients died from progressive pulmonary MAC infection, and none of these patients had an

underlying immunodeficiency or other contributing disease (389). The prognosis of *M. avium* pulmonary disease may be worse than that of *M. intracellulare* disease. In one survey, 3 of 28 patients with *M. avium* died and 1 was cured, while none of 27 patients with *M. intracellulare* died and 6 were cured of disease (497).

Patients with an underlying immunodeficiency are at risk for pulmonary MAC disease, including those compromised by cytotoxic chemotherapy, corticosteroids, or allogeneic bone marrow, renal, or cardiac transplantation. Such patients commonly present with atypical radiographic features (292), and attempts at establishing a diagnosis may be difficult and complicated by the presence of multiple pathogens. Also, the administration of steroids may mask the clinical symptoms. Pulmonary MAC disease in children is rare and is usually a component of disseminated infection in



FIG. 4. Posterior-apical chest roentgenogram of a 39-year-old, HIV-infected male with isolated pulmonary MAC infection of the superior posterior portion of the left lower lobe. Note the absence of a pleural effusion or scarring, cavitation, or hilar lymphadenopathy.

the presence of an underlying immunodeficiency (216, 305). The role of MAC in one special pediatric population, cystic fibrosis patients, is unclear; however, the isolation of MAC organisms from respiratory secretions of older cystic fibrosis patients is not uncommon (283).

In most cases, the diagnosis of MAC pulmonary disease can be established without lung biopsy, but in patients with low numbers of organisms or an unexplained or atypical radiographic presentation, percutaneous, transbronchial, or open lung biopsy may be necessary. A recent study identified MAC organisms in the sputum of 11 of 97 patients with active tuberculosis (cultures were first incubated at 42°C for 3 weeks to suppress the growth of *M. tuberculosis*) (456); however, the clinical significance of *M. avium* in these patients was not entirely clear. Antibodies to *M. avium* detected in serum or pleural fluid are not specific, and antibodies in the pleural fluid most likely reflect passive diffusion from sera and not localized production (298).

Histopathologic presentations are varied; both caseating and noncaseating granulomatous necroses are common and may be associated with a granulomatous bronchitis. Ill-formed granulomata with histiocytic reaction are more commonly reported in immunodeficient patients but also are seen in immunocompetent hosts. A granulomatous vasculitis (histologically similar to Wegener's granulomatosis) or a non-specific interstitial pneumonitis with organizing pneumonia may be the only finding (310). A survey of 20 resected

solitary pulmonary nodules with histologic evidence of granulomata and acid-fast bacilli indicated that 12 (60%) were due to MAC, 1 was due to *M. tuberculosis*, and 5 were culture negative (188).

#### Subacute Lymphadenitis

Granulomatous inflammation accounts for approximately 20% of cases of upper anterior cervical, submandibular, submaxillary, and pre-auricular lymphadenopathy in children 1 to 5 years of age. Most of these cases are the result of infection due to the MAC, *M. scrofulaceum*, or the etiologic agent of cat scratch disease. Mycobacterial lymphadenitis usually presents as an insidious, painless, unilateral process involving one or more nodes in a regional distribution (20, 170, 264, 293, 417, 468); axillary and inguinal nodes are occasionally involved (98). Spontaneous sinus tract formation occurs in approximately 6% (264). Children above the age of 12 years are rarely infected except in circumstances of immunodeficiency or disseminated disease (293).

Of the mycobacteria isolated from the nodes of children which can be characterized, 63 to 80% are MAC, 10 to 20% are *M. scrofulaceum*, and approximately 10% are *M. tuberculosis* (20, 170, 264, 293, 468). These findings are in distinct contrast to mycobacterial lymphadenitis in persons older than 12 years, 95% of which is due to infection with *M.*

*tuberculosis* and only 3% of which is due to infection with MAC organisms (293).

While more than 90% of children with mycobacterial lymphadenitis have a positive skin test reaction to PPD-B (264), safe, standardized, antigenic material is not available for routine diagnostic purposes. Such patients would, however, have a negative tuberculin skin test, unless they were coinfecting with *M. tuberculosis*. Fine-needle aspiration may yield the diagnosis with a positive culture in less than 50% of cases (8, 438). Histopathologic presentations of lymphadenitis are varied but generally demonstrate caseating granulomatous inflammation and necrosis, epithelioid histiocytes, and occasional giant cells. Rarely, histiocytic inflammation and a lack of granulomatous inflammation occur, chiefly in children with selective immunodeficiency (347).

### Disseminated Infection

An excellent review of disseminated MAC infection in non-AIDS patients is provided by Horsburgh et al. (230), and several comprehensive reviews of the spectrum of clinical disease have been provided elsewhere (253, 305, 468, 482, 487); the following presents a brief overview of disseminated disease and of unusual sites of involvement.

Disseminated infection with the MAC was extremely unusual prior to the AIDS epidemic. Typically, the disease occurred in individuals with underlying malignancy or inherited or therapeutic immunodeficiency, especially children and young adults with hematogenous malignancy or severe combined immunodeficiency syndrome, transplant recipients, and patients receiving cytotoxic chemotherapy or corticosteroids (230, 361, 468, 482). A specific immune defect may predispose patients with hairy cell leukemia to disseminated disease (64, 318, 397, 440, 476, 481). In one large series, 5% of patients with hairy cell leukemia were diagnosed with NTM infections (21), and other data indicate an association of disseminated NTM infections in cardiac transplant recipients with prior nocardiosis (430). Holland (223) recently described a possible X-linked deficiency of CD45RO cell IFN- $\gamma$  production in a child with disseminated MAC infection; two maternal uncles of the child had chronic disseminated MAC infection and abnormally low levels of IFN- $\gamma$ .

The most frequent presentation of disseminated infection in the immunocompromised host is fever of undetermined etiology. Dissemination may involve any organ system but, most commonly, the lungs and large airways, the mononuclear phagocyte system including the liver, spleen, and retroperitoneal nodes, the gastrointestinal tract, the skeletal system, and the skin (76, 157, 230, 305, 415, 482). Rarely, the brain, cerebrospinal fluid, and orbit are involved (147, 282, 305, 459). Mycobacteremia was seldom reported previously, but with the improvement in isolation techniques, bacteremia may be identified in more than 90% of non-AIDS patients with disseminated infection (282).

Massive histiocytic infiltration with innumerable acid-fast bacilli, resembling the "foamy" histiocytes of lepromatous leprosy, occurs in some patients and may immediately suggest the diagnosis. However, the histopathologic changes in severely immunocompromised hosts are often nonspecific with necrotizing acute and chronic inflammation, histiocytosis, and a lack of granulomatous inflammation or apparent acid-fast bacilli (150). Chronic ulceration of duodenal and colonic mucosa with histiocytic infiltration, which was ultimately fatal due to gastrointestinal hemorrhage, has been reported (337). Despite administration of multiple antimycobacterial

bacterial agents, most cases of disseminated disease have been fatal (55 to 100%), particularly in children and immunocompromised hosts (230, 305, 482).

Stone et al. (441) recently presented two cases of disseminated MAC disease in children without HIV infection and reviewed an additional 30 cases of serious MAC disease in children involving visceral dissemination, localized pulmonary disease, disseminated osteomyelitis, mastoiditis, otomastoiditis, meningitis, and mediastinal mass. The overall mortality for all of the patients included in this study was 41%; however, for children with visceral dissemination, the mortality was 82% (approximately one-third of the patients had visceral disseminated disease). In contrast, patients with localized disease or osteomyelitis had a favorable outcome.

### Unusual Sites of Infection

The MAC has been implicated in numerous articular and periarticular infections, causing granulomatous inflammation of any joint, bursa, or tendon sheath, but with the joint spaces of the hands and wrist most commonly involved (141, 217, 445, 499). Extension to adjacent bone and soft tissue occasionally occurs. Trauma, puncture wounds, and needle injection are common inciting risk factors, but hematogenous dissemination, particularly in patients with underlying disease, is likely. The disease is typically indolent and delays in diagnosis are common; at least 40% of the cases of NTM in one series had received intra-articular steroids for non-specific tenosynovitis or arthritis prior to recognition of the infection (217). In only 15% of the cases can the diagnosis be made on culture of joint aspirate and surgical biopsy, and culture of synovial material is necessary for diagnosis in most cases. The majority of cases respond, with preservation of joint function, to a combination of surgical excision of infected material and antituberculous chemotherapy (141). A single case of reactive arthritis in a patient with *M. avium* pulmonary infection has been described (313).

Osteomyelitis, usually with multiple bony lesions, skeletal destruction, contiguous abscess formation, and draining sinuses, is rare (305, 482). It most commonly occurs in children who have hematologic malignancy, but rarely in apparently healthy individuals (19, 97, 259).

NTM infection of the urinary tract, which may be clinically indistinguishable from tuberculosis, is uncommon (90, 377) but can involve any structure in the genitourinary system including granulomatous prostatitis in a recently reported unusual case in an immunocompetent elderly male (336). The presence of MAC in the urine does not necessarily imply tissue infection, however.

Numerous cases of cutaneous abscesses, ulcerations, or nodules due to infection with MAC organisms have been reported, and these have been a result of either direct inoculation, trauma, or surgery or, more often, a consequence of hematogenous dissemination in an immunosuppressed patient (96, 157, 189, 307). Frank cellulitis is rare (415). Localized infection of breast tissue after breast augmentation and silicone injection due to *M. avium* has been reported (379), but *M. fortuitum* and *M. chelonae* are more commonly the cause of these mycobacterial infections.

Acute otolaryngeal, mastoid, and mediastinal infections have been described, probably as a result of extension of infection from the adjacent pharyngeal spaces (274, 285, 469). Also, there are reports of mycotic aneurysmal infection (135, 149), peritonitis associated with ambulatory peritoneal dialysis (390), and corneal ulceration (288).



## CLINICAL DISEASE IN PATIENTS WITH AIDS

### Focal Disease

Patients with AIDS may present with infection of the respiratory tree or gastrointestinal tract; such infection may be symptomatic or asymptomatic. Distinction between colonization and infection is often difficult, particularly in asymptomatic patients. The MAC is not uncommonly isolated from sputum or stool culture specimens in patients with AIDS (22, 202, 214, 231, 257, 388, 436), and patients may have a single positive culture of either sputum or stool or episodic excretion of organisms without apparent disease. While isolation of MAC organisms in stool is common in the absence of apparent clinical disease in HIV-infected patients without AIDS, 20 to 45% of patients with AIDS and positive stool cultures will have evidence of disseminated disease (120, 186, 388, 436). The presence of the MAC in cultures of either sputum or stool is a risk factor for disseminated disease, but approximately 64 to 75% of patients who develop bacteremia have no previous evidence of colonization (87). The detection of MAC organisms in cultures of stool or respiratory secretions in patients at risk for disseminated disease should therefore prompt a thorough search for evidence of focal or disseminated disease should therefore prompt a thorough search for evidence of focal or disseminated disease, but the routine screening of stool and sputum specimens is not advocated.

Some patients with AIDS may present with focal pulmonary infection due to *M. avium* without evidence of dissemination (342, 468). The clinical presentation is similar to that of immunocompromised hosts but is generally milder than tuberculosis (342). Patients may complain of persistent productive cough, dyspnea, fever, sweats, malaise, and weakness; hemoptysis rarely occurs. The pattern of radiographic involvement is varied. Diffuse interstitial or reticulonodular infiltrates occur in approximately 50%, alveolar infiltrates occur in 20%, and apical scarring or upper lobe involvement occurs in <10% of patients. In contrast to non-AIDS patients with pulmonary MAC infection, cavitary disease is unusual (<5%). The thick pleural reaction often seen in normal hosts with chronic pulmonary disease is not seen, and pleural effusions are rare (Fig. 3 and 4).

MAC pulmonary disease may be clinically and radiographically indistinguishable from bacterial pneumonia or pulmonary disease due to pneumocystosis, tuberculosis, aspergillosis, cryptococcosis, or coccidioidomycosis. Determination of the etiologic agent may be difficult, and more than one pathogen may be present. Despite the isolation of *M. avium* or *M. intracellulare* from cultures of sputum or bronchoalveolar lavage fluid, a careful search for other potential pathogens should be made. In a patient who has a single sputum or bronchoalveolar lavage culture positive for MAC, radiographic evidence of pulmonary infiltrative disease more likely signals the presence of a pathogen other than MAC organisms (314). Transbronchial biopsy or percutaneous needle biopsy may be necessary, but open lung biopsy should be considered in those patients in whom other measures have failed to reveal the diagnosis and in whom assessment suggests that the benefits outweigh the risks.

In the absence of data specific for patients with HIV infection, HIV-positive patients with sputum repeatedly culture positive for MAC and with persistent symptoms and/or evidence of radiographic disease, not attributable to another pathogen, may be considered candidates to receive antimycobacterial therapy. However, any HIV-positive patient with isolation of acid-fast bacilli in the sputum which

has not yet been identified, particularly those with CD4 counts of >100 per mm<sup>3</sup> or abnormalities on chest radiographs, regardless of the results of PPD skin testing, should receive empiric therapy active against *M. tuberculosis* until the identity of the organism can be established.

Peripheral lymphadenitis due to *M. avium*-*M. intracellulare* occasionally occurs in patients with HIV infection without evidence of disseminated disease, sometimes associated with overlying cutaneous lesions (14). In patients with fever of undetermined etiology and negative mycobacterial blood cultures, gallium scanning may identify infected lymph nodes accessible for biopsy (12a, 308). Using the modified Diff-Quik methods, smears of fine-needle aspirate material may reveal histiocytes with negatively stained linear cytoplasmic inclusions, termed pseudogaulcher cells (438). On histopathologic examination, poorly defined granulomas with histiocytes filled with mycobacteria are common; well-formed granulomas with fibrosis, necrosis, epithelioid histiocytes, lymphocyte infiltration, and Langhans' giant cells are present in less than one-third of cases (287). While lymphadenitis may occur in patients who have disseminated MAC infection, isolated peripheral node involvement is more likely due to *M. tuberculosis* (342). Patients with histopathologic evidence of granulomatous inflammation or acid-fast bacilli that have not yet been identified or do not grow in culture should probably receive empiric antituberculous therapy. It is important to point out that some cases of culture-negative disease could be caused by one of the recently recognized species of mycobacteria, *Mycobacterium haemophilum* and *Mycobacterium genavense*, which grow only under certain culture conditions (62, 105, 402).

### Disseminated Infection

Disseminated infection due to the MAC in patients with AIDS commonly causes a progressive illness characterized by intermittent fever, sweats, weakness, anorexia, and weight loss; it is believed to be a major cause of wasting syndrome in patients with AIDS. Most patients, by the time they present for evaluation, will complain of 2 to 6 weeks of recurrent fever and unexplained weight loss. Approximately 40% will have nausea or diarrhea, 20% will complain of vomiting, and a few may complain of intractable, crampy abdominal pain (278, 342). On examination, hepatic and splenic enlargement is common, but significant peripheral lymphadenopathy (>1.0 cm) is unusual (<9% of cases). Possible clues to the presence of disseminated disease in a patient at risk and who has unexplained fever may be either worsening anemia or a markedly elevated alkaline phosphatase, not necessarily associated with comparable elevations in hepatic transaminases (266, 275, 279).

While the mononuclear phagocyte system is the predominant site of infection, almost any organ system can be involved, including the skin (14, 359), bone and joints (59), eyes (94, 202), thyroid (202), large airways (330, 374), adrenals (202), testis (133), and brain. Isolation of *M. avium* from the cerebrospinal fluid has been reported in patients with disseminated disease (255), but the significance of this finding is not known. Although the adrenals are commonly infected, adrenal insufficiency or a blunted response to adrenocorticotropin stimulation is more likely due to concomitant infection with cytomegalovirus (174).

