SCIENTIFIC OPINION

Scientific Opinion on the public health hazards to be covered by inspection of meat (swine)[1]

EFSA Panel on Biological Hazards (BIOHAZ)[2, 3]

EFSA Panel on Contaminants in the Food Chain (CONTAM)[4, 5]

EFSA Panel on Animal Health and Welfare (AHAW)[6, 7]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

A qualitative risk assessment identified *Salmonella* spp., *Yersinia enterocolitica*, *Toxoplasma gondii* and *Trichinella* spp. as the most relevant biological hazards in the context of meat inspection of swine. A comprehensive pork carcass safety assurance is the only way to ensure their effective control. This requires setting targets to be achieved in/on chilled carcasses, which also informs what has to be achieved earlier in the food chain. Improved Food Chain Information (FCI) enables risk-differentiation of pig batches (hazard-related)

[1] On request from the European Commission. Question Nos. EFSA-Q-2010-00886, EFSA-Q-2010-01019 and EFSA-Q-2010-00930, adopted on 31 August 2011.

[2] BIOHAZ Panel members: Olivier Andreoletti, Herbert Budka, Sava Buncic, John D Collins, John Griffin, Tine Hald, Arie Havelaar, James Hope, Günter Klein, Kostas Koutsoumanis, James McLauchlin, Christine Müller-Graf, Christophe Nguyen-The, Birgit Noerrung, Luisa Peixe, Miguel Prieto Maradona, Antonia Ricci, John Sofos, John Threlfall, Ivar Vågsholm and Emmanuel Vanopdenbosch. Correspondence: biohaz@efsa.europa.eu

[3] Acknowledgement: The BIOHAZ Panel wishes to thank the members of the Working Group on the public health hazards to be covered by inspection of meat from swine: Sava Buncic, Birgit Noerrung, Marcelo De Las Heras, Gunter Klein, Truls Nesbakken, Katharina Staerk Spallek, Iva Steinhauserova and Frans van Knappen for the preparatory work on this scientific opinion and ECDC staff member Vicente Lopez and EFSA staff: Pablo Romero-Barrios and Ernesto Liebana for the support provided to this scientific opinion.

[4] CONTAM Panel members: Jan Alexander, Diane Benford, Alan Boobis, Sandra Ceccatelli, Bruce Cottrill, Jean-Pierre Cravedi, Alessandro Di Domenico, Daniel Doerge, Eugenia Dogliotti, Lutz Edler, Peter Farmer, Metka Filipič, Johanna Fink-Gremmels, Peter Fürst, Thierry Guérin, Helle Katrine Knutsen, Miroslav Machala, Antonio Mutti, Josef Schlatter, Martin Rose and Rolaf van Leeuwen. Correspondence: contam@efsa.europa.eu

[5] Acknowledgement: The CONTAM Panel wishes to thank the members of the Working Group on meat inspection and contaminants: Johanna Fink-Gremmels, Peter Fürst, Steve Mcorist and Michael O'Keeffe for the preparatory work on this scientific opinion and EFSA staff: Silvia I. Nicolau-Solano and Valeriu Curtui for the support provided to this scientific opinion.

[6] AHAW Panel members: Anette Bøtner, Donald Broom, Marcus G. Doherr, Mariano Domingo, Jörg Hartung, Linda Keeling, Frank Koenen, Simon More, David Morton, Pascal Oltenacu, Albert Osterhaus, Fulvio Salati, Mo Salman, Moez Sanaa, James M. Sharp, Jan A. Stegeman, Endre Szücs, Hans-H. Thulke, Philippe Vannier, John Webster and, Martin Wierup. Correspondence: ahaw@efsa.europa.eu

[7] Acknowledgement: The AHAW Panel wishes to thank the members of the AHAW Working Group on meat inspection: Simon More, Donald Broom, Marcus G. Doherr, Mariano Domingo, Frank Koenen, Pascal Oltenacu, Mo Salman, Moez Sanaa, Martin Wierup for the preparatory work on this scientific opinion and EFSA staff: Milen Georgiev and Ana Afonso for the support provided to this scientific opinion.

Suggested citation: EFSA Panels on Biological Hazards (BIOHAZ), on Contaminants in the Food Chain (CONTAM), and on Animal Health and Welfare (AHAW); Scientific Opinion on the public health hazards to be covered by inspection of meat (swine). EFSA Journal 2011;9(10):2351. [198 pp.] doi:10.2903/j.efsa.2011.2351. Available online: www.efsa.europa.eu/efsajournal

and abattoirs (process hygiene-related). Risk reduction measures at abattoir level are focused on prevention of microbial contamination through technology- and process hygiene-based measures (GMP/GHP- and HACCP-based), including omitting palpation/incision during *post-mortem* inspection in routine slaughter, as well as hazard reduction/inactivation meat treatments if necessary. At farm level, risk reduction measures are based on herd health programmes, closed breeding pyramids and GHP/GFP. Chemical substances listed in Council Directive 96/23/EC were ranked into four categories. Dioxins, dioxin-like polychlorinated biphenyls and chloramphenicol were ranked as being of high potential concern. However, chemical substances in pork are unlikely to pose an immediate or short term health risk for consumers. Opportunities for risk-based inspection strategies by means of differentiated sampling plans taking into account FCI were identified. Regular update of sampling programmes and inclusion of inspection criteria for the identification of illicit use of substances were also recommended. Meat inspection is a key component of the overall surveillance system for pig health and welfare but information is currently under-utilised. The changes proposed to the pig meat inspection system will lead to some reduction in the detection probability of diseases and welfare conditions. The difference is likely to be minimal for diseases/conditions that affect several organs. To mitigate the reduced detection probability, palpation and/or incision should be conducted as a follow-up to visual inspection whenever abnormalities are seen.

KEY WORDS

Meat inspection, swine, surveillance, safety, *ante-mortem, post-mortem*, contaminants, residues

SUMMARY

Following a request from the European Commission, the Panel on Biological Hazards (BIOHAZ) and the Panel on Contaminants in the Food Chain (CONTAM) were asked to deliver a Scientific Opinion on the public health hazards (biological and chemical respectively) to be covered by inspection of meat for several animal species. This Opinion is the first of the series and deals with swine. Briefly, the Panels were asked to identify and rank the main risks for public health that should be addressed by meat inspection, to assess the strengths and weaknesses of the current meat inspection methodology, to recommend inspection methods fit for the purpose of meeting the overall objectives of meat inspection for hazards currently not covered by the meat inspection system and to recommend adaptations of inspection methods and/or frequencies of inspections that provide an equivalent level of protection. In addition, the Panel on Animal Health and Welfare (AHAW) was asked to consider the implications for animal health and animal welfare of any changes suggested in the light of public health risks to current inspection methods.

In order to fulfill its mandate, EFSA's Panels made the following key conclusions and recommendations:

On biological hazards, a qualitative risk assessment of foodborne hazards was conducted using data on prevalence in/on chilled carcases, incidence and severity of disease in humans, and source attribution of hazards to pork, with the chilled carcasses as the target. Based on this assessment, *Salmonella* spp. were considered of high relevance and *Yersinia enterocolitica*, *Toxoplasma gondii* and *Trichinella* spp. as of medium relevance presently in the EU, and were specifically addressed. The risk reduction measures indicated for *Salmonella* spp. and *Y. enterocolitica* would also be beneficial for controlling a number of other microbial hazards.

Also in the area of biological hazards, food safety-related strengths identified were that *ante-mortem* inspection enables using Food Chain Information (FCI), the detection of clinically observable zoonotic diseases, animal identification enabling traceability, and evaluation of visual cleanliness of animals. Also, *post-mortem* inspection enables detection of macroscopic abnormalities caused by some zoonotic agents, visual contamination, as well as of *Trichinella* spp. by laboratory examination.

The following food safety-related weaknesses were also identified: practical difficulties to clinically examine animals individually *ante-mortem* and that current use of FCI does not include all indicators to classify the pigs in relation to public health risk. In addition, current *ante-* or *post-mortem* inspection does not enable detection of the bacterial and parasitic foodborne hazards of most relevance as identified above; and microbial agents associated with common pathological conditions detected *post-mortem* are caused by non-zoonotic or zoonotic hazards which pose an occupational rather than foodborne risk. Also, using palpation/incision techniques during *post-mortem* inspection mediates bacterial cross-contamination. The Panel considered that the current judgement of the fitness of meat for human consumption does not differentiate food safety aspects from meat quality aspects, control of animal diseases or occupational hazards.

With respect to inspection methods for biological hazards, it was concluded that a comprehensive pork carcass safety assurance, with a range of preventive measures and controls applied both on-farm and at-abattoir in an integrated way is the only way to ensure an effective control of the main hazards. This would require setting targets with respect to the main hazards to be achieved for chilled carcasses, which would then inform what has to be achieved at earlier steps in the food chain. At the abattoir, the goal would be risk reduction for the main hazards through programmes based on Good Manufacturing Practices (GMP)/Good Hygienic Practices (GHP) and Hazard Analysis and Critical Control Points (HACCP), including: hygienic practice- and technology-based measures to avoid cross-contamination; additional interventions if necessary such as surface decontamination of carcasses (for bacterial hazards); and/or heat/freezing treatments (for parasitic hazards) as an

alternative to related laboratory testing; and use of FCI to differentiate incoming pig batches with respect to the risk they pose in respect to the main hazards and to differentiate abattoirs according to risk-reduction capacity (based on process hygiene). At farm level, the goal is risk reduction for the main hazards, which can be achieved through measures such as herd health programmes and closed breeding pyramids, GHP and GFP.

Finally, it was considered that palpation/incisions used in current *post-mortem* inspection should be omitted in pigs subjected to routine slaughter, because of the risk of microbial cross-contamination. These techniques should be limited to suspect pigs identified through FCI/*ante-mortem* inspection and/or *post-mortem* visual detection of relevant abnormalities and where it would lead to risk reduction. In such situations, palpation/incision should be performed separately from the slaughterline and accompanied by laboratory testing as required. The elimination of abnormalities on aesthetic/meat quality grounds can be ensured through a meat quality assurance system.

A series of recommendations were made regarding biological hazards on data collection, future evaluations of the meat inspection system and hazard identification/ranking, training of all parties involved in the pork carcass safety assurance system, and needs for research on testing methodologies, validation of carcass treatments and methods to assess abattoir process hygiene.

On chemical hazards, the current meat inspection methodology related to the occurrence of chemical compounds in pigs was assessed. Such compounds can result from the exposure of pigs to contaminants in feed materials as well as following the application of authorized and possibly non-authorized drugs. It was concluded that chemical substances are unlikely to pose an immediate or short term health risk for consumers. In the current meat inspection procedures, these contaminants and chemical residues are not specifically addressed. The only measure taken at the abattoir is the sampling of tissue specimens according to the National Residue Control Plans (NRCP) as defined in Council Directive 96/23/EC.

Considering the outcome of the NRCP for the period 2005-2009, as well as substance specific parameters such as the toxicological profile and the likelihood of the occurrence of residues in pig meat, a ranking of substances is presented. This ranking comprises four categories, denoted as high, medium, low and negligible potential concern. Dioxins, dioxin-like polychlorinated biphenyls (DL-PCBs) and the banned antibiotic chloramphenicol were ranked as being of high potential concern. Ranking should be updated regularly when new data become available.

Opportunities were identified to develop strategies for risk-based inspection of chemical hazards by means of differentiated sampling plans taking into account FCI data. It was also suggested to include competent *ante-* and *post-mortem* inspection criteria for the identification of illicit use of substances and to encourage analyses at the farm level. It was noted, however, that all measures taken to improve the efficacy of meat inspection protocols need to address the compliance of imports from Third Countries into the EU with these strategies.

In this mandate, the implications for animal health and welfare and surveillance of changes to the current meat inspection system proposed were also evaluated. These changes included a shortened duration of transport and lairage, removal of palpation and incision from post-mortem inspection, and the introduction of risk categorisation. In broad terms, surveillance for animal health and welfare is conducted for early detection, case-finding and estimating prevalence, and measurements of surveillance quality vary according to surveillance purpose. Two methodologies (qualitative and quantitative) were used to assess the quality of both the current and proposed modified meat inspection systems. The former relied on expert opinion and a review of the literature, and the latter used a three stage epidemiological modelling approach. During current systems of meat inspection, the probability of detection is often low, particularly for non-typical cases. There will be some reduction in detection probability with a shift from the current to the proposed modified system of pig

meat inspection. The magnitude of this difference will vary, depending on the disease/condition. For typical cases of diseases/conditions that generally affect several organs, the difference is likely to be minimal. To mitigate the reduced disease/condition detection probability of the proposed modified system, palpation and/or incision should be conducted as a follow-up to visual inspection whenever abnormalities are seen. Meat inspection, both ante- and post-mortem, was highlighted as a key component of the overall surveillance system for pig health and welfare. There have been several occasions within the EU where outbreaks of epidemic diseases have first been detected during meat inspection. It was also noted that pig health and welfare surveillance information is currently greatly under-utilised. Several recommendations were made.

TABLE OF CONTENTS

BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Regulation (EC) No 854/2004 of the European Parliament and of the Council lays down specific rules for the organisation of official controls on products of animal origin intended for human consumption.[8] Inspection tasks within this Regulation include:

- Checks and analysis of food chain information
- *Ante-mortem* inspection
- Animal welfare
- *Post-mortem* inspection
- Specified risk material and other by-products
- Laboratory testing

The scope of the inspection includes monitoring of zoonotic infections and the detection or confirmation of certain animal diseases without necessarily having consequences for the placing on the market of meat. The purpose of the inspection is to assess if the meat is fit for human consumption in general and to address a number of specific hazards: in particular the following issues: transmissible spongiform encephalopathies (only ruminants), cysticercosis, trichinosis, glanders (only solipeds), tuberculosis, brucellosis, contaminants (e.g. heavy metals), residues of veterinary drugs and unauthorised substances or products.

During their meeting on 6 November 2008, Chief Veterinary Officers (CVO) of the Member States agreed on conclusions on modernisation of sanitary inspection in slaughterhouses based on the recommendations issued during a seminar organised by the French Presidency from 7 to 11 July 2008. The CVO conclusions have been considered in the Commission Report on the experience gained from the application of the Hygiene Regulations, adopted on 28 July 2009. Council Conclusions on the Commission report were adopted on 20 November 2009 inviting the Commission to prepare concrete proposals allowing the effective implementation of modernised sanitary inspection in slaughterhouses while making full use of the principle of the 'risk-based approach'.

In accordance with Article 20 of Regulation (EC) No 854/2004, the Commission shall consult EFSA on certain matters falling within the scope of the Regulation whenever necessary.

EFSA and the Commission's former Scientific Committee on Veterinary Measures relating to Public Health have issued in the past a number of opinions on meat inspection considering specific hazards or production systems separately. In order to guarantee a more risk-based approach, an assessment of the risk caused by specific hazards is needed, taking into account the evolving epidemiological situation in Member States. In addition, methodologies may need to be reviewed taking into account risks of possible cross-contamination, trends in slaughter techniques and possible new inspection methods.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The scope of this mandate is to evaluate meat inspection in order to assess the fitness of the meat for human consumption and to monitor food-borne zoonotic infections (public health) without jeopardizing the detection of certain animal diseases nor the verification of compliance with rules on animal welfare at slaughter. If and when the current methodology for this purpose would be considered not to be the most satisfactory to monitor major hazards for public health, additional

[8] OJ L 226, 25.6.2004, p. 83.

methods should be recommended as explained in detail under points 2 and 4 of the terms of reference. The objectives of the current legal provisions aimed at carrying out meat inspection on a risk-based analysis should be maintained.

In order to ensure a risk-based approach, EFSA is requested to provide scientific opinions on meat inspection in slaughterhouses and, if considered appropriate, at any other stages of the production chain, taking into account implications for animal health and animal welfare in its risk analysis. In addition, relevant international guidance should be considered, such as the Codex Code of Hygienic Practice for Meat (CAC/RCP 58-2005), and Chapter 6.2 on Control of biological hazards of animal health and public health importance through *ante-* and *post-mortem* meat inspection, as well as Chapter 7.5 on slaughter of animals of the Terrestrial Animal Health Code of the World Organization for Animal Health (OIE).

The following species or groups of species should be considered, taking into account the following order of priority identified in consultation with the Member States: domestic swine, poultry, bovine animals over six weeks old, bovine animals under six weeks old, domestic sheep and goats, farmed game and domestic solipeds.

In particular, EFSA, in consultation with the European Centre for Disease Prevention and Control (ECDC), is requested within the scope described above to:

1. Identify and rank the main risks for public health that should be addressed by meat inspection at EU level. General (e.g. sepsis, abscesses) and specific biological risks as well as chemical risks (e.g. residues of veterinary drugs and contaminants) should be considered. Differentiation may be made according to production systems and age of animals (e.g. breeding compared to fattening animals).

2. Assess the strengths and weaknesses of the current meat inspection methodology and recommend possible alternative methods (at *ante-mortem* or *post-mortem* inspection, or validated laboratory testing within the frame of traditional meat inspection or elsewhere in the production chain) at EU level, providing an equivalent achievement of overall objectives; the implications for animal health and animal welfare of any changes suggested in the light of public health risks to current inspection methods should be considered.

3. If new hazards currently not covered by the meat inspection system (e.g. *Salmonella*, *Campylobacter*) are identified under terms of reference (TOR) 1, then recommend inspection methods fit for the purpose of meeting the overall objectives of meat inspection. When appropriate, food chain information should be taken into account.

4. Recommend adaptations of inspection methods and/or frequencies of inspections that provide an equivalent level of protection within the scope of meat inspection or elsewhere in the production chain that may be used by risk managers in case they consider the current methods disproportionate to the risk, e.g. based on the ranking as an outcome of terms of reference 1 or on data obtained using harmonised epidemiological criteria (see annex 2[9]). When appropriate, food chain information should be taken into account.

[9] Annex 2 of the original European Commission mandate.

APPROACH TAKEN TO ANSWER THE TERMS OF REFERENCE

1. Scope

The scope of the mandate is to evaluate meat inspection in a Public Health context; animal health and welfare issues will be covered in respect to the possible implications of adaptations/alterations to current inspection methods, or the introduction of novel inspection methods proposed by this mandate.

Issues other than those of public health significance but that still compromise fitness of the meat for human consumption (Regulation (EC) No 854/2004, [10] Annex I, Section II, Chapter V) are outside the scope of the mandate. Examples of these include sexual odour ('boar taint'). TSEs are also outside the scope of the mandate.

The impact of changes to meat inspection procedures on occupational health of abattoir workers, inspectors, etc is outside the scope of the mandate. Additionally, biological hazards representing primarily occupational health risk, the controls related to any biological hazards at any meat chain stage beyond abattoir, and the implications for environmental protection, are not dealt with in this document.

2. Approach

In line with Article 20 of Regulation (EC) No 854/2004[10] the European Commission has recently submitted a mandate to EFSA (M-2010-0232) to cover different aspects of meat inspection. The mandate comprises two requests: one for Scientific Opinions and one for Technical Assistance.

EFSA is requested to issue scientific opinions related to inspection of meat in different species. In addition, technical assistance have also been requested on harmonised epidemiological criteria for specific hazards for public health that can be used by risk managers to consider adaptation of meat inspection methodology.

Meat inspection is defined by Regulation 854/2004[10]. The species or groups of species to be considered are: domestic swine, poultry, bovine animals over six weeks old, bovine animals under six weeks old, domestic sheep and goats, farmed game and domestic solipeds.

Taking into account the complexity of the subject and that consideration has to be given to zoonotic hazards, animal health and welfare issues, and to chemical hazards (e.g. residues of veterinary drugs and chemical contaminants), the involvement of several EFSA Units was necessary. More specifically, the mandate was allocated to the Biological Hazards (BIOHAZ), Animal Health and Welfare (AHAW) and Contaminants in the Food Chain (CONTAM) Panels, and to the Biological Monitoring (BIOMO), Scientific Assessment Support (SAS), and Dietary & Chemical Monitoring (DCM) Units of the Risk Assessment & Scientific Assistance Directorate for the delivery of the Scientific Opinion, and of the Technical Assistance, respectively.

This Scientific Opinion therefore concerns the assessment of meat inspection in swine, and it includes the answer to the terms of reference proposed by the European Commission. Due to the complexity of the mandate, the presentation of the outcome does not follow the usual layout. For ease of reading, main outputs from the three Scientific Panels (BIOHAZ, CONTAM and AHAW) are presented at the beginning of the document. The scientific justifications of these outputs are found in the various

[10] Regulation (EC) No. 854/2004 of the European Parliament and of the Council of 30 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption. OJ L 139, 30.4.2004, p. 206. Corrigendum, OJ L 226, 25.6.2004, p. 83-127.

Appendices as adopted by their respective Panels, namely biological hazards (Appendix A), chemical hazards (Appendix B), and the potential impact that the proposed changes envisaged by these two could have on animal health and welfare (Appendix C).

CONCLUSIONS AND RECOMMENDATIONS ANSWERING THE TERMS OF REFERENCE

CONCLUSIONS

1. **TOR 1.** ***To identify and rank the main risks for public health that should be addressed by meat inspection at EU level. General (e.g. sepsis, abscesses) and specific biological risks as well as chemical risks (e.g. residues of veterinary drugs and contaminants) should be considered. Differentiation may be made according to production systems and age of animals (e.g. breeding compared to fattening animals).***

Conclusions BIOHAZ Panel

- Identification and ranking of foodborne hazards, based on their prevalence in/on chilled carcases, incidence and severity of disease in humans, and source attribution of hazards to pork, in the context of meat inspection was considered with the chilled carcasses as the target. Many data for ranking of hazards were insufficient, and expert judgement was used instead.

- Based on a qualitative risk assessment, *Salmonella* spp. are considered of high relevance and *Yersinia enterocolitica*, *Toxoplasma gondii* and *Trichinella* spp. as of medium relevance. Other hazards were considered of low relevance.

- The risk reduction measures indicated in this document specifically for *Salmonella* spp. and *Y. enterocolitica* would also be applicable to, and beneficial for control of, a number of other microbial hazards currently classified as of low relevance.

Conclusions CONTAM Panel

- Chemical residues and contaminants in slaughter animals are unlikely to pose an immediate or short term health risk for consumers. However, certain bioaccumulating contaminants are of potential concern because they will contribute to the overall exposure. In addition, the presence of chemical residues of certain pharmacologically active substances may be of potential concern as they are indicative either of non-compliance with existing regulations or of illicit use of non-authorized substances, with implications for risk management.

- As a first step in the identification and ranking of chemical substances of potential concern, the CONTAM Panel considered all substances listed in Council Directive 96/23/EC[11] and evaluated the outcome of the residue monitoring plans for the period 2005-2009. The available aggregated data indicate the numbers of samples that were non-compliant with the current legislation. However, in the absence of substance-specific information, such as the tissues used for residue analysis and the actual concentration of a residue or contaminant measured, these data do not allow a reliable assessment of consumer exposure.

- Other criteria used for the identification and ranking of chemical substances of potential concern included the identification of substances that bio-accumulate in the food chain, substances with a specific toxicological profile, and the likelihood that a substance under

[11] Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 84/469/EEC and Decisions 89/187/EEC and 91/664/EEC, OJ L 125, 23.5.1996, p. 10-32.

consideration will occur in pig carcasses. Taking into account these criteria the individual contaminants were ranked into four categories denoted as high, medium, low, and negligible potential concern.

- Dioxins and dioxin-like polychlorinated biphenyls (DL-PCBs) were ranked as being of high potential concern due to their known bioaccumulation in the food chain, the risk of exceedance of maximum levels, and in consideration of their toxicological profile.

- Chloramphenicol was ranked as being of high potential concern, as residues in pig carcasses have been found in the course of the residue control programmes in various Member States (MSs), although this antibiotic is not licensed for use in food producing animals in the European Union (EU).

- Non-dioxin-like polychlorinated biphenyls (NDL-PCBs) and polybrominated diphenyl ethers (PBDEs) also bioaccumulate, but were ranked in the category of medium potential concern, because they are less toxic than dioxins and DL-PCBs.

- The chemical elements cadmium, lead and mercury were allocated to the medium potential concern category, taking into account that the aggregated data from the national residue control programmes indicate non-compliance with current maximum limits in more than 1 % of samples analysed.

- The mycotoxin ochratoxin A was allocated to the medium potential concern category due to its slow elimination in pigs and its potential to accumulate in edible tissues.

- Nitrofurans and nitroimidazoles were ranked as being of medium potential concern. These two classes of antimicrobials are prohibited for use in food producing animals. However, results from the national residue control programmes indicated the occasional presence of non-compliant samples from pigs and hence it can be assumed that these compounds are infrequently used in slaughter pigs.

- Residues originating from other substances listed in Council Directive 96/23/EC[11] were ranked in the low or negligible potential concern category due to the low toxicological profile of residues of these compounds. These two categories include, among others, organochlorines, organophosphates, perfluorinated compounds, natural plant toxins, mycotoxins (others than ochratoxin A), as well as residues of veterinary medicinal products, and prohibited substances such as thyreostats, stilbenes, steroids, resorcylic acid lactones, and *beta*-agonists.

- The CONTAM Panel emphasised that this ranking into specific categories of potential concern is based on the current knowledge regarding the toxicological profiles, usage in pig husbandry and likelihood of occurrence of residues in edible tissues of pigs.

- Differentiation in sampling plans can be made according to the current production systems and the age of animals. Pigs reared for fattening are slaughtered at a young age and generally originate from farms with operational HACCP-based protocols and with full Food Chain Information (FCI) data. This homogeneous animal population has a low-risk profile regarding exposure to contaminants and tissue residues. In contrast, non-specialised farms produce animals of different age groups and with different reasons for slaughter. These animals are generally not accompanied by complete FCI data. Therefore, this group has a higher-risk profile for exposure to contaminants and for tissue residues

2. TOR 2. ***To assess the strengths and weaknesses of the current meat inspection methodology and recommend possible alternative methods (at* ante-mortem *or* post-mortem *inspection, or validated laboratory testing within the frame of traditional meat inspection or elsewhere in the production chain) at EU level, providing an equivalent achievement of overall objectives; the implications for animal health and animal welfare of any changes suggested in the light of public health risks to current inspection methods should be considered.***

Conclusions BIOHAZ Panel

The main elements of the current pig meat inspection are *ante-mortem* examination of animals including food chain information (FCI) analysis, and *post-mortem* examination of carcasses and organs. The strengths and weaknesses of the current meat inspection were assessed only in relation to food safety.

Strengths

- *Ante-mortem* inspection enables utilising FCI (presently only to a limited extent), the detection of clinically observable zoonotic diseases, animal identification enabling traceability and evaluation of visual cleanliness of animals.

- *Post-mortem* inspection enables detection of macroscopic lesions caused by some zoonotic agents e.g. mycobacteria, *Taenia solium*, *Brucella* spp. and *Erysipelothrix rhusiopathiae*, as well as to detect *Trichinella* spp. by laboratory examination. These hazards are currently rare and some of them pose an occupational rather than foodborne risk. Also, *post-mortem* inspection detects visual faecal contamination.

Weaknesses

- At *ante-mortem* inspection, the high number of pigs arriving for slaughter does not allow for proper clinical examination of individual animals. Currently FCI does not include all indicators to classify the pigs in relation to public health risk.

- Current *ante-* or *post-mortem* inspection cannot macroscopically detect the bacterial and parasitic foodborne hazards of most relevance as identified above.

- Manual handling of meat including use of palpation/incision techniques during *post-mortem* inspection mediates cross-contamination with bacterial hazards.

- Microbial agents associated with common pathological conditions detected at *post-mortem* pig inspection (e.g. pneumonia, abscesses) are caused by non-zoonotic and/or zoonotic hazards, and the latter pose an occupational rather than foodborne risk.

- Judgement of the fitness of meat for human consumption in current *post-mortem* inspection does not differentiate food safety aspects related to the spread of zoonotic agents through the food chain from meat quality aspects, prevention of animal diseases and occupational hazards.

Conclusions CONTAM Panel

Strengths

- The current meat inspection system facilitates tissue sampling for the analysis of residues of contaminants, veterinary medicinal products and non-authorized substances as listed in Council Directive 96/23/EC.[11]

- The current procedures of sampling and testing are well-established and involve a regular evaluation of analytical procedures in all EU Member States addressing the performance of analytical methods (Commission Decision 2002/657/EC[12]), laboratory accreditation (ISO/IEC 17025) and quality assurance schemes (QAS).

- There are well-developed systems and follow-up mechanisms following identification of non-compliant samples. Follow-up on non-compliant samples is typically through intensified sampling (suspect sampling), withholding of carcasses or pigs with the same history for slaughter, subject to positive clearance as compliant, and on-farm investigations potentially leading to intervention, penalties and/or prosecutions.

- The prescribed regular sampling and testing for chemical residues is a proven disincentive for the development of bad practices.

- The prescriptive sampling system of the current methodology allows for equivalence between EU domestic pork and Third Country imports.

Weaknesses

- The presence of residues and contaminants cannot be determined by the current *ante- and post-mortem* meat inspection procedures at the abattoir and hence no immediate measures can be taken.

- According to Council Directive 96/23/EC,[11] sampling of tissue specimens for the analysis of residues or contaminants is prescriptive in terms of the number of samples that need to be taken. Hence, testing is not entirely based on actual feed chain information or on species-specific information about the likelihood of animal exposure. Therefore, animals that would be considered at risk of being residue-positive when based on FCI data might not be included in the current sampling and testing plans.

- There is limited flexibility to amend sampling plans and to include emerging substances or actual findings from feed monitoring or other actual food chain information into the national sampling and testing programmes.

Conclusions AHAW Panel

Meat inspection

- Meat inspection, both ante- and *post-mortem*, is a key component of the overall surveillance system for pig health and welfare.

- There have been several occasions within the EU where outbreaks of epidemic diseases have first been detected during meat inspection.

[12] Commission Decision of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results (2002/657/EC), OJ L 221, 17.8.2002, p. 8-36.

- Pig health and welfare surveillance information is currently being greatly underutilised.
- The sensitivity of detection of welfare conditions for the purposes of case-finding will generally be higher during abattoir surveillance in comparison to passive farmer reporting.
- The use of welfare-outcome indicators at the slaughterhouse is valuable for monitoring welfare on-farm and during transport and pre-slaughter handling.

On the proposed modifications (as per terms of references 3 and 4)

- By definition, the proposed modified (visual only) inspection will not detect conditions where palpation and/or incision are required for detection.
- There will be some reduction in detection probability with a shift from the current to the proposed modified (visual only) systems of pig meat inspection. The magnitude of this difference will vary, depending on the disease/condition:
  - For typical cases of diseases/conditions that generally affect several organs, the difference is likely to be minimal.
  - For early cases of a range of diseases, the difference may be substantial.
  - For conditions (such as *Taenia solium* cysticercosis or early cases of tuberculosis) where pathology is limited to one or a small number of organs with detection reliant on palpation and/or incision, there will be either a substantially reduced probability of detection or the disease will not be detected at all .
- Transport-related welfare cases would not be detected if abattoir-based *ante-mortem* inspection were removed.
- To mitigate the reduced disease/condition detection probability of the proposed modified (visual only) system, it is emphasised that palpation and/or incision should be conducted as a follow-up to visual inspection whenever relevant abnormalities are seen.
- A shortening of transport and lairage would improve pig welfare, without adversely affecting pig health, based on the assumption that transport quality is equivalent.

<u>Current and proposed meat inspection</u>

- The sensitivity of both the current and the proposed modified component of the surveillance systems is low.
- The role of meat inspection for early detection of epidemic diseases of pigs is well-recognised. Its potential role in surveillance of welfare and endemic disease of pigs (with case-finding and estimating prevalence) is equally important.
- Risk categorisation, based on increased usage of food chain information on pig health and welfare, may provide opportunities for improved surveillance and monitoring. However, risk categorisation may result in surveillance being conducted on biased samples that are not representative of the entire population with respect to animal health and welfare.
- Categorisation based on food-borne human health risks will likely have medium positive impact on pig health and welfare surveillance. This would be less beneficial if journey times from the farm to the abattoir were increased.

3. TOR 3. *If new hazards currently not covered by the meat inspection system (e.g.* Salmonella, Campylobacter*) are identified under TOR 1, then recommend inspection methods fit for the purpose of meeting the overall objectives of meat inspection. When appropriate, food chain information should be taken into account.*

Conclusions BIOHAZ Panel

- A comprehensive pork carcass safety assurance, combining a range of preventative measures and controls applied both on-farm and at-abattoir in a longitudinally integrated way is the only way to ensure effective control of the main hazards (*Salmonella* spp., *Yersinia enterocolitica*, *Toxoplasma gondii* and *Trichinella* spp.) in the context of meat inspection.

- A prerequisite for effective pork carcass safety assurance system is setting measurable targets in respect to the main hazards to be achieved in/on final, chilled carcasses. These would also inform what has to be achieved at earlier steps in the food chain and would focus related control measures.

- At abattoir level, the primary goal is the risk reduction for the main hazards that can be achieved through integrated programs based on GMP/GHP and HACCP, including:
  - hygienic practice- and technology-based measures aimed at avoiding direct and indirect cross-contamination with *Salmonella* spp. and *Yersinia enterocolitica*;
  - additional interventions such as surface decontamination of carcasses if considered necessary;
  - heat- or freezing-based treatments of carcass meat to inactivate intramuscular parasites *Toxoplasma gondii* and *Trichinella* spp. if considered necessary and as alternative to related laboratory testing of carcasses;
  - FCI should be used to differentiate incoming pig batches in respect to the *Salmonella* spp., *Yersinia enterocolitica*, *Toxoplasma gondii* and *Trichinella* spp. risks (based on herd status *via* sampling at farms or abattoirs), and differentiate risk-reduction capacity of abattoirs (process hygiene).

- At farm level, the primary goal is the risk reduction for the main hazards, which can be achieved through preventive measures such as herd health programs and closed breeding pyramids, GHP and GFP and finally categorisation of animals based on the carrier state of these agents.

Conclusions CONTAM Panel

- Polychlorinated substances such as dioxins and DL-PCBs have been ranked as being of high potential concern. They are not yet included in the Council Directive 96/23/EC. Therefore, these compounds have to be considered as 'new' hazards.

- A number of other contaminants also bioaccumulate in the food chain. However, current knowledge on their prevalence and their actual levels in edible tissues of slaughter pigs is limited. In spite of their likelihood of being of medium or low concern, they should be monitored. This is the particular case of (i) non dioxin-like polychlorinated biphenyls (NDL-PCBs), (ii) brominated flame retardants, including polybrominated diphenyl ethers (PBDEs) as well as hexabromo-cyclododecane (HBCDD) and, (iii) perfluorinated compounds (PFC) such as perfluorooctanesulfonic acid (PFOS) and perfluorooctanoic acid (PFOA).

4. TOR 4. ***To recommend adaptations of inspection methods and/or frequencies of inspections that provide an equivalent level of protection within the scope of meat inspection or elsewhere in the production chain that may be used by risk managers in case they consider the current methods disproportionate to the risk, e.g. based on the ranking as an outcome of terms of reference 1 or on data obtained using harmonised epidemiological criteria. When appropriate, food chain information should be taken into account.***

Conclusions BIOHAZ Panel

- Palpation/incisions used in current *post-mortem* inspection should be omitted in pigs subjected to routine slaughter, because the risk of microbial cross-contamination is higher than the risk associated with potentially reduced detection of conditions targeted by these techniques.

- The use of these manual techniques during *post-mortem* examination should be limited to suspect pigs identified through FCI/*ante-mortem* inspection or *post-mortem* visual detection of relevant abnormalities where it would lead to risk reduction.

- *Post-mortem* examination involving palpation and incision, where necessary, should be performed separately from the slaughterline operation and accompanied with laboratory testing as required.

- Elimination of abnormalities on aesthetic/meat quality grounds can be ensured through meat quality assurance systems.

Conclusions CONTAM Panel

- Considering that pig farming in the EU is diverse, it is suggested to develop tailored sampling plans taking into account these differences. National residue control plans have the potential to distinguish between farms producing only pigs for fattening under conditions of fully implemented HACCP-based protocols providing professional and reliable FCI, from those other farms that have a mixed pig population without HACCP-based quality control protocols.

- In line with the development of tailored sampling plans, all information from national quality controls of feedstuffs should be integrated into the residue control plans. Moreover, animal species (i.e. pig-specific) information that is not considered in current sampling strategies and testing procedures deserves more consideration.

- The currently limited flexibility to amend sampling plans hinders the inclusion of emerging substances in national sampling plans. The possibility for *ad hoc* amendments should be incorporated in forthcoming sampling strategies.

- Any amendments in the EU meat inspection procedures need to include provisions for the control of imports from Third countries.

RECOMMENDATIONS

1. **TOR 1.** ***To identify and rank the main risks for public health that should be addressed by meat inspection at EU level. General (e.g. sepsis, abscesses) and specific biological risks as well as chemical risks (e.g. residues of veterinary drugs and contaminants) should be considered. Differentiation may be made according to production systems and age of animals (e.g. breeding compared to fattening animals).***

Recommendations BIOHAZ Panel

- Because the hazard identification and ranking relates to the EU as a whole at the time of preparation of this document, refinements reflecting differences between regions or production systems are recommended if/where hazard monitoring data indicate.
- Furthermore, as new hazard(s) might emerge and/or hazards that presently are not a priority might become more relevant over time or in some regions, the risk ranking is to be revisited regularly.
- To provide a better evidence base for future rankings, studies should be carried out to:
  - systematically collect data for source attribution;
  - collect data to identify and rank emerging pork-borne hazards

Recommendations CONTAM Panel

- Regular updates of sampling plans should take into account any new information regarding the toxicological profile of residues and contaminants, usage in pig production, and actual occurrence of individual substances in pigs.
- Any amendments in the EU meat inspection procedures need to include provisions for the control of imports from Third countries.

2. **TOR 2.** ***To assess the strengths and weaknesses of the current meat inspection methodology and recommend possible alternative methods (at* ante-mortem *or* post-mortem *inspection, or validated laboratory testing within the frame of traditional meat inspection or elsewhere in the production chain) at EU level, providing an equivalent achievement of overall objectives; the implications for animal health and animal welfare of any changes suggested in the light of public health risks to current inspection methods should be considered.***

Recommendations CONTAM Panel

- Considering that a major weakness of the current sampling protocol is its prescriptive nature and the lack of flexibility towards emerging contaminants in the food chain, improvement of flexibility and differentiation of sampling plans according to the animal history, species-specific and food chain information data, particularly the results from quality programmes for feedstuffs are recommended.
- Considering that the current procedure of data aggregation at the Community level does not allow any reliable exposure assessment linked to the occurrence of non-compliant samples, it is

recommended that a database collecting the results from the individual national residue monitoring programmes is established at the Community level.

- Considering that certain non-authorized substances exert specific patho-physiological alterations in the animal, forthcoming meat inspection protocols should include appropriate ante-/post-mortem inspection criteria indicative of the illicit use of non-authorized substances.

Recommendations AHAW Panel

- There should be an assessment of the relative contribution of meat inspection to the overall system of surveillance and monitoring of pig health and welfare.
- There should be a critical evaluation of the efficiency and utility of risk-based approaches to meat inspection of pigs, using risk categorisation from the perspective of pig health and welfare.
- There should be development and application of standards (including indicators of welfare outcomes and major endemic diseases) to enable ongoing evaluation of the quality of pig health and welfare surveillance during meat inspection.
- Options should be examined to better utilise existing abattoir data and records on pig health and welfare.

3. **TOR 3.** ***If new hazards currently not covered by the meat inspection system (e.g.* Salmonella, Campylobacter*) are identified under TOR 1, then recommend inspection methods fit for the purpose of meeting the overall objectives of meat inspection. When appropriate, food chain information should be taken into account.***

Recommendations BIOHAZ Panel

- Systematic FCI data collection and analysis for the main hazards at herd and abattoir levels, as well as other (re-)emerging agents at EU or regional levels is a prerequisite for the proposed pork carcass safety assurance system, and it is therefore recommended. Research on the optimal ways of using the collected FCI data for risk categorisation and differentiated slaughter of pigs, as well as on the following benefit for public health is required.
- Further research on development of the hazard testing that could be used within the proposed pork carcass safety assurance system is recommended.
- The development of systematic methodologies for assessing abattoir process hygiene and related differentiation of abattoirs is recommended.
- The efficacy of various carcass treatments to be used for elimination/inactivation of the main hazards need to be validated.

Recommendations CONTAM Panel

- Control programmes for residues and contaminants should consider all substances ranked in the categories of substances of high and medium concern. Regular updates of these categories are recommended as the profile of residues and contaminants in pig carcasses can change.

4. **TOR 4.** ***To recommend adaptations of inspection methods and/or frequencies of inspections that provide an equivalent level of protection within the scope of meat inspection or elsewhere in the production chain that may be used by risk managers in case they consider the current methods disproportionate to the risk, e.g. based on the ranking as an outcome of terms of reference 1 or on data obtained using harmonised epidemiological criteria. When appropriate, food chain information should be taken into account.***

Recommendations BIOHAZ Panel

- The overall public health impact of the modified pig meat inspection system, as compared to the current status, should be evaluated regularly after its implementation in practice.

Recommendations CONTAM Panel

- Information-based sampling strategies for the control of residues and contaminants taking into account the origin of slaughtered pigs and the available FCI should be implemented. This includes differentiated sampling plans for pigs reared for fattening on specialised farms and pigs from other farms slaughtered for different reasons.
- For pigs raised for fattening on farms with operational HACCP-based protocols and with full FCI data, a tailored sampling plan directed primarily to the emerging contaminants in the food chain and/or to other substances not covered by FCI data should be implemented, taking into account also the farm size (i.e. sampling of a defined percentage of animals from the same farm rather than a given percentage of all slaughter pigs).
- For pigs raised on farms without an operational quality control system, prescriptive sampling remains recommended, but should also incorporate emerging contaminants in the food chain. Sampling strategies also need to take into account the farm size (i.e. sampling of a defined percentage of animals from the same farm rather than a given percentage of all slaughter pigs).
- Analytical techniques covering multiple analytes should be encouraged and incorporated into national residue control programmes.
- Measures to identify the illicit use of non-authorized substances at the farm level, prior to transport and slaughter, should be promoted.
- Any measures taken to improve the efficacy of meat inspection protocols need to address also the compliance of imports into the EU with these strategies.

General recommendation BIOHAZ Panel

- It is recommended that all parties involved in the proposed pork carcass safety assurance system, including official veterinarians, official auxiliaries and abattoir staff, be trained in the skills required for this system.

APPENDICES

APPENDIX A FROM THE PANEL ON BIOLOGICAL HAZARDS (BIOHAZ PANEL)

TABLE OF CONTENTS

ASSESSMENT

1. Introduction

When considering whether and which changes in current meat inspection are necessary with aim to improve it, logically, the starting point is the actual definition of meat inspection. However, it seems that there is not a precise, universally agreed and used definition of *meat inspection* as a whole. Pieces of the current EU legislation (Regulation (EC) No 854/2004) related to all official controls define inspection in a wider sense as "the examination of establishments, of animals and food, and the processing thereof, of food businesses, and their management and production systems, including documents, finished product testing and feeding practices, and of the origin and destination of production inputs and outputs, in order to verify compliance with the legal requirements in all cases". However, the term *meat inspection*, in narrower sense, is not described specifically; rather, there are references to elements of the inspection process for meat such as *ante-* and *post-mortem* inspection, food chain information, etc. Also, Codex Alimentarius in its Code of Hygienic Practice for Meat (CAC/RCP 58-2005) describes *ante-mortem* inspection as "*any procedure or test conducted by a competent person on live animals for the purpose of judgement of safety and suitability and disposition*" and *post-mortem* inspection as "*any procedure or test conducted by a competent person on all relevant parts of slaughtered/killed animals for the purpose of judgement of safety and suitability and disposition*"; but a definition of *meat inspection* as a whole is not stated. Consequently, the current understanding of the term *meat inspection* is probably based more on its practical application and somewhat intuitive, than on specific, formal definition.

The foundation of meat inspection originates from an empirical recognition that there is a connection between health problems in animals used for food and those in people. This was probably recognised early in human history, but the first written proofs of such considerations can be traced to Aristotle, Virgil and Hippocrates. Later, progress in medical sciences and better understanding of the significance of food for human health led to the beginnings of meat inspection in Europe: in France in the mid-12th century, in England in the early 14th century, and in Germany in the late 14th century. Subsequently, traditional meat inspection system was fully developed in Germany in mid-19th century, adopted by most other European countries, and spread wider. Over many following decades, it contributed significantly to controls of classical zoonotic diseases in food animals as well as to prevention of their transmission to humans *via* meat. It has been used without major changes until today; current meat inspection procedures are still primarily based on the guiding publication "Handbuch der Fleischbeschau" (von Ostertag, 1892).

However, in more recent times, a consensus of opinion that traditional meat inspection is no longer capable of assuring the consumers' health adequately has been formed. Nowadays, based on available monitoring/surveillance data, the main threats to public health in developed countries are: a) bacterial zoonotic agents that can be carried and excreted (primarily *via* faeces) by animals without symptoms, such as *Campylobacter*, *Salmonella* and *Y. enterocolitica* species; and b) the presence of residues of pharmacologically-active substances (authorised and unauthorised) and/or contaminants in slaughter animals. All those are undetectable by traditional meat inspection. In Europe, there has been a stream of published expert opinions making a case for, and gradually leading to, necessary revisions of traditional meat inspection system since 1980s. In 1984, Scientific Committee on Veterinary Measures Related to Veterinary Public Health (SCVMRPH) prepared an interim report for the European Commission (EC) suggesting measures for the improvement of inspection practices (e.g. *ante-mortem* inspection, health certification, pathogen monitoring, etc.). At the same time, several expert working groups also prepared reports on microbiological and residue issues in meat. Subsequently, in 1995, the SCVMRPH considered and indicated elements of alternative meat inspection system, but no further action was taken; at that time, the proposals did not foresee the changing approach towards the systems managed by the producers.

In 2000, the SCVMRPH produced an Opinion on the "Revision of Meat Inspection Procedures" that recommended the introduction of an alternative meat inspection system in fattening pigs, with the main aim to minimize cross-contamination by avoiding incision and palpation on the slaughter-line. The Opinion also stressed a necessity of a vertically integrated ("plant-driven") quality assurance system, as the food industry should carry the responsibility to ensure the safety of own products. Because, sometimes, conflicts of interest between technological/sensory considerations and the safety of the product occur, it should be stressed that safety must have the highest priority to which all quality aspects are subordinate (SCVMRPH, 2001).

Subsequently, newly introduced EU regulations (Reg (EC) No 854/2004/EU) took a significant step towards modernization of the meat inspection system, by adopting some key principles:

- Alternatives for traditional inspection procedures can be used, provided that these lead to a level of safety that at least equals that offered by the traditional procedures.
- Risk assessment based system of meat safety assurance, accompanied with auditing mechanisms, is superior and more durable than traditional meat inspection procedures.
- Concerns with individual establishments, as well as the conditions for importation of foodstuffs of animal origin (including meat) from non EU countries, depend upon assessed risks. For both, food chain information (FCI) should be available and used.
- A two-ways flow of information ("forward" and "backward" along the meat chain) on animal and public health hazards, as well as on animal welfare, should be used to optimise risk management interventions along the food chain.
- If such, in principle, there should be no reason why an appropriate and adequate quality assurance system in the meat industry could not incorporate some aspects of ensuring meat safety that are traditionally entrusted to official meat inspection - provided a multidisciplinary, longitudinally integrated approach is implemented, validated and verified-audited.

These principles are also reflected in documents by the Codex Alimentarius, for example in The Code of Hygienic Practice for Meat (CAC/RCP 58-2005) including the statement: "*A contemporary risk-based approach to meat hygiene requires that hygiene measures should be applied at those points in the food chain where they will be of greatest value in reducing food-borne risks to consumers. This should be reflected in application of specific measures based on science and risk assessment, with a greater emphasis on prevention and control of contamination during all aspects of production of meat and its further processing*".

Nevertheless, the meat inspection as described in Reg (EC) No 854/2004/EU regulation did not provide more detailed descriptions about how the above principles should be fully applied in practice; so it still has certain shortcomings and needs further improvements. Appropriate assessment of public health risks associated with final carcasses and identification of those that need to be specifically targeted, and adjustment of the risk management activities accordingly, is a prerequisite for any sound modernization of current meat inspection procedures, as well as any transparent meat trade within EU and between EU and non-EU countries. However, main relevant conditions (e.g. farming systems, degrees of integration of the meat chain, epidemiological situation in respect to zoonotic meatborne hazards and meat industry structure-performance) affecting the risks are markedly diverse within the EU. Therefore, it is not likely that some rigid, inflexible ("one fits all") meat safety risk management system would have been compatible with those varying risks. Rather, to improve the meat safety assurance beyond its current status, the EU regulatory authority indicated intention to use a generic framework including appropriate indicators ("criteria") for MSs to carry their own risk analysis so to be able, where appropriate, to adapt appropriate inspection methods within the given framework.

Therefore, based on the given remit and related discussions with the European Commission's representatives, the main scope of this Scientific Opinion of the BIOHAZ Panel is, briefly, identification and qualitative ranking of the most relevant pig meat safety risks, strengths/weaknesses evaluation of the current meat inspection system including alternatives to current methods, as well as outlining a generic framework for inspection/control (including related methodology) of those among the most relevant risks that are not covered by the current system. It should be noted that biological hazards representing primarily occupational health risk, the controls related to any biological hazards at any meat chain stage beyond abattoir, and the implications for environmental protection, are not dealt with in this document.

Chemical hazards and associated pig meat safety risks are considered (by the CONTAM Panel) in a separate part of this Opinion (see Appendix B). Also, although public health aims of the improvements in the biological/chemical meat safety system are given a priority, the implications for animal health and animal welfare of any changes are also considered (by the AHAW Panel) in a separate part of this Opinion (see Appendix C). Furthermore, issues related to epidemiological indicators and associated sampling/testing methodologies for hazards dealt with in this Opinion are addressed by the Biological Monitoring Unit in a separate document (EFSA, 2011c). For information on those other hazards or aspects, the reader is referred to those documents.