Although the gastrointestinal tract may be an initial site of infection (22, 120, 231, 257, 388), patients with histologic evidence of gastrointestinal involvement invariably have disseminated disease (120, 186, 388, 436). Duodenal or rectal

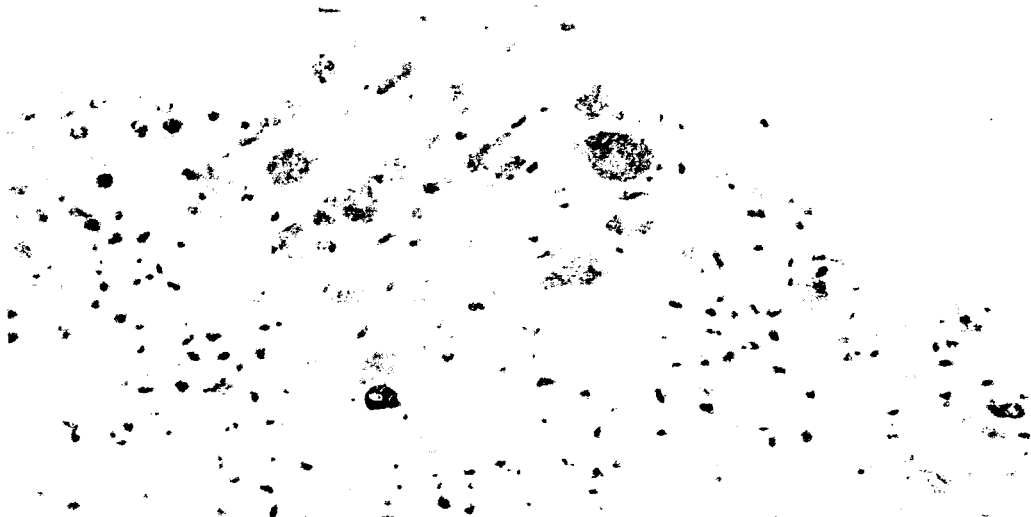


FIG. 5. Intracellular replication of MAC within fixed-tissue macrophages in a bone marrow biopsy specimen obtained from a patient with AIDS. The tissue was fixed and stained with a mixed polyclonal rabbit antimycobacterial antibody immunoperoxidase stain (478). Photomicrograph is courtesy of Stephen D. Nightingale and Elizabeth L. Wiley.

biopsies may be diagnostic. In one series, fine white mucosal nodules believed to be characteristic of MAC infection were visualized in the duodenum on endoscopy in 88% of patients with documented gastrointestinal involvement; associated malabsorption, as determined by the D-xylose test, was common (186). Colonic, sigmoid, and rectal involvement is also common, and esophageal, colonic, and rectal erosions and ulcerations due to MAC organisms may occur (120, 186, 405, 484). Upper gastrointestinal studies may reveal dilatation and thickening of the mucosal folds of the small bowel which may be clinically indistinguishable from lymphoma (463). Multiple large retroperitoneal and mesenteric lymph nodes are often demonstrated on abdominal computed tomographic scans (363). Patients may have marked histiocytic and mycobacterial infiltration on histopathologic specimens which, when visualized in the small intestine, resembles bovine paratuberculosis (Johne's disease) or Whipple's disease (185a, 287, 405, 463).

Bacteremia, with the organism found almost exclusively in circulating monocytes, occurs in 86 to 98% of patients with disseminated disease. Most patients have colony counts in the range of  $10^1$  to  $10^3$  CFU/ml of whole blood (200), but high levels of mycobacteremia, with up to  $10^6$  CFU/ml, are not uncommon (202, 342, 466, 485). The tissue load of infection may be  $10^2$  to  $10^5$  times greater than that in the blood. While a few patients have continuous low levels of mycobacteria in their bone marrow and bloodstream, suggesting that they have, to a limited degree, control of the infection, intracellular replication within macrophages is unchecked in many patients (Fig. 5). The large numbers of organisms within circulating monocytes and fixed-tissue macrophages, even after prolonged treatment, are evidence of an immune deficiency that

profoundly impairs the ability of the host immune system to restrict the intracellular growth of these mycobacteria.

While it is not known to what degree the level of mycobacteremia correlates with the level of infection in tissues, the assessment of changes in the numbers of circulating mycobacteria has evolved as a surrogate marker of therapeutic efficacy (88, 123, 202, 278). The use of quantitative bacteremia as an endpoint in clinical trials is based on the presumption that mycobacteremia will not decrease or disappear spontaneously. While limited data suggest that the level of bacteremia progressively increases in patients who do not receive treatment (123, 257), a preliminary study suggests that the correlation between the level of infection in tissues and that in the bloodstream may be poor (479). Recent data indicate that patients who have disseminated MAC infection may have fluctuating low levels of mycobacteremia and intermittently negative blood cultures.

We identified 9 patients, including 7 of 60 patients (12%) enrolled in a prospective randomized clinical trial of MAC bacteremia (276, 277), in whom bacteremia became undetectable in the absence of antimycobacterial therapy (275). All patients had at least two negative blood cultures by both lysis-centrifugation and BACTEC methods 1 to 57 days after their first positive blood culture. Such patients reported fewer and less severe symptoms and survived longer than patients with sustained bacteremia (59 versus 31 weeks, respectively). Although the data were not statistically significant, the mean alkaline phosphatase level was lower in patients with transient bacteremia than in patients with sustained bacteremia (0.96 versus 1.68 times the upper limit of normal, respectively), and there was no apparent difference in the duration of AIDS, leukocyte count, hematocrit,



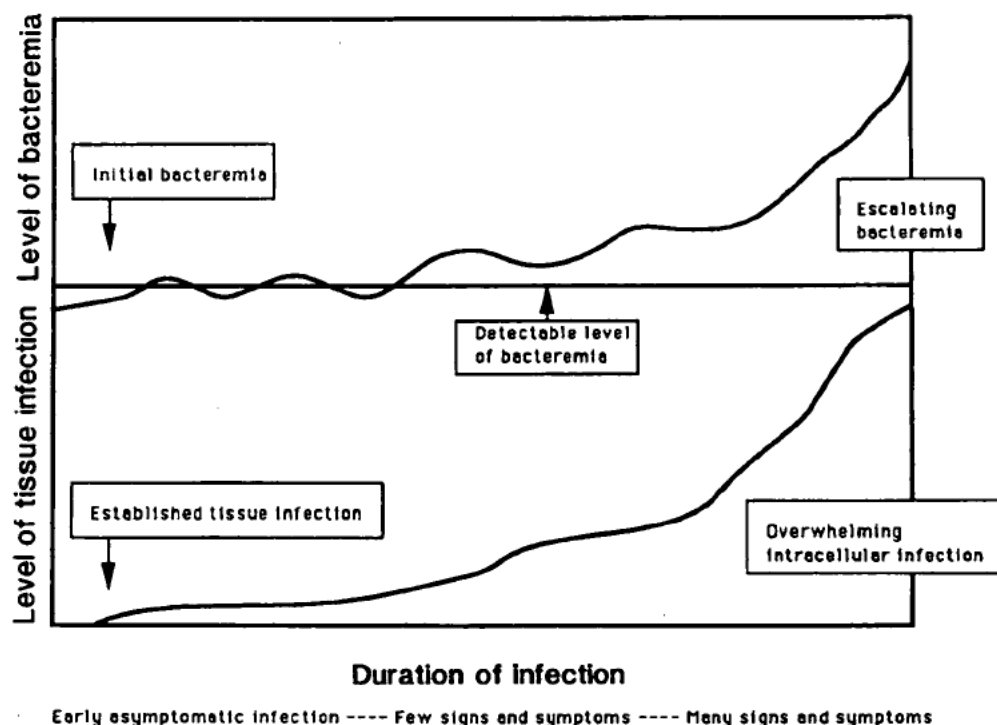


FIG. 6. Schematic representation of the course of disseminated MAC disease characterized by initial fluctuations in both mycobacteremia and clinical symptomatology but inexorably leading to a sustained and substantial mycobacteremia, most likely reflecting the underlying and often overwhelming infection of tissue.

CD4<sup>+</sup> cell count, or body weight between the two groups. Whether patients with transient bacteremia were diagnosed at an earlier stage of disease or whether they had inherently better immunity to combat infection is not known, but it is likely that these patients had less total body load of organisms than patients with sustained bacteremia. Despite the administration of one or more antimycobacterial agents for varied periods of time, six of the nine patients had subsequent recurrence of bacteremia 4 to 45 weeks after their negative pretreatment cultures, four of which occurred after treatment had been discontinued. These data suggest that these patients had established tissue sites of infection in which microorganisms were suppressed for varied periods of time but were released in transient "showers," just above the level of detection of bacteremia (Fig. 6).

Of interest, data obtained during the large rifabutin MAC prophylaxis trials (74, 181) suggest that at the time the first positive blood culture was obtained only approximately 36% of patients had self-reported fever or sweats. Approximately 30% of persons who first developed MAC bacteremia had no apparent signs or symptoms, although most became symptomatic within 1 to 2 months. Many had only one or two signs or symptoms suggestive of MAC infection, including a 5% weight loss, a decrease in hemoglobin of >1.0 g/dl, or an increase in alkaline phosphatase of >300 U/liter. Less than 30% of patients had fever (or sweats) and a 5% weight loss, and only 7% of the patients had the classic constellation of fever (or sweats), weight loss, and anemia at the time bacteremia was first detected. These data suggest that it may be difficult to recognize the presence of early infection in patients receiving prophylaxis.

#### Delayed Confirmation of Clinical Diagnosis

Delay in identification of acid-fast bacilli visualized by smear from respiratory secretions, tissue specimens, or stool smears is particularly problematic in the management of AIDS patients. While several clues may facilitate the management of a patient with an infection due to an unidentified mycobacterium, because of the fulminant nature of tuberculosis in patients with AIDS, the availability of effective therapies, and the public health implications of an untreated infection, the possibility of *M. tuberculosis* infection requires a guarded and conservative approach (Table 1). Empiric antituberculous therapy is probably warranted for those patients who have isolated peripheral lymphadenitis or clinical and radiographic pulmonary disease and culture or smear evidence of infection due to an unidentified mycobacterium. The presence of a positive blood culture for mycobacteria in these circumstances, however, makes the diagnosis of tuberculosis somewhat less likely. Blood cultures are positive in 86 to 98% of patients with disseminated MAC, often within 14 days (reflecting the high level of bacteremia), but are rarely positive in patients with tuberculosis (202, 342, 466, 485). While sputum smears are much more likely to be positive in patients with tuberculosis than in those with MAC infection (83 versus 16%), both organisms are isolated with fairly equal frequency from lymph node, bone marrow, and stool specimens (342). The frequency of tuberculosis also depends, to some degree, on the patient's sex, ethnicity, and HIV risk group.

TABLE 1. Features which may distinguish between MAC and *M. tuberculosis* (MTB) infection in HIV-infected patients also infected with an unidentified mycobacterium\*

Feature	MAC patients	MTB patients
Sex, ethnicity, HIV risk group	More likely non-Hispanic, white homosexual male	More likely African-American, Hispanic, Haitian, female, or intravenous drug user
AIDS status	>90% have preexisting AIDS	70% do not have AIDS
CD4 counts	Rarely >100/mm <sup>3</sup>	Any level of immunity
Chest radiograph	Usually normal (75%)	Frequently abnormal (83%)
Pulmonary disease	Unusual, 4–10%	Occurs in 70%
Pulmonary findings	Unusual to have hilar lymphadenopathy, cavitary disease, or pleural effusions	25% with hilar lymphadenopathy; cavitary disease and pleural effusions may occur
Sputum	16% of smears positive; 25% of cultures positive	60% of smears positive; 70% of cultures positive
Extrapulmonary disease	Common	Common
Bacteremia	>85% of patients	2–12% of patients
Blood cultures	Positive in 1–4 wk	Positive in 4–8 wk
Stool	40–50% of smears and cultures positive	40–50% of smears and cultures positive

\* Compiled, in part, from several sources (233, 245, 342, 468).

In addition to these findings, the onset of mycobacterial disease relative to the onset of AIDS may be helpful in distinguishing between tuberculosis and MAC disease. Tuberculosis occurs at any level of immunity, characteristically precedes the diagnosis of AIDS in 40 to 67% of cases, and occurs as the AIDS-defining illness or concurrent with AIDS in 26% of cases (342, 433). In contrast, only 3 to 13% of MAC infections represent the AIDS-defining illness, frequently concurrent with another opportunistic infection, and the majority of cases usually occur late in the course of AIDS (199, 234, 358). Differentiation between the two infections may be more difficult in patients with severely depressed immunity. While the presentation of tuberculosis in patients with HIV infection and relatively intact immunity is similar to that of non-HIV-infected patients, patients with severely depressed CD4<sup>+</sup> cell counts often present with atypical radiographic features, a lack of cavitary disease or lymphadenopathy, and a greater incidence of extrapulmonary disease (95). Despite a high incidence of anergy, skin test reactivity should be determined and, when negative, repeated in 1 to 4 weeks. Credence should not be given to a negative skin test with PPD in a patient strongly suspected of having tuberculosis.

## THERAPEUTIC AGENTS AND TREATMENT

### Licensed Therapeutic Agents

The agents most commonly used in the treatment of infection due to MAC include parenterally administered amikacin and orally administered clofazimine, ciprofloxacin, ethambutol, isoniazid, rifampin, and rifabutin. In clinical trials in patients with AIDS, two recently introduced macrolides, clarithromycin and azithromycin, demonstrated remarkably impressive bacteriologic activity. The therapeutic dosages and adverse side effects of these agents are addressed in Table 2.

**Amikacin.** Amikacin, a semisynthetic aminoglycoside antibiotic derived from kanamycin, remains one of the most bactericidal agents against MAC both in vitro and in the beige mouse model (49, 161, 165, 246). Analysis of in vitro susceptibilities of clinical isolates indicates that 9% of MAC isolates are susceptible to 12 µg of amikacin per ml, but 75% are susceptible to 30 µg/ml (317). In the beige mouse model, administration of amikacin resulted in 1.2- and 2.6-log<sub>10</sub>

reductions in splenic and pulmonary CFU per milliliter, respectively, by 2 weeks (165). The addition of clofazimine to amikacin also was effective, resulting in a more than 4-log<sub>10</sub> reduction in colony counts in spleen tissue, but the addition of rifabutin did not appear to enhance the microbiologic activity of the two-drug combination. Unfortunately, amikacin is not absorbed from the gastrointestinal tract and requires parenteral administration, usually in a single or divided dose of 7.5 to 15 mg/kg of body weight per day. The most significant adverse effects are ototoxicity and nephrotoxicity, and ototoxicity may develop in up to 13% of patients with AIDS (23, 278). Some of these dose-related toxicities may be ameliorated by lower dosages and a shorter total course of administration.

**Azithromycin and clarithromycin.** The macrolide antibiotics azithromycin and clarithromycin are similar in structure to erythromycin (384) and concentrate to high levels in tissues and macrophages with little toxicity. Clarithromycin differs by a single substitution of a methyl group for a 6-hydroxyl group in the 14-membered ring of erythromycin. This substitution increases its bioavailability, decreases metabolism of the drug, and enhances the microbiologic activity. Clarithromycin is resistant to the intramolecular cyclization at acidic pH; thus it lacks much of the gastrointestinal side effects commonly observed with erythromycin. Clarithromycin is metabolized in the liver to 14-OH-clarithromycin, which is biologically active against many microorganisms and partially active against MAC. Clarithromycin is rapidly absorbed, with a bioavailability of approximately 55%; peak blood levels of 2 to 3 µg/ml are seen 2 h after a 500-mg dose. The serum half-life after a 500-mg dose is 5 to 6 h, while that of 14-OH-clarithromycin is 7 h.