2. Identification and ranking of main risks for public health

2.1. Identification of public health hazards associated with pig carcasses and consumption of pork

According to its basic definition, "public health risk" refers to the final product at the time of its consumption; so a public health risk assessment in principle requires the effects of all food chain stages to be taken into account. However, the scope and the target of meat inspection are limited to the public health-related status of the final carcass at the end of abattoir operation. Accordingly, in the context of pig meat inspection and for the purpose of this document, public health risks are assessed only as posed by, i.e. in relation to, the final (chilled) pork carcass, whilst all subsequent (beyond abattoir) stages of the pork chain are taken as staying unchanged, i.e. "fixed". The fact that there are situations where using such an approach is needed and sufficient is indicated also in the WHO/FAO Guidance on Microbiological Risk Assessment (2009) stating that "*A farm-to-table model may be most appropriate …in practice, however, the scope of the assessment may be limited to those sections of the food chain within the risk manager's area of authority ….For some risk questions, analysis of epidemiological data or a model of part of the food chain may be adequate….Some risk assessments may be undertaken to ascertain whether existing food safety regulations and existing intervention strategies are adequate, or most appropriate, and if they require review*". Nevertheless, as some of the post-abattoir steps in the food chain can either increase (e.g. growth) or reduce (e.g. inactivation) the risk to consumers, the outcome of the assessment presented here can be interpreted as potential risk in relation to public health.

This assessment focuses on microbiological hazards while chemical hazards, as explained above, are dealt with within the CONTAM Panel (see Appendix B). TSEs (as agreed with the EC) and hazards that – according to current evidence and consensus of the Panel – have no public health significance in respect to consumption of pork are explicitly excluded from the mandate. Based on the evidence provided in the literature, current textbooks, through reporting data, earlier assessments and the Panel's experience, the Panel collated a list of hazards to be considered (Table 1, "Long list"). Estimates of frequency of occurrence in pigs in Europe and confirmed cases in humans are also provided, with essential input from ECDC. However, data are missing or uncertain for several hazards in the list. It should be noted that data provided in Table 1 are aggregated from different European Union Member States (MSs) and not all MSs provide data for every disease. In addition, the final outcome of many patients is unknown while they are considered as confirmed cases. Not all hazards listed in Table 1 were considered in the final ranking. Selection criteria and considerations made by the Panel are provided below.

Previous work was conducted by EFSA in its Panels and Working Groups on the following hazards occurring in pigs: *Salmonella* spp. (EFSA, 2007d, 2008a, 2008b, 2009a, 2010d, 2011a), *Trichinella* spp. (EFSA, 2004, 2005b, 2005c, 2011a), bacteria resistant to antimicrobials, including *Staphylococcus aureus* (EFSA, 2008d, 2009c, 2009e, 2010a, 2010b), *Campylobacter* spp. (EFSA, 2005a, 2011a), *Brucella suis* (EFSA, 2009d), *Toxoplasma* spp. (EFSA, 2007c). These Opinions and related information were consulted during the preparation of this document.

The following hazards are covered by the Community Summary Report[13] according to Directive 2003/99/EC, can occur in pigs and were therefore considered in a first instance: *Campylobacter* spp., *Brucella suis*, *Clostridium botulinum* and *Clostridium perfringens, Taenia solium* (cysticercosis), *Echinococcus* spp., *Listeria monocytogenes*, *Mycobacterium* spp., *Toxoplasma gondii*, verotoxigenic *Escherichia coli* (VTEC), *Yersinia enterocolitica.* In this Opinion *Yersinia enterocolitica* is defined as human enteropathogenic *Y. enterocolitica* with biotype/serotype combinations that have their main

[13] See "The European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks in 2009", available at http://www.efsa.europa.eu/en/efsajournal/pub/2090.htm

reservoirs in pigs, in particular biotype 4/serotype O:3, biotype 2/serotype 9, but also biotype 2/serotype O:5,27.

Ideally, for the purpose of this document, human data should have been considered for cases attributable to pork only. However, such data are very limited and only available for very few hazards. Several methods are used for attribution to sources and such information – where available – is considered later in the assessment (see Section 2.2.3).

Alonso et al. (2011) proposed the use of a classification tree to systematically identify relevant food-borne hazards to be considered in a public health risk assessment related to meat inspection. Using this approach, results from a systematic review of the literature (Fosse et al., 2008a, 2008b) and taking into account consideration provided in 2.1.1 below, the hazards listed in Table 1 remained relevant for the further steps.

Table 1: Biological hazards for which there is evidence that they occur or may occur in pigs in Europe and that can be transmitted *via* food to humans. Data reported by EU MSs in the frame of the Zoonoses Directive (2003/99/EC) and as described in Decision (2119/98/EC) on communicable diseases

Hazard	**Prevalence in/on pig carcasses or fresh pig meat [number of member states reporting]**	**Reported number of confirmed cases in humans per 100,000 population* by year**			**Number of deaths among confirmed cases (total number of confirmed cases in brackets) – the proportion can be used as a proxy for severity* by year**		
	2007-2009	2007	2008	2009	2007	2008	2009
Sarcocystis suihominis	na	na	na	na	na	na	na
Taenia solium cysticercus	0.0% [2] [(a)]	na	na	na	na	na	na
Toxoplasma gondii	2.4% [6] [(b)]	0.58	0.42	0.65	0 (1,517)	1 (1,211)	0 (1,262)
Trichinella spp.	0.0004% [27] [(c)]	0.2	0. 1	0.16	0 (787)	0 (670)	0 (748)
Campylobacter (Thermophilic*), including jejuni/coli*	2.6% [12][(d)]	45.2	40.7	45.57	17 (203,736)	31 (193,552)	21 (201,605)
Clostridium botulinum	na	0.03	0.02	0.03	2 (129)	2 (112)	5 (132)
Clostridium difficile	na	na	na	na	na	na	na
Clostridium perfringens	na	na	na	na	na	na	na
*Listeria monocytogenes**	2.2% [14][(e)]	0.3	0.3	0.36	165 (1,364)	137 (1,462)	131 (1,682)
Mycobacterium spp. (*Mycobacterium bovis* in human cases)**	0.0004% [10] [(f)]	0.02	0.02	-	0 (107)	0 (115)	
Staphylococcus aureus	na	na	na	na	na	na	na
Salmonella spp. *(excluding S. typhi and S. paratyphi)*	8.3% [13][(g)]	33.84	29.37	23.67	81 (154,324)	67 (134,441)	41 (108,615)
Yersinia spp.	2.2% [8][(h)]	2.8	1. 8	1. 65	0 (8,874)	2 (8,193)	1 (7,686)
Human pathogenic *E. coli* VTEC*	0.3% [10][(i)]	0.6	0.7	0.75	2 (2,946) (H103)	2 (3,186) (H146)	6 (3,698) (H242)
Hepatitis E virus	na	na	na	na	na	na	na

[(a)] Monitoring data on *Taenia solium cysticercus* collected at slaughterhouse or unspecified sampling point ('species context'). Two MSs, Estonia and Sweden, reported data in 2009, while in 2007 and 2008 data were only reported by Estonia (EFSA, 2009b, 2010c, 2011a).

[(b)] Since no information was available on *Toxoplasma gondii* in pig meat, animal data (pigs) were used to calculate the prevalence. Data were only presented for sample size ≥25 tested animals. Overall, six different MSs reported data during 2007-2009. Specifically, three MSs reported data in 2009 and 2007, while four MSs reported in 2008 (EFSA, 2009b, 2010c, 2011).

[(c)] Monitoring data used to calculate the prevalence of *Trichinella* spp. Twenty-seven MSs reported data in 2009, while 25 MSs reported data in 2008 and 2007 (EFSA, 2009b, 2010c, 2011).

[(d)] Monitoring data on *Campylobacter* collected at slaughterhouse/processing plant/cutting plant/retail or unspecified sampling point ('species context'). Data were only presented for sample size ≥25 tested units. Overall, 12 MSs reported data during 2007-2009. Specifically, seven MSs reported in 2009 and 2007 and eight MSs reported in 2008 (EFSA, 2009b, 2010c, 2011).

[(e)] Monitoring data on *Listeria monocytogenes* collected at slaughterhouse/processing plant/cutting plant/retail/catering or unspecified sampling point ('species context'). Data were only presented for sample size ≥25 tested units. Overall, 14 MSs reported data during 2007-2009. Specifically, ten MSs reported data in 2009, 11 MSs reported in 2008 and nine MSs in 2007 (EFSA, 2009b, 2010c, 2011).

(f) Monitoring data on *Mycobacterium* spp. collected at slaughterhouse or unspecified sampling point ('species context'), no data at farm were considered. Data were only presented for sample size ≥1000 tested units. Overall, ten MSs reported data during 2007-2009. Specifically, seven MSs reported data in 2009, six MSs reported in 2008 and eight MSs in 2007 (EFSA, 2009b, 2010c, 2011).
(g) Data on *Salmonella* derived from carcass swab samples collected by 13 MSs during the EU-wide baseline survey in slaughter pigs carried out in 2006-2007. The prevalence presented is the weighted prevalence of carcasses contaminated with *Salmonella* spp. in the group of 13 MSs that collected carcass swab samples (EFSA, 2008a).
(h) Monitoring data on *Yersinia enterocolitica* from fresh pig meat (no data from meat preparations and meat products were considered). Data were only presented for sample size ≥25 tested units. Overall, eight MSs reported data during 2007-2009. Specifically, seven MSs reported data in 2009, five MSs reported in 2008 and four MSs in 2007 (EFSA, 2009b, 2010c, 2011).
(i) Monitoring data on verotoxigenic *E. coli* (VTEC) from fresh meat at slaughterhouse/cutting plant/retail or unspecified sampling point ('species context'). Data were only presented for sample size ≥25 tested units. Overall, ten MSs reported data during 2007-2009. Specifically, six MSs reported data in 2009, nine MSs reported in 2008 and five MSs in 2007 (EFSA, 2009b, 2010c, 2011).

* Human data extracted from TESSy (The European Surveillance System), provided by ECDC (European Centre for Disease Prevention and Control). The following specifications were made for specific hazards: cases of listeriosis that are pregnancy-associated are labelled 'P' within brackets; cases of verotoxigenic *E. coli* (VTEC) that developed Haemorrhagic Urinary Syndrome (HUS) are labelled 'H' within brackets. In addition, the final outcome of many patients is unknown but they are considered as confirmed cases. Data are incomplete or missing for some years which is indicated with "-".
** *Mycobacterium avium* was not considered to be relevant in the context of meat-borne transmission. Current evidence suggests a possible association with consumption of milk, but no relationship has been established with pork consumption.

Note: The data in the table are aggregated from the different European Union countries; not all the countries provided data for every disease.

2.1.1. Hazards considered but not included in the assessment

Ascaris suum has very occasionally been associated with visceral *larva migrans*, and even some parasite infection has been detected in the human intestine. In addition, some serological studies link asthma in children with contact with this parasite. However, no evidence of this pathology being associated with pork meat consumption has been shown, therefore this infection does not meet the basic requisites to be considered as a potential hazard in pork meat. *Echinococcus* spp. were excluded for the same reason.

Although *Taenia solium cysticercus* is currently not considered to be present in Europe, it was kept in the list in order to raise awareness for this pathogen. It might be emerging in the future or in some regions, as observed in the Americas.

With regard to bacteria, in *Anonymous* (SCVMRPH, 2000), the main transmission pathways for *Brucella suis, Erysipelotrix rhusiopathiae* and *Streptococcus suis* were not considered to be foodborne. This also applies to *leptospirae*. In the absence of new evidence these pathogens were excluded from the assessment.

Regarding antimicrobial resistance (AMR), EFSA has already published a detailed opinion (EFSA, 2008d) addressing the extent to which food serves as a source for the acquisition, by humans, of antimicrobial-resistant bacteria or bacteria-borne antimicrobial resistance genes. Foodborne bacteria, including known pathogens and commensal bacteria, display an increasing, extensive and diverse range of resistance to antimicrobial agents, although the risk to consumers they pose has not been assessed in detail.

Within pathogenic bacteria, the risk to public health arising from antimicrobial resistant *Campylobacter* in pigs is considered to be very low, as there are currently no reports linking foodborne antimicrobial resistant *Campylobacter* in pigs to human infections (EFSA, 2008d). True figures are expected to be lower than the one shown in Table 1 as the latter is not limited to carcass sampling and therefore likely to include post-slaughter contamination. Resistance among VTEC strains is considered still relatively low (Walsh et al., 2006), and similarly, it is not a therapeutic problem in the treatment of listeriosis. On the other hand, pork is one of the vehicles implicated in human infection with resistant *Salmonella*. In a study by Hald et al. (2007) pork was an important source for resistant and multidrug-resistant *Salmonella* infection. In addition, an outbreak in 1998 of multiresistant *S.* Typhimurium with additional resistance to quinolone antimicrobials involving 15 persons, was traced through the food chain to pigs (Molbak et al., 1999). Pork-derived products also remain a potential source of meticillin-resistant *Staphylococcus aureus* (MRSA), with CC398 being the MRSA lineage most commonly associated to intensively reared food-producing animals. However, there is currently no evidence for increased risk of human colonisation or infection following contact or consumption of food contaminated by CC398 both in the community and in hospital (EFSA, 2009e; Smith et al., 2011).

Commensal bacteria (those bacteria that live in or upon the host without causing disease) that contaminate food can harbour transferable AMR genes**.** During the passage through the intestine, these bacteria may transfer their resistance genes to host-adapted bacteria or to pathogens, and this exchange can also occur in the kitchen environment (Kruse and Sorum, 1994; Walsh et al., 2008). The most studied species are commensal antimicrobial resistant *Escherichia coli* and *Enterococcus* spp., especially vancomycin resistant *Ent. faecalis* and *Ent. faecium* strains (VRE). In addition, *E. coli* carrying extended-spectrum beta-lactamases (ESBL) and AmpC ß-lactamases (AmpC) are increasingly being considered as an emerging public health concern. Antimicrobial resistant *E. coli* (Gousia et al., 2011; Jakobsen et al., 2010) and VRE (Freitas et al., 2011; Gambarotto et al., 2001; Kempf et al., 2008; Manero et al., 2006) have been isolated from pigs and pork. ESBL- and AmpC-producing bacterial strains and genes relevant for public health have also been reported in pigs and pork products (in particular CTX-M, TEM-52, SHV-12 and CMY-2)(EFSA, 2011b). This suggests

that the animal reservoir presents a definite risk of resistance genes being transferred to virulent human strains through food and other routes. The relative importance of pork borne transmission of these genes, compared to transmission *via* other foods or pathways is currently unknown.

Acknowledging the remaining uncertainty of the public health risk related to consumption of resistant bacteria, this is considered to be significantly lower than the pathogens listed in Table 1. It was therefore concluded not to consider this characteristic of microbiological hazards in isolation, but as one of pathogenicity attributes when ranking them, especially for *Salmonella* and MRSA.

2.2. Criteria for ranking of public health hazards, previous work and approaches

The hazards identified and listed in Table 1 were qualitatively ranked according to risk in order to obtain a "short list". Risk was defined as consisting of two components: 1) the probability of the hazard occurring on a carcass after chilling and 2) the public health consequences (i.e. frequency of transmission and severity of disease). Additionally, consideration of consequences included the availability of options for risk reduction by standard carcass treatment practices and the risk for hazard's growth. The concept of the ranking algorithm was based on Fosse et al (2008a, 2008b) and Mataragas (2008). The objective was to rank the hazards in order to identify the top pathogens in terms of public health importance as related to pork carcasses and potential foodborne infection. An approach using more detailed information and calculation (Havelaar et al., 2010) was also considered but a quantitative approach was not pursued due to strict time constraints as well as data limitations. Instead, a qualitative classification was used for the purpose of this document and as agreed with the EC. Namely, the purpose of a risk assessment is to help the risk manager make a more informed choice and to make the rationale behind that choice clear to any stakeholders; thus, in some situations, a simple risk assessment may be quite sufficient for a risk manager's needs (WHO/FAO, 2009).

It is important to note that the Table 1 relates to fresh (chilled) pork carcasses. Subsequent microbial growth is not relevant in the context of risk related to chilled pork carcass and hazards originating from pigs. The decision algorithm used in this document is described in the following sections.

2.2.1. Probability of hazard occurring on chilled pork carcasses

For some of the hazards listed in Table 1, data on prevalence or occurrence in/on pig carcasses are systematically collected (e.g. *Trichinella* spp.) while data are sparse or absent for others. The Panel is therefore very aware of data limitations and variability in data quality between hazards. Keeping these limitations in mind, using the data provided in Table 1, the hazards were categorised regarding frequency of occurrence as shown in Table 2. The ranges for the categories were chosen such that there was reasonable discrimination between pathogens. The ranges are relatively narrow indicating that none of the pathogens is commonly found on pig carcasses in the EU. Figures for pathogens that are sensitive to the effects of drying during air carcass chilling, most notably *Campylobacter* spp., are over-estimated due to samples being collected pre-chilling.

Table 2: Qualitative risk categories based on frequency of detection of hazards in pork carcasses after chilling

Qualitative category	Descriptor	Hazards in this category
High	>5%	*Salmonella enterica*
Medium	0.1-5%	VTEC*, *Campylobacter* spp.**, *Listeria monocytogenes, Toxoplasma gondii, Yersinia enterocolitica*
Low	<0.1	*Mycobacterium* spp., *Trichinella* spp., *Taenia solium cysticercus*
Unknown, but likely to be present	?	*Sarcocystis suihominis, Clostridium difficile, Clostridium perfringens, Staphylococcus aureus* (including MRSA), Hepatitis E virus
Unknown and unlikely to be present	?	*Clostridium botulinum*

*measured during processing or at retail, no data available at slaughterhouse level
**data collected at slaughterhouse/processing plant/cutting plant/retail or unspecified sampling point (see Table 1)

2.2.2. Frequency of transmission and severity of disease

EU data on human cases are available for selected pathogens that are reportable in the member states. Statistics are published in the Community Zoonoses Report (EFSA, 2011a). The severity of human infection was assessed using lethality among confirmed cases as an indicator (also see Table 1). These data do not take into account whether pork was identified as a source of infection of a case. Also, the completeness of data reported is likely to vary considerably between MSs. Pathogens with a "low risk" category in terms of number of human cases but a high frequency of lethal outcome, are also considered "medium risk" overall. This is applicable to *Clostridium botulinum*, *Listeria monocytogenes* and VTEC.

Table 3: Qualitative risk categories of hazards found in pork based on frequency and severity of infection (expressed as case fatality) in humans

Qualitative category	Descriptor (frequency)	Case-fatality [% of confirmed cases] reported to ECDC*	
		>0.1	**≤0.1**
High	>10/100,000		*Campylobacter* spp. [0.0104] *Salmonella* spp. [0.0377]
Medium	1-10/100,000		*Y. enterocolitica* [0.0130]
Low	<1/100,000	*Clostridium botulinum* [3.79], *Listeria monocytogenes* [7.79], VTEC [0.16]	*Mycobacterium* spp. [0], *Toxoplasma gondii* [0], *Trichinella* spp. [0]
Unknown because of lack of data	?		*Sarcocystis suihominis, Clostridium difficile, Staphylococcus aureus,* Hepatitis E virus

* Human data extracted from TESSy (The European Surveillance System), provided by ECDC (European Centre for Disease Prevention and Control)

Using a different approach by calculating a severity index, Fosse et al. (2008a) ranked *L. monocytogenes* highest, followed by *C. botulinum*, and *Y. enterocolitica, Salmonella* spp. and *Campylobacter* spp. all considerably lower. This severity ranking was consistent with the classification shown in Table 3. For *Sarcocystis suihominis*, the required infectious dose was demonstrated to be relatively high and the severity of infection is considered to be low (Fayer, 2004).

A recent publication from the United States (Scallan et al., 2011) identified *Salmonella* spp., *Toxoplasma gondii* and *Listeria monocytogenes* as leading causes of death among foodborne hazards. This paper did, not, however, distinguish between sources and is therefore not directly transferable to pork and data are not directly comparable to the data presented here.

In Table 4, the outcome of the preliminary qualitative risk assessment of foodborne hazards associated with chilled pork carcasses is shown. In this preliminary assessment, source attribution data - other than occurrence of the pathogens on pig carcasses - are not yet considered.

Table 4: Preliminary qualitative risk assessment of foodborne hazards associated with chilled pork carcasses (combining information from Tables 2 and 3)

***Preliminary* qualitative evaluation of the risk level: probability of occurrence against severity of consequences**		**Severity of consequences**			
		High severity of consequences: human cases >10/100,000, and case-fatality <0.1%	**Medium severity of consequences: human cases 1-10/100,000, and case-fatality <0.1%**	**Low severity of consequences:**	
				human cases <1/100,000, and case-fatality >0.1%	**human cases <1/100,000, and case-fatality <0.1%**
Probability of occurrence	High probability: incidence on chilled carcass >5%	HIGH RISK *Salmonella* spp.			
	Medium probability: incidence on chilled carcass 0.1-5%	MEDIUM RISK *Campylobacter*[3] spp.	MEDIUM RISK *Yersinia enterocolitica*	MEDIUM RISK *L. monocytogenes*[5] VTEC[4]	LOW RISK *Toxoplasma gondii*
	Low probability incidence on chilled carcass <0.1%			LOW RISK *Cl. botulinum*[1,5]	LOW RISK *Sarcocystis suihominis*[1,2] *T. solium cysticercus* *Trichinella* spp. *Cl. difficile*[1,5] *Cl. perfringens*[1,5] *Mycobacterium* spp. *Staph. aureus* (MRSA)[5] HEV[1,2]

[1] Unknown occurrence on carcasses, but the experts considered them to be low at present (excluded from present considerations; to be monitored in the future)

[2] Unknown incidence of human disease, but the experts considered them to be low at present (excluded from present considerations; to be monitored in the future)

[3] The consideration included occurrence data collected at slaughterhouse/processing plant/cutting plant/retail or unspecified sampling point (see Tables 1 and 2), and not only on chilled carcasses, and also major dying off during chilling occurs, so probably actual occurrence on chilled carcasses was lower

[4] Data on occurrence on meats relate to processing-retail and not to abattoir-level, the main concern is ruminant carcasses and not porcine (excluded from present considerations; to be monitored in the future)

[5] The main risk factors include contamination and/or growth at processing-retail-domestic levels (excluded from present considerations; to be monitored in the future)

2.2.3. Source attribution

In addition to the frequency of occurrence in/on pig carcass and human cases, the Panel took into account the evidence suggesting epidemiological links between human cases and pork. This can be formally established by using methods for source attribution (Pires et al., 2010). Briefly, there are a number of methods available to link human cases to specific food sources, including outbreak data, microbial subtyping, epidemiological studies, comparative exposure assessment and structured expert

opinion (EFSA, 2008c). Each method of source attribution has different strengths and weaknesses and addresses different points in the food chain. The choice of method depends on the specific question that needs answering and the data and resources.

However, information on source attribution for specific hazards in pork is scarce (Table 5). To fill the gaps, an appraisal was conducted by the Panel, based on literature and expert opinion; the results are shown in Table 5. The information on source attribution was considered as a moderating factor in the final ranking of hazards. Source attribution information is rarely available specifically for hazards present on carcasses after chilling, but also include contamination occurring later in the food chain (e.g. *Listeria monocytogenes*). This was taken into account when applying the information in the final risk ranking.