Clarithromycin inhibited more than 90% of MAC strains at concentrations that are therapeutically achievable in humans (153, 350). The MICs, as determined by broth microdilution at neutral to slightly alkaline pH, were 0.25 to 0.5 µg/ml for most strains (212, 378). Administration of clarithromycin to beige mice resulted in a significant reduction in the number of mycobacteria in tissue and blood (153). The intracellular activity of clarithromycin in J774 cells and in alveolar macrophages from HIV-infected patients was enhanced by the addition of ethambutol and rifampin, but the addition of ciprofloxacin did not improve intracellular killing (493). The activity of this three-drug regimen (clarithromycin, etham-

TABLE 2. Antimycobacterial agents commonly used in the treatment of MAC infection<sup>a</sup>

Agent	Adult dose	Pediatric dose <sup>b</sup>	Adverse effects
<b>Common agents</b>			
Amikacin	7.5–15 mg/kg QD <sup>c</sup>	10–15 mg/kg QD i.v. <sup>c</sup>	Ototoxicity, nephrotoxicity
Azithromycin	500 mg/day <sup>d</sup>	10–20 mg/kg/day <sup>e</sup>	Diarrhea, nausea, vomiting, abdominal pain, headache, dizziness, elevations in hepatic enzymes
Ciprofloxacin	750 mg BID	20–30 mg/kg/day, divided, Q12h <sup>f</sup>	Anorexia, nausea, vomiting, abdominal pain, diarrhea, rash, (rarely) mental status changes
Clarithromycin	500–1,000 mg BID <sup>g</sup>	30 mg/kg/day, divided, Q12h <sup>e</sup>	Diarrhea, nausea, vomiting, elevations in hepatic enzymes, abdominal pain, renal insufficiency
Clofazimine	100–200 mg/day <sup>h</sup>	1–2 mg/kg/day <sup>i</sup>	Skin discoloration, ichthyosis, anorexia, nausea, vomiting, abdominal pain, peripheral neuropathy, (rarely) ocular changes
Ethambutol	15 mg/kg/day <sup>j</sup>	15–25 mg/kg/day <sup>k</sup>	Anorexia, nausea, vomiting, diarrhea, rash, mental status changes, retrobulbar neuritis
Rifampin	10 mg/kg/day <sup>j</sup>	10–20 mg/kg/day <sup>m</sup>	Anorexia, nausea, vomiting, diarrhea, rash, elevations in hepatic enzymes
Rifabutin	300 mg/day <sup>n</sup>	No recommendation <sup>n</sup>	Anorexia, nausea, vomiting, diarrhea, rash, myalgias, arthralgias, headache
<b>Alternative agents</b>			
Cycloserine	10–20 mg/kg/day	10–20 mg/kg/day	Somnolence, headache, tremor, vertigo, mental status changes, visual changes, seizures
Ethionamide	15–20 mg/kg/day	15–20 mg/kg/day	Anorexia, nausea, vomiting, diarrhea, rash, elevations in hepatic enzymes, mental status changes, seizures, neuropathy

<sup>a</sup> QD, once a day; i.v., intravenously; BID, twice a day; Q12h, every 12 h.<sup>b</sup> Pediatric dosages are not to exceed maximum adult dosages.<sup>c</sup> Or equivalent dose twice a day.<sup>d</sup> Dosages of 600 to 1,200 mg/day in a lactose-free formulation are being studied in a dose-ranging fashion.<sup>e</sup> Pediatric suspension formulations are available for both azithromycin and clarithromycin; azithromycin maximum dose, 40 mg/kg.<sup>f</sup> Ciprofloxacin is not recommended for children under 18 years of age; however, ciprofloxacin and other quinolones have been, when necessary, administered to children with few serious adverse effects (418).<sup>g</sup> Dosages of up to 2,000 mg orally twice a day have been used in the treatment of MAC infection but are associated with higher rates of toxicity and should probably be reserved for those patients failing to respond to lower dosages.<sup>h</sup> Dosages of up to 300 mg/day have been used in the treatment of other diseases and can be administered to patients with AIDS and MAC bacteremia but are associated with a higher incidence of skin discoloration and gastrointestinal toxicity.<sup>i</sup> Dosages of up to 50 mg/day have been given to children less than 4 years of age (approximately 4 mg/kg/day) (297), but a pediatric formulation is not available.<sup>j</sup> Dosages of up to 25 mg/kg/day can be given for short durations (<1 month); dose should not exceed 600 to 1,000 mg/day.<sup>k</sup> Caution is recommended in children under 12 years of age; monthly vision checks should be performed on pediatric patients receiving ethambutol or adults receiving >15 mg/kg/day for more than 1 month. The maximum dose is 2.5 g.<sup>l</sup> Dosages of 150 to 600 mg/day have been used in both AIDS and non-AIDS patients with MAC infection, but the relative efficacies of these various dosages are not known.<sup>m</sup> The maximum rifampin dose is 600 mg/day.<sup>n</sup> Dosages of 75 mg/day have been given to children less than 4 years of age (approximately 6 mg/kg/day) (297), but a pediatric formulation is not available. Higher dosages up to 150 mg/day (6 to 25 mg/kg/day) have been used (301).

butol, and rifampin) has been confirmed in other in vitro analyses (439). In one small trial, the combination of clofazimine and clarithromycin resulted in clearance of bacteremia in all 11 patients after only 1 week of therapy (409). In another recent clinical trial in patients with AIDS, 75% of patients developed negative blood cultures after 1 to 2 months of single-agent therapy (123). After administration for more than 10 to 22 weeks, however, drug resistance and rebound bacteremia were seen in some patients. Clarithromycin administered in a dose of 500 to 1,000 mg twice daily is moderately well tolerated. While adverse effects are reported in approximately 4% of patients (384), gastrointestinal side effects are apparently more common in patients with AIDS.

Azithromycin, an azalide, has an additional nitrogen in the erythromycin ring structure, resulting in a 15-member derivative. The drug is well absorbed and has a terminal half-life of 68 h. Peak serum concentrations after single or multiple 500-mg doses range from 0.40 to 0.62 µg/ml, but the drug concentrates within macrophages and in tissues to remarkably high concentrations, as high as 2,000 µg/g (49, 172, 173). The in vitro activity of azithromycin appears modest, with a broad range of MICs from 32- to 64-fold above the peak serum concentration in humans. Nevertheless, in beige mice, azithromycin had significant activity against the MAC, resulting in a 95% survival and a significant decrease in the number of mycobacteria in blood, liver, and spleen (247). The therapeutic efficacy most likely reflects the high tissue

concentrations of the drug. A recent uncontrolled pilot trial showed that, when patients with AIDS and MAC bacteremia received 20 to 30 days of azithromycin alone (500 mg/day), colony counts in the bloodstream were reduced from  $2 \times 10^3$  to  $1.4 \times 10^2$  CFU/ml; fever resolved in 71% of patients who were febrile at entry to the study and sweats resolved in 83% (505). Long-term administration of azithromycin resulted in recrudescence of bacteremia and high-level resistance. Thus, the administration of azithromycin or clarithromycin as a single agent is not recommended. Adverse reactions reportedly occur in less than 12% of patients and include diarrhea (3.6%), nausea (2.6%), and abdominal pain (2.5%), as well as headaches and dizziness (1.3%) (384), but gastrointestinal complaints appear more common in patients with AIDS. Deafness has been reported in a small number of patients during long-term administration but is apparently reversible upon discontinuation of the drug.

**Clofazimine.** Clofazimine is an iminophenazine red dye with a long elimination half-life; the elimination half-life from fatty tissues and the mononuclear phagocyte system is approximately 70 days (167); the drug is highly concentrated in tissues. Clofazimine has been a mainstay of leprosy therapy. The drug is very active (on a weight basis) in vitro against most MAC isolates; the MIC for 90% of *M. avium* isolates (MIC<sub>90</sub>) is approximately 3 µg/ml and that for *M. intracellulare* isolates is approximately 2 µg/ml (306, 452). In the beige mouse model, clofazimine is extremely effective in combination with amikacin (165); however, in patients with AIDS and MAC bacteremia, clofazimine, administered as a single agent (200 mg/day), resulted in a median reduction of only 0.20 log<sub>10</sub> CFU/ml in the bloodstream (18% reduction in baseline colony counts) by 4 weeks (277). These data suggest that effective clofazimine therapy may require longer periods of treatment to saturate the tissues; e.g., in patients with leprosy, it may take up to 4 months to achieve a 99% reduction in tissue colony counts. Clofazimine is administered in a 100- to 200-mg daily dose (up to 300-mg daily doses have been used in the treatment of other diseases), and the drug is fairly well tolerated, with skin discoloration as the most frequent side effect. Dose-limiting intolerance occurs in approximately 2.5% of patients with AIDS (278), but the skin discoloration is more common at dosages of  $\geq 200$  mg/day. Clofazimine crystals may be deposited in organs and cause intractable abdominal pain, a symptom often confused with MAC infection (167, 239, 416). While clofazimine crystals are found in the tears of 32% of leprosy patients receiving long-term therapy (273), ocular effects, such as corneal-conjunctival pigmentation and a "bull's-eye" retinopathy, are unusual (112, 273, 429). Clofazimine treatment also has been associated with peripheral neuropathy.

**Ciprofloxacin.** Ciprofloxacin and the other fluoroquinolones (e.g., ofloxacin, levofloxacin, lomefloxacin, sparfloxacin, and WIN 57273) have varied in vitro activities against the MAC (211, 246, 303, 503). MIC<sub>50</sub> and MIC<sub>90</sub> values of ciprofloxacin against *M. avium*, as determined by broth dilution susceptibility tests on large numbers of isolates, are 4 and 16 µg/ml, and those against *M. intracellulare* are 1 and 8 µg/ml, respectively (303). Only 30% of MAC isolates were susceptible to 2 mg of ciprofloxacin per ml. Values for ofloxacin were similar. Quinolone resistance is common and related, in part, to the mechanism of action (inhibition of DNA synthesis). Ciprofloxacin is administered in a dosage of 750 mg twice daily and is moderately well tolerated. Dose-limiting side effects, primarily gastrointestinal, occur in up to 15% of patients with AIDS (278); rash, headaches, and mental status changes may occur. Ciprofloxacin should not

be administered in conjunction with magnesium- or aluminum-containing antacids or sucralfate. Absorption of ciprofloxacin is effectively negligible after ingestion of 2.0 g of sucralfate. Ciprofloxacin inhibits the metabolism of methylxanthines, including theophylline, and there is an intriguing, but preliminary, observation that quinolones may induce IL-2 production and decrease IL-2 receptor expression, resulting in prolonged IL-2 kinetics (398).

**Ethambutol.** Ethambutol is a dextro-2,2'-(ethylenediamine)-di-1-butanol-dihydrochloride with a high degree of antituberculous activity. A recent analysis demonstrated that only 7% of MAC isolates tested were susceptible to 5 µg of ethambutol per ml, but 76% of isolates were susceptible to 10 µg/ml (317). Although these susceptibility tests suggest that ethambutol should not be a very effective agent, ethambutol may potentiate the action of combined therapies as a result of the effect of this drug on cell wall permeability (220, 268, 490). Nevertheless, recent animal and human studies indicate that ethambutol alone has significant anti-MAC activity. In one study, ethambutol reduced colony counts in beige mice in a dose-response fashion; at 6 mg/kg per day, mycobacteria were reduced by approximately 1.0 log<sub>10</sub> by 9 weeks (183). Furthermore, ethambutol (15 mg/kg/day), administered as a single agent, significantly reduced mycobacteremia by a median 0.6 log<sub>10</sub> CFU/ml after 4 weeks in patients with AIDS and MAC bacteremia (276). Ethambutol is commonly administered in a dose of 15 mg/kg of body weight per day, usually as a single dose, and is fairly well tolerated in the treatment of MAC disease. Dose-limiting side effects, primarily gastrointestinal, may occur in 5 to 10% of patients with AIDS, but severe toxicity is unusual (278, 433). Higher doses (25 mg/kg of body weight) have been used, but may be associated with retrobulbar neuritis and loss of color vision. These side effects are uncommon, typically associated with long-term use (longer than 1 month), and in most cases, reversible if the drug is promptly discontinued.

**Rifampin.** Rifampin is a 3,4-(methylpiperazinyl-iminomethylidene)-rifamycin SV and is in the rifamycin group of antimicrobial agents. Rifampin is a broad-spectrum antimicrobial agent with antituberculosis activity but only modest anti-MAC activity. The concentration of rifampin in tissues is significantly higher than that in serum, and rifampin is concentrated fourfold above serum levels in mouse macrophages and fivefold above serum levels in human monocytes (410). The in vitro activity of rifampin is heterogeneous, with significant differences between the various MAC serovars (452), but most MAC isolates are resistant in vitro, with rifampin MICs of  $> 100$  µg/ml (317). The activity of rifampin in combination with other agents is not known, but in vitro data indicate that some combinations are synergistic (490). In patients with AIDS and MAC bacteremia, logarithmic colony counts in the bloodstream actually increased 17% after 4 weeks of rifampin alone (276). The commonly administered dose for the treatment of MAC disease is 600 mg/day as a single or divided dose for patients weighing 50 kg or more (typically 10 mg/kg of body weight). It is well absorbed when taken without food (patients should be advised to take rifampin at least 2 h before or after any meal), and a peak serum concentration of approximately 10 mg/ml occurs within 2 h of oral administration. Rifampin is moderately well tolerated, but approximately 12% of patients with AIDS will have adverse effects, usually gastrointestinal, necessitating discontinuation of the drug (278, 433).

**Rifabutin.** Rifabutin, an ansamycin derived from rifamycin-S, has significantly better in vitro activity against the

**Adams, Susan**

**From:** White, Sally  
**Sent:** Friday, March 28, 2008 12:47 PM  
**To:** Adams, Susan  
**Subject:** FW: Letter to Under Secretary Raymond  
**Attachments:** Ubrief OVD08.643 van DGH aan Raymond.pdf; Ubrief 08.0490.IH TB testing.doc.pdf; Presentatie serodiagnosis Mycobacterium avium 02.11.06.pdf

Please print off and fill out sheet for logging.

**From:** (b) (6) s [mailto:(b) (6)@minbuza.nl]  
**Sent:** Friday, March 28, 2008 12:44 PM  
**To:** Caughey, Savonne -USDA  
**Cc:** White, Sally; Smith, David; Goodwin, Nancy; (b) (6); (b) (6); (b) (6)@minlnv.nl;  
(b) (6)@minlnv.nl  
**Subject:** Letter to Under Secretary Raymond

Dear (b) (6),

I would like to forward to you this letter (with annexes) from Director-General (b) (6) of the Netherlands Ministry of Agriculture, Nature and Food Quality to Under Secretary Dr Richard Raymond with a further clarification of the question on chain inspection of hogs Dr Raymond asked during the conversation with Mr (b) (6) on August 6th, 2007. For your clarification, Mr (b) (6) is the successor of Mr (b) (6) who has retired.

Mr (b) (6) invites Under Secretary Raymond to come to the Netherlands to see for himself how the system works. We would be very happy to combine this particular subject of his possible visit with other subjects in which he would be interested. For instance, I understood Dr Raymond was also very much interested in methods for humane slaughtering of animals.

This letter and its annexes are an electronic copy. The hard copy is now on its way to the US and will be send to you as soon as possible after arrival.

Best wishes,

(b) (6)  
Counselor for Agriculture,  
Nature and Food Quality  
Embassy of the Kingdom of the Netherlands

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U.S. Department of Agriculture  
Food Safety and Inspection Service  
Under Secretary for Food Safety  
Dr. Richard Raymond  
1400 Independence Avenue, S.W.  
Washington, D.C. 20250  
UNITED STATES OF AMERICA



landbouw, natuur en  
voedselkwaliteit

your letter of	your reference:	our reference	date
		VD 08.643/IH	March 27, 2008
re:		extension no.	enclosures
Supply chain inspection of pork		+31(0)(b) (6)	2

Dear Dr. Raymond,

On 6 August 2007 you discussed pork supply chain inspection with my predecessor (b) (6). The Dutch veterinary authorities had submitted the dossier to USDA/FSIS in October 2006 to assess whether inspection methods were equivalent. The issue of equivalence had been discussed in November 2006 and discussions were concluded successfully. Early in 2007, an FSIS inspector visited The Netherlands to assess our supply chain inspection system. This visit too was a success.

When Mr. (b) (6) visited you on 6 August, 2007, you asked him about tuberculation and our CVO sent you a written reply on 5 March, 2008 (enclosed). During discussions with Ms. Sally White and Dr. David Smith, Mr. (b) (6) deputy CVO, gave further details on 13 March, 2008. Following this, I am now sending you additional information. I hope you have received sufficient information now and expect this will conclude matters, so that we can come to an equivalence determination for supply chain inspection in the very short term. I would also like to invite you to The Netherlands to come and see our inspection procedures in practice.

Before answering your question in detail, allow me to sketch the context within which my answer is to be understood. In classic meat inspection lymph node incisions are made to detect macroscopic irregularities. In many cases these concern *Arcanobacterium pyogenes*, or *Rhodococcus equi* which are not so relevant for public health. Lymph node incision is not the best method for the detection of *M. avium*, as cases may be overlooked (bacteriological positive results but no visible signs). Lymph node incision is not a very specific or a very sensitive detection method (see publications sent to you earlier).

Bacteriological tests of lymph nodes for *M. avium* are both specific and sensitive, but these tests take 3 to 6 months and are therefore not very practical for slaughterhouse use. For the same reason such tests are not suitable for the classification and monitoring of farms.

Tuberculation of pigs by means of an intradermal test is a possibility. The tuberculin must be administered directly behind the pig's ear. A positive reaction produces redness

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and swelling of the skin. Research (see appendix) shows this is a very sensitive diagnostic test. The drawback however is that pigs need to be fixed twice, which may produce a great deal of stress in the animals. Distinguishing tested from non-tested animals may also give rise to problems.

How then do we guarantee the absence of *M. avium* contamination in pork? In my earlier letter of 5 March I said that *M. avium* incidence rates in The Netherlands are very low. However, we do want to rule out *M. avium* contaminations. To this end The Netherlands has decided to use a preventive approach, which involves classifying farms and introducing specific preventive measures that can be taken into account at meat inspections in slaughterhouses. In other words, a preventive approach is used rather than identifying individual pigs.

Farms are classified as follows. From every three consecutive batches presented for slaughter (in The Netherlands, the average batch consists of 100 pigs) 6 blood samples per batch are taken for serological tests. If all samples test negative the farm is given a neutral status. In this case supply chain inspection will be possible. Monitoring the farm is continued (which means two blood samples are taken from every batch). After 36 negative results in a row the farm is given the status low while monitoring continues. If a positive sample is found in the first 18 samples, chain inspection is not allowed and the farm will be visited and subjected to a risk analysis. Hygiene must be improved. When later samples test positive the farm is visited again to be subjected to specific inspections.

Blood tests are a sensitive detection method. Our research results show that pigs infected at an early age (at 2.5 weeks, for instance) or at different subsequent intervals (at 2.5, 4.5 and 18 weeks) test 100% positive. The same is true for pork pigs that are infected at 4.5 weeks of age (with 5 out of 8 pigs testing positive). Pigs infected later in life (18 weeks) show 2 out of 8 with positive results.

In view of the fact that on infected farms pigs are generally infected at an early age and a minimum of 18 samples are taken for the initial categorisation of farms after which they continue to be monitored, it can fairly be concluded that the use of serological tests is a very suitable detection method.

It should also be noted that serological tests show cross-reactivity with other forms of tuberculosis like *M. bovis* and *M. tuberculosis*. Not much has yet been published about this test, which has to do with intellectual property, but details will appear in scientific magazines.

This is, therefore, a preventive approach with farms classified on the basis of measurable data. Farms that cannot be classified or whose test results are worsening are not allowed to be included in supply chain inspection until they have improved their performance. In short, supply chain inspection is only feasible for farms with a good track record. This kind of inspection is a more effective approach to the detection of *M. avium* than the classic meat inspection procedures. In this case serological testing is more effective than tuberculation.

Date

Reference

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— I would suggest that you contact the Agricultural Counsellor of the Kingdom of The Netherlands in Washington so that a date for your visit can be arranged.

Yours sincerely,

DIRECTOR-GENERAL  
FOR THE MINISTER OF AGRICULTURE, NATURE AND  
FOOD QUALITY,

(b) (6)



U.S. Department of Agriculture  
Ms. Savonne Caughey, Confidential Assistant  
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landbouw, natuur en  
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your letter of	your reference	our reference	date
		VD 08.490/IH	March 5, 2008
re:		extension no.	enclosures
PM inspection procedures market hogs; tuberculosis testing		+31(0)(b) (6)	2

Dear Ms. Caughey,

During a meeting between the Under Secretary for Food Safety, Dr. Richard A. Raymond, and Director General (b) (6) of The Netherlands Ministry of Agriculture, Nature and Food Quality, which took place in August of last year, the access to the U.S. market of Dutch pork processed by the (b) (4) slaughterhouses in The Netherlands was discussed. Pigs slaughtered in these slaughterhouses are monitored for *Mycobacterium avium* subsp. *avium* (MAA) infections via a new chain inspection system in which blood tests were used for the detection of MAA infections. During the meeting between the Under Secretary and the Director General a technical question arose about the reliability of blood tests for the detection of tuberculosis infections.

In order to answer this question I will first provide some background information about tuberculosis infections in humans and animals. Subsequently I will discuss the post mortem procedures for the detection of MAA infections in pigs and the new chain inspection system.

#### *Human Tuberculosis*

Human Tuberculosis (TB) is an acute or chronic infection, mainly caused by the tubercle bacillus *Mycobacterium tuberculosis*. Humans are the primary reservoir, diseased cattle rarely act as reservoirs. TB in man is diagnosed by a consideration of the clinical presentation, tuberculin skin test using the Mantoux procedure, radiographic examination, sometimes including CT scans and culture for the *M. tuberculosis*.

#### *Bovine Tuberculosis*

Bovine Tuberculosis is an infectious disease sustained by *Mycobacterium bovis*, which poses major problems of animal health and a substantial zoonotic risk. Bovine Tuberculosis has therefore been targeted by extensive control and eradication programs for a long time. The Netherlands is officially free of Bovine Tuberculosis. In 1951 The Netherlands started an extermination program, which included tuberculation of individual cows. Animals found positive for the presence of bovine tuberculosis were disposed of. This approach led to a rapid decline of the prevalence of Bovine Tuberculosis and as a result of this the Bovine Tuberculosis free status was granted to The Netherlands. For monitoring Bovine Tuberculosis since 1993 the compulsory tuberculation test has been substituted by a monitoring system in slaughter plants. During ante mortem and post mortem examination of cows during the meat inspection attention is being paid to

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Date	Reference	Following page
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the results of 1996 (Komijn et al 2007). However, in contrast to the results of the study in 1996, in 2004 targeting herds at risk, no MAA bacteria could be detected in these lymph nodes after bacteriological examination. Apparently, the prevalence of MAA infections in The Netherlands in 2004 was considerably less when compared with the prevalence in 1996. This significant decrease in prevalence can be explained by additional management measures within the IKB system for production chain control of the Dutch Product Boards for Livestock, Meat and Eggs, which came into effect in 2001, tightening biosecurity on the farm even further.

#### Conclusion

The prevalence of MAA infections of pigs in The Netherlands is very low. Results of scientific research showed that incision of the mandibular lymph nodes during post mortem inspection for diagnosis of MAA infections has a low sensitivity and specificity. The blood testing for anti MAA antibodies offers an attractive alternative. This procedure combined with additional measures on the farm results in safer pork.

I trust that I have answered Dr. Raymond's question adequately and that this will complete the information necessary to make an equivalence determination of the chain inspection system for market hogs.

Sincerely yours,

THE CHIEF VETERINARY OFFICER

(b) (6)

#### Enclosures:

1. Ruud E. Komijn, Petra E.W. de Haas, Margriet M.E. Schneider, Tony Eger, Jan H.M. Nieuwenhuijs, Remco J. van den Hoek, Douwe Bakker, Fred G. van Zijderveld, Dick van Soelingen.  
Prevalence of *Mycobacterium avium* in Slaughter Pigs in The Netherlands and Comparison of IS1245 Restriction Fragment Length Polymorphism Patterns of Porcine and Human Isolates.  
Journal of Clinical Microbiology, May 1999; Vol. 37, No. 5: P. 1254-1259
2. Ruud E. Komijn, Henk J. Wisselink, Vincent M.C. Rijsman, Norbert Stockhofe-Zurwieden, Douwe Bakker, Fred G. van Zijderveld, Tony Eger, Jaap A. Wagenaar, Frans F. Putirulan, Bert A.P. Urlings.  
Granulomatous lesions in lymph nodes of slaughter pigs bacteriologically negative for *Mycobacterium avium* subsp. *avium* and positive for *Rhodococcus equi*.  
Veterinary Microbiology 120 (2007); p. 352-357; Elsevier publishing 2006 Nov 28.

## Prevalence of *Mycobacterium avium* in Slaughter Pigs in The Netherlands and Comparison of IS1245 Restriction Fragment Length Polymorphism Patterns of Porcine and Human Isolates

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 National Institute of Public Health and the Environment, 3720 BA Bilthoven,<sup>2</sup> Department of  
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Received 11 May 1998/Returned for modification 9 July 1998/Accepted 25 January 1999

A significant increase in the incidence of caseous lesions in the lymph nodes of slaughter pigs prompted a large-scale investigation in five slaughterhouses in The Netherlands. In total, 158,763 pigs from 2,899 groups underwent gross examination. At least one pig with caseous lesions in the submaxillary and/or mesenteric lymph nodes was observed in each of 154 of the 2,899 groups examined (5%). In total, 856 pigs (0.5%) were affected. As many as five pigs in each of 141 of the 154 positive groups (91.5%) had lymph node lesions. Greater numbers of pigs with affected lymph nodes were found in 13 groups (8.5%). Four pigs had lesions in the kidneys, liver, or spleen. Acid-fast bacteria were detected by microscopic examination of 121 of 292 Ziehl-Neelsen-stained smears of caseous lesions (41%). In a follow-up study, *Mycobacterium avium* complex (MAC) bacteria were isolated from 219 of 402 affected lymph nodes (54.2%). Ninety-one of the isolated strains were analyzed by restriction fragment length polymorphism (RFLP) typing with insertion sequence IS1245 as a probe. All but 1 of these 91 strains contained IS1245 DNA, indicating that pigs in The Netherlands carried almost exclusively *M. avium* bacteria and no other bacteria of MAC. Only one pig isolate exhibited the bird-type RFLP pattern. MAC isolates from 191 human patients in The Netherlands in 1996 were also typed by RFLP analysis. Computer-assisted analysis showed that the RFLP patterns of 61% of the human isolates and 59% of the porcine isolates were at least 75% similar to the RFLP patterns of the other group of strains. This indicates that pigs may be an important vehicle for *M. avium* infections in humans or that pigs and humans share common sources of infection.

Severe *Mycobacterium avium* complex (MAC) infections in humans, especially in human immunodeficiency virus-positive and other immunodeficient individuals, have been reported (8, 13). The origin of MAC infections in humans is still a matter of speculation. Previous studies have shown that the MAC bacteria are present in birds, soil, compost, water, animals, pigs, and even cigarettes (2, 3, 5, 6, 8, 11, 19). As suggested by the designation *M. avium*, infections were once thought to be derived from birds. Later, serotyping showed that only some of the MAC bacteria isolated from humans represent serotypes 1, 2, and 3, which are the most common serotypes among bird isolates (1, 7).

Recently, new molecular tools like restriction fragment length polymorphism (RFLP) typing with the insertion sequence IS1245 (IS1245 RFLP analysis) have become available (2, 6, 12). Genotyping of *M. avium* strains from various sources in Switzerland indicated that both pigs and humans were infected with strains carrying a large number of IS1245 elements (2). IS901 and IS1245 RFLP typing showed that 47 *M. avium* iso-

lates from birds in The Netherlands invariably belonged to a well-conserved separate taxon within MAC. Bird-type RFLP patterns were observed only as an exception among isolates from other hosts (2, 12). These facts rule birds out as significant sources of *M. avium* infections in humans in The Netherlands (12).

The current study was undertaken to determine the prevalence of MAC in the lymph nodes of pigs. Furthermore, in order to examine the significance of *M. avium* infections in slaughter pigs with regard to public health aspects, the IS1245 RFLP patterns of porcine isolates were compared with those of the *M. avium* strains isolated from humans in The Netherlands in 1996.

### MATERIALS AND METHODS

Gross examination of pigs. In an initial study, special attention was given to the gross examination of the submaxillary and mesenteric lymph nodes of pigs in five slaughterhouses during a 2-week period at the end of 1996. The submaxillary lymph nodes were incised, and the mesenteric lymph nodes were palpated. The following information was collected: the farm identification numbers of the pigs slaughtered, the number of pigs slaughtered per farm, the number of pigs with caseous lesions in the submaxillary or mesenteric lymph nodes, and the number of pigs whose spleen, liver, or kidneys were also affected. Whenever possible, up to three specimens per group were studied by microscopic examination of Ziehl-Neelsen-stained smears.

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Sampling, culture, and identification of mycobacteria from pigs. In a follow-up study performed in early 1997, the presence of mycobacteria in caseous lesions was determined by culture. For this purpose, macroscopically positive submaxillary and mesenteric lymph nodes were collected at six slaughterhouses and were frozen at  $-20^{\circ}\text{C}$ . In the first part of the follow-up study, samples were taken from each of three to four pigs in 44 groups in which several animals were affected. In the second part of the follow-up study, 144 groups with only one or two affected animals each were sampled. After arrival at the laboratory, the samples were thawed, and direct smears were produced. Ziehl-Neelsen-stained material was then examined microscopically. In addition, cultures were grown from all lesions by the following procedure: all lesions were ground, decontaminated by oxalic acid-sodium hydroxide treatment, and inoculated onto Löwenstein-Jensen medium, Stenobrink egg medium, and Middlebrook 7H10 agar, followed by incubation for 4 weeks at  $37^{\circ}\text{C}$ .