Table 5: Source attribution information and considerations for hazards occurring in pigs and food-borne disease in humans; for hazards where the information is missing expert judgment was used

Hazard	Proportion of cases caused by pig meat (method of attribution)	References on source attribution	Panel judgement on attribution human cases to pork as a source	Other references
Sarcocystis suihominis	10 (combination of incidence data and expert opinion)	Fosse et al., 2008a	Highly relevant in principle, as pigs are the most important source of the hazard	Fayer et al., 2004
Taenia solium cysticercus	N/A		Highly relevant, as pigs are the most important source of the hazard (but not currently present in Europe)	SCVMRPH, 2000; Schantz et al., 1998
Toxoplasma gondii	26 (expert judgement) 10 (combination of incidence data and expert opinion)	Havelaar et al., 2008 Fosse et al., 2008a	Medium relevance. Cook et al. showed geographical variation for relative importance of different types of meat. Case-control study from Norway showed odds ratio of 3.4 for undercooked pork and 4.1 for undercooked minced meat. Data collected by EFSA show that the prevalence in pigs is <1%	Kapperud et al., 1996, EFSA, 2007b; Cook et al., 2000; Tenter et al., 2000
Trichinella spp.	55.9 (combination of incidence data and expert opinion)	Fosse et al., 2008a	Highly relevant as pigs are the most important source of the hazard in most countries	
Campylobacter (thermophilic), including *jejuni/coli*	2.68 (0.13-9.64) (outbreak data) 1.03 (0.73-1.45)	Pires et al., 2010 Domingues et al., 2009	Low relevance due to the significant reduction seen after carcass chilling (in particular blast chilling, see section 2.3 for references)	Kapperud et al., 1992; Kapperud et al., 2003; Fosse et al., 2008a; Pires et al., 2010
Clostridium botulinum	24 (combination of incidence data and expert opinion)	Fosse et al., 2008a	Low relevance, attribution reflects preserving practices in different EU countries, e.g. cases due to pork vary from 0% in Scandinavian countries or UK to over 80% in Poland	Brett, 1999; Aureli et al., 1999; Kuusi et al., 1999; Galazka and Przybylska, 1999; McLauchlin and Grant, 2007
Clostridium difficile	N/A		Low relevance. It is found on meat (pork) regularly, but it is not sure to contribute to disease in humans	Keessen et al., 2011

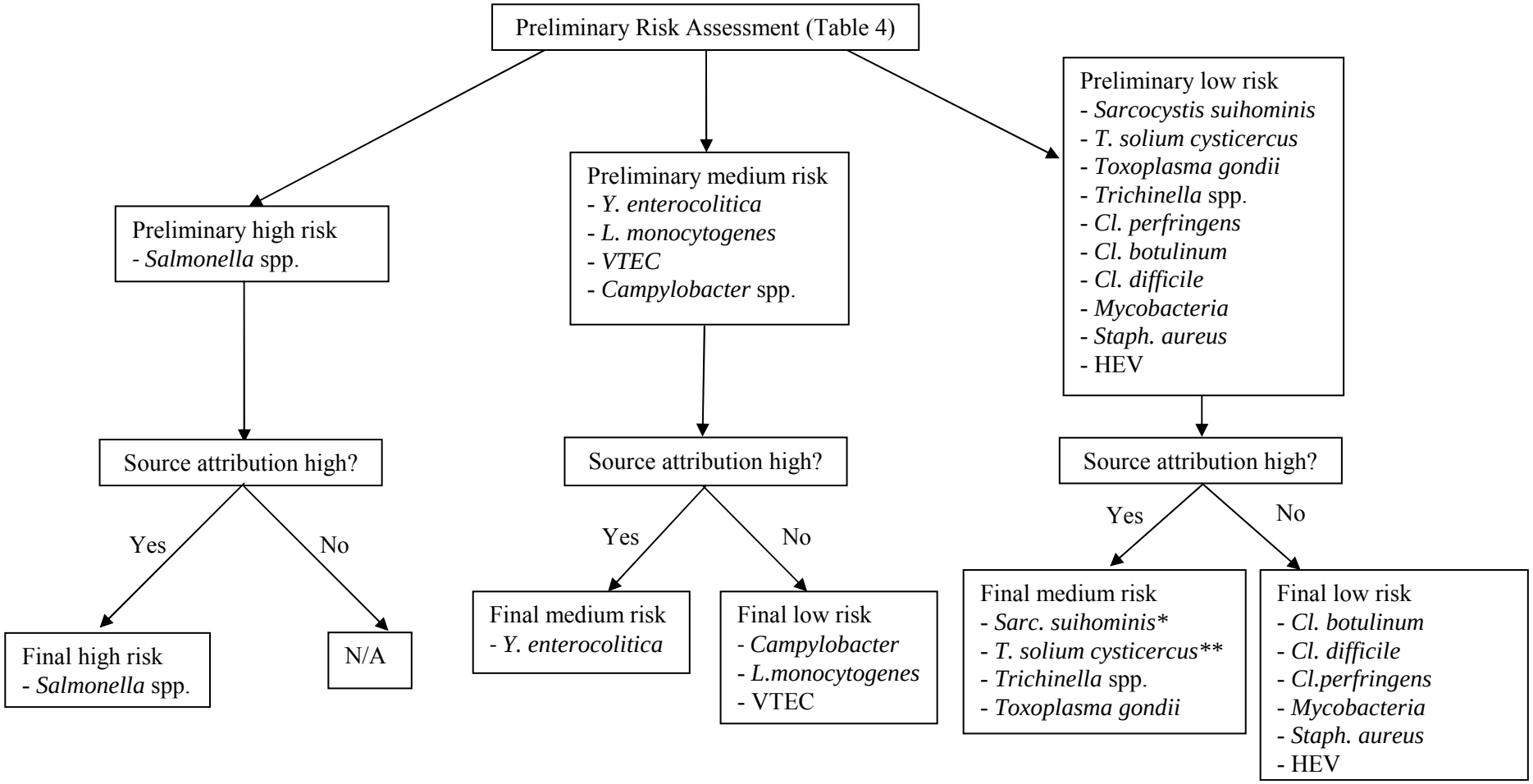
Hazard	Proportion of cases caused by pig meat (method of attribution)	References on source attribution	Panel judgement on attribution human cases to pork as a source	Other references
Clostridium perfringens	11 (expert judgement) 20 (combination of incidence data and expert opinion)	Havelaar et al., 2008 Fosse et al., 2008a	Low relevance, other studies suggest that pork is not a main source of *C. perfringens* in outbreaks	Dalton et al., 2004; Lahti et al., 2008; McLauchlin and Grant, 2007
Listeria monocytogenes	6.2 (expert judgement) 14 (combination of incidence data and expert opinion)	Havelaar et al., 2008 Fosse et al., 2008a	Low relevance, since cases are attributed to all types of ready-to-eat products where growth has been possible and products are often contaminated from processing environment	Lappi et al., 2004; Nakamura et al., 2004; Thimothe et al., 2004; Thevenot et al., 2006, EFSA, 2007c
Mycobacterium spp.	17.2 (expert judgement) 33 (combination of incidence data and expert opinion)	Havelaar et al., 2008 (M. avium) Fosse et al., 2008a	Low relevance, no clear evidence of meat borne transmission of *Mycobacteria*. With regards to *M. avium* spp. *paratuberculosis*, evidence for the zoonotic potential was not strong, but should not be ignored. However, milk was the main potential exposure route for humans considered	Cosivi et al., 1998; Thoen et al., 2006; Waddell et al., 2008; Ingram et al., 2010; LoBue et al., 2010; Michel et al., 2010
Staphylococcus aureus (MRSA)	N/A		Low relevance. Attribution studies estimate the proportion of cases of *S. aureus* due to pork to be 7 - 12 but other references indicate that pork has not been associated with MRSA transmission	Havelaar et al., 2008; Fosse et al, 2008; EFSA, 2009e
Salmonella enterica	7.5 (2.2-16.4) [S. Typhimurium only] 9-15,7 (microbial typing, DK) 21 (microbial typing NL) 0.72 (0.19-1.59) (outbreak data) 6 (expert opinion) 10-20	Pires et al., 2010 EFSA, 2008c EFSA, 2008c Pires et al., 2010 EFSA, 2008c EFSA, 2010d	High relevance for specific serotypes	Pires et al., 2010

Hazard	Proportion of cases caused by pig meat (method of attribution)	References on source attribution	Panel judgement on attribution human cases to pork as a source	Other references
Yersinia enterocolitica	77.3 (combination of incidence data and expert opinion)	Fosse et al., 2008a	Highly relevant, as pigs are an important source of the hazard	Ostroff et al., 1994; Tauxe et al., 1987; Lee et al., 1990; Jones et al., 2003
Human pathogenic *E. coli* VTEC	2 (expert judgement)	Havelaar et al., 2008 (O157)	Low relevance, "Pigs and poultry have not been identified to be major sources of VTEC in Europe and where these have yielded this group of bacteria, these have not been associated with the seropathotypes associated with human disease" (EFSA, 2007b)	EFSA, 2007c
	3.8 (expert judgement)	Havelaar et al., 2008 (non-O157)		
	4.5 (combination of incidence data and expert opinion)	Fosse et al., 2008a		
	0/100,000 servings modelled (QRA[1])	Kosmider et al., 2010		
Hepatitis E virus (HEV)	10.4 (expert judgement)	Havelaar et al., 2008	No evidence for one main transmission route of HEV infection or risk factor for hepatitis E. A small case-control study identified eating of raw pig liver sausage as a risk factor for hepatitis E in France	Casas and Martin, 2010; Lewis et al., 2010; Colson et al., 2010

N/A: not available
[1] Farm-to-fork quantitative risk assessment model

2.3. Risk ranking

Based on the input provided in the section above, the Panel reached a final classification of hazards (Figure 1).



*No information on occurrence in carcasses and human cases in EU (see Tables 1-4) so actual relevance in EU unknown; excluded from further considerations but to be monitored in future
**Not currently considered relevant in the EU pig population; excluded from further considerations but to be monitored in future

Figure 1: Final ranking of the main risks associated with chilled pork carcasses in the EU

The approach taken in this document, based on the TORs and the scope, was that only the most relevant hazards are to be included in further considerations in this document, whilst other hazards are not to be dealt with further.

Final high risk, included in further considerations

The risk ranked most highly is that posed by *Salmonella*, which is justified by a wealth of scientific evidence and related publications, so it is included in further considerations. This pathogen was also highly ranked (although below *Y. enterocolitica*) by Fosse et al (2008a) based on the French situation.

Final medium risks

The medium risk category includes *Yersinia enterocolitica*, *Trichinella* spp., *Toxoplasma gondii, T. solium cycticercus* and *Sarcocystis suihominis*.

a) Final medium risks, included in further considerations

Case-control studies of yersiniosis conducted in Belgium (Tauxe et al., 1987) and in Norway (Ostroff et al., 1994) have identified consumption of pork as an important risk factor for infection in humans. In the USA, case-control studies showed that household preparation of chitterlings (raw pork intestines) was associated with *Y. enterocolitica* infection in children (Jones, 2003; Lee et al., 1990). Furthermore, *Y. enterocolitica* was ranked highest by Fosse et al. (2008a). Hence, it was included in further considerations.

With respect to *Toxoplasma*, it does occur in pork, and epidemiological studies points to consumption of raw or undercooked mutton and pork to be an important risk factor for infection during pregnancy (Kapperud et al., 1996; Tenter et al., 2000). Recent studies show that the prevalence of *T. gondii* in meat-producing animals decreased considerably over the past 20 years in areas with intensive farm management (Skjerve et al., 1996; Tenter et al., 2000). However, pig meat originating from outdoor pig husbandry systems including those that are more welfare friendly such as free roaming, poses higher risk compared to indoor system, so could lead to an increase in toxoplasmosis infection (Gebreyes et al., 2008). However, due to the overall relatively small role of pork as a source, it remains classified as posing medium risk overall. Ranking by Fosse et al. (2008a) did not include *Toxoplasma gondii* and was not focused on fresh pork but pig meat in general, including retail and later stages. Considering all this, it was included in further considerations.

Trichinella spp. were also ranked medium risk, due to its significance in certain MSs and outdoor husbandry systems, and also because it is one of the key causative agents of outbreaks associated with pig meat; hence it was included in further considerations.

b) Final medium risks, but excluded from further considerations

T. solium cysticercus and *Sarcocystis suihominis* were ranked as medium risk ***solely*** on the basis of high source attribution. However, there is absence of information on occurrence of related human diseases in the EU, and also data on their occurrence in pork carcasses in the EU is either absent (*Sarc. suihominis*) or limited but with no positives (*T. solium cycticercus*). Consequently, it was considered that - presently - there is no evidence confirming actual relevance of these two hazards in the EU situation. Therefore, *T. solium cysticercus* and *Sarcocystis suihominis* were excluded from further considerations in this document, but with intention to stress a necessity for their monitoring and re-evaluation in the future should new data suggest that they are re-emerging.

Final low risks, excluded from further considerations

Campylobacter was ranked as low risk, and the key rational for this was the impact of drying during chilling, which could not be assessed because data available included sampling of pre-chilling carcasses. It should be noted that most pigs are carriers of *Campylobacter coli* in the gastro-intestinal tract, and the surface of pig carcasses are frequently contaminated with this agent. However, most slaughterhouses in Europe have implemented blast chilling resulting in the reduction in the occurrence of campylobacters seen after blast chilling due to the sensitivity of the bacterium to both freezing and drying (Bracewell et al., 1985; Nesbakken et al., 2008; Oosterom et al., 1985). Even after traditional slow chilling there is a significant decline of this agent (Chang et al., 2003). Accordingly, pig carcasses and pork are not regarded as an important source of *Campylobacter* in a public health context as confirmed by most epidemiological studies (Kapperud et al., 2003; Kapperud et al., 1992) and analysis by Domingues et al (2009). This conclusion is in contrast to Fosse et al. (2008a) who ranked the *Campylobacter* as high risk, although lower than *Y. enterocolitica*. Pires et al. (2010) also reported a small proportion of cases attributed to pork based on outbreaks related to pork meat but some of these data were not weighted as high as the results from epidemiological studies. Considering all that, *Campylobacter* was excluded from further considerations presently, but should be monitored in the future.

Listeria monocytogenes illness has almost always been associated with ready-to-eat products (including of pork origin) where growth has been possible and contamination has occurred from processing environment, so it was considered as low risk as related to pork carcasses.

Pigs and poultry have not been identified to be major sources of VTEC in Europe and where they have yielded this group of bacteria, these have not been associated with the seropathotypes associated with human disease (EFSA, 2007b). For these reasons the source attribution to pork is considered low.

Clostridium botulinum, Clostridium difficile, Clostridium perfringens, Mycobacterium spp., *Staphylococcus aureus* and Hepatitis E virus, were all classified as "low risk" but the reasons for that differed between them. For *Clostridium botulinum* and *Clostridium perfringens* need to grow at high temperatures to achieve concentrations of public health relevance and thus the risk of disease seems not to be correlated with occurrence in raw meat but rather to improper hygiene and storage. *Clostridium difficile* has been isolated from fresh pork but there is currently no evidence of human disease attributable to this source (Smith et al., 2011).

For *Mycobacterium* spp. there is currently no evidence of pork-related transmission (Brown and Tollison, 1979; Offermann et al., 1999; Waddell et al., 2008).

For *Staphylococcus aureus* the risk of disease also seems not to be correlated with occurrence in raw pork but rather to improper food handling and storage enabling growth-related toxin production. The risk of MRSA *via* pork exposure is currently considered to be low (Smith et al., 2011).

Some genotypes of Hepatitis E virus are commonly found in pigs, and antibodies can be detected in healthy humans, but there is limited evidence for pork to be an important source of human disease (Smith et al., 2011). However, Hepatitis E caused by certain strains is increasingly recognised as both a zoonotic and foodborne disease (Meng, 2011), indicating the need for continued monitoring of this pathogen and its role as a foodborne hazard.

In general it should be noted that the present ranking is only valid under current husbandry, slaughter and inspection practices. It is assumed that, in the future, hazards presently classified as "low" will be monitored and, after possible changes in meat inspection have been implemented, considered as to whether such changes will have had a negative impact on their currently favourable risk situation.

Also, due to differences in epidemiological situations, exposure pathways and production practices, there will be risk differences between MS.

3. Assess the strengths and weaknesses of the current meat inspection methodology

3.1. General background

Protection of public health is the top priority objective of meat inspection. The origin of Western European meat inspection goes back to the end of the 19th century, when it became obvious that meat could play a role in the transmission of disease and that animal trade, meat and meat products needed some sort of safety and quality assurance (von Ostertag, 1892). No doubt that the meat inspection procedures were highly risk-based at that time.

Ever since, an *ante-mortem* and *post-mortem* inspection has been carried out on each slaughter animal. The *ante-mortem* inspection is a simple clinical examination aiming at identifying sick or abnormal animals before entering the abattoir. The *post-mortem* inspection is a pathological-anatomical examination aiming at detecting and eliminating of macroscopic abnormalities that could affect fitness of meat for human consumption. It is based on visual inspection, palpation, incisions and, when required, laboratory examinations. It is obvious that *post-mortem* inspection is laborious and expensive.

Changes in animal husbandry practices have led to an enormous rise in numbers of slaughtered animals especially after World War II. Improvements in animal husbandry including preventive and therapeutic use of veterinary drugs have increased the health and growth rate of the animals. The previous situation of slaughtering few animals originating from a farm has evolved into large numbers of uniform, relatively young and healthy animals presented for slaughter, and which have a common genetic background and prior history. Technology and work practices in modern high throughput slaughterhouses have led to an increased pressure on meat inspectors in such way that efficiency of the detection and exclusion of pathological/anatomical abnormalities in slaughtered animals may have declined. Furthermore, slaughter animals may carry residues of pharmacologically-active substances (authorised and unauthorised) and/or contaminants and/or be asymptomatic carriers of pathogenic microorganisms; neither will be detected at *ante-* or *post-mortem* inspection unless specific laboratory tests are carried out.

The state of art of current meat inspection in the European Union (EU) and six selected exporting countries outside the EU has been reviewed and summarised recently[14] in an external report. The elements of meat inspection in the EU are specified in Regulation (EC) No 854/2004, which also includes a possibility of modifications of the existing meat inspection practices if certain requirements are met. For further, more detailed information on the current EU meat inspection system, the reader is referred to that report.

3.2. Evaluation of current meat inspection procedures for pigs

3.2.1. *Ante-mortem* inspection of pigs

Strengths

The public health related strengths of *ante-mortem* inspection include inspection of individual animals, animal identification, the evaluation of animal cleanliness and the use of Food Chain Information (FCI). However, in current practice, the latter is actually utilized in relation to public

[14] External scientific report: Overview of current practices of meat inspection in the European Union. Available from www.efsa.europa.eu/en/supporting/pub/190e.htm

health only to a slight degree. Since pigs carrying currently most relevant zoonotic agents do not or only very seldom show clinical symptoms, the strengths of *ante-mortem* inspection are mainly related to animal welfare and animal health; however this part of the Opinion deals only with food safety aspects.

Weaknesses

The main reason for the mentioned fact that, in practice, FCI is insufficiently utilised is the lack of adequate and harmonized indicators that could help risk-classifying the pigs according to the risk to public health they may pose. Also, usually there is a lack of information about many aspects of the history of the animals presented for *ante-mortem* examination, which would help to perform a better focused and more uniform *ante-mortem* inspection. Furthermore, the very large numbers of animals arriving for slaughter - which are all usually healthy at first observation - reduce opportunities and motivation for proper clinical examination.

3.2.2. Post-*mortem* meat-inspection of pigs

Strengths

As in the case of *ante-mortem* inspection, the strengths of *post-mortem* inspection are mainly related to animal welfare and animal health aspects, which are not dealt with in this part of the document. Classical zoonotic diseases, such as tuberculosis, trichinellosis, brucellosis, which can be detected by *post-mortem* examination, have become controlled in many areas where modern systems of animal husbandry, disease control and animal health care were introduced. Hence, the ability of current *post-mortem* meat inspection to detect lesions caused by e.g. mycobacteria or *Taenia solium cysticercus* (macroscopically) or *Trichinella* spp. (by specific laboratory methods) is only relevant in regions where they are present. For example, the relatively easily detectable parasitic worm infections (e.g. cysticercosis) are not important human health issues currently in most European member states.

Other visible, more meat quality-related abnormalities such as pale, soft and exudative (PSE) or dark, firm and dry (DFD) meat are also detectable at *post-mortem* inspection, but they are primarily indicators of animal health and/or welfare.

Sometimes septicaemia (pathogenic microorganisms in the blood) is detected at *post-mortem*. It is an acute, systemic and always serious condition that is expected to be detected before slaughter (on farm or at *ante-mortem* inspection of pigs), although septicaemia associated with some foci of infection in tissue like abscesses can be less acute and detectable only at *post-mortem* examination. Various bacteria have been found associated with acute septicaemia in pigs, among them *Streptococcus suis*, *Erysipelotrix rhusiopathie*, *Salmonella* Typhimurium, and *Bacillus anhtracis* that may have zoonotic implications although not all *via* foodborne route. Nevertheless, viruses, fungi or protozoa and other agents also can enter the blood stream and be disseminated to edible tissues. However, under abattoir conditions using routine inspection methods, it is not possible to differentiate the organisms causing septicaemia and any animal with suspected lesions indicating septicaemia is normally condemned.

Weaknesses

As indicated above, currently relevant potential threats to public health associated with slaughtered pigs including agents like *Salmonella* spp., *Y. enterocolitica* and *Toxoplasma gondii* are carried by animals without symptoms, but current meat inspection was not designed to detect and/or eliminate these agents (Table 7).

It is doubtful whether the bacterial species isolated from pathological/anatomical abnormalities detected at current *post-mortem* inspection of pigs (Table 6) impose a serious health threat to consumers. This is likely the consequence of the discrepancy between goals and techniques used in

traditional meat inspection and the types of diseases currently affecting animals in Western Europe. For example, the *Arcanobacterium* (syn. *Actinomyces* or *Corynebacterium*) *pyogenes* types isolated from abscesses, pneumonia, osteomyelitis, endocarditis cases and skin inflammation are a seldom cause of infection in humans (Gahrn-Hansen and Frederiksen, 1992) and most often these infections are a result of occupational exposure; *A.* pyogenesis should be considered as posing an insignificant risk for the public health of the consumers *via* foodborne route. Nevertheless, finding abscesses is one of the reasons to declare the affected meat unfit for human consumption as a meat quality issue and aesthetically unacceptable. Also, haemolytic *Streptococcus* species, haemolytic *Staphylococcus* species and *Erysipelothrix* might represent occupational hazards for personnel in the abattoirs but are not involved in foodborne disease.

Post-*mortem* inspection (through palpation, incision and visual examinations) is very likely not sufficiently sensitive in detection of even detectable conditions and the restriction of examinations to so called "predilection sides" diminishes even further the detection sensitivity in some cases (e. g. *Taenia solium cysticercosis*). Moreover, abnormalities with a low prevalence are more often missed than abnormalities with a high prevalence. Other negative influences reducing inspector's concentration and affecting the detection performance include poor illumination, background noise, uncomfortable draughts, small available working space and high line speed. Laboratory examination of detected pathological-anatomical abnormalities rarely leads to isolation of potential human pathogens in terms of foodborne infections. Table 6 represents an example in this context, showing data from the Danish meat inspection of pigs from 2005 (Nordic Council of Ministers, 2006); the vast majority of the laboratory diagnoses do not represent foodborne risks to human health. On the other hand, a summary evaluation of public health benefits (from food safety perspective) due to current *post-mortem* meat inspection procedures is presented in Table 7. It should be noted that there is no overlap between agents in Table 7 and those in Table 6.

Table 6: The frequency of various abnormalities detected, the frequency of their condemnation and the microorganisms most often involved (Nordic Council of Ministers, 2006; with updated species names)

Diagnosis	% detected	% condemned	Microorganisms most often involved
Acute pneumonia	0.04	0.03	*Actinobacillus pleuropneumoniae*, Mycoplasms
Chronic pneumonia	0.65	0.01	*A. pleuropneumoniae, Pasteurella multocida*
Acute pleuritis	0.06	0.04	*A. pleuropneumoniae, Haemophilus parasuis*
Chronic pleuritis	28.38	0.01	*A. pleuropneumoniae*
Abscesses	5.31	0.19	*Arcanobacterium pyogenes*, *Staphylococcus aureus, Streptococcus* spp.
Atrophic rhinitis	0.06	-	*Bordetella bronchiseptica* and *P. multocida*
Arthritis	0.39	0.02	*H. parasuis, Erysipelothrix, Streptococcus suis, Strept.* spp., *S. aureus*
Eczema	0.55	-	
Pyemia and abscesses	0.16	0.10	*A. pyogenes, S. aureus, Strept*. spp. (pyogenic)
Osteomyelitis	0.44	0.17	*A. pyogenes, S. aureus, Strept.* spp.
Tail bite and infection	1.39	0.14	*A. pyogenes, S. aureus, Strept*. spp. (pyogenic), *Pseudomonas aeruginosa*
Scars	1.44	-	-
Bone fractures	0.78	0.01	-
Peritonitis	0.84	0.03	*Actinobacillus suis, A. pyogenes*
Muscle degeneration	0.02	-	-
Hernia	1.26	0.01	-
Pericarditis	0.61	0.01	*A. suis, Pasteurella* spp., *Strep*. spp.
Hepatitis	0.01	-	Several, often secondary
Hip dislocation	0.05	-	-
Infected wound	0.04	0.01	*A. pyogenes, S. aureus, Strept*. spp., *Pseudomonas aeruginosa*
Nephritis	0.05	0.01	*Strept*. spp., *Erysipelothrix, A. pyogenes, S. aureus, Proteus* spp., *E. coli*
One testis	0.39	-	-
Other diagnoses	0.41	0.21	-

Data from the Danish meat inspection of pigs, 2005. Total number of pigs slaughtered: 20,581,562

Table 7: Effectiveness of current meat inspection on reduction of human health risks due to pork consumption.

Agent	Efficacy
Sarcocystis suihominis	-
Taenia solium cysticercosis	+
Toxoplasma gondii	-
Trichinella spp.	++
Campylobacter spp.	-
Clostridium spp.	-
Listeria monocytogenes	-
Mycobacterium spp.	0
Salmonella enterica	-
Yersinia enterocolitica	-
Human pathogenic *E. Coli* VTEC	-
Viral infections	-
Antimicrobial resistance	-

- none; 0 questionable; + some reduction; ++ clear

The point at the slaughterline where *post-mortem* inspection is conducted and the role of the official veterinarian in this matter might be considered as break-point in terms of cross-contamination control. Until the inspection point, the carcasses on slaughterline are treated separately and should not be exposed to contamination from operators, tools and equipment. Accordingly, there are requirements for regular between-animal decontamination of equipment and hands. After the *post-mortem* inspection point, there are no specific requirements when it comes to meat hygiene. Possible cross-contamination during handling at later steps, such as at trimming and grading points, where between-carcasses decontamination of tools and hands is not used routinely, is an important meat safety issue.