Subcultures were made from colonies suspected of representing MAC bacteria. The MAC bacteria of the subcultures were identified by the following characteristics: growth after 2 to 4 weeks of incubation, negative or doubtful acid phosphatase reaction, negative nitrate reductase reaction, weakly positive catalase reaction ( $<45\text{ mm}$ ) at room temperature, variable catalase reaction at  $68^{\circ}\text{C}$ , negative  $\beta$ -D-galactosidase reaction, positive nicotinamidase and pyrazinamidase activities, and negative urease activity by the amidase test of Bönicke. All but 1 of the 91 isolated MAC strains contained IS1245, which is characteristic of *M. avium* (2, 6, 12). To ensure this identification, 30 IS1245-containing MAC isolates were subjected to the Accuprobe test specific for *M. avium*, and they were found to be positive.

MAC bacteria from humans. In 1996, 191 MAC isolates originating from 35 peripheral laboratories were received at the National Institute of Public Health and the Environment (RIVM) in The Netherlands. This number covers at least 80% of all human MAC strains isolated in The Netherlands in 1996.

Serotyping. MAC isolates were tested by slide agglutination, as described by Engel et al. (4), to determine their serotypes. The panel of test sera represented serotypes 1 to 4 and 8.

DNA fingerprinting. *M. avium* isolates were DNA fingerprinted by RFLP typing; IS1245 was used as a probe, as described previously (12, 16). Internal and external molecular size markers and high-resolution gels (24 cm) were applied to facilitate computer-assisted analysis.

Computer-assisted RFLP analysis. Analysis of the IS1245 fingerprints was done with computer assistance, using GelCompar software, version 4.1 (Applied Maths, Kortrijk, Belgium), as described in a proposal for standardization of IS1245 RFLP typing (16). The band positions of the IS1245-containing restriction fragments were compared with those of a set of internal molecular weight markers by superimposing the autoradiograms of the IS1245 DNA fingerprints and the autoradiograms of the internal markers. The patterns were compared by the unweighted pair group method with the arithmetic averages clustering method and with the Dice coefficient according to the instructions of the manufacturer of GelCompar.

## RESULTS

**Examination of affected lymph nodes by microscopy and culture.** A total of 158,763 pigs in 2,899 groups were inspected during the initial study at the end of 1996. Each of 154 groups (5%) included at least one pig with caseous lesions in the submaxillary and/or the mesenteric lymph nodes. Altogether, 856 pigs (0.5%) were affected. For practical reasons, only 292 lesion smears were microscopically examined. Acid-fast bacteria were seen in 121 of them. Five or fewer pigs in each of 141 of the affected groups had caseous lesions. Greater numbers of affected pigs were detected in the remaining 13 groups. The average percentage of affected pigs in these 13 groups amounted to 31, and the range was between 8 and 78%. Only four pigs also had macroscopic deviations in the kidney, liver, or spleen.

In order to examine whether *M. avium* was the etiologic agent of these caseous lesions, a follow-up study was planned for early 1997. In the first part of the follow-up study, 239 lymph nodes with caseous lesions from pigs from 44 farms were examined (Table 1). These farms were not the same ones as those in the initial study. MAC bacteria were isolated from 166 of the lymph nodes (69%) from 39 of the groups examined (89%). Seventy-eight percent of the affected mesenteric lymph nodes and 52% of the submaxillary lymph nodes yielded growth of MAC bacteria. In the second part of the follow-up study, lymph nodes from 163 pigs from 144 farms were examined (Table 1). MAC bacteria were isolated from 53 of the pigs

TABLE 1. Correlation of culture results and microscopic examination of affected lymph nodes in the first and second parts of the follow-up study<sup>a</sup>

Study part and lymph node	No. of samples	No. (%) of samples with positive cultures			No. (%) of samples with negative cultures		
		Total	ZN pos	ZN neg	Total	ZN pos	ZN neg
First part							
Mesenteric	159	124	100 (81)	24	35	27 (77)	8
Submaxillary	80	42	32 (76)	10	38	30 (79)	8
Total	239	166	132		73	57	
Second part							
Mesenteric	61	30	26 (87)	4	31	24 (77)	7
Submaxillary	102	23	20 (87)	3	79	67 (85)	12
Total	163	53	46		110	91	

<sup>a</sup> ZN, microscopic examination of Ziehl-Neelsen-stained material; pos, positive; neg, negative.

(33%), which originated from 46 of all groups examined (32%). Forty-nine percent of the affected mesenteric lymph nodes and 23% of the submaxillary lymph nodes were found to be positive for MAC by culture. From the mesenteric and submaxillary lymph nodes with a positive culture for MAC bacteria, a total of 82 and 80% of the samples, respectively, were also found to be positive by microscopic examination (Table 1). However, also a total of 79 and 83% of the mesenteric and submaxillary lymph nodes with negative cultures for MAC bacteria, respectively, yielded acid-fast bacilli in the microscopic examination (Table 1). Furthermore, rapidly growing mycobacteria from 53 lymph nodes were cultured and were found to have an orange pigment. These non-*M. avium* mycobacteria were mainly (40 of the 53) isolated from the submaxillary lymph nodes.

**Serotyping.** The serotypes of the MAC isolates were determined by the slide agglutination method, and the results are given in Fig. 1. Most strains were of serotype 3 (18 strains) or 4 (20 strains), and 39 isolates did not react with the panel of sera that we used. A minority of the isolates were of serotype 2, 8, or 4/8. No correlation was found between the serotypes and the IS1245 RFLP patterns.

**IS1245 RFLP typing of porcine isolates.** To get an impression of the occurrence of IS1245 RFLP types in various geographic regions, 10 to 20 isolates from pigs from each of the six slaughterhouses enrolled in this study were genotyped. Figure 1 shows a dendrogram of all 91 DNA fingerprint patterns. Only one of the IS1245 RFLP patterns, consisting of three bands, represented the bird-type DNA fingerprint (2, 6, 12). One other MAC isolate was devoid of IS1245 DNA, indicating that this strain represents a grouping other than *M. avium* in the MAC. The number of copies for the other 89 strains ranged from 9 to 34, with an average of 21 per strain. In general, the degree of polymorphism among the DNA fingerprints of pig isolates was large. However, most of the isolates could be grouped into genotype families that shared a similarity of at least 75% among the IS1245 RFLP patterns (Fig. 1).

The *M. avium* isolates subjected to RFLP typing originated from 91 pigs from 75 farms. A single pig from each of 63 farms was examined, and two or three pigs from each of 12 farms were inspected. In the case of 11 of the 12 multiple isolates from the same farm, two or more different DNA fingerprints were found (Fig. 1). This indicates the presence of multiple *M. avium* strains in pigs from 11 of 12 farms from which more than one porcine *M. avium* isolate was obtained. In contrast, identical DNA fingerprints were found among isolates from



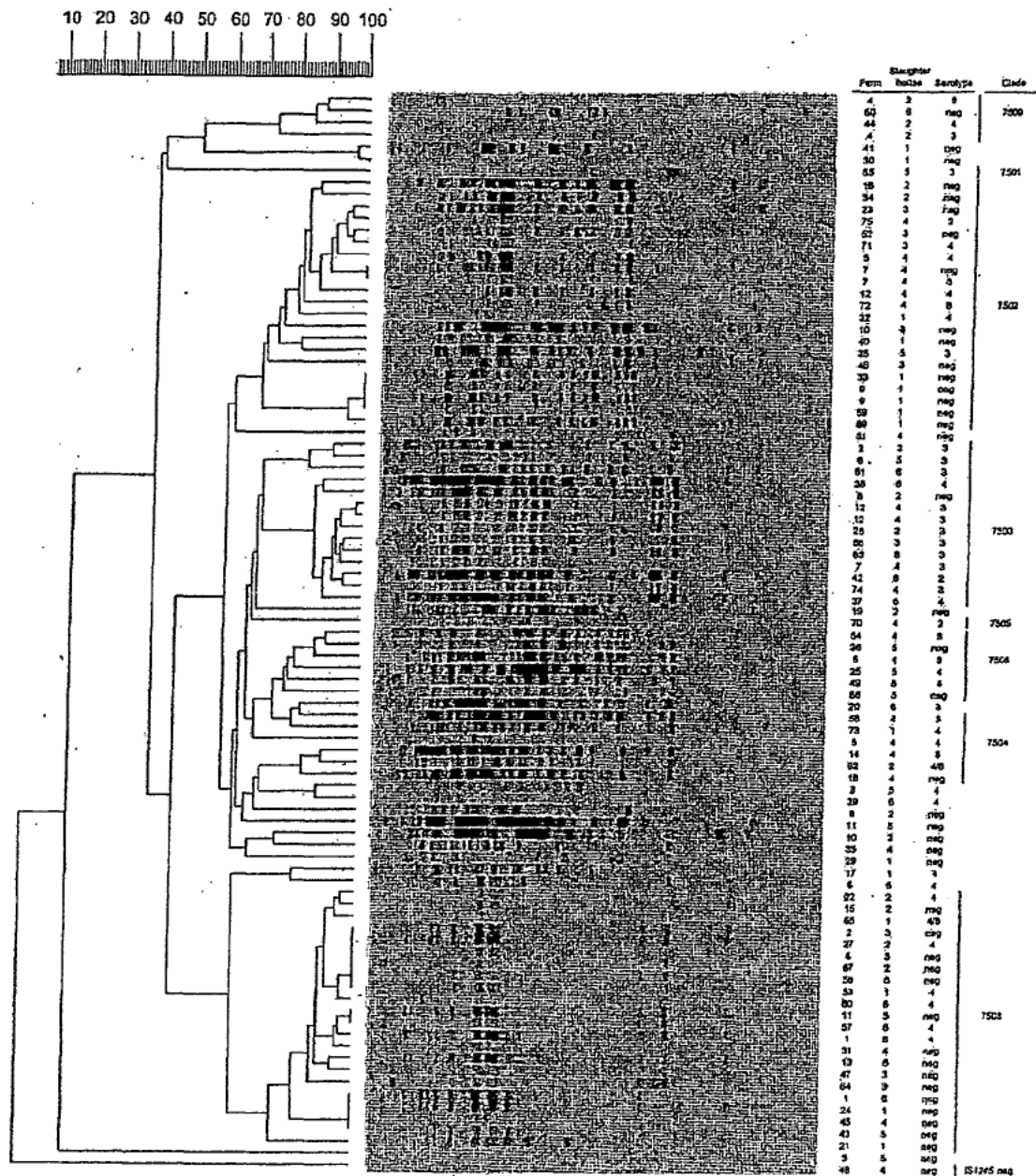


FIG. 1. Dendrogram of the 91 IS1245 RFLP patterns of *M. avium* complex isolates from pigs. The columns indicate (i) the farms where the pigs originated, (ii) the slaughterhouses where the pigs were processed, (iii) the serotypes of the isolates, and (iv) the IS1245 RFLP genotype family (clade) to which the isolate belongs. The numbers at the top represent percent relatedness.

different farms. In total, nine clusters, with a cluster size of two to six isolates, comprised 30 strains originating from 28 farms in a widespread geographic area.

Comparison of RFLP patterns of human and porcine *M. avium* isolates. In 1996, 191 MAC isolates from the same number of human patients were subjected to IS1245-based

RFLP typing in the framework of an epidemiological population-based study on MAC infections in The Netherlands (13). Forty-eight of the 191 isolates (25%) lacked IS1245 DNA, indicating that these strains do not represent *M. avium* but represent other groupings within MAC. Computer-assisted analysis helped compare the 90 porcine *M. avium* isolates with

TABLE 2. Occurrence of MAC isolates from humans and pigs in IS1245 RFLP genotype families with at least 75% similarity

Genotype family	No. of isolates from the following:		
	Total	Pigs	Human
7501	4	1	3
7502	16	14	2
7503	16	8	8
7504	91	20	71
7505	4		4
7506	7	6	1
7507	22	22	
7508	16	4	12
IS1245 negative	41	1	40
Not in a clade	41	15	26
Total	258	91	167

the 143 IS1245-containing human *M. avium* isolates from 1996. Nine genotype families were defined on the basis of at least 75% similarity between the IS1245 RFLP patterns of human and porcine isolates. The occurrence of isolates from both sources in these nine clades is given in Table 2. In total, 59% of the pig isolates and 61% of the human strains were in common genotype families. The largest family (clade 7502) comprised 21 isolates from pigs and 83 isolates from humans (Fig. 2). Two genotype families comprised only four human isolates (clade 7507; data not shown) and only 22 pig isolates (clade 7508; Fig. 1).

#### DISCUSSION

The average prevalence of caseous lesions in slaughtered pigs was 0.5%, which is unexpectedly high, taking into account the fact that positive pigs were selected only by eye on the basis of deviations in lymph nodes. In an earlier study in Switzerland, Offermann (10) isolated *M. avium* from the mesenteric lymph nodes from 48 of 345 (13.9%) healthy slaughter pigs without any lesions in these lymph nodes. Therefore, the true prevalence of *M. avium* in slaughter pigs in The Netherlands might be much higher.

Molecular typing and computer-assisted analysis facilitate the comparison of human and porcine isolates on a large scale. Although no identical DNA fingerprints of porcine and human origin were found, 60% of the isolates from both sources had a similarity of at least 75% among the IS1245 RFLP patterns. This means that, for IS1245 RFLP patterns consisting of 20 bands, at least 15 band positions are shared. Taking into account the high degree of IS1245-based polymorphism among *M. avium* strains in general, this justifies the conclusion that humans and pigs are infected with the same types of *M. avium* strains. It is currently not clear whether humans and pigs share common sources of infection or that pork products prepared without appropriate heating may infect susceptible humans. Long-term epidemiological studies are needed to examine this hypothesis. Such studies might find direct links between the consumption of contaminated pork products and infections in humans. However, such studies are complicated by the fact that pigs from various parts of The Netherlands are slaughtered at about 26 large and 30 small slaughterhouses scattered over the whole country. In addition, approximately 70% of the pork and pork products are exported.

Isolation of *M. avium* by culture is considered the "gold standard" test for the diagnosis of porcine mycobacterial infections. A sensitivity for microscopic examination of Ziehl-Neelsen-stained smears of 15% for MAC culture-positive

lymph nodes has been reported by Margolis et al. (9). In the follow-up part of the current study, a much greater sensitivity was found by microscopic examination: in total, 80% for the submaxillary lymph nodes and 82% for the mesenteric lymph nodes. However, 81% of all samples with a negative MAC culture result also yielded acid-fast bacilli by microscopic examination. Furthermore, large differences between the predictive value of positive microscopic examinations of submaxillary lymph nodes (26%) and that of positive microscopic examinations of mesenteric lymph nodes (71%) were observed. This low predictive value regarding positive microscopic examinations of the submaxillary lymph nodes is presumably due to a high prevalence of other, non-MAC bacteriological infections caused by injuries as a result of fighting and/or culling of dents. In our study we found more than 50 positive cultures that yielded orange-pigmented acid-fast mycobacterial rapid growers.

The occurrence of IS1245 is restricted to *M. avium* (6, 12). Only 1 of 91 porcine isolates lacked IS1245 DNA in this study, revealing that the porcine MAC isolates almost invariably represented true *M. avium*. Among the human isolates, 25% of the strains did not hybridize to the IS1245 probe. This indicates that a proportion of the human MAC isolates much larger than that of the porcine isolates represented other groupings within MAC. This presumably reflects the fact that humans have sources of infection not shared with pigs. The identification of the IS1245-negative MAC strains is described elsewhere (13).

In the current study, MAC isolates from pigs at one farm were usually infected with various genotypes of *M. avium*, and identical fingerprints were found among isolates from pigs from different farms. This suggests that there is no ongoing transmission among pigs but, rather, that pigs are infected from environmental sources, and these may be shared by farms at different geographic locations. In a study by Engel et al. (5) of three farms in The Netherlands in 1977, *M. avium* serotype 2 was isolated from 12 of 13 pigs on one farm and occasionally from pigs on two other farms. Since serotypes 1, 2, and 3 were commonly found among bird isolates, this finding at that time strongly suggested a role of birds in the transmission of "avian" tuberculosis. However, in our previous study (12), we found multicopy IS1245 RFLP patterns among *M. avium* serotype 2 and 3 strains apart from the frequently found bird-type RFLP pattern. The multicopy patterns clearly do not represent the bird type RFLP pattern. This means that serotyping is not a reliable method of recognizing *M. avium* strains that originate in birds. The serotyping results in this study also reflect this. Although 21 of the 91 porcine isolates represented serotype 2 or 3, only one of these 21 strains had the bird-type IS1245 RFLP pattern. This finding, combined with the fact that 47 *M. avium* strains from birds in The Netherlands invariably exhibited the bird-type IS1245 RFLP pattern (12), excludes birds as significant sources of MAC infections in pigs.

Engel et al. (5) used a pig infection model to demonstrate that tuberculous lymphadenitis can be induced by feeding pigs compost. However, it is assumed that compost can no longer be suspected as a main factor in the etiology of *M. avium* infections in pigs, because compost is disinfected nowadays by heating and is thought not to contain viable *M. avium* bacteria.

In this study, slaughter pigs were examined by selecting lymph nodes with caseous lesions. Macroscopically negative lymph nodes and the dissemination of MAC infections to other organs must be examined to estimate the true prevalence of MAC bacteria in pigs. Furthermore, detailed studies are need-



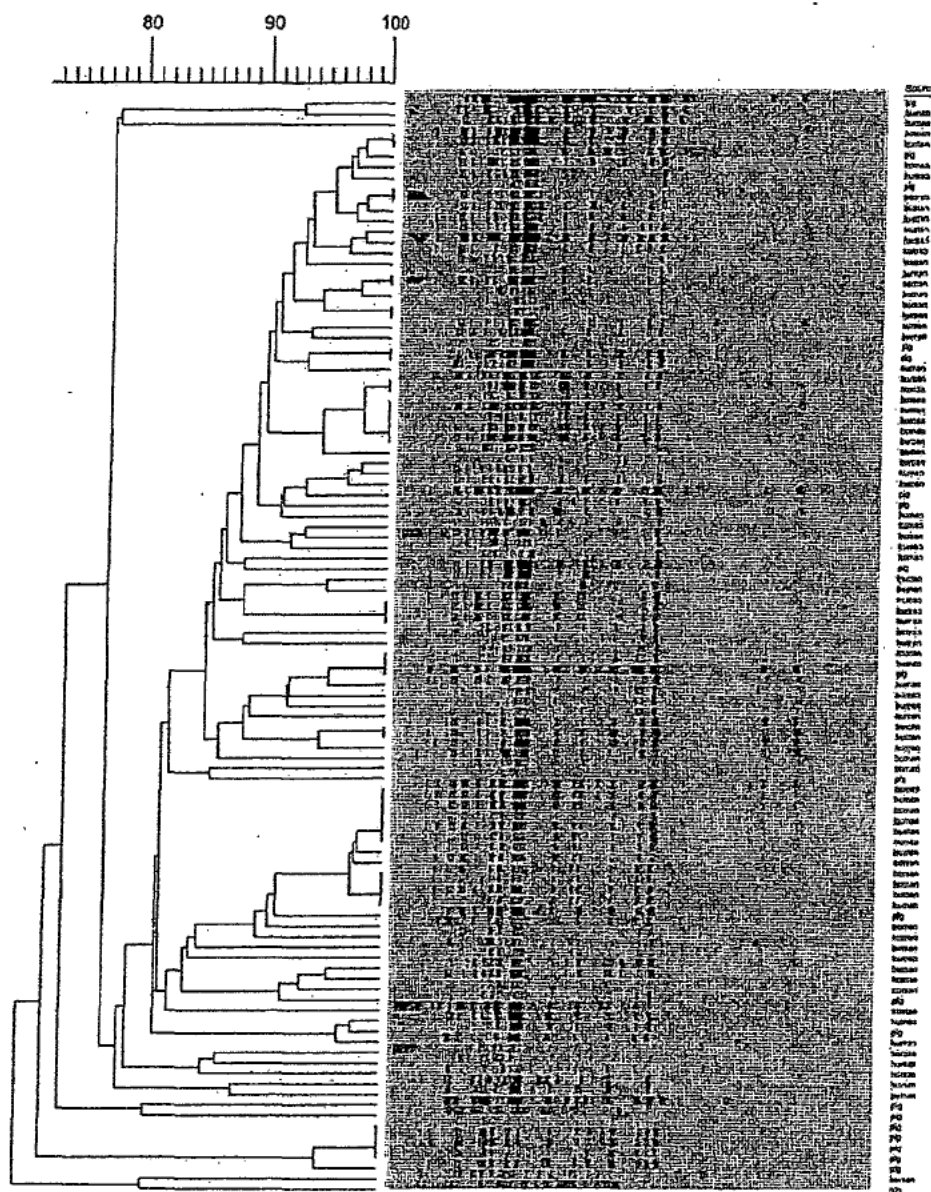


FIG. 2. Dendrogram of IS1245 DNA fingerprints of pig and human isolates in clade 7502. The numbers at the top represent percent relatedness.

ed to further investigate possible sources of infection at farms with a high incidence of MAC-positive pigs.

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Short communication

## Granulomatous lesions in lymph nodes of slaughter pigs bacteriologically negative for *Mycobacterium avium* subsp. *avium* and positive for *Rhodococcus equi*

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### Abstract

The prevalence of granulomatous lesions in lymph nodes of pigs was studied. From January till August 2004 in two slaughterhouses in The Netherlands 2,116,536 pigs were examined for the presence of granulomatous lesions in the sub-maxillary lymph nodes. In 15,900 (0.75%) of these pigs, lesions could be detected. Nine farms with the highest incidence of lesions were selected for a more detailed pathological and bacteriological examination. On these farms, the prevalence of lesions in sub-maxillary lymph nodes ranged from 2.3 to 5.7% with a mean of 3.0%. From 1276 pigs that were sampled, 98 (7.7%) displayed granulomatous lesions in the sub-maxillary lymph nodes and one (0.1%) pig showed lesions in its mesenteric lymph node. *Mycobacterium avium* subsp. *avium* (MAA) could not be isolated from the lymph nodes of the 99 pigs with lesions and from a selection of lymph nodes ( $n = 61$ ) of pigs without lesions. *Rhodococcus equi* was isolated from 44 out of 98 (44.9%) of the sub-maxillary lymph nodes with granulomatous lesions and from two mesenteric lymph nodes without lesions. A comparison of former studies and the current results indicate that the prevalence of MAA infections in slaughter pigs has strongly decreased over the last decade, whereas *R. equi* is highly prevalent. The high incidence of granulomatous lesions associated with the bacteriological presence of *R. equi* could be considered as a serious cause of misdiagnosis of MAA infections in cases where meat inspection is carried out by inspection for granulomatous changes of lymph nodes only.

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**Keywords:** *Mycobacterium avium*; Swine mycobacteriosis; Lymphadenitis; Bacteria; Diagnosis; *Rhodococcus equi*

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## 1. Introduction

*Mycobacterium avium* subsp. *avium* (MAA) is a potential zoonotic pathogen, which belongs to *M. avium* complex bacteria (MAC). MAA can cause opportunistic infections in humans, especially in those suffering from a HIV infection (Wagner and Young, 2004; Biet et al., 2005). In addition, MAA can cause cervical lymphadenitis in young, otherwise healthy children between 0 and 4 years of age (Haverkamp et al., 2004). The reservoir for infection with MAA in humans is unknown. MAA is ubiquitous and can be isolated from water, soil, compost, bedding materials in stables and other environmental sources (Engel et al., 1978; Thoen, 1992; Matlova et al., 2003, 2004). MAA can also be isolated from animals, most frequently from birds and pigs (Thoen, 1992). Genotyping of MAA strains isolated from humans and pigs revealed that these strains have a high homology (Komijn et al., 1999). This could indicate that pigs are a source of infection for humans or that pigs and humans share common sources of infection, e.g. the environment.

In pigs, infections with MAA are usually limited to the lymph nodes. Especially the sub-maxillary and mesenteric lymph nodes are affected (Thoen, 1992). MAA infections in pigs have no apparent effect on the health of the animal and diagnosis by physical examination of the live pig is usually impossible. Since MAA is a potential zoonotic pathogen it is necessary to exclude MAA from the food chain. In accordance to European Union legislation (Regulation 2004/854/EC), infections caused by *Mycobacteria* in pigs are diagnosed presumptively in slaughter houses by meat inspectors. The sub-maxillary lymph nodes of slaughter pigs are incised and examined at post-mortem inspection for granulomatous lesions. Furthermore, the mesenteric lymph nodes are inspected for granulomatous lesions visually, by palpation and if necessary by incision.

It is considered that granulomatous lesions in lymph nodes are typical for an infection with mycobacteria (Brown and Neuman, 1979). However, *Rhodococcus equi* is also frequently isolated from lesions in sub-maxillary lymph nodes of pigs with granulomatous lymphadenitis (Prescott, 1991; Takai et al., 1996a; Hondalus, 1997; Dvorska et al., 1999). *R. equi* can cause disease in horses, especially in young

foals. In humans, it mainly causes disease in those infected with HIV, and the infection occurs mainly in lungs (Prescott, 1991; Hondalus, 1997). The reservoir of the human infection is not elucidated. *R. equi* is a robust soil organism widespread in the environment and will potentially multiply in the presence of horse manure (Takai et al., 1996b). Prescott (1991) reviewed the history of 32 AIDS patients suffering from an infection with *R. equi* and found a possible animal source of infection for 12 of these patients, confirming the zoonotic potential of this species.

The prevalence of granulomatous lesions in the sub-maxillary and/or mesenteric lymph nodes of Dutch slaughter pigs was determined in 1996 to be 0.5% (Komijn et al., 1999). From 54.2% of these lesions, MAA was isolated. This study was performed to determine the prevalence of granulomatous lesions in pigs in The Netherlands in 2004 and to compare the results with the previous study performed in 1996. Furthermore, on selected farms, sub-maxillary and mesenteric lymph nodes with and without lesions were sampled at slaughter and examined bacteriologically for MAA and *R. equi*.

## 2. Materials and methods

### 2.1. Lesions of pigs at post-mortem meat inspection

The prevalence of granulomatous lesions in slaughter pigs was determined for the period January till August 2004. Two slaughterhouses (I and II), where a system was used to register lesions during the post-mortem meat inspection, were selected. Both slaughterhouses were located in the southern part of The Netherlands and in each slaughterhouse approximately 6000 pigs were slaughtered daily. The total number of pigs slaughtered and the number of pigs from which the heads were condemned for reasons of granulomatous lesions in the sub-maxillary lymph nodes were counted and prevalence of lesions was calculated.

### 2.2. Selection of farms and sampling

In order to obtain a considerable number of lymph nodes with granulomatous lesions for bacteriological

and pathological examination, farms were selected with a recent history for such lesions. Therefore data were used from the registration of lesions at post-mortem meat inspection in slaughterhouse I for the period September till December 2003. Nine farms were selected and in January and February 2004 in several deliveries from these farms the sub-maxillary and mesenteric lymph nodes were examined pathologically for granulomatous lesions at slaughter. From each delivery, at least five pigs without and all pigs with granulomatous lesions in the sub-maxillary lymph nodes were sampled for further examination.

### 2.3. Bacteriological examination

To culture for MAA the lymph nodes were ground, decontaminated by 1 M sodium hydroxide for 15 min at room temperature followed by a 5% oxalic acid treatment also for 15 min at room temperature. Samples were inoculated onto Löwenstein-Jensen medium, Stonebrink egg medium and Middlebrook 7H10 agar followed by incubation for 12 weeks at 37 °C. Ziehl-Neelsen stain was performed to identify acid-fast bacilli. To culture for *R. equi*, lymph nodes were inoculated onto normal blood agar plates supplemented with 5% sheep blood and incubated for 48 h at 37 °C. Suspected colonies were tested for a synergistic hemolytic reaction (CAMP test) with *Staphylococcus aureus* on 5% sheep blood agar plates, which is an essential criterion for identification of *R. equi* (Prescott, 1991). To confirm the identification of *R. equi*, 16S ribosomal sequencing was performed. In short: DNA was purified using QIAquick spin columns, according to the procedure described by the manufacturer (Qiagen). Target DNA sequence was amplified by PCR using universal primers 8FPL and 806R (Reiman, 1993). DNA analysis was performed using an ABI carried out on 3100 Avant genetic analyzer and compared with the NCBI database using BLAST (Applied Biosystems).

## 3. Results

### 3.1. Prevalence of lesions

During meat inspection at two slaughterhouses in The Netherlands for the period January till August

2004 in total 2,116,536 pigs were examined for the presence of granulomatous lesions in the sub-maxillary lymph nodes. In 15,900 (0.75%) of these pigs, lesions were detected. The prevalence of granulomatous lesions in slaughterhouse I was higher than in slaughterhouse II. From 898,858 pigs slaughtered in slaughterhouse I 9649 (1.05%) pigs displayed lesions in the sub-maxillary lymph nodes whereas from the 1,217,678 pigs slaughtered in slaughterhouse II 6,251 (0.51%) pigs showed lesions.

### 3.2. Selection of farms and sampling

Nine farms with the highest incidence of lesions in the sub-maxillary lymph nodes were selected for a more detailed pathological and bacteriological examination. During the period September to December 2003 the prevalence of lesions in lymph nodes on these farms ranged from 2.3 to 5.7% with a mean of 3.0%. Prevalence on these farms was calculated on the basis of results at meat inspection in slaughterhouses of minimal 5 and maximal 27 successive deliveries of slaughter pigs, in total 111 deliveries and 18,855 pigs. In January and February 2004 the sub-maxillary- and mesenteric lymph nodes from 1276 pigs from these nine farms were sampled.

### 3.3. Pathological and bacteriological examination

The results of the pathological examination showed that 98 (7.7%) out of the 1276 examined pigs had granulomatous lesions in the sub-maxillary lymph nodes and only one pig had lesions in its mesenteric lymph node. The remaining 1177 (92.2%) pigs were free of lesions in their lymph nodes. Bacteriological examination of the lymph nodes of the 99 pigs with lesions and from a selection of lymph nodes ( $n = 61$ ) of pigs without lesions showed that they were all negative for Mycobacteria, including MAA. However, *R. equi* was isolated from 44 out of 98 (44.9%) sub-maxillary lymph nodes with granulomatous lesions (Table 1). In sub-maxillary lymph nodes without lesions no *R. equi* was detected. From the 160 examined mesenteric lymph nodes, *R. equi* was isolated from two lymph nodes in which no lesions were detected during pathological examination (Table 1). *R. equi* was isolated from affected lymph

Table 1

Pathological and bacteriological examination from sub-maxillary and mesenteric lymph nodes of 160 pigs originating from nine farms with a recent history of granulomatous lesions

Lymph node	No. (%) of lymph nodes							
	Pathological positive				Pathological negative			
	MAA <sup>a</sup> positive	<i>R. equi</i> <sup>b</sup> positive	MAA and <i>R. equi</i> negative	Total	MAA positive	<i>R. equi</i> positive	MAA and <i>R. equi</i> negative	Total
Sub-maxillary	0 (0.0)	44 (44.9)	54 (55.1)	98 (100)	0 (0.0)	0 (0.0)	62 (100)	62 (100)
Mesenteric	0 (0.0)	0 (0.0)	1 (100)	1 (100)	0 (0.0)	2 (1.3)	157 (98.7)	159 (100)

<sup>a</sup> *Mycobacterium avium* subsp. *avium*.