The hygiene, which is a pre-requisite for production of safe meat, is also hampered by manual meat inspection procedures. Making further incisions in tissues/organs following incision of even "normal-appearance" lymph nodes is a perfect way of spreading pathogens such as *Salmonella* spp. and *Yersinia enterocolitica* over the carcass, and possibly between carcasses (Nesbakken et al., 2003; Pointon et al., 2000). Consequently, incising lymph nodes - for example to detect tuberculosis-like lesions - can have detrimental effect on the overall microbial safety of meat, that may exceed the health protection effects of detecting abscesses caused by related *Mycobacterium*. Similarly, the requirement for simultaneous presentation of the head, organs and carcasses for inspection also means that handling and incising of highly contaminated pig heads represent a great opportunity for cross-contamination of the carcasses and/or other organs. There is published scientific evidence that leaving out incisions does not lower the specificity and sensitivity of the visual observation (Hamilton et al., 2002; Mousing et al., 1997). This goes beyond the basic question that these traditional inspection methods altogether have a disputable sensitivity to protect public health.

Examples of successful application of various interventions against relevant microbial hazards in the meat chain up to and including the chilled carcass stage, such as *Campylobacter* (air chilling, especially blast chilling, of carcasses), *Salmonella* (categorisation at herd level and/or carcass decontamination), verotoxigenic *E. coli* (VTEC; carcass decontamination) and *Yersinia enterocolitica* (slaughter hygiene) have been mainly initiated by the industry, and have not been part of the current meat inspection system.

Judgement of fitness of meat for human consumption in current *post-mortem* inspection is based on the identification of "conditions making meat unfit for human consumption" but does not make a clear foodborne risk distinction between different sub-categories i.e. between non-zoonotic conditions making meat unfit (inedible) on aesthetic/meat quality grounds (e.g. repulsive/unpleasant appearance or odour), non-zoonotic conditions making meat unfit in order to prevent spreading of animal diseases (e.g. swine fever), zoonotic conditions making meat unfit due to transmissibility to humans *via* foodborne route (e.g. trichinellosis) and zoonotic conditions making meat unfit due to transmissibility *via* routes other than foodborne (e.g. erysipelas).

4. Improving the current meat inspection system in respect to the main pork-borne hazards

As stressed previously, the original sources of the main bacterial and parasitic pork-borne pathogens *Salmonella* spp., *Y. enterocolitica*, *Toxoplasma gondii* and *Trichinella* spp. are usually asymptomatic pigs. Because current meat inspection of pigs does not target, and is not able to protect the consumer against, the most important "new hazards" (*Salmonella* spp., *Y. enterocolitica*, *Toxoplasma gondii*), appropriate procedures for these hazards have to be developed anew. Whilst the current meat inspection targets "old hazard" *Trichinella* spp., the approach used can be further developed so to be more dynamic and flexible.

Faecally excreted *Salmonella* spp. and *Y. enterocolitica* are further disseminated on-farm and along the meat production chain *via* various direct or indirect routes due to cross-contamination. This ultimately results in contamination of carcasses with such pathogens, and subsequent human exposure to those pathogens *via* pork. Detection and quantification of those hazards in/on pigs and pork carcasses is possible only through laboratory testing. The occurrence and levels of *Salmonella* spp. or *Y. enterocolitica* on pig carcasses are highly variable depending on various factors, including particularly: a) their occurrence in pigs before slaughter and the application and the effectiveness of related pre-slaughter controls strategies; b) the extent of direct and/or indirect faecal cross-contamination during slaughter line operation; and c) the application and the effectiveness of possible interventions to eliminate/reduce them on carcasses (e.g. decontamination). Therefore, as far as the presence of these bacteria in/on carcass meat is concerned, the risk reduction strategies – and related controls – are focused on these three aspects.

Intramuscular parasites *Toxoplasma gondii* and *Trichinella* spp., similarly to above mentioned bacterial pathogens, most commonly do not cause visible pathological conditions so are usually also "invisible" and can only be detected during pig meat inspection by laboratory examination. The presence of their viable forms in meat depends on two main factors: a) the occurrence in pigs before slaughter and the application and the effectiveness of related on-farm control strategies; and b) the application and the effectiveness of possible interventions to kill them in invaded carcasses (e.g. freezing, heat treatment). Therefore, as far as the presence of these parasites in carcass meat is concerned, risk reduction strategies – and related controls – are focused on these two aspects.

Understandably, because of the lack of their macroscopic detectability and the impracticality of their examination in/on each carcass individually, an effective overall control of both the "new hazards" not covered by current meat inspection (*Salmonella* spp., *Y. enterocolitica, Toxoplasma gondii*) and the "old" hazard (*Trichinella* spp.) in pig carcass meat is possible only through a more comprehensive system ("meat safety assurance") combining a range of preventative measures and related controls – applied at both on-farm and at-abattoir levels in a longitudinally integrated way. A generic framework and elements of such a system is considered below.

4.1. Setting what has to be achieved by abattoirs and farms in respect to the main pork-borne hazards

It seems unrealistic to expect that any longitudinally integrated food safety assurance system, based on the main responsibility for the meat safety being allocated to the food operators, would be effective unless the main participants in the food chain are given clear and measurable targets and/or related criteria indicating what they should achieve in respect to particular hazard-food combinations. These are set by regulators as prevalence/levels of the hazards in the food in question, to be met by operators; as a part of the food safety objectives-driven concept introduced by Codex Alimentarius and International Commission on Microbiological Specifications for Foods (CAC/ICMSF). The main elements of that concept are:

- Appropriate Level of Protection (ALOP; WTO 1994): The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.
- Food Safety Objective (FSO): The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP).
- Performance Objective (PO): The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides, or contributes to, an FSO or ALOP, as appropriate.
- Performance Criterion (PC): The effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a PO or an FSO.

These elements and their relationships are explained in more detail in a previous scientific opinion (EFSA, 2007a). ALOP and FSO are wider issues and their considerations, including in respect to the main pork-borne hazards (*Salmonella* spp., *Y. enterocolitica*, *Toxoplasma gondii* and *Trichinella* spp.), are outside the scope of this document. However, setting and using POs and PCs for pig abattoirs in respect to these hazards would need to be an integral part of an improved pork safety assurance system and are included in considerations within this document. Although the terminology used for targets/criteria in the current EU Food Hygiene legislation ("food safety criteria" and "process hygiene criteria") is somewhat different from those used by CAC/ICMSF, their existence confirms that necessity of setting what the operators have to achieve has been recognised in principle. With current EU legislation, the "process hygiene criterion" indicating maximum acceptable prevalence of *Salmonella* spp. on porcine carcasses at the end of slaughter line actually has the nature of a *Salmonella*-related PO for abattoirs. However, in the current EU legislation, there are no comparable targets/criteria for pig abattoirs related to *Y. enterocolitica*, *Toxoplasma gondii* and *Trichinella* spp.; although the legislation indicating judgement of fitness for human consumption designate pork carcasses where *Trichinella* spp. was detected as unfit. Overall, to avoid confusion due to the mentioned differences in the terminology i.e. performance objective or process hygiene criteria, only the term "target" will be used further in the document when referring to what has to be achieved in respect to each hazard in/on final, chilled carcasses and/or pigs presented for slaughter.

Where possible, establishing appropriate targets for abattoirs in respect to each of the main pork-borne hazards (*Salmonella* spp., *Y. enterocolitica*, *Toxoplasma gondii*, *Trichinella* spp.) in/on chilled carcasses needs to be considered because it would:

a) provide a measurable and transparent focus for their meat safety assurance system;

b) differentiate between "acceptably" and "unacceptably" performing abattoirs;

c) represent a basis for "backward"-generating of appropriate targets for farms delivering pigs to the abattoirs and/or indicators for risk categorisation of incoming pigs; and

d) enable related pre-determined FSOs to be satisfied, hence ALOP as well.

Furthermore, where established, a target for chilled carcasses in respect to each of the main hazards would serve as a benchmark to derive correlated performance criteria (PCs) for the abattoir process. The PCs are meant to define an outcome of a step or a combination of steps during the abattoir process required so to ultimately achieve a related target. The main principle (Koutsoumanis and Sofos, 2004) that should be kept in mind is: abattoir PCs need to address initial level of a hazard and the reduction of that hazard during production process. In the process of creating PCs for abattoirs for each hazard, the main question that needs to be considered is whether PCs should be linked to

individual stages of the process (e.g. reduction of a hazard's occurrence/level at a selected one or more specific steps along the slaughterline) or only related to the starting and the end point of the process (e.g. reduction of a hazard's occurrence/level in/on the final carcass meat compared to that in/on incoming pigs).

However, because abattoirs have only limited hazard-reducing capacity, it is important to keep in mind that achievability of a target set for carcasses for a given hazard is also dependent on the occurrence/level of the hazard in/on incoming pigs. Therefore, occurrences/levels of the hazard in pigs that the farms should target to achieve is a function of – and should be "backward" derived from and related to – the abattoir target set for the chilled carcasses. *In other words, a target is set first for chilled carcasses at abattoirs in respect of a given hazard, and then it serves as a basis for setting correlated target for farms delivering pigs.* For that reason, the structure of subsequent sections in this chapter will follow such order: *from chilled carcasses at abattoir towards pigs on farms.*

Further information on epidemiological indicators and related methodologies for the main hazards, that can be used when considering establishment of targets for carcasses and performance criteria for abattoirs, as well as targets for incoming pigs, is provided in the Biological Monitoring Unit's Report (EFSA, 2011c). Therefore, this Opinion and the mentioned Report should be used in combination.

4.2. At-abattoir element of the pork safety assurance in respect to the main hazards

4.2.1. At-abattoir pork safety assurance in respect to *Salmonella* spp. and *Y. enterocolitica*

4.2.1.1. Abattoir technology-based measures to control *Salmonella* spp. and *Y. enterocolitica*

Salmonella spp. and *Y. enterocolitica* are carried in the gastrointestinal tract and/or on the skin of pigs presented for slaughter, and carcass meat becomes contaminated due to direct or indirect cross-contamination that is highly abattoir technology-dependant. While technical aspects of individual steps of pig slaughterline operation may vary considerably between abattoirs, the type and the order in which these steps are carried out are less variable and are generally as follows: *transport/lairaging – stunning – sticking/bleeding – scalding – dehairing – singeing – polishing – washing – evisceration – splitting/trimming – washing – chilling – boning/cutting.*

Each of these operations carries different microbial risks and contributes differently to the final microbial load of the carcass (Gill et al., 1997; Gill and Bryant, 1993; Gill et al., 1995; James, 2002; James and James, 1995; James et al., 1999). Furthermore, a global characteristic of pig abattoir operations is that repeated changes of skin microbiota regularly occur during several successive slaughterline steps, including: *scalding decreases bacterial counts on the skin* - **dehairing increases them** - *singeing decreases them* - **polishing increases them** - *postpolishing washing decreases them* - **evisceration increases them** - *final washing decreases them* (EFSA, 2006). The extent of each of these changes is dependent on technical parameters associated with each of these steps. Also, the common practices of tongue separation from the mouth cavity/pharynx during evisceration step, as well as leaving the head on the carcass and splitting it lengthwise during the operation of carcass splitting, mediates carcass cross-contamination with *Y. enterocolitica* frequently present in tonsils (Van Damme and De Zutter, 2011), and with other microbial pathogens present in the tonsils-mouth-pharyngeal region. In addition, microbiota on carcasses is affected by carcass chilling, as the growth of those microorganisms that are unable to multiply at the refrigeration temperature is prevented, and also a significant proportion of some organisms die off due to combined low temperature-drying effects of the blast chilling (e.g. *Campylobacter* spp.). Furthermore, carcass microbiota may be affected by the "house microflora" i.e. cross-contamination from the slaughterhouse environment (e.g. surfaces, equipment), which is dependant on the antimicrobial effectiveness of the cleaning-sanitation regimes. Generally, when considering possible modifications of pig abattoir operations aimed at

improving microbial status of pork carcasses, the most effective modifications would be those targeting the microbiologically key steps (EFSA, 2006). These measures would include following:

- transport, lairaging and in-same-box stunning of pigs lead to animal-animal and/or animal-surfaces-animal microbial cross-contamination of their skins: minimizing transport and lairaging duration, physical separation of batches of pigs during these steps and regular and effective sanitation of related environmental surfaces can reduce the risks;
- tank scalding, although reducing overall microbial load, also leads to cross-contamination: replacing submersion-scalding with spray-scalding can reduce the risk;
- faeces-voidage-mediated contamination occurs in dehairing machines: related technical modifications and/or previous plugging of anus can reduce the risk;
- "good" singeing can produce a 1.5-3 log microbial reduction, but these effects can be largely negated by common re-contamination during subsequent polishing step: avoiding of polishing step, or inversing of the singeing-polishing order, or repeating of the singeing step, can prevent such a negation and reduce the risk;
- high speed of pig slaughterlines leaves short time for laborious but contamination-prone operations such as evisceration: slowing down the speed at such points through "branching" the line so to use multiple evisceration stations can reduce the risk;
- total prevention of microbial carcass contamination is unachievable in practice: inclusion of single or multiple decontamination steps, e.g. a post-evisceration and/or final carcass hot water treatment, can significantly reduce the microbial load on the carcasses;
- tonsil-mouth cavity-pharyngeal region is often contaminated with *Y. enterocolitica* but also with other bacterial pathogens: complete separation of head from carcass before any handling (i.e. tongue separation, head splitting), its protection (e.g. in plastic bag) and removal before conducting its further handling away from the slaughterline ("in isolation") can reduce the risk of carcass cross-contamination with zoonotic bacteria, in particular *Y. enterocolitica*. In other words, the safest procedure is separation of the head (including tongue and tonsils) from the carcass as early as possible and hygienic transfer onto a separate line;
- use of blast-chilling contributing to significant dying off of some bacterial pathogens, particularly *Campylobacter* spp.

It has been demonstrated that application of any single measure in isolation has a limited impact upon level of pork carcass contamination with *Salmonella* spp. at abattoirs; rather, the largest *Salmonella* spp. reduction is achievable when several improvements are applied concurrently (Alban and Stark, 2005). In any case, the meat safety relevance of above measure is illustrated by the findings of a recent quantitative risk assessment of *Salmonella* spp. in pigs (EFSA, 2010d), indicating that a reduction of two logs (99%) of *Salmonella* spp. numbers on contaminated carcasses would result in a 60-80% reduction of the number of human salmonellosis cases attributable to pig meat consumption.

Unfortunately, as indicated previously (EFSA, 2006), general design of the individual operations, and their order, in industrial high-throughput pig abattoirs have not changed significantly (apart from individual machinery) for decades. The present design/order is dictated primarily by a desire for ever higher speed/throughput and cost-reduction but, to date, their actual microbiological effects may appear as a "secondary" criterion. However, to effectively carry allocated main responsibility for meat safety, the operators would have to do everything possible/feasible to reduce *Salmonella*/*Yersinia* risks including optimising the technology according to its meat microbiology effects.

Overall, it has been well-recognised that the pork safety assurance for *Salmonella* spp. and *Y. enterocolitica* in abattoirs relying on direct testing of all carcasses for their presence/levels is

unfeasible and/or ineffective. Related pork safety - defined through pre-set *Salmonella* spp. and *Y. enterocolitica* targets for chilled carcasses - is more readily achievable through a process management system based on monitoring of the production process, so on prevention rather than end product testing. As indicated by Koutsoumanis and Sofos (2004), the main principle is that if a product of known quality/safety characteristics (i.e. pigs) enters the process and is subjected to a series of verifiable operations of known effect, then the quality/safety will be achieved without the need for laborious inspection/testing of the end product (i.e. carcass). This principle is incorporated in Hazard Analysis and Critical Control Points (HACCP) and quality management (QM) systems; the former should be applied to manage the processes and the interventions to control the enteric bacterial pathogens, whilst the latter is more related to meat quality and shelf-life. Although the two systems fundamentally differ and ideally should be separated to avoid confusion, there are some common aspects e.g. the same monitoring methods and the same points where controls are applied. Because quality control points (QCPs) can be established as equivalent to critical control points (CCPs) (Koutsoumanis and Sofos, 2004), the QM system could also be used to contribute to achieving some goals of the meat safety assurance system.

4.2.1.2. Process hygiene assessment for *Salmonella* spp. and *Y. enterocolitica* and related differentiation of abattoirs

It has been well-recognised that any programme for assessment of the actual effectiveness of food safety system (e.g. HACCP auditing) needs to be based on food safety risk classification of premises and associated operations (FAO/WHO, 1998; Motarjemi, 2000). This is due to the fact that individual operators within the same type of food industry, including abattoirs, can vary considerably in respect to the hygienic characteristics of the technology and the equipment used, the extent to which the procedures are standardized and documented, the technical knowledge available in the operator, the level of food hygiene training and its application, and the motivation of staff and management. These variations individually and their combinations lead to between-abattoirs differences in *process hygiene performances* and, consequently, in the hygienic status of the final carcass.

A number of published studies have confirmed the variability of pig abattoirs in respect to the final outcome, microbiological status of carcasses (Borch et al., 1996; Small et al., 2006). For example, a recent comprehensive study (Delhalle et al., 2008) demonstrated relatively large variability between the ten largest pig slaughterhouses in Belgium in respect to the microbial outcomes of their operations, as measured through microbiological testing of carcasses. *Salmonella* spp. prevalence in microbiologically "the best" and "the worst" abattoirs differed approximately by 13-fold (i.e. from 2.6 to 34.3%), median *Escherichia coli* count (ECC) by 35-fold and aerobic bacteria colony count (ACC) by 19-fold. These results confirmed the variability of the technical feasibility of minimizing contamination among abattoirs, the relevance of which was confirmed through identification of between-abattoirs technical differences in analogue of the production processes and their relatedness to *Salmonella* spp. prevalence on carcasses. In general, good slaughtering and dressing procedures (Good Manufacturing Practices (GMP) and Good Hygienic Practices (GHP) will have substantial effect on microbiological contamination of carcasses. The development of GMP and a total process control (e. g. HACCP) can substantially contribute to safety and quality of meat. However, GMP and GHP are often not sufficient during slaughtering and dressing of pigs belonging to herds with carriers of *Salmonella* spp. Berends et al. (1997) have shown that "*there is a strong correlation between the number of live animals that carry* Salmonella *spp. in their faeces and the number of contaminated carcasses at the end of the slaughterline. Live animals that carry* Salmonella *spp. are 3–4 times more likely to end up as a positive carcass than* Salmonella*-free animals; currently, about 70% of all carcass contamination results from the animals themselves being carriers, and 30% because other animals were carriers (i.e. cross contamination)*".

Furthermore, in Norway, the decline in human cases of yersiniosis from about 200 cases in the beginning of the nineties to about 50 human cases last year is probably a result of implementation of

improved slaughtering methods during 1994 and 1995, including enclosure of the anus into a plastic bag after rectum-loosening (Nesbakken, 2009)(Figure 2). It is important to keep in mind that, in pigs at the age of 150 to 180 days (when most fattening pigs are slaughtered), the tonsils may be a more important source of human pathogenic *Y. enterocolitica* than the intestinal contents as its occurrence in the latter is reduced over time (Nesbakken et al., 2006). Accordingly, hygienic handling of the head and the pluck during slaughter, dressing, and *post-mortem* inspection, is very important to avoid/reduce contamination of the carcass.

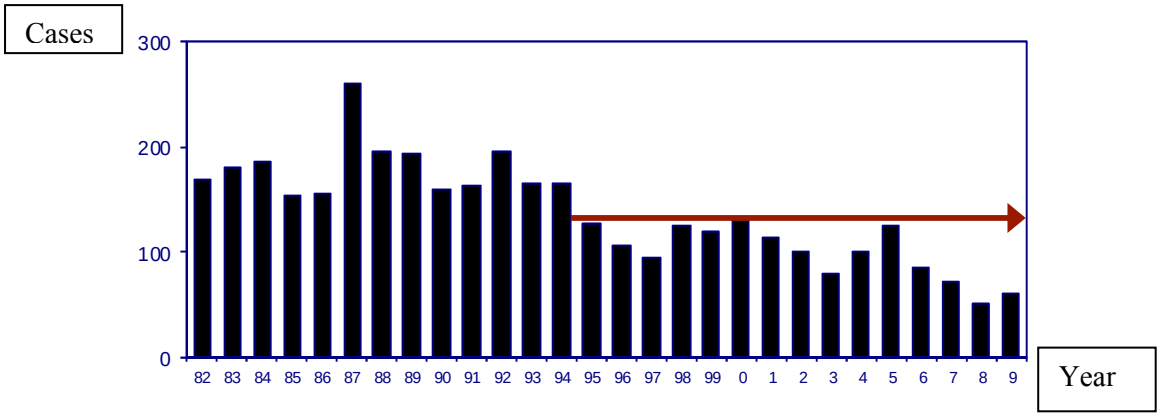


Figure 2: Cases of human yersiniosis in Norway based on bacteriological identification of *Y. enterocolitica* infection (Norwegian Surveillance System for Communicable Diseases (MSIS), 1982-2009 (www.msis.no); the decline is marked by arrow.

Overall, the pork safety risks in respect to *Salmonella* spp. and *Y. enterocolitica* in pig abattoir operations are: a) strongly influenced by process hygiene performance of the operators; and b) between-abattoir variable. Consequently, it seems both necessary and possible to classify ("risk categorise") the pig abattoir operations in respect to those hazards through their differentiation based on individual process hygiene performance. For that, existence of a standardized methodology and criteria for assessment of process hygiene is a prerequisite.

In the EU, currently, Regulation (EC) No 2073/2005[15] sets down *Process Hygiene Criteria* (PHC) which gives guidance on, and is an indicator of, the acceptable functioning of HACCP-based abattoir processes. It sets indicative microbial contamination values for carcasses above which corrective actions are required in order to maintain the hygiene of the process in compliance with food law. The maximum values are set for indicators of overall contamination (total viable count of bacteria; TVC), indicators of contamination of enteric origin (*Enterobacteriaceae* counts; EC) and *Salmonella* spp. prevalence. However, as stressed previously (EFSA, 2007a), because:

- the set contamination values are applicable only to the product at the end of the manufacturing process (final carcass), and
- they are not related to the (normally highly variable) initial contamination values of the raw materials at the individual operator level,

the nature of the PHC is similar to that of so-called "end-product" criteria. In other words, current PHC for abattoirs actually do not provide information on ratios between initial contamination

[15] Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs. Official Journal of the EU L 338, 22.12.2005, p. 1–26

associated with incoming animals *versus* final contamination associated with carcasses i.e. on actual capacity of the process to reduce the incoming contamination, but only on the process outcomes. This might be either an advantage or a disadvantage depending whether the purpose is to microbiologically characterize the process itself (dealt with in this subsection), or to characterize the microbiological status of the final product only.

This shortcoming in assessing red meat (including pig) abattoir process hygiene had been recognised earlier, so characterisation of the process by analyzing microbial loads at multiple stages was advocated (Bolton et al., 2000; Gill and Jones, 1997). Also, principles of a simplified approach were suggested (Blagojevic et al., 2011; Vivas Alegre and Buncic, 2004), with which determining the ratio between mean TVC and/or EC on final carcasses and those on skins of corresponding incoming animals (post-slaughter, pre-scalding) would enable more precise assessment of the capacity of each abattoir process to reduce the contamination, as well as more reliable differentiation between abattoirs.

It is important to note that there is a general recognition in the scientific literature that indicator microorganisms are much better suited for use in process hygiene assessment than pathogenic microorganisms (Blagojevic et al., 2011; Bolton et al., 2000; Koutsoumanis and Sofos, 2004). This is due to the facts that pathogens occur in animals/on carcasses relatively rarely, are affected also by on-farm factors, are difficult to count/quantify and require more laborious handling in better equipped laboratories. Pathogen testing is much more valuable for the purposes of consumer exposure assessment and pathogen reduction programmes; so is more related to setting of targets for abattoirs.

- Overall, it is clear that a methodology as well as criteria for actual microbiological characterization and proper assessment of process hygiene in pig abattoirs, as well as for related between-abattoir differentiation, must be available. However, no single related method has been widely accepted to date, hence has yet to be developed and standardized in the EU. Such more accurate information would enable *differentiation* ("*risk categorisation")* *of abattoirs* in respect to *Salmonella* spp. and *Y. enterocolitica* which, in turn, would enable *different risk management options for different risk categories of abattoirs* to be used, including:
- optimization of balancing *Salmonella*/*Yersinia* risk categories of pigs (see 4.3 section) with risk categories of abattoirs where they are to be slaughtered;
- optimization of decision whether/where additional interventions e.g. carcass decontamination step are to be applied;
- better differentiation between the farm of origin-associated and the abattoir-associated contaminations with *Salmonella*/*Yersinia*, as well as more reliable feed-back information to farm of origin;
- more stringent requirements for monitoring/verification/auditing programmes for higher-risk abattoirs;
- clearer identification of abattoirs where improvement of the technology is needed.