<sup>b</sup> *Rhodococcus equi*.

nodes from all nine sampled farms (Table 2). The number of lymph nodes with lesions varied from 3 to 28 per farm and the number of isolations of *R. equi* from 3 to 12 (Table 2).

The isolated *R. equi* strains showed a synergetic hemolytic reaction on 5% sheep blood agar with *S. aureus*. To confirm the identification, from one isolate the 16S rDNA was amplified by PCR and sequenced. Its sequence showed that the isolate was identical to *R. equi*.

#### 4. Discussion

In 1996 the prevalence of granulomatous lesions in lymph nodes of slaughter pigs in The Netherlands was

0.5% and in 54.2% of the cases MAA was isolated (Komijn et al., 1999). The results of this study showed that the prevalence of granulomatous lesions in lymph nodes in 2004 was 0.75%, an increase in comparison to the results of 1996. However, in contrast to the results of the study in 1996, in 2004 no MAA bacteria could be detected in lymph nodes after bacteriological examination. Apparently, the prevalence of MAA infections in The Netherlands in 2004 was considerably less when compared with the prevalence in 1996. One of the reasons for the decrease in prevalence of MAA infections could be the change in use of compost on pig farms. Pigs fed with compost can develop granulomatous lymphadenitis (Engel et al., 1978). In a search for possible sources of MAA infections in pigs on two farms of the survey of 1996 it appeared that

Table 2

Distribution of pigs with granulomatous lesions in sub-maxillary and mesenteric lymph nodes across farms and their outcome after bacteriological examination for *Mycobacterium avium* subsp. *avium* (MAA) and *Rhodococcus equi*

Farm	No. of examined pig carcasses	No. (%) of pigs with lesions					
		Sub-maxillary lymph nodes			Mesenteric lymph nodes		
		Pathological	Bacteriological		Pathological	Bacteriological	
			MAA	<i>R. equi</i>		MAA	<i>R. equi</i>
1	155	5 (3.2)	0 (0.0)	3 (1.9)	0	0 (0.0)	0 (0.0)
2	114	11 (9.6)	0 (0.0)	3 (2.6)	0	0 (0.0)	2 (0.0) <sup>a</sup>
3	68	3 (4.4)	0 (0.0)	2 (2.9)	0	0 (0.0)	0 (0.0)
4	117	7 (5.6)	0 (0.0)	3 (2.6)	1	0 (0.0)	0 (0.0)
5	69	3 (4.3)	0 (0.0)	3 (4.3)	0	0 (0.0)	0 (0.0)
6	153	14 (9.2)	0 (0.0)	7 (4.6)	0	0 (0.0)	0 (0.0)
7	139	19 (13.7)	0 (0.0)	12 (8.6)	0	0 (0.0)	0 (0.0)
8	235	28 (11.9)	0 (0.0)	8 (3.4)	0	0 (0.0)	0 (0.0)
9	226	8 (3.5)	0 (0.0)	3 (1.3)	0	0 (0.0)	0 (0.0)
Total	1276	98 (7.7)	0 (0.0)	44 (3.4)	1	0 (0.0)	2 (0.0) <sup>a</sup>

<sup>a</sup> No percentages are given because the two lymph nodes bacteriologically positive for *R. equi* showed no lesions after pathological examination.

samples of compost contained MAA bacteria (Komijn, 1999). At present no pig farms, except for organic pig farms in The Netherlands use compost anymore including the nine farms from which we sampled lymph nodes for bacteriological examination.

A difference in prevalence of granulomatous lesions between the two slaughterhouses was observed. A possible explanation for this finding is a true difference in prevalence of lesions in lymph nodes of pigs on farms. Another explanation may be a difference in methodology of scoring for lesions between slaughterhouses. Lesions are scored visually at slaughter and it cannot be excluded that such subjective observation will influence the outcome of the scoring.

*R. equi* was frequently isolated from granulomatous lesions in sub-maxillary lymph nodes (44 out of 98) and no other bacteria were detected. Apparently, in this survey *R. equi* was the most important bacterium in causing lymphadenitis in pigs. As *R. equi* is also known as a bacterial species with zoonotic potential, the presence of *R. equi* and the food borne attribution to human *R. equi* infections should be analysed in more detail.

The isolation of *R. equi* was nearly exclusively from the sub-maxillary lymph nodes (44 out of 160) and not from the mesenteric lymph nodes (2 out of 160). These findings are in agreement with reports of others indicating that isolation of *R. equi* was usually limited to respiratory tract lymph nodes (Prescott, 1991; Dvorska et al., 1999). Furthermore, we found that isolation of *R. equi* was nearly exclusively from lymph nodes with granulomatous lesions (44 out of 46). Several reports confirm these findings but and in contrast to our findings, *R. equi* may also be recovered from normal sub-maxillary lymph nodes in healthy pigs (Prescott, 1991; Takai et al., 1996a; Dvorska et al., 1999).

A high number of lymph nodes with granulomatous lesions (54 out of 98) was bacteriologically negative for MAA and *R. equi*. Similar observations have been made earlier in The Netherlands (Komijn et al., 1999), in the US (Brown and Neuman, 1979) and in Czech Republic (Dvorska et al., 1999). Reasons for these observations could be that the granulomatous lesion are merely aesthetic or that the process had healed and no living bacteria were present. Another possible explanation was given by Dvorska et al. (1999), who suggested that during the immune response of the host

organism to the infection, the subsequent lesion forming results in a total devitalisation of the agent. Experimental infections with MAA in pigs with bacteriological, pathological and immunological examinations at different time intervals after infection might reveal whether this is the case.

The results from our study show that detection of granulomatous lesions in pig lymph nodes by eye is not a reliable diagnostic test to determine an infection with MAA. Furthermore, additional examinations by culture methods appear to be necessary to estimate the true prevalence of MAA infections in pigs. However, this approach is time-consuming and laborious. Therefore, other more fast and reliable tests for the detection of MAA infections in pigs are strongly needed. Finally, the high occurrence of *R. equi* in lymph nodes of pigs provokes the question to the risk of *R. equi* transmission from pigs to the human population.

#### Acknowledgements

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**Serodiagnosis of *Mycobacterium avium* subsp. *avium* infections in pigs**

Henk Wisselink, Conny van Soit-Smits, Norbert Stockhofe-Zurwieden, Herma Bergen-Buys and Jelle Thole



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**Content**

- Introduction *M. avium* subsp. *avium*
- Prevalence studies in the Netherlands
- Experimental infection in pigs
- Development of a serological ELISA assay
- Validation ELISA assay
- Scientific publications

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***Mycobacterium avium* subsp. *avium* (MAA)**

- Humans
  - Opportunistic infections
    - HIV infected
    - Suffering from COPD
  - Cervical lymphadenitis in healthy children between 0 and 4 years of age
- Pigs
  - Lymph node lesions
  - Mesenteric and mandibular lymph nodes

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### Mycobacterium avium complex (MAC)

- MAC: 28 serotypes
- Serotypes 1-6, 8-11 and 21 belong to MAA
- Serotypes 1, 2 and 3: MAA "bird" type (naming avium)
- Other serotypes MAC "non-bird" types
  - Isolated from humans and pigs
  - But also from the environment (soil, compost, water)

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### Reservoir of infection

- MAA strains isolated from humans and pigs
  - Genotyping
  - High agreement
- Conclusions
  - Humans and pigs share reservoirs either/or
  - Pigs can form a reservoir

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### Diagnosis

- Diagnosis in live pigs usually not possible
  - MAA infection no apparent effect on the health of pig
- Diagnosis in slaughterhouse
  - During meat inspection
  - Mandatory incision of lymph nodes EU legislation
  - Mandibular lymph nodes
    - Incision and assessment of lesions
    - If lesions are observed the heads are condemned
  - Mesenteric lymph nodes
    - Visual inspection for lesions
    - If lesions are observed intestine is condemned

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### Test characteristics slaughterhouse inspection

- Laborious
- Low specificity
  - *Rhodococcus equi* is also a cause of lesions
- Low sensitivity
  - Lesions can easily be missed
  - Lymph nodes bacteriologically positive for MAA without lesions

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### Prevalence of MAA in the Netherlands in 1996 and 2004

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### Prevalence MAA 1996

- 0.8 % of slaughterpigs lesions mandibular lymph nodes on the basis of pm inspection (VWA)

#### Targeted sampling

- From 20% of the lesions, MAA were isolated

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#### Sources of infection 1996

- Search for possible sources on two farms:
  - Samples of compost contained MAA-bacteria
- 2001
  - IKB: only compost, free for viable MAA was allowed as bedding for pigs

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#### Prevalence 2004

- 0.75% of slaughterpigs on the basis of pm inspection of mandibular lymph nodes (VWA)
- Period: Jan. – August 2004

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#### Prevalence MAA 2004 (1)

Targeted sampling based on risk

- Selection of 9 pig farms
  - Recent history of high percentage of lesions in mandibular lymph nodes
  - Period Sept. – Dec. 2003
- Sampling of 160 pigs
  - Mandibular and mesenteric lymph nodes
  - Period Jan. – Febr. 2004

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### Prevalence MAA 2004 (2)

- Lesions
  - 98 pigs with lesions in mandibular lymph nodes
  - 1 pig with lesions in mesenteric lymph node
- Bacteriological examination of lymph nodes
  - Negative for MAA
  - Isolation of *R. equi*
    - 44 out of 98 mandibular lymph nodes with lesions
    - 1 out of 159 mesenteric lymph nodes without lesions

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### Summary and conclusions

- Prevalence of MAA infections in the Netherlands in 2004 probably very low
- A strong decrease in MAA infections in the Netherlands during the last decade

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Pathological and bacteriological examination of lymph nodes of pigs after experimental infection with *Mycobacterium avium* subsp. *avium*

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### Goal

- Correlation between bacteriological and pathological status of lymph nodes
- Influence of an early and late infection on bacteriological and pathological status of lymph nodes

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### MAA strain and pigs

- MAA strain
  - Serotype 4
  - Isolated from a lymph node of a field pig in The Netherlands (1996)
- Pigs
  - High health status farm
  - 4 groups of 8 pigs

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### Groups of pigs experimentally infected

Group	Age of pigs experimental infection (weeks)		
	2.5	4.5	18
1	X		
2		X	
3			X
4	X	X	X

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### Inoculation

- Inoculum
  - 5 ml MAA ( $10^9$  CFU) suspension
- Inoculation
  - Deposition of inoculum in the caudal area of the pharynx
- Pharynx epithelial tissue
  - Scarified with a cotton swab

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### Skin tuberculation

- Carried out 72 hours before autopsy
- Intradermal tuberculin test in the ear
  - MAA strain D4
- Assessment after 24, 48 and 72 hours
- Results:
  - 31 out of 32 pigs positive (red, swelling)

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### Evaluation experimental infection

- Autopsy at an age of 24 weeks
- Pathological and bacteriological examination of
  - Lnn mandibularis
  - Lnn mesenterialis
  - Lnn inguinalis
  - Lnn trachea-bronchialis (left and right)
  - Lnn retro-pharyngeal
  - Tonsil

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## Granulomatous lesions in Lnn mandibularis

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## Granulomatous lesions in Lnn mesenterialis

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## Pathological examination of lymph nodes (1)

Group	Age exp. infection (weeks)			Lesions in lymph nodes	
	2.5	4.5	18	Mean (n)	Pigs (n)
1	X			2.1	7
2		X		2.5	7
3			X	0	0
4	X	X	X	0.3	2

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02/11/2006

Pathological examination of lymph nodes (2)							
Group	Number of pathological lesions in lymph nodes per group						
	Tonsil	Mand.	Mes.	Ing.	Trach. br. (le)	Trach. br. (ri)	Retro- phar.
1	1	3	6	0	2	2	3
2	0	7	7	0	0	2	4
3	0	0	0	0	0	0	0
4	0	0	2	0	0	0	0
Total	1	10	15	0	2	4	7
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Bacteriological examination of lymph nodes							
Group	Number of pigs bacteriologically positive for MAA per group						
	Tonsil	Mand.	Mes.	Ing.	Trach. br. (le)	Trach. br. (ri)	Retro- phar.
1	2	5	8	0	2	3	7
2	2	8	7	2	1	1	6
3	8	8	5	0	0	0	6
4	4	6	7	0	1	0	3
Total	16	27	27	2	4	4	22
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Diagnosis of pigs experimentally infected with MAA						
Group	Number of pigs					
	Lnn mandibularis		Lnn mesenterialis		Lnn mand + Lnn mes	
	Path.	Bact.	Path.	Bact.	Path.	Bact.
1	3	5	6	8	7	8
2	7	8	7	7	7	8
3	0	8	0	5	0	8
4	0	6	2	7	2	8
Total	10	27	15	27	16	32
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### Summary and conclusions

- The infection model works fine
- Lesions visible 20 and 22 weeks after infection
- Six weeks too short to develop lesions
- Pathological examination less sensitive than bacteriological examination, especially in pigs recently infected

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Development of an ELISA test for the serodiagnosis of *M. avium* subsp. *avium* infections in pigs

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### Meat inspection

- Legislation EU 2004
  - Authorities may decide:
    - On the basis of epidemiological data
    - To refrain from incision of lymph nodes

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### Serological test for MAA

- Development serological assay
  - Detection of antibody titers in blood of slaughterhouse pigs (26 weeks)
- Little is known of immuneresponse against MAA
  - Experimental infection with MAA (Thoene et al., 1979):
    - Pigs became bacteriological positive for MAA
    - Immunoresponse 10-12 weeks after infection

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### Lipids

- Cellwall of Mycobacteria
  - Rich with lipids
  - Outside cellwall glycolipidstructure
- Glycolipids of Mycobacteria
  - Many of them are species specific
  - Glycopeptidolipids (GPL's) of MAC
    - Immunodominant antigens
    - Serological diagnosis of human MAC infections

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### Materials

- MAA field strain (1996) for isolation of lipids
- Sera obtained from:
  - Pigs bacteriologically negative for MAA
    - Prevalence study of 2004
  - Pigs experimentally infected with MAA
    - Longitudinal sera

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### Fractionating lipids

- Culture MAA field strain
- Extraction of lipids
  - Crude fraction tested in ELISA
    - High titers in sera of pigs experimentally infected
    - Low titers in field sera of pigs bacteriologically negative for MAA
  - Comparison of polair and apolair fraction in ELISA
    - Polair fraction most important

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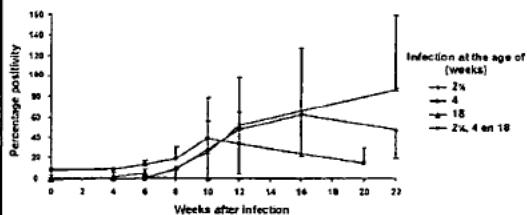
### Execution of ELISA

- Coating ELISA plates with polair lipids
- Serum of pigs tested in dilution of 1:200
- In each plate a negative and positive control serum (in duplo)
  - Negative: Pig (field) bacteriologically negative for MAA
  - Positive: Pig experimentally infected
- Calculation of PP%:  

$$\frac{OD(\text{sample}) - OD(\text{negative control})}{OD(\text{positive control}) - OD(\text{negative control})} \times 100\%$$

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### Antibody titers in pigs experimentally infected with *Mycobacterium avium* subsp. *avium*