4.2.2. At-abattoir pork safety assurance in respect to *Toxoplasma gondii*

As indicated in previous sections, *T. gondii* does not cause symptoms in pigs so cannot be macroscopically detected during current meat inspection of pigs either *ante-* or *post-mortem*. The hazard can be detected only through laboratory testing. The testing methods are based on direct detection of *T. gondii* in tissues or on the indirect detection of specific antibodies in serum. Currently used molecular or histological methods are insensitive to detect *T. gondii* in pork because the density of these parasites in meat is low (one tissue cyst per 25 gram or more) (Dubey, 2009). However, recently a more sensitive method to detect *T. gondii* in meat was described based on pre-enrichment

of the parasites DNA by magnetic capture followed by PCR (Opsteegh et al., 2010). Nevertheless, there may be practical difficulties with routine use of the method for testing of individual carcasses in abattoirs, including issues related to storing the carcasses and organs whilst awaiting the result and availability of appropriate laboratory facilities; hence the method's feasibility has yet to be evaluated under industry conditions. Furthermore, PCR testing detects the parasite's genome rather than its viability. For more information about testing methods for *T. gondii* see the Biological Monitoring Unit's Report (EFSA, 2011c).

Therefore, alternative approaches to pork safety assurance in respect to tissue cysts of *T. gondii* have to be considered for high risk populations. They are primarily based on meat treatments with aim to inactivate (devitalize) the cysts. It seems that currently the most reliable cyst inactivation treatments are based on application of either adequate meat heating regimes or adequate meat freezing regimes. Temperature-time regimes of these treatments are presented in Table 8.

Table 8: Inactivation treatments for *Toxoplasma gondii* cysts in fresh meat

Type of treatment	Stage of parasite	Conditions	References
Heat treatment	Tissue cysts of *T. gondii*	58°C for 9.5 min or 61°C for 3.6 min	Dubey et al. 1990
Heat treatment	Tachyzoites	55°C for 5 min	Dubey, 1998
Freezing	Tissue cysts	-20°C during 11 days	Dubey, 1974
Freezing	Tissue cysts	-12°C during 2 days	Kotula et al., 1991

T. gondii may occur in three evolution forms: tachyziotes, bradyzoites (in tissue cysts) and sporozoites (located in oocysts). Tachyzoites are typical for acute phase of infection. Bradyzoites are located in tissue cysts (cluster of several hundred of bradyzoites) and are typical for chronical phase of infection. Tissue cysts can be located in various organs but predilection sites for their occurrence are skeletal and cardiac muscles. Oocysts are found mainly in water, contaminated soil or on the surface of contaminated fruit and vegetables, and therefore are not relevant to this assessment.

Because there is no issue of between-animal cross-contamination with *T. gondii* at slaughter, it is not necessary to handle pigs from negative and positive herds separately during the transport-lairage-slaughterline period. However, incoming batches of pigs can be categorised into those from *T. gondii*-free herds and infected herds (sows are particularly at-risk). The categorisation can be based on historical testing results e.g. by serological testing of meat juice. Both categories can undergo usual slaughter, dressing and chilling operations, but after chilling carcasses from pigs originating from *T. gondii*-infected herds would have to be treated by a reliable and validated cyst-inactivating method (e.g. freezing) before de-boning/cutting or distribution as whole carcasses. Alternatively, meat from positive animals can be heat-treated after de-boning. In contrast, carcasses from pigs originating from *T. gondii*-free herds would not need such treatments.

4.2.3. At-abattoir pork safety assurance in respect to *Trichinella* spp.

Direct identification of *Trichinella* spp. larvae in pig muscles, those where the largest number is expected (predilection sites) including diaphragm, tongue and masseter, is possible only during *post-mortem* inspections of carcasses (Gamble et al., 2000). The current examination method for the detection of *Trichinella* spp. larvae is based on isolation of the larvae by artificial digestion and microscopic identification; with the sensitivity of at least one to three larvae per gram.

However, as with *T. gondii*, alternative approaches to pork safety assurance in respect to muscle larvae of *Trichinella* spp. can be considered. They are primarily based on meat treatments with aim to inactivate (devitalize) the larvae. It seems that currently the most reliable larvae inactivation treatments (Gamble et al., 2000, 2007) are based on application of:

- adequate meat heating regime e.g. 71°C/at least one min;
- adequate meat freezing regime e.g. at least -15°C/three weeks (if meat is cut in pieces up to 15 cm in thickness) or -15°C/4 weeks (if meat pieces are up to 50 cm thickness), but should be noted that *T. britovii* in pork can survive up to three weeks at -20°C;
- adequate irradiation e.g. 0.3 kGy (recommended for sealed packaged food).

Although meat treatments based on curing and smoking have also been reported as able to inactivate *Trichinella* spp. larvae, they are not recommended because it is difficult to reliably monitor and control these processes (Gamble et al., 2000).

Because there is no issue of between-animals cross-contamination with *Trichinella* spp. at slaughter, it is not necessary handle pigs from negative and positive herds separately during the transport-lairage-slaughterline period. However, as with *T. gondii*, incoming batches of pigs could be categorised into low and higher-risk categorises (sows are particularly at-risk) based on historical testing results. After slaughter, meat from low risk pigs could be passed without having to be either tested or treated. In contrast, meat from higher-risk pigs could undergo one of the two options: either to be examined for *Trichinella* spp. using the current detection methodology, or to be treated by a reliable and validated larvae-inactivating treatment.

4.3. On-farm element of the pork safety assurance in respect to the main pork-borne hazards

4.3.1. Summary of the on-farm aspects of the main pork-borne hazards

4.3.1.1. *Salmonella* spp. at herd level

A wide range of *Salmonella* spp. serotypes is shed by pigs, often intermittently or transiently, without any evident symptoms of illness. Young animals are more susceptible than older animals to infection with *salmonellae*. In addition to infection of the gastrointestinal tract, *salmonellae* may occur in the mesenteric and hepatic lymph nodes, and sometimes in the gall bladder and in the liver and spleen (Kampelmacher, 1963). *Salmonellae* may be present in these lymph nodes even when *salmonellae* no longer can be detected in intestinal contents. *Salmonellae* can also be found in tonsils and submaxillar lymph nodes (Pointon et al., 2000; Wood et al., 1989). Clinical illness was formerly often caused by the host-adapted *S*. Cholerae-suis, but control measures have significantly reduced the number of outbreaks due to this serotype. In particular *S.* Typhimurium dominates the infection between animals, while different serotypes originate from the feed and the environment. The emergence of *Salmonella* spp. is often related to changes that have occurred in livestock farming. Farm sizes have increased and animal husbandry methods have also become more intensive. However, monitoring programmes established during the early nineties in Finland, Norway and Sweden indicating that less than 0.1% of the pigs in these countries are carriers of *Salmonella* spp. show that it is possible to control this agent by categorisation at herd level (Nordic Council of Ministers, 2006).

4.3.1.2. Yersinia enterocolitica at herd level

Young pigs become healthy carriers of *Y. enterocolitica* in tonsils and faeces when they are about 60 to 80 days old, and become seropositive shortly thereafter (Nesbakken et al., 2006). According to Skjerve et al. (1998) *Y. enterocolitica* was less frequent in mixed breeding-finishing herds than in fattening herds in which piglets are purchased from other herds. The use of an own farm vehicle for transport of slaughter pigs to abattoirs, daily observations of a cat with kittens at the farm, and using straw bedding for slaughter pigs were some of the independent risk factors identified. A study of the health and breeding pyramid of the Norwegian Specific Pathogen Free (SPF) herds in the period from

1996 to 2006 indicates that it is possible to establish clusters free from *Y. enterocolitica* and to keep the herds free from this human pathogenic variant for many years (Nesbakken et al., 2007).

4.3.1.3. Toxoplasma gondii at herd level

Livestock production including pigs in developed countries continues to undergo major structural changes, including marked reductions in numbers of farms and corresponding increases in herd size, mainly for economic and efficiency reasons. However, simultaneously, there is a rise in numbers of smaller farms and outdoor breeding pig farms; for sociological, ethical, environmental or sanitary reasons (Davies, 2011).

There are some important aspects which can fundamentally influence the occurrence of *T. gondii* in pigs; the most important include:

- Level of production system (zoo-sanitary conditions) and size of farms;
- Farming method (indoor or outdoor system);
- Age of animals (fattening pigs or sows).

The prevalence of *T. gondii* in pigs is influenced by management systems. Studies in several European countries have associated marked declines in *T. gondii* seroprevalence with intensification of pork production (Tenter et al., 2000). Dramatic reduction in *T. gondii* prevalence seen in commercial pork production has been affected by changes in pig farming systems. For example, in Austria, seroprevalence of 14 % in 1982 decreased to 0.9% in 1992 (Edelhofer, 1994). Similarly, in the Netherlands it decreased from 54% in 1969 to almost 0% in 1981 (van Knapen et al., 1982). Many routine practices in modern pig farms (biosecurity measures including confinement rearing, systematic rodent control, more hygienic feed handling procedures, exclusion of cats) are combined to reduce the risk of exposure of pigs to *T. gondii*.

However, on farms where pigs have outdoor access there is an elevated risk of *T. gondii* infection (Gamble et al., 1999; Garcia-Bocanegra et al., 2010; Hove et al., 2005). Studies of wild pigs reported a mean prevalence of around 20% (Dubey, 2009). It is considered that recent trend of rearing pigs outdoors in European countries is likely to increase seroprevalence in pigs in Netherlands (Kijlstra et al., 2008; Meerburg et al., 2006; van der Giessen et al., 2007). Also, in poorly managed, non-confinement systems, seroprevalence in pigs was a high a 68% (Gamble et al., 1999). Therefore, very high prevalence of bradyzoites in pork may still occur in pigs reared in less controlled conditions. It has been suggested that low or negligible *T. gondii* seroprevalence at farm level can be used as an indicator of good hygiene practices (van Knapen et al., 1995). Regarding the age of pigs, the seroprevalence in sows is higher compared with slaughter age pigs, and is epidemiologically relevant with respect to transmission of *T. gondii*.

4.3.1.4. *Trichinella* spp. at herd level

Infection of humans occurs only *via* ingestion of *Trichinella* spp. larvae that are encysted in muscle tissue from infected pigs (and other domestic or wild animals). The most frequent species is *Trichinella spiralis* which is most adapted to domestic and wild swine, but can also include synantrophic rats in its life cycle. The most widely distributed species within sylvatic life cycles in Europe is *Trichinella britovi*, but this species can also affect domestic pig populations mainly *via* extensive grazing systems or feed containing scraps or carrion originating from sylvatic carnivores. *T. britovi* is the second-most common species of *Trichinella* spp. that may affect human health (Pozio, 2007; Pozio et al., 2006).

Trichinella-free herds have to fulfil several requirements. An efficient surveillance system is necessary (Daszak et al., 2000). A number of requirements are related to biosecurity/general hygiene and rodent control. In addition, fattening pigs (from *Trichinella*-free herds) are not allowed to have access to outdoor facilities as of their fourth week and only if strict conditions are met during the first four weeks. Additional requirements apply to categories of herds that may be recognized as *Trichinella*-free, including the need for a ten-year national surveillance programme that would have detected a prevalence exceeding 0.0001% (Gottstein et al., 2009). It is relatively easy to recognise finishing pigs in low risk areas/farms in which probably control of *Trichinella* spp. in each pig can be omitted with low additional human risk. On the other hand, in member states without data or even with positive human/animal cases the traditional meat inspection procedures should be followed (Alban et al., 2011). In addition wildlife must be monitored. Wild boar plays a key role in the maintenance and spread of *T. spiralis* through the sylvatic cycle. The wild boar population increased in Europe in the past years. This phenomenon should be monitored because the wild boar is an important reservoir of *T. spiralis* and it may pose a risk of transmission to backyard and free-ranging pigs (Root et al., 2003).

4.3.2. Diagnostics and indicators for the main pork-borne hazards at farm (herd) level

4.3.2.1. General role

It is possible to categorise herds using serological or bacteriological testing of herds for the main pork-borne hazards. Although diagnostic procedures can be applied either at herd level or during the slaughtering process, the results relate to and are used for differentiation between pig farms in respect to the hazard prevalence status. Both the sample matrix and the method of the test can be chosen according to the target and the purpose of the testing. For example, with *Salmonella* spp. and *Y. enterocolitica* testing, sampling of blood/meat juice and use of serological methods can provide evidence of the pig exposure to the hazard but not of its current presence, the latter can be determined by sampling of intestinal content/lymph nodes and use of microbiological methods. In contrast, sampling of carcasses and use of microbiological methods cannot provide accurate data on prevalence of the hazard in pigs on-farm, because the presence of these bacterial pathogens on carcasses can be due to post-farm cross-contamination taking place during the transport-lairaging-slaughterline chain of events.

The results that reflect the history of the herd can be used to:

- differentiate ("risk categorise") pig herds in respect to carriers of the main pork-borne hazards (*Salmonella* spp., *Y. enterocolitica*, *Toxoplasma gondii* and *Trichinella* spp.);
- apply strategies, based on herd health programs, closed breeding pyramids, Good Hygienic Practices (GHP) and Good Farming Practices (GFP), to reduce the prevalence of herds carrying the hazards;
- handle pig batches from farms of different risk categories separately so to avoid cross-contamination or infection of negative herds in respect to *Salmonella* spp. and *Y. enterocolitica* (but not for *Toxoplasma*/*Trichinella* where there is no cross-contamination) including balancing between different risk categories of incoming pigs and different risk categories of abattoirs in respect to their process hygiene (see section 4.2.1.2), so to maximise chances of achieving related targets set for final carcasses; and
- select appropriate technology-based control strategies to be implemented at-abattoir (see section 4.2.1.1), such as surface pasteurisation with hot water of the carcasses (for *Salmonella*/*Y. enterocolitica*) or heat-treatment/freezing (for *Toxoplasma*/*Trichinella*) of the meat, that originate from positive batches/animals, so to maximise chances of achieving related targets set for final carcasses.

4.3.2.2. Generic principles of risk categorisation of pigs at herd level in respect to the main pork-borne hazards

For the risk categorization of pig batches for each of the main hazards, first an appropriate historical database must be established i.e. a defined number of samples must be investigated over a defined period of time. Therefore categorisation comprises the following phases:

- Initial phase: data sampling according to sampling plan;
- Neutral phase: decision on status can be made on the basis of preliminary data;
- Final phase: final decision on status can be made until change in data occurs.

Following these phases, also three types of status can be identified:

- Unknown status: not enough data has yet been sampled for categorization;
- Neutral status: initial phase of data sampling showed only negative results of tests, therefore the preliminary categorization in neutral status can be made;
- Low risk status: data sampling is completed and showed results that conform to a pre-specified criteria, status is unchanged until the agreed criteria is exceeded.

If positive samples occur, each animal batch is categorized in a risk group according to a decision plan. Depending on the epidemiological situation regarding a given pork-borne hazard, a single threshold can be defined i. e. presence or absence of antibodies/live cells of that hazard.

4.3.2.3. Generic example of risk categorization of pigs at herd level

Systems for *Salmonella* spp. risk categorization of pig herds, based on meat juice/blood samples and use of serological method, are already in place in some MSs (e.g. Germany, Denmark, UK) and the experiences can be used for outlining a generic example. An outline of this system is given in general terms below. Other systems rely on blood samples targeted also to improve the situation on the farm. An example is the system for *Trichinella spiralis* in the Netherlands in the period 1979-1995. Besides the official European control of trichinellosis in each individual pig in the Netherlands, serosurveillance was also introduced in 0.5-1% of all finishing pigs slaughtered (at that time around 20 million a year). This was done in order to get information about the real prevalence of *T. spiralis* infection in pigs in the Netherlands, because the abattoir method (artificial digestion) was too insensitive to measure light infection in pigs (van Knapen, 1991; van Knapen, 1994). There are other approaches, for example the system for *Mycobacterium avium* subsp. *paratuberculosis* (MAP) in pigs in Germany and the Netherlands using blood samples (for details see Annex). MAP monitoring was introduced because of legal requirements of the current legislation. The monitoring should be considered as equivalent to the incision of the mandibular lymph node and should replace this incision. The choice of MAP as target of the monitoring was therefore not the result of a formal risk assessment. It is worth noting that in this opinion MAP is not considered as a hazard with a high or medium risk ranking (section 2.3).

A generic testing scheme can be defined as follows: the frequency of animals with antibodies against zoonotic agent X in a random sample of 60 slaughtered pigs per herd and year[16] is evaluated.

The samples for this serological monitoring are either meat juice samples taken at slaughter or blood serum samples taken not earlier than 14 days prior to slaughter. Normally meat juice samples are taken at the slaughterhouse because of the easier access there. Either kind of sample is analysed *via*

[16] QS-Website: Guideline *Salmonella* programme pig (http://www.q-s.de/dc_agriculture_pig_production.html) Accessed 20 June 2011

Enzyme Linked Immunoabsorbant Essay (ELISA). The actual cut-off of the monitoring for agent X depends on the epidemiological situation in the region or member state and is e.g. for *Salmonella* spp. in Germany 40% OD (optical density)[8]. The cut-off may be lowered if the overall sero-prevalence at a national level is lowered as well (Blaha, 2004).

The samples must not be taken all at once, but must be spread over a 12 month period among the groups sent to slaughter in order to receive an as accurate as possible representation of the serological status of the herd, which tends to change over time.

The categorisation can be made after one year of testing, as follows:

- Category I: less than x% of all samples taken are antibody positive for the pork-borne hazard X (e.g. 20%)
- Category II: between x% and y% of all samples taken are antibody positive for the pork-borne hazard X (e.g. 20 - 40%)
- Category III: more than y% of all samples taken are antibody positive for the pork-borne hazard X (e.g. >40%).

For example, for *Salmonella* spp. a rolling average can be calculated over regular time once a herd has been risk-categorized for the first time. For this purpose at the end of each period, the results of the "oldest" samples are taken out of the calculation of the average, while the results of the then "newest" samples are included into the pool. Thus there are again 60 samples that are taken into account for the re-categorization. A shorter or longer period of sampling for the rolling average can be applied, but longer periods would result in higher insensitivity to current problems. On the other hand shorter periods will lack in statistical validity, as lower numbers of animals would be sent to the abattoir. Herds in Category III are required and herds in Category II are encouraged to find the cause of the problem with zoonotic agent X and implement measures against it in order to reduce the sero-prevalence of the herd (Blaha, 2004). Other methods to estimate the *Salmonella* spp. herd prevalence include Bayesian predictive modelling at slaughterhouse level (Benschop et al., 2010).

Similarly categorisation can be made for other main pork-borne hazards identified in section 2 according to geographical area, abattoir, etc. Preferably, diagnostics targeting all those main pork-borne hazard should be combined in one technological platform (minichip) for practical reasons e.g. to take advantage of sampling at slaughterhouse level.

5. Outline of a generic framework for pork (carcass) safety assurance in respect to the main pork-borne hazards

This document deals with meat inspection that is executed at abattoir by definition, hence, understandably, the abattoir plays a central role and is centrally placed in the generic pork safety assurance framework considered here. The framework includes considerations of the on-farm status of the pigs in respect to the main hazards at the time of their presentation for slaughter, as well as considerations of at-abattoir measures aimed at ensuring adequate status of final carcasses in respect to these hazards. However, it does not deal with other controls of these hazards taking place before or after the pig slaughter stage e.g. not with controls aimed at earlier preventions of infection of pigs with the hazards or controls aimed at elimination/reduction of the hazards at meat processing-distribution-preparation stages. Whilst some of those other controls may be useful and effective in the context of global pork safety, they are outside the scope of the present considerations - as indicated previously.

In this section, a generic framework for pork (carcass) safety assurance in respect to "new hazards" *Salmonella* spp., *Y. enterocolitica* and *Toxoplasma gondii* is considered "anew", whilst for "currently covered" hazard *Trichinella* spp. possible improvements or additions to existing inspection method are considered.

5.1. *Ante-mortem* inspection of pigs and generic pork (carcass) safety assurance framework

In the current system, *ante-mortem* inspection of pigs is conducted by an official veterinarian at abattoir during pre-slaughter period (unloading and lairaging). Globally, the information gathered during *ante-mortem* serves towards protecting the public from foodborne disease and zoonoses, protecting the slaughter staff from zoonoses, protecting animal health through surveillance for serious and notifiable disease, and also protecting animal welfare (Small et al., 2006). *Ante-mortem* inspection aims to sort animals into three broad categories:

- those that can progress to slaughter and subjected to routine *post-mortem* examination;
- those that must be removed from the food chain;
- those that require to be processed separately from the routine kill and/or more detailed *post-mortem* examination.

These goals are achieved by taking into consideration information gathered from the holding of origin, clinical findings which will assist in the final judgement of the resultant carcass, as well as a visual assessment of cleanliness and any abnormalities of the animal in motion and at rest during the 24 hour period just prior to slaughter.

Current *ante-mortem* inspection does not contribute to detection of any of the main pork-borne hazards (*Salmonella* spp., *Y. enterocolitica*, *Toxoplasma gondii* and *Trichinella* spp.) considered in this document, as none produce observable signs in pigs. The only aspect of *ante-mortem* inspection that has some relevance for *Salmonella*- and *Y. enterocolitica*-related pork safety assurance is assessment of visual cleanliness of pigs. Overall, visual cleanliness of animals for microbial status of carcasses is more relevant for slaughtered ruminants than for pigs, because pigs are subjected to scalding. Nevertheless, although visual cleanliness and dirtiness of the skin alone cannot be used as indicator of absence or presence, respectively, of the two hazards in pigs, in case of pig batches from *Salmonella*- and *Y. enterocolitica*-positive farms being presented for slaughter, it could be assumed that the dirtier animals are with faecal material, the higher risk exists of cross-contamination of the slaughterline environment including the carcasses. Therefore, as far as the generic pork safety

assurance framework in respect to the main pork-borne hazards is concerned, no changes of the current *ante-mortem* inspection of pigs are required.

However, as indicated in previous sections, keeping the pig transport-lairaging period as short as possible, including avoiding lairaging altogether ("slaughter from trucks") if/where possible and allowable from animal welfare aspect, may be beneficial in terms of reducing associated cross-contamination of pigs with *Salmonella* spp. and *Y. enterocolitica*.

5.2. Food chain information (FCI) and generic pork (carcass) safety assurance framework

The main rationale behind the use of FCI is that - based on appropriate and detailed information on their pre-history, as well as on *ante-mortem* inspection findings - pigs intended for slaughter can be categorised into groups potentially posing higher or lower risk; preferably before arriving at the abattoir or at least before slaughter. The two groups can be subsequently handled differently including application of detailed or simplified *post-mortem* examinations. Currently, the main factor taken into account when considering FCI-based grouping of animals is whether they are coming from so-called "integrated" or "non-integrated" systems.

Integrated animal production systems had been defined by relevant expert groups (SCVMRPH, 2000, 2001) and were subsequently included in EU legislation (Regulation (EC) No 854/2004). The criteria can be divided into two main groups: a) they must operate by using Good Farming Practice (GFP), Good Hygiene Practice (GHP) and fundamentals of Hazard Analysis and Critical Control Points (HACCP) philosophy; and b) they must have quality assurance systems in place ensuring control over, and information availability about, a number of aspects including:

- Animal identification (movement, traceability);
- Epidemiological intelligence (data from herd health plans, monitoring/surveillance, medicines and veterinary treatments);
- Farm animal management and QA (welfare; housing and handling facilities; feed composition, storage and use; biosecurity);
- Environment and hygiene management.

However, in respect to each of the four main hazards, *Salmonella* spp., *Y. enterocolitica*, *Toxoplasma gondii* and *Trichinella* spp., as indicated in previous chapters, an important element of the generic framework for pork safety assurance is risk categorisation of pig batches (herds) based on use of historical testing data and application of hazard-specific harmonised epidemiological criteria. Furthermore, in case of hazards for which the ultimate risk reduction on carcasses depends also on process hygiene performance of abattoirs (i.e. *Salmonella* spp. and *Y. enterocolitica*), it is necessary that related historical data are also considered within FCI. In other words, information about each abattoir should become an additional, abattoir-related element of FCI information and to be used by the risk manager in combination with incoming pigs-related element of FCI. Therefore, in respect to *Salmonella*/*Y. enterocolitica*, current FCI should be improved accordingly.

Overall, to enhance likelihood of achieving adequate risk reduction on carcasses and to meet targets for the four main hazards in/on the porcine carcass meat, the improved FCI (including abattoir process hygiene- and incoming pig batches-related information) can be used to decide which of the possible scenarios will be applied in each given situation; some possibilities are illustrated below:

- Slaughtering lower-risk pig batches (with no or very low prevalence/levels of *Salmonella*/*Y. enterocolitica*) in low-risk abattoirs (with good *Salmonella*/*Y. enterocolitica* risk reduction capacity) where just usual, hygienic slaughter-dressing process may be applied.

- Slaughtering higher-risk batches (with certain prevalence/levels of *Salmonella*/*Y. enterocolitica*/*Toxoplasma*/*Trichinella*) in abattoirs where usual, hygienic slaughter-dressing process may be combined with additional risk-reduction interventions so to eliminate or inactivate the hazards from final carcasses.
- Other appropriate scenarios based on balancing between risk category of the incoming pigs and risk category of the abattoir operation.