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### Summary and conclusions

- Development of a serological assay
  - Use of polar lipid fraction
- Experimental infected pigs (single infection)
  - Increase in antibody titer from 6-8 weeks after infection
  - Highest titers 10-12 weeks after infection

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### Validation ELISA assay

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### Calculation of cut off

- For application of the test calculation of cut off needed
- Use of field sera of pigs
  - Bacteriologically negative for MAA, 2004 (N=153)
- Result ELISA field sera
  - 150 (98%) PP% < 10
  - Highest result 16 PP%
- Calculation of cut off
  - 7.5 PP% (5.0 -14.4)

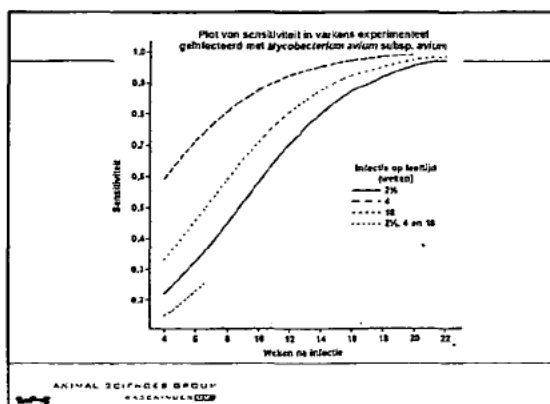
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Diagnosis of pigs experimentally infected with MAA								
Group	Number of pigs							Serological ( $> 7.5$ PP%)
	Lnn mand		Lnn mes		Lnn mand + Lnn mes			
	Mac	Bt	Mac	Bt	Mac	Bt		
1	3	5	6	8	7	8	8	
2	7	8	7	7	7	8	5	
3	0	8	0	5	0	8	2	
4	0	6	2	7	2	8	8	
Total	10	28	15	27	16	32	23	

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Sensitivity of the assay
<ul style="list-style-type: none"> <li>Calculated with sera of pigs experimentally infected (longitudinal)</li> </ul>

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### Continuous improvement

- A follow up on positive farms
- e.g.
  - Positive farms identified on serology
  - Skin tuberculation
  - Management review on farm, adjustment of procedures
  - Sampling of lymph nodes and blood in slaughterhouse
  - Bacteriological and serological examination

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### Summary and conclusions

- Sensitivity of ELISA test sera pigs experimentally infected
  - 0.1 – 0.6 at 4 weeks after infection
  - 0.9 – 0.95 at 20 weeks after infection
- Procedure for follow-up positive farms

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### Scientific publications MAA The Netherlands

- Komijn et al., 2000
  - J. of Clinical Microbiology
  - Content: Prevalence of MAA in 1996
- Wisselink et al., 2006
  - IPVS Conference Copenhagen, Denmark
  - Content: Experimental infection with MAA in pigs
- Komijn et al., 2007
  - Accepted for publication in Veterinary Microbiology
  - Content: Prevalence of MAA in 2004

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**NL Visual Inspection of Market hogs- Briefing for the Under Secretary**  
**August 2, 2007**

- **We reviewed the visual inspection documents and found visual inspection to be equivalent because it met the following criteria:**
  1. The government has an inspection program that is at least as effective at identifying and removing, adulterated carcasses, parts as FSIS inspection procedures..
  2. The incidence of diseases in market hogs no higher than the incidence in the United States.
  3. The market hogs must be born and raised in the country.
  4. The government implements a inspection verification program to check the accuracy of the visual inspection program.
  5. The government requires the use of prerequisite programs that reduce the incidence of food-borne pathogens in market hog carcasses.

**During our last briefing, you had asked a question on the use of ELISA test, which is one part of the prerequisite program. We received further information from Netherlands. This information was reviewed with technical expert and found acceptable. This information is provided in Attachment 2.**

**Would you like me to briefly discuss this information?**

**If answer is NO, then I will STOP.**

**However,**

**If answer is yes, then I will say the following:**

- Based on the Netherlands data, ELISA test was about 75% sensitive in hogs infected with *M. avium* subspecies *avium* (MAA).
- Netherlands data did not address the **specificity** of the ELISA method. (They only used one strain of *M. avium*. )
  - Based on the Netherlands' data, the ELISA test, by itself, is not the most reliable test for the detection of MAA. However, it can become a dependable if it is combined with the following safeguards.:
    - i. The production/slaughter is a vertically integrated operation,
    - ii. There is a established frequency of follow-up testing for MAA.

- iii. Only hogs born and raised in Netherlands are allowed in the program.
- iv. There is a TB testing program for the farm workers.
- v. There is an environmental testing program for MAA
- vi. Companies have a program for controlling insects and other pests.

*Netherlands has proposed these safeguards as part of its equivalence request.*

***NOTES for Ghias Mughal for any follow up discussion.***

***NB: They have not reduced number of inspectors from the post mortem line)***

***Q. 1 Why was this Criteria selected?***

***Ans. Based on food safety objective to remove unwholesome and adulterated carcasses and parts from human food supply.***

***Q. 2 What is testing frequency for ELISA test?***

***Ans.***

Only neutral and low risk farms are eligible to participate in visual inspection.

2 pigs per lot. from a low risk farm.

***Q. What is the reason for this submission?***

***Ans.***

***To reduce salmonella.***

***(Literature. suggests that cross contamination with salmonella is increased after incision of Mandibular LN)***

**Comparison between:**

#### **HIMP and NL Visual Inspection**

FSIS post-mortem inspection procedures under HIMP are similar to the Netherlands visual ante-mortem and post-mortem inspection except that FSIS requires the establishment to incise mandibular lymph nodes.

#### **FSIS traditional inspection and NL Visual Inspection**

FSIS' post-mortem inspection procedures under traditional inspection are similar to the Netherlands' visual post-mortem inspection procedures except FSIS inspectors incise and observe mandibular lymph nodes, observe and palpate portal and bronchial lymph nodes, observe liver, lungs and kidneys.

#### ***HIMP:***

FSIS conducts three types of inspection activities in the HIMP establishments; Systems Inspection, Carcass Inspection and Verification Inspection.



**Systems Inspection** involves the evaluation of in-plant inspection findings and is intended:

To determine the effectiveness of the overall design and execution of all establishment slaughter processes under HACCP and process control plans.

**Carcass Inspection** involves the examination of each carcass and its parts to determine if they are adulterated.

**Verification Inspection** involves the evaluation of the effectiveness of the establishment's HACCP plan and process control plan in meeting the relevant performance standards.

*Inspection procedures under HIMP were developed to reduce reliance on organoleptic inspection, to shift to prevention-oriented inspection systems based on risk assessment, and to redeploy inspection resources in a manner that better protects the public from food-borne diseases.*

Farms are categorized according to risk of *M. avium* infection based on the results of ongoing sampling results. If a farm has 18 consecutive negative results (sampled from no more than 6 pigs in each of 3 deliveries), it is assigned a neutral risk. When the farm has 18 additional negative samples (collected from 2 pigs in each of 9 deliveries), it is assigned a low risk. When a farm has a single positive result or two intermediate results within 18 samples, it is placed in the high risk category. Only neutral and low risk farms are eligible to participate in visual inspection. Market hogs from high risk farms are subject to traditional inspection. In addition, animal health authorities assist the farms in identifying and reducing risk factors for *M. avium* infection.

**SENSITIVITY:** An operating characteristic of a diagnostic test that measures the ability of a test to detect a disease (or condition) when it is truly present. Sensitivity is the proportion of all diseased patients for whom there is a positive test, determined as the number of true positives divided by the sum of true positives + false negatives. (Contrast with specificity.)


**SPECIFICITY:** An operating characteristic of a diagnostic test that measures the ability of a test to exclude the presence of a disease (or condition) when it is truly not present. Specificity is the

proportion of nondiseased patients for whom there is a correctly negative test, expressed as the number of true negatives divided by the sum of true negatives + false positives. (Contrast with sensitivity.)

## **EQUIVALENCE DETERMINATION**

### **ALTERNATE POST-MORTEM INSPECTION PROCEDURE FOR MARKET HOGS**

The equivalence determination book was handed over to the Assistant Administrator, OIA, during the first week of December 2006 for concurrence on the decision. IES is still waiting for a decision from the Assistant and the book has not been returned to the IES staff.

  
M.. Ghias Mughal, DVM; Ph.D.  
Senior Equivalence Officer,  
IES, OIA  
11-1-07

U.S. Department of Agriculture  
Food Safety and Inspection Service  
Office on International Affairs  
Director, Ms. Sally White  
International Equivalence Staff  
1400 Independence Avenue, SW  
Room 2137, South Building  
Washington, DC 20250-3700  
UNITED STATES OF AMERICA



landbouw, natuur en  
voedselkwaliteit

Your letter of	your reference	our reference	date
April 23, 2007		VD 07.1265.IH	May 29, 2007
re:		extension no.	enclosures
Establishment (b) (4)	(b) (4)	+31 (b) (6)	

Dear Ms. White,

In reply to your letter of April 23, 2007, concerning the eligibility of pork, which has been subjected to visual post-mortem inspection, for export to the United States, I have taken due note of your decision that product, which has already been produced under those conditions in USA-approved establishments, and which is currently being stored pending the completion of the equivalency determination of the pertinent EU legislation, will not allowed to be exported to the United States.

Your letter of October 12, 2006, in particular your remarks on the suspension of exports of pork from U.S. certified establishments, which are producing with use of visual post-mortem inspection of swine carcasses, has also been considered.

As you know, as a result of this letter, those U.S. certified establishments, which are operating with visual post-mortem inspection, have voluntary suspended exports to the United States since then. Needless to say, I am looking forward to continued progress on the equivalence determination of visual post-mortem inspection, based on data from the production chain.

Ministry of Agriculture,  
Nature and Food Quality  
Department of Food  
Quality and Animal Health  
International Affairs  
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Date	Reference	Following page
May 29, 2007	VD 07.1265.IH	2

I have now received official confirmation from the Food and Consumer Product Safety Authority (VWA) in The Netherlands, that one of these establishments, i.e. est. (b) (4) (b) (4) has reversed its post-mortem inspection method effective May 21, 2007, and brought it back in compliance with the US-EC Veterinary Equivalency Agreement which currently still uses Directive 64/433 as its legal basis.

In view of this action, est. (b) (4) is now fully eligible for exports to the United States and certification of their product to the U.S. will be resumed shortly. I would very much appreciate receiving your confirmation of this information.

Sincerely,

THE CHIEF VETERINARY OFFICER,

(b) (6)

Cc: VWA: (b) (6), VWA: (b) (6), Agriculture Councillor in Washington (b) (6).  
(b) (6)

2007  
Certification

## FOREIGN OFFICIAL MEAT ESTABLISHMENT CERTIFICATE

I hereby certify that the establishments listed below fully comply with requirements of The Netherlands equivalent to all the inspection, building construction standards, and other requirements for the slaughter and preparation of the carcasses, parts thereof, meat and meat food products of cattle, sheep, swine, goats and equines applied to official establishments in the United States under the Federal Meat Inspection Act and otherwise meet the requirements of 327.2(a) of the regulations governing meat inspection of the U.S. Department of Agriculture.

ESTABLISHMENT #	NAME	ADDRESS	TYPE OF OPERATION
61	Vion Boxtel B.V.	Boseind 10 5281 RM Boxtel	Slaughterhouse & cutting plant/hogs
82	Vion Scherpenzeel B.V.	't Zwarte Land 13 3925 CK Scherpenzeel (Gld.)	Cutting plant/pork
124	Vion Beuningen B.V.	Zilverwerf 8 6641 TD Beuningen (Gld.)	Cutting plant/pork
129	Zwanenberg Food Group Almelo	Sluisweg 7 7602 PR Almelo	Processing plant/pork
153	Zwanenberg Food Group B.V.	Westdorplaan 225 8101 PN Raalte	Processing plant/pork
193	Vion Meppel B.V.	Galgenkampsweg 10A 7942 HD Meppel	Slaughterhouse/hogs
236	Vion Druten B.V.	Kerkstraat 40 6651 KG Druten	Slaughterhouse & cutting plant/hogs
312	Vion Apeldoorn B.V.	Laan van Malkenschoten 77 7333 NP Apeldoorn	Slaughterhouse & cutting plant/hogs
378	Vion Helmond B.V.	Graandijk 5 5704 RB Helmond	Slaughterhouse & cutting plant/hogs
404	Vion Doetinchem B.V.	Voltastraat 21 7006 RS Doetinchem	Cutting plant/pork
584	Lau van Haren Coldstores B.V.	Metaalweg 15 6551 AC Weurt	Cutting plant & cold storage/pork
589	Bussink Vrieshuis	Van Weerden Poelmanweg 5 7602 PC Almelo	Cutting plant & cold Storage/pork

slaughter Pro  
5 + 3  
8

Date : January 30, 2007

Signature:

(b) (6)

Official Title: Chief Veterinary Officer

[ 2 cold stores  
2 Processing Z. GP ]

**MINUTES OF REVIEW —  
INDIVIDUAL SANITARY MEASURE  
Denmark**

Daniel Oestmann and Priya Kadam  
David Smith and Kevin Gillespie

**EQUIVALENCE REQUEST:**

Denmark requested an equivalence determination for an alternative post-mortem inspection i.e. visual inspection instead of palpation and incision of lung and liver and their associated lymph nodes of slaughtered market hogs.

**BACKGROUND:**

On December 16, 2008 in an FSIS-Denmark bilateral meeting a team of FSIS experts met and reviewed Denmark's Supply Chain Inspection system, and presentations by Danish officials. The Supply Chain Inspection system allows inspection of market hogs raised under an integrated quality control program coupled with an on-site verification at slaughter establishments of visually inspected carcasses and organs to ensure that passed carcasses and parts are wholesome and not adulterated. As a part of this inspection system, on December 24, 2008, FSIS approved Denmark's use of an alternative post-mortem inspection procedure i.e. to omit the incision of mandibular lymph nodes for market hogs.

As a part of this Supply Chain Inspection system, in April 2010, Denmark proposed another alternate post mortem inspection procedure, i.e. visual inspection instead of palpation of mesenteric lymph nodes of slaughtered market hogs. After reviewing a risk assessment supporting this alternate procedure, FSIS approved it on February 29, 2012.

On September 13, 2013 Denmark proposed an additional alteration in the post-mortem inspection procedure i.e. visual inspection instead of palpation of lung and liver and their associated lymph nodes of slaughtered market hogs. The following evaluation is for this inspection procedure. Granting equivalence for this alternate post mortem inspection will result in visual inspection in the entirety of the finisher pigs from controlled housing to the slaughter house.

**FSIS FOOD SAFETY MEASURE:**

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

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

**OBJECTIVE OF THE FOOD SAFETY MEASURE:**

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

**EQUIVALENCE CRITERIA:**

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

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

**EQUIVALENCE EVALUATION:**

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

This criterion is met. As per Denmark's Supply Chain Inspection system, Denmark uses a combination of pre-slaughter data collection and post-mortem inspection to ensure the identification and removal of diseased carcasses and parts from the food supply. Pre-slaughter data must be presented to the slaughter establishment prior to slaughter of the



swine. The Official Veterinarian at the slaughter establishment will verify that this information is supplied to the slaughter establishment. Without this information, swine will not undergo slaughter. This system allows for full traceability of swine and provides the health information of all swine prior to slaughter. Ante-mortem inspection occurs in the same way as conducted by FSIS. The proposed alteration to post-mortem inspection is related to the visual inspection instead of palpation of the lung and liver and their associated lymph nodes of slaughtered market hogs. Denmark has conducted, and submitted to FSIS, a risk assessment<sup>1</sup> 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

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<sup>1</sup> 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.