Defining criteria for lower and higher risk categories of both batches and abattoir processes is a regulatory responsibility, and decisions on which of the possible scenarios is to be applied in specific batch-abattoir situations is also a risk management responsibility. From a practical perspective, FCI analysis and related decision making is a complex task, as in some situations the same incoming pig batch may represent different risk categories in respect to different hazards; e.g. lower risk in respect to *Salmonella* spp.but higher risk in respect to *Toxoplasma gondii*, etc; which requires that the risk manager has necessary training and competence.

The operational aspects of the incoming pig batch- and abattoir-related data for each of the main hazards (*Salmonella* spp., *Y. enterocolitica*, *Toxoplasma gondii* and *Trichinella* spp.) including appropriate sampling plans (that can be executed either on farm or at abattoir) and related methods, as well as the harmonised epidemiological indicators (HEI), are considered and described in the EFSA Biological Monitoring Unit Report on HEI for those hazards (EFSA, 2011c). Therefore, the generic pork safety assurance framework described in this document and the HEI described in the Biological Monitoring Unit Report – for the same hazards – should be considered and interpreted in combination. However, whilst the two documents together provide generic principles/mechanisms for the risk categorisation of pig batches/abattoirs in respect to each of the four main hazards, neither provides specific numerical values as a basis for actual/practical differentiation of the batches/abattoirs. This is understandable, for two basic reasons:

- Setting such numerical values for each of the main hazards for both pigs and abattoirs is a regulatory responsibility, and not a risk assessment activity conducted in this document;
- For each of the main hazards, the criteria for pigs must be derived from, and be a function of, regulatory pre-set, correlated target for chilled carcasses at abattoirs (see next subsections) which, in turn, must be derived from, and be a function of, regulatory pre-set, correlated food safety objective (FSO).

Therefore, should the generic pork safety framework be implemented, those pre-requisites need to be provided by the regulator.

5.3. *Post-mortem* inspection of pigs and generic pork (carcass) safety assurance framework

The current EU legislation (Reg. (EC) No 854/2004/EU) describes *post-mortem* inspection that uses macroscopic techniques (visual, palpation, incision) to examine carcass, offal and blood (where appropriate) as well as sampling for some mandatory laboratory examinations (e.g. residues, *Trichinella* spp.). The macroscopic examination is designed to, and can, provide following information about the slaughtered animal (Buncic, 2006):

- Age and sex
- State of nutrition
- Local/general oedema
- Efficacy of bleeding
- Swelling/deformity

- Abnormal colour, odour or taste
- Condition of mucosa and serosa (e.g. pleura and peritoneum)
- Any other localized or generalized (e.g. septicaemia) abnormality
- Signs of specific diseases

The information is then used to make a decision on the fitness for human consumption. The presence of the main hazards (*Salmonella* spp., *Y. enterocolitica*, *Toxoplasma gondii*, *Trichinella* spp.) in slaughtered pigs cannot be confirmed or excluded through detection of any of above conditions macroscopically observable by current *post-mortem* inspection. Nevertheless, *Trichinella* spp. is detectable within the current *post-mortem* inspection through muscle sampling and laboratory testing, although the hazard occurs very rarely, only in some areas, and the testing is laborious and costly. However, current macroscopic *post-mortem* inspection does not contribute in any way to the detection of *Salmonella* spp., *Y. enterocolitica* and *Toxoplasma gondii* so it cannot contribute to related judgement of fitness of contaminated/infected pork for human consumption either. The abattoir process hygiene assessment required by the current EU legislation includes sampling of pig carcasses at the end of the slaughterline (before chilling) and examination for presence of *Salmonella* spp.; the HACCP-based meat safety system of the abattoir has to be reviewed and corrected if the *Salmonella* spp. prevalence exceeds related regulatory criteria. However, as indicated in previous sections, interpreting this *Salmonella* spp. testing in the context of the meat inspection is problematic, for various reasons including: a) current *Salmonella* spp. testing is placed within verification of HACCP-based system as a whole, and is not aimed at judging the fitness (acceptability or unacceptability) of individual carcasses; b) its nature is end-product testing rather than process hygiene assessment; and c) current *Salmonella* spp. criterion for carcasses is not linked to the *Salmonella* spp.status of incoming pigs so the abattoir process is not microbiologically characterised in terms of the hazard reduction or otherwise.

Therefore, the approach to achieving public health protection in respect to *Salmonella* spp., *Y. enterocolitica* and *Toxoplasma gondii* in pig carcass meat at abattoir level has to be designed anew, and in respect to *Trichinella* spp. can be amended through alternative approaches; the main aspects of which are outlined in following subsections.

5.3.1. *Post-mortem* element of generic pork (carcass) safety assurance framework in respect to *Salmonella* spp. and *Y. enterocolitica*

The starting point, and a pre-requisite, of the effective control of these two bacterial foodborne pathogens at abattoir level is the target for chilled porcine carcass to be achieved by the abattoir for each hazard. As indicated above, the target for the chilled porcine carcass is the function of what is planned/expected to be achieved from a more global food safety perspective i.e. derived from food safety objective (FSO) and appropriate level of protection (ALOP) in respect to the same hazard. Once the *Salmonella*/*Y. enterocolitica* targets are set for chilled carcasses at abattoir, achieving them depends on following global factors individually and in combination: a) abattoir process hygiene; and b) presence/level of the hazards in incoming pigs (described in section 5.2, above). Therefore, to predictably and reliably keep achieving the targets, both these aspects have to be effectively controlled, as illustrated in Figure 3.

Abattoir process hygiene contribution to achieving *Salmonella*/*Y. enterocolitica* targets is primarily through technology- and hygiene-based preventative measures to reduce direct and indirect cross-contamination of the carcass meat with these pathogens (see 4.2.1.1). Furthermore, all these measures are equally applicable to, and are useful for, both *Salmonella*- and *Y. enterocolitica*-risk reduction. In addition, *Y. enterocolitica*-risk reduction hygienic measures include separation of the head from the carcass before head opening/splitting and tongue separation so to prevent cross-contamination with *Y.*

enterocolitica "residing" in pig tonsils/lymph nodes/mouth, and its further handling separately from the slaughterline. Indeed, this measure may also be beneficial in respect to *Salmonella* spp., which is also often found in the pig mouth cavity. Furthermore, it can be assumed that all these abattoir technology- and process hygiene-related measures are beneficial for risk reduction of other microbial hazards of similar origin and of similar cross-contamination routes at the slaughterline (e.g. *L. monocytogenes*, VTEC, *C. perfringens*, *C. botulinum*, *B. cereus*, etc), although they are not specifically included in considerations in the context of the proposed generic pork (carcass) safety assurance framework. Furthermore, the *Salmonella*/*Y. enterocolitica* preventative measures should also include prevention of within- and between-carcass cross-contamination with these microbial hazards mediated by palpation/incisions which are used in current meat inspection. This can be best achieved by omitting of these manual inspection techniques. It is considered that the food safety risks of *Salmonella*/*Y. enterocolitica* cross-contamination exceeds the food safety risks posed by hazards associated with conditions targeted by the palpation/excision within current meat inspection; in addition, some of those conditions can be controlled through meat quality assurance system (see section 5.4. below). Furthermore, because contamination can sometimes occur during carcass handling between *post-mortem* inspection and chilling e.g. during trimming and grading/weighting steps, the *post-mortem* inspection point or points need to be located in such a way so to enable detection of contamination occurring at all slaughterline stages.

It has been recognised that certain microbial contamination of carcasses during slaughter and dressing process, even when conducted under best hygiene conditions, is unavoidable – particularly where incoming contamination from pigs is significant. In situations where consistent and reliable achieving of the pre-set *Salmonella*/*Y. enterocolitica* targets for chilled carcasses is uncertain in spite of appropriate process hygiene-based measures, additional measures based on effective antimicrobial (decontamination) treatments of carcasses can be considered and used. However, these treatments should not be a substitute for, but only addition to, process hygiene-based measures. Should the carcass decontamination treatments aimed at *Salmonella*/*Y. enterocolitica* inactivation be used in abattoir, their application parameters must be specified and their effectiveness subjected to appropriate validation, monitoring and verification within HACCP-based system.

Finally, carcass refrigeration and maintenance of the cold chain primarily aimed at suppression of the growth of microbial hazards, mandated in the current legislation, remain a vital element of the generic pork safety assurance framework. Appropriate and well-controlled chilling is particularly relevant as very important *Campylobacter*-risk reduction measure.

To ensure that the measures, indicated above, aimed at preventing/reducing *Salmonella*/*Y. enterocolitica* risks at individual steps of the abattoir operation are effective, they have to be specified, implemented, monitored, documented and verified through GMP/GHP prerequisite programmes and HACCP-based meat safety assurance system. To assess and control such a system in a given abattoir, as well as to differentiate contamination-reduction capacities between abattoirs (i.e. to "risk categorise" abattoirs), it is necessary to introduce and use measurable and objective process hygiene assessment-related criteria. As indicated in previous sections, in principle, such criteria could be either based on a reduction of the *Salmonella*/*Y. enterocolitica* occurrence/level achieved by the process, or on a reduction of indicator organisms. However, the latter is much more practical, more universally applicable and enables better statistical analysis of trends, hence is preferred in the published literature. The contamination-reduction capacity could be measured on basis of the difference in the measured organism(s) between two selected points of the process - at the beginning and at the end either of the slaughterline process or of a selected step/operation. At present, such process hygiene assessment-related criteria for abattoirs, which would enable related differentiation of abattoirs, have been neither fully developed nor regulated yet. Although some initial, novel research-based suggestions have been published recently, further work on these issues is required.

5.3.2. *Post-mortem* element of generic pork (carcass) safety assurance framework in respect to *Toxoplasma gondii* and *Trichinella* spp.

Similarly to the situation with *Salmonella*/*Y. enterocolitica* mentioned above, the starting point, and a pre-requisite, of the effective control of *Toxoplasma gondii* and *Trichinella* spp. at abattoir level are the targets for chilled porcine carcasses to be achieved by the abattoir for the parasitic hazards. The current EU legislation (Reg. (EC) No 854/2004/EU) requires that meat from animals infected with *trichinellae* is to be declared unfit for human consumption. Furthermore, the qualitative risk assessment (see subsections 2.1 and 2.2) identified *Trichinella* spp. as posing a significant risk. For both reasons, it could be presumed that *Trichinella*-related target for pig abattoirs would be absence of its viable forms in the meat. On the other hand, the current EU legislation (Reg. (EC) No 854/2004/EU) does not indicate requirement in respect to fitness for human consumption of *Toxoplasma*-infected meat. However, because the qualitative risk assessment (see subsections 2.1 and 2.2) identified *Toxoplasma gondii* as posing a significant risk, it could be presumed that *Toxoplasma*-related target for pig abattoirs would be absence of its viable forms in the meat. Therefore, these presumptions will be used when considering *Trichinella* spp. and *Toxoplasma gondii* further in the generic pork safety assurance framework, although actual setting of those targets (and their derivation from related FSOs and ALOP) is a regulatory responsibility.

As indicated in previous sections (4.2.2, 4.2.3, 4.3.1.3, 4.3.1.4), the abattoir-related strategy to achieve the targets of no viable forms of *Toxoplasma*/*Trichinella* in the meat at the end of the abattoir process is based on two main elements, as illustrated in Figure 4:

a) categorisation of incoming pig batches into low and higher risk in respect to the parasites before slaughter; and

b) application of measures to control the presence or infectivity of the parasites in meat during the abattoir process.

When setting the criteria defining low or higher *Toxoplasma*/*Trichinella* risk categories – which is a risk management/regulatory responsibility – analysis of FCI and corresponding HEI, related sampling plans and methods for each of the hazards (described in the EFSA Biological Monitoring Unit Report) need to be taken into account. Therefore, again, the considerations of the hazards in this document and those in the Report need to be interpreted in combination.

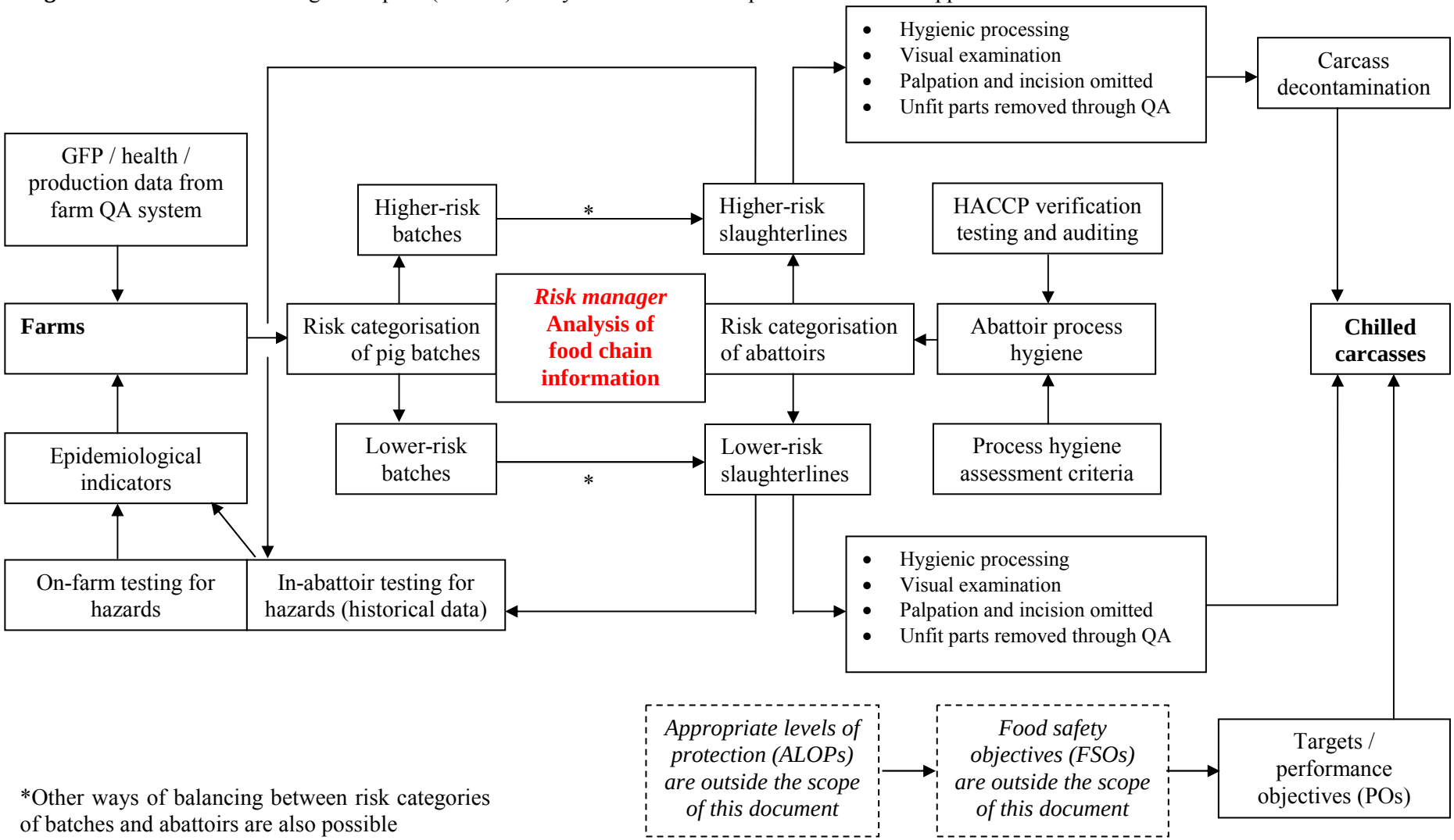
The low risk batches of incoming pigs in respect to *Toxoplasma gondii* and *Trichinella* spp. could be slaughtered and processed without application of other *Toxoplasma*/*Trichinella*-control measures in abattoirs, as long as the allocation of the low risk category to the batches was based on sufficient and reliable FCI including *Toxoplasma*/*Trichinella* historical testing data and application of hazard-specific harmonised epidemiological criteria (see section 5.2) ensuring achievement of the above mentioned targets for final carcasses.

The higher risk batches of incoming pigs in respect to *Toxoplasma gondii* and *Trichinella* spp. would have to be subjected to additional post-slaughter measures ensuring achievement of the above mentioned targets for final carcasses i.e. absence of their viable forms in meat (see 4.2.2 and 4.2.3). In case of *Toxoplasma gondii*, these control measures probably would be only based on selected treatments e.g. heat- or freezing-based that ensure complete inactivation of viable *Toxoplasma gondii* forms in meat, because ensuring absence of *Toxoplasma gondii* only through examination of meat does not appear feasible at present. In the case of *Trichinella* spp., these post-slaughter measures may be based either a) on sampling and laboratory examination of selected muscles, in the same manner as described in the current EU regulations, or b) on heat or freezing treatments that ensure complete inactivation (killing) of *trichinellae* in the meat.

Where *Toxoplasma*- or *Trichinella*-inactivation treatments are used, they can be applied: a) post-chilling but pre-boning of carcasses; or b) post-boning. The latter option may be problematic in

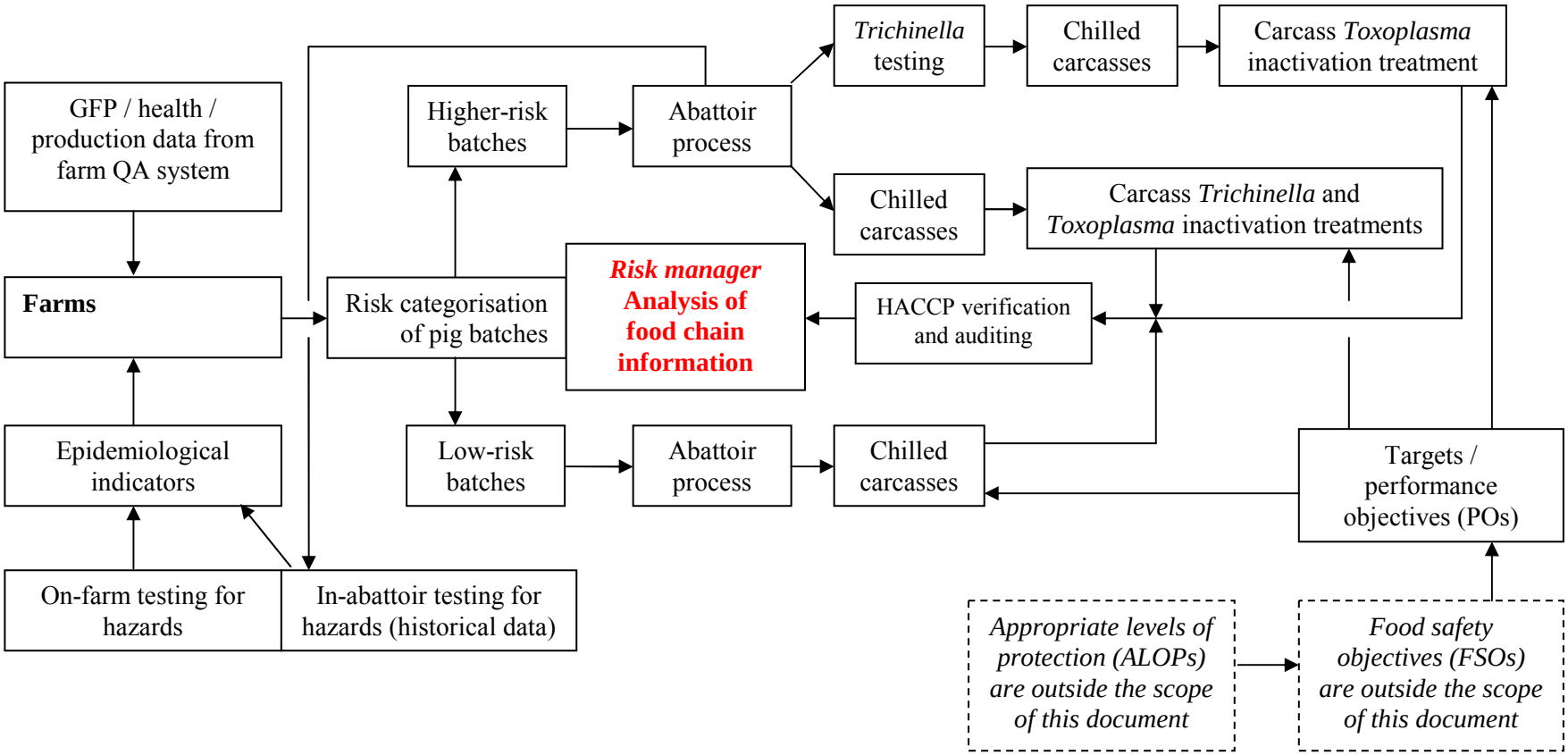
respect to ensuring full traceability and that every - even the smallest - piece of meat separated during boning is subjected to the inactivation treatment. Should the heat- or freezing-based treatments aimed at inactivation of either of the two parasites be used in abattoir, their time-temperature parameters must be specified and their effectiveness subjected to appropriate validation, monitoring and verification within HACCP-based meat safety system.

Figure 3: Main elements of generic pork (carcass) safety assurance with respect to *Salmonella* spp. and *Y. enterocolitica*



*Other ways of balancing between risk categories of batches and abattoirs are also possible

Figure 4: Main elements of generic pork (carcass) safety assurance with respect to *Toxoplasma gondii* and *Trichinella* spp.



5.4 The effects of the proposed generic pork (carcass) safety assurance framework on other risks targeted by the current meat inspection

5.4.1. Effects on risks targeted by current ante-mortem inspection

The current EU legislation (Reg. (EC) No 854/2004/EU) requires that, when it is found at *ante-mortem* examination that animals have a disease or condition that may be transmitted to animals or humans through handling or eating meat and, in general, that they show clinical signs of systemic disease or emaciation, they are not to be slaughtered for human consumption. Such animals must be killed separately, under conditions such that other animals or carcases can not be contaminated, and declared unfit for human consumption. Furthermore, the slaughter of animals suspected of having a disease or condition that may adversely affect human or animal health is to be deferred. Such animals are to undergo detailed *post-mortem* and, if necessary, laboratory examination in order to make a diagnosis and are to be slaughtered separately from those undergoing routine slaughtering.

Because the main hazards (*Salmonella* spp., *Y. enterocolitica*, *Toxoplasma gondii*, *Trichinella* spp.) are not detectable by current *ante-mortem* inspection, changes of the *ante-mortem* inspection are neither considered nor proposed in this document. Therefore, the proposed generic pork (carcass) safety assurance framework would not have any effect on other risks targeted by the current *ante-mortem* meat inspection. Furthermore, ensuring through current *ante-mortem* inspection that only visually clean pigs and without observable abnormalities enter the routine slaughtering process helps the proposed approach. Namely, microbial loads on skins of clean incoming pigs are reduced, and together with omitting palpation/incision at *post-mortem* examination of pigs without *ante-mortem* detected abnormalities; both aspects contribute to reduction of *Salmonella*/*Y. enterocolitica* cross-contamination.

5.4.2. Effects on risks targeted by current Food Chain Information (FCI)

The current EU legislation (Reg. (EC) No 854/2004/EU) requires that FCI for incoming pigs (including farm production data, epidemiological intelligence data, animal health data, identification whether from integrated or non-integrated systems, etc) is analysed before slaughtering. Because the use of FCI contributes also to controlling the main hazards (*Salmonella* spp., *Y. enterocolitica*, *Toxoplasma gondii*, *Trichinella* spp.) in slaughtered pigs, continuation of the use of FCI is supported in this document and the proposed generic pork (carcass) safety assurance framework would not have any effect on other risks targeted by the current FCI analysis. Even, the use of FCI is further improved and strengthened in the proposed generic framework in respect to the main hazards, as indicated in section 5.2.

5.4.3. Effects on pork safety risks targeted by current post-mortem inspection

Effects on risks targeted by current visual inspection

The current EU legislation (Reg. (EC) No 854/2004/EU) requires visual examination of the skin, carcass (including skin, joints, pleura/peritoneum, cut carcass muscles), head, liver, lungs, heart, kidneys, spleen and all other visible organs/tissues carcasses and organs of slaughtered pigs for signs of abnormalities during *post-mortem* inspection. This current visual inspection is aimed at detecting a range of diseases and conditions. Because the main hazards (*Salmonella* spp., *Y. enterocolitica*, *Toxoplasma gondii*, *Trichinella* spp.) are not detectable by the visual inspection, changes of the visual examination during *post-mortem* inspection are neither considered nor proposed in this document. Therefore, the proposed generic pork (carcass) safety assurance framework would not have any effect on detection of other risks targeted and detectable by the current visual examination of carcasses and all organs.

Effects on risks targeted by current palpation/incision

As previously indicated (subsection 5.3.1), in the proposed generic pork (carcass) safety assurance framework, it is considered that palpation and incisions should be omitted during *post-mortem* inspection of pigs from routine slaughter that had no abnormalities found at *ante-mortem* inspection. The main reason is to prevent *Salmonella*/*Y. enterocolitica* cross-contamination mediated by use of these techniques and reduce related pork safety risks. Considerations of the effects of omitting palpation/incision on risks targeted by current use of these examination techniques are summarised in Table 9.

It should be noted that omitting of palpation/incision is not proposed for *post-mortem* inspection of pigs outside routine slaughter i.e. those suspected at *ante-mortem* inspection to have a disease or condition that may adversely affect human or animal health, which are to be slaughtered separately from routine slaughter and subjected to detailed *ante-mortem* and *post-mortem* examinations including laboratory testing if necessary. Also, it is assumed that in cases where abnormalities of potential public health relevance are detected by routine visual inspection, further examination may be necessary to diagnose them properly including by application of palpation, incision and laboratory tests as necessary, but this should be performed in such a way that cross-contamination of carcasses and other organs is prevented (i.e. away from the slaughterline). In any case, given the importance of visual inspection in situations of omitted palpation/incision techniques, the conditions for visual inspection e.g. lighting, time and space available need to be such that they ensure its effectiveness.

Head inspection. According to current EU legislation, mandibular lymph nodes are incised with aim of detecting caseous necrosis indicating possible infection with mycobacteria. In pigs, this lesion occurs rarely, and in such cases mostly is caused by non-mycobacteria microorganisms that do not represent a meatborne risk. If mycobacteria are present, usually *M. avium* is involved and possibly but much less likely *M. bovis*. *Mycobacterium avium* subspecies *avium* (MAA) and *Mycobacterium avium* subspecies *hominisuis* (MAH) belong to the *Mycobacterium avium - intracellulare* complex (MAC). MAC bacteria are ubiquitous in the environment and can be isolated in potable water, soil, plants and even house dust (Falkinham, 1996). Humans can be infected by gastrointestinal (Gray and Rabeneck, 1989) or bronchial (Horsburgh et al., 1991) penetration of the bacteria. Young and elderly individuals are vulnerable to infections (Colville, 1993; Wagner and Young, 2004). MAC infections are reported in 30-80% of patients with AIDS (Bermudez et al., 1992). However, there is no evidence of human disease caused by either of the organisms *via* consumption of pork, as human infection occurs *via* other foods (i.e. milk) or *via* animal environment (direct contact/inhalation), but *Mycobacterium* spp. represent an animal health/welfare risk. Consequently, according to current EU legislation, in cases of detected localised caseous necrosis only the affected lymph node and corresponding organ is condemned – but the carcass is passed as fit for human consumption. Also, based on analysis of individual hazards in slaughtered pigs in this document, *Mycobacterium* spp. are considered as posing low meatborne risk (section 2.3). For all these reasons, it is considered that omitting incision of mandibular lymph nodes in pigs from routine slaughter could potentially slightly increase public health risk in respect to *Mycobacterium* spp. but the risk would still remain within low category. On the other hand, it is considered that the routine incision of the submaxillary lymph nodes may affect food safety, as hazardous cross contamination with e.g. *Salmonella* spp. and *Y. enterocolitica* can occur (Hamilton et al., 2002; Nesbakken et al., 2003; Pointon et al., 2000; SCVMRPH, 2000). Therefore, omitting incision of mandibular lymph nodes, as well as head separation from the carcass as early as possible and its separate further handling, would significantly reduce the risk of cross-contamination with *Y. enterocolitica* and *Salmonella* spp. (posing medium and high meatborne risk, respectively; section 2.3), so the net result would be an overall public health benefit. Nevertheless, in cases where abnormalities on mandibular lymph nodes are visually observed, they must be removed as unfit for human consumption and subsequently can be subjected to further examinations. It is presumed that in case of any visually undetected head abnormalities, both detection and the removal of the lymph nodes with abnormality can be ensured through a specified, documented and verifiable procedure of head handling during cutting/boning operation away from the slaughterline - within the abattoir meat quality assurance system. In this way, the head would not be

manipulated twice (during both inspection and cutting) but only once, and not on the slaughterline together with carcasses. However, responsibility allocation for such a procedure is up to the regulators.

Lung and trachea inspection. According to current EU legislation, lungs are palpated, and are also incised if intended for human consumption, with aim of detecting abnormalities which mainly include pneumonia or bronchopneumonia, and sometimes hydatic cysts (*Echinococcus* spp.). Associated with this, trachea and its main branches are cut open, with main aim of detecting parasitic worms (*Metastrongylus* spp.) and presence of scalding water. Pneumonia/bronchopneumonia in pigs is caused by microorganisms that are not transmissible *via* meat consumption (only, *P. multocida* may cause contact infections), hydatic cysts are not transmissible *via* meatborne route and *Metastrongylus* worms are not zoonotic; all these conditions are of animal health/welfare relevance. Risk of scalding water in lungs is a technology/process hygiene issue. Therefore, omitting palpation/incision of lungs would not increase pork safety risk, but would reduce *Salmonella*/*Y. enterocolitica* risk due to cross-contamination. Nevertheless, in cases where abnormalities in lungs/trachea are visually observed, they must be removed as unfit for human consumption and subsequently can be subjected to further examinations. It is presumed that in case of any visually undetected lungs/trachea abnormalities, both detection and the removal of the abnormalities can be ensured through a specified, documented and verifiable procedure of lungs handling during cutting operation away from slaughterline - within the abattoir meat quality assurance system. However, responsibility allocation for such a procedure is up to the regulators.

Heart inspection. According to current EU legislation, the heart is incised lengthwise including the septum, with the main aim of detecting pericarditis and endocarditis. Endocarditis may indicate presence of septicaemia or bacteraemia, in which case there is a possibility of the causative microorganisms spreading to other organs/tissues *via* blood circulation. Nevertheless, it is expected that pigs with acute septicaemia would show clinical symptoms at *ante-mortem* inspection. Furthermore, the conditions are caused mainly by microorganisms that are not transmissible to humans *via* pork consumption (only, *Streptococcus* and *Erysipelotrix* may cause contact infections), hence omitting incision of heart would not increase microbial pork safety risk, but would reduce *Salmonella*/*Y. enterocolitica* risk due to cross-contamination. On the other hand, zoonotic and pork-transmissible *Taenia solium cysticercus* can also be found in heart muscle, so omitting of heart incision would potentially increase related pork safety risk. However, the parasite is considered as not prevalent in European pigs and posing low pork safety risk, but omitting incision-mediated cross-contamination would reduce *Salmonella*/*Y. enterocolitica* risk which is comparably higher (section 2.3). Furthermore, any present cysticerci would be inactivated in those carcasses that are subjected to *Toxoplasma*/*Trichinella* inactivation treatments, which would further reduce the overall *T. solium cysticercus* risk. In cases where abnormalities in heart are observed, it must be removed as unfit for human consumption and subsequently can be subjected to further examinations. It is presumed that in case of any visually undetected heart abnormalities, both detection of pericarditis/endocarditis and cysticerci and the removal of the affected heart can be ensured through a specified, documented and verifiable procedure of heart handling during cutting operation away from the slaughterline - within the abattoir meat quality assurance system. However, responsibility allocation for such a procedure is up to the regulators.

Liver inspection. According to current EU legislation, liver including hepatic lymph nodes is palpated (and incised only if necessary), with the main aim to detect parasites (hydatic *cysts* and *Ascaris suum*-related "milk spots"), abscesses and hepatitis. The parasites are not transmissible to humans *via* pork consumption, but *via* other routes, and also hydatic cysts are often detectable visually. Abscesses are caused by microorganisms that are either not zoonotic, or by those that are zoonotic but not transmissible to humans *via* pork consumptions (*Streptococcus*), or by those that represent a low pork safety risk (*Staph. aureus*; see section 2.3) and their foodborne harmfulness is associated only with their presence in high counts. Also, in many cases abscesses are detectable visually. Hepatitis can be caused by several agents and is often secondary; it is presumed that the condition is usually visually detectable (liver enlargement, change of colour). Overall, it is considered that omitting mandatory palpation of liver would not increase pork safety risks, with only exception of slight increase of *Staph. aureus* risk but which would remain in low category. In cases where abnormalities in liver are observed, it must be removed as unfit for human consumption and

subsequently can be subjected to further examinations. It is presumed that in case of any visually undetected liver abnormalities, both detection of parasitic cysts, abscesses and hepatitis and the removal of the affected liver can be ensured through a specified, documented and verifiable procedure of liver handling during cutting operation away from the slaughterline - within the abattoir meat quality assurance system. However, responsibility allocation for such a procedure is up to the regulators.

Gastro-intestinal tract (GIT) inspection. According to current EU legislation, GIT including mesentery lymph nodes is palpated (and incised only if necessary), with the main aim of detecting caseous necrosis indicating possible infection with mycobacteria. In that respect, all the mycobacteria-related considerations, justification for omitting palpation/incision and its effect on risks targeted by palpation/incision described for the head inspection (above) are equally applicable to GIT inspection. Other GIT conditions targeted by its current inspection include enteritis, but it is presumed that it is detectable at *ante-mortem* inspection and/or visually at *post-mortem*. Also, in case of any visually undetected GIT abnormalities, both detection and the removal of the lymph nodes with abnormality can be ensured through a specified, documented and verifiable procedure of GIT handling away from the slaughterline - within the abattoir meat quality assurance system.

Udder inspection. According to current EU legislation, udder inspection includes incision of its lymph nodes, with main aim of detecting abscesses, which applies to sows only. In that respect, all the abscess-related considerations, justification for omitting palpation/incision and its effect on risks targeted by palpation/incision described for the liver inspection (above) are equally applicable to udder inspection. Other udder conditions targeted by its current inspection include mastitis, but it is presumed that it is detectable at *ante-mortem* inspection and/or visually at *post-mortem*. Also, in case of any visually undetected udder abnormalities, both detection and the removal of the lymph nodes with abnormality can be ensured through a specified, documented and verifiable procedure of udder handling away from the slaughterline - within the abattoir meat quality assurance system.

Inspection for other abnormalities. According to current EU legislation, *post-mortem* inspection also includes detection of abnormalities that render affected parts unfit for human consumption primarily because they are unacceptable on aesthetical and meat quality grounds, although they may not pose a risk for humans *via* pork consumption. Such conditions are not specifically targeted by any current inspection procedure/technique, but are looked for whilst conducting inspection targeting risks indicated above. Such abnormalities include, for example, meat/organs with significantly changed/abnormal appearance and/or sensory qualities, foetuses, tumours, physical injuries, visible contamination, etc. In cases where any of such abnormalities are visually observed, they must be removed as unfit for human consumption and subsequently can be subjected to further examinations if necessary. It is presumed that in case of any visually undetected such abnormalities, both their detection and the removal of the affected parts can be ensured through a specified, documented and verifiable procedure of the carcass handling during cutting operation away from the slaughterline - within the abattoir meat quality assurance system. However, responsibility allocation for such a procedure is up to the regulators.

5.4.4. Effects on emerging and/or re-emerging risks

The outlined generic pork safety assurance framework targets the hazards that are considered as most relevant at the time of preparation of this document. One of the main intentions with the approach proposed is to obtain a flexible and risk-based framework, adaptable to variable and changeable situations occurring in practice. In accordance with this, if the risks from the existing hazards targeted by the proposed framework significantly decreased over time, it is expected that the main attention would be redirected towards other hazards that might have become comparably more relevant. For example, new hazard(s) posing significant pork safety risk might emerge and/or the risks from existing hazards that presently are not a priority (e.g. *T. solium cysticercus*, zoonotic mycobacteria) might increase over time or in some regions. Therefore, it is important that the proposed framework is used in association with a robust zoonoses monitoring/surveillance system accompanied with emerging risks alert mechanisms, which would enable

timely notification of significant changes in pork safety risks. Reliable epidemiological data about zoonotic agents in slaughter pigs and the incidence of human disease caused by these agents are needed for each country/area, as such information is a crucial requirement for a change from a strict uniform meat inspection system to a dynamic FCI- and risk-based system. If/when the situation significantly changes; it is assumed that the proposed framework would be re-evaluated in respect to its effectiveness to handle the emerged/re-emerged risks and adaptations would be introduced if/as necessary. Nevertheless, it is considered that the main principles of the proposed framework – FCI incorporating risk categorisation of pig batches and abattoir processes, verifiable HACCP-based risk reduction strategies, as well as hazard-related targets for pork carcasses – would continue to be the fundamentals also of the adapted framework.

Table 9: Summary of the main effects of omitting palpation/incision within the generic pork (carcass) safety assurance framework on risks targeted by the current meat inspection

Current meat inspection procedures involving mandatory palpation and/or incision and targeted conditions				**Overall evaluation of the effects of omitting palpation/incision on the risks targeted by the current procedures**					
Mandatory visual inspection	***Mandatory palpation***	***Mandatory incision***	***Intended condition to be detected (occurrence in slaughtered pigs)***	***Causative agents involved in typical lesions (occurrence in the lesion)***	***Agent transmissible to humans via consumption of pork?***	***Is there clear evidence that the disease occurred via pork ingestion?***	***Main benefit from the palpation/incision***	***Main consequences of omitting the palpation/incision (but visual examination conducted)***	***Alternative ways of detection or control***
Head	Not mandatory	Yes, mandibular lymph nodes	Caseous necrosis indicating possible tuberculosis (0.01-0.02%) (Alban et al., 2008)	*M. avium* (0%), *M. bovis* (0%), *R. equi* (63%), *Nocardia farcinica* (2%) (Alban et al., 2008)	No, except potentially *M. bovis*. *M. avium* only for immuncompromised patients	No	Animal health	Reduced sensitivity/rate of detection of the condition Slightly increased Tb public health (PH) risk, not *via* pork consumption and but remaining in low category Reduced risk from *Salmonella*/*Y. enterocolitica* (and probably other microbial pathogens)	On-farm controls; food chain information; meat quality assurance at cutting operations
Lungs	Yes; including lymph nodes	Yes, if intended for human consumption	Pneumonia, bronchopneumonia and other "inflammatory" lung conditions	*A. pleuropneumoniae,* Mycoplasms, *P. multocida* (Nordic Council of Ministers, 2006)	No	No	Animal health	Somewhat reduced sensitivity/rate of detection of the condition (but is often visually observable) Slightly increased *P. multocida* PH risk, but not *via* pork consumption and remaining in very low category Reduced risk from *Salmonella*/*Y. enterocolitica* (and probably other microbial pathogens)	On-farm controls; food chain information; meat quality assurance (at cutting operations); lungs normally are not sold but are directed to cooked sausages

Current meat inspection procedures involving mandatory palpation and/or incision and targeted conditions				Overall evaluation of the effects of omitting palpation/incision on the risks targeted by the current procedures					
Mandatory visual inspection	***Mandatory palpation***	***Mandatory incision***	***Intended condition to be detected (occurrence in slaughtered pigs)***	***Causative agents involved in typical lesions (occurrence in the lesion)***	***Agent transmissible to humans via consumption of pork?***	***Is there clear evidence that the disease occurred via pork ingestion?***	***Main benefit from the palpation/incision***	***Main consequences of omitting the palpation/incision (but visual examination conducted)***	***Alternative ways of detection or control***
Trachea and main branches	Not mandatory	Yes, if lungs are intended for human consumption	Parasites, scalding water	*Metastrongylus* spp.; dirt and potentially pathogenic microorganisms	Parasites: no Scald water: potentially, if present microbial pathogens	No	Parasites: animal health Scald water: meat quality (safety?)	Reduced sensitivity/rate of detection of the condition PH risk *via* meat consumption not increased Reduced risk from *Salmonella*/*Y. enterocolitica* (and probably other microbial pathogens)	On-farm controls; food chain information; scalding technology modification; meat quality assurance (at cutting operations); trachea normally is not sold but are often discarded or at least directed to cooked sausages
Heart	Not mandatory	Yes	Endocarditis (0.01%) (Alban et al., 2008)	*Streptococcus* spp. (51%), *E. rhusiopathiae* (32%), *Lactobacillus* (5%), *Arcanobacterium pyogenes* (1%) (Alban et al., 2008)	No	No	Animal health	Reduced sensitivity/rate of detection of the condition Slightly increased *Streptococcus* and *E. rhusiopathiae* PH risk, but not *via* pork consumption and remaining in very low category Reduced risk from *Salmonella*/*Y. enterocolitica* (and probably other microbial pathogens)	On-farm controls; food chain information; meat quality assurance (at cutting operations)
			Pericarditis	*A. suis*, *Pasteurella* spp., *Streptococcus*. spp. (Nordic Council of Ministers, 2006)	No	No	Animal health	Sensitivity/rate of detection unchanged (is visually observable) *Streptococcus* PH risk unchanged Reduced risk from *Salmonella*/*Y. enterocolitica* (and probably other microbial pathogens)	On-farm controls; food chain information; visually observable; meat quality assurance (at cutting operations)

Current meat inspection procedures involving mandatory palpation and/or incision and targeted conditions				**Overall evaluation of the effects of omitting palpation/incision on the risks targeted by the current procedures**					
Mandatory visual inspection	***Mandatory palpation***	***Mandatory incision***	***Intended condition to be detected (occurrence in slaughtered pigs)***	***Causative agents involved in typical lesions (occurrence in the lesion)***	***Agent transmissible to humans via consumption of pork?***	***Is there clear evidence that the disease occurred via pork ingestion?***	***Main benefit from the palpation/incision***	***Main consequences of omitting the palpation/incision (but visual examination conducted)***	***Alternative ways of detection or control***
			Parasitic cysts	*T. solium cysticercus*	Yes	Yes	Public health; animal health	Possibly reduced rate of detection of the condition to unknown extent, as the condition is detectable by visual inspection of cut carcass muscles Slightly increased (if any) *T. solium* PH risk, but remaining in low category Reduced risk from *Salmonella*/*Y. enterocolitica* (and probably other microbial pathogens)	Visual inspection of cut carcass muscles (currently mandatory); on-farm controls; food chain information; meat quality assurance (at cutting operations)
Liver	Yes (and lymph nodes)	Not mandatory	Hepatitis	Several, often secondary (Nordic Council of Ministers, 2006)	Potentially (HAE virus?)	?	Animal health; Public health (?)	Possibly detection rate somewhat reduced, but hepatitis is visually detectable Slightly increased HAE PH risk (?), but remaining in low category Reduced risk from *Salmonella*/*Y. enterocolitica* (and probably other microbial pathogens)	On-farm controls; food chain information; visually observable; meat quality assurance (at cutting operations)

Current meat inspection procedures involving mandatory palpation and/or incision and targeted conditions				**Overall evaluation of the effects of omitting palpation/incision on the risks targeted by the current procedures**					
Mandatory visual inspection	***Mandatory palpation***	***Mandatory incision***	***Intended condition to be detected (occurrence in slaughtered pigs)***	***Causative agents involved in typical lesions (occurrence in the lesion)***	***Agent transmissible to humans via consumption of pork?***	***Is there clear evidence that the disease occurred via pork ingestion?***	***Main benefit from the palpation/incision***	***Main consequences of omitting the palpation/incision (but visual examination conducted)***	***Alternative ways of detection or control***
			Parasites	*Ascaris suum* (milk spots), *Echinococcus* (hydatic cysts)	No	No	Animal health	Reduced sensitivity/rate of detection of the condition Parasites' PH risk somewhat increased, but not *via* meat ingestion and remaining in very low category Reduced risk from *Salmonella*/*Y. enterocolitica* (and probably other microbial pathogens)	Visual inspection liver (currently mandatory); on-farm controls; food chain information; meat quality assurance (at cutting operations)
			Abscesses	*A. pyogenes*, *Streptococcus*. spp. , *S. aureus* (Nordic Council of Ministers, 2006)	No, except potentially *S. aureus* toxin if present in high counts	No, except *S. auresu* toxin if present (usually human-origin strains involved?)	Animal health; Human health (*S. aureus*)	Somewhat reduced sensitivity/rate of detection of the condition, but is often visually detectable Slightly increased S. aureus PH risk, but remaining in low category Reduced risk from *Salmonella*/*Y. enterocolitica* (and probably other microbial pathogens)	On-farm controls; food chain information; often visually observable; meat quality assurance (at cutting operations)
Gastrointestinal tract	Yes (including mesentery lymph nodes)	Not mandatory	Caseous necrosis indicating tuberculosis	Same as with mandibular lymph nodes (above)	Same as with mandibular lymph nodes (above)	Same as with mandibular lymph nodes (above)	Same as with mandibular lymph nodes (above)	Same as with mandibular lymph nodes (above)	Same as with mandibular lymph nodes (above)

Current meat inspection procedures involving mandatory palpation and/or incision and targeted conditions				**Overall evaluation of the effects of omitting palpation/incision on the risks targeted by the current procedures**					
Mandatory visual inspection	***Mandatory palpation***	***Mandatory incision***	***Intended condition to be detected (occurrence in slaughtered pigs)***	***Causative agents involved in typical lesions (occurrence in the lesion)***	***Agent transmissible to humans via consumption of pork?***	***Is there clear evidence that the disease occurred via pork ingestion?***	***Main benefit from the palpation/incision***	***Main consequences of omitting the palpation/incision (but visual examination conducted)***	***Alternative ways of detection or control***
Udder and its lymph nodes	Not mandatory	Yes (supramammary lymph nodes in sows only)	Abscesses, mastitis	Same as with abscesses in liver (above)	Same as with abscesses in liver (above)?	Same as with abscesses in liver (above)?	Same as with abscesses in liver (above)?	Same as with abscesses in liver (above)? Mastitis is detectable by visual inspection, so related PH risk is not increased Reduced risk from *Salmonella*/*Y. enterocolitica* (and probably other microbial pathogens)	Same as with abscesses in liver (above); Udder commonly not intended for human consumption

CONCLUSIONS AND RECOMMENDATIONS

The conclusions and recommendations relate only to biological, foodborne public health hazards in the context of meat inspection; whilst other hazards are addressed in a separate part of this document.

TOR 1: Identify and rank the main risks for public health that should be addressed by meat inspection at EU level. General (e.g. sepsis, abscesses) and specific biological risks as well as chemical risks (e.g. residues of veterinary drugs and contaminants) should be considered. Differentiation may be made according to production systems and age of animals (e.g. breeding compared to fattening animals).

CONCLUSIONS

- Identification and ranking of foodborne hazards, based on their prevalence in/on chilled carcases, incidence and severity of disease in humans, and source attribution of hazards to pork, in the context of meat inspection was considered with the chilled carcasses as the target. Many data for ranking of hazards were insufficient, and expert judgement was used instead.

- Based on a qualitative risk assessment, *Salmonella* spp. are considered of high relevance and *Yersinia enterocolitica*, *Toxoplasma gondii* and *Trichinella* spp. as of medium relevance. Other hazards were considered of low relevance.

- The risk reduction measures indicated in this document specifically for *Salmonella* spp. and *Y. enterocolitica* would also be applicable to, and beneficial for control of, a number of other microbial hazards currently classified as of low relevance.

RECOMMENDATIONS

- Because the hazard identification and ranking relates to the EU as a whole at the time of preparation of this document, refinements reflecting differences between regions or production systems are recommended if/where hazard monitoring data indicate.

- Furthermore, as new hazard(s) might emerge and/or hazards that presently are not a priority might become more relevant over time or in some regions, the risk ranking is to be revisited regularly.

- To provide a better evidence base for future rankings, studies should be carried out to:

  – systematically collect data for source attribution;

  – collect data to identify and rank emerging pork-borne hazards

TOR 2: Assess the strengths and weaknesses of the current meat inspection methodology and recommend possible alternative methods (at *ante-mortem* or *post-mortem* inspection, or validated laboratory testing within the frame of traditional meat inspection or elsewhere in the production chain) at EU level, providing an equivalent achievement of overall objectives; the implications far animal health and animal welfare of any changes suggested in the light of public health risks to current inspection methods should be considered.

CONCLUSIONS

The main elements of the current pig meat inspection are *ante-mortem* examination of animals including food chain information (FCI) analysis, and *post-mortem* examination of carcasses and organs. The strengths and weaknesses of the current meat inspection were assessed only in relation to food safety.

Strengths

- *Ante-mortem* inspection enables utilising FCI (presently only to a limited extent), the detection of clinically observable zoonotic diseases, animal identification enabling traceability and evaluation of visual cleanliness of animals.

- *Post-mortem* inspection enables detection of macroscopic lesions caused by some zoonotic agents e.g. mycobacteria, *Taenia solium*, *Brucella* spp. and *Erysipelothrix rhusiopathiae*, as well as to detect *Trichinella* spp. by laboratory examination. These hazards are currently rare and some of them pose an occupational rather than foodborne risk. Also, *post-mortem* inspection detects visual faecal contamination.

Weaknesses

- At *ante-mortem* inspection, the high number of pigs arriving for slaughter does not allow for proper clinical examination of individual animals. Currently FCI does not include all indicators to classify the pigs in relation to public health risk.

- Current *ante-* or *post-mortem* inspection cannot macroscopically detect the bacterial and parasitic foodborne hazards of most relevance as identified above.

- Manual handling of meat including use of palpation/incision techniques during *post-mortem* inspection mediates cross-contamination with bacterial hazards.

- Microbial agents associated with common pathological conditions detected at *post-mortem* pig inspection (e.g. pneumonia, abscesses) are caused by non-zoonotic and/or zoonotic hazards, and the latter pose an occupational rather than foodborne risk.

- Judgement of the fitness of meat for human consumption in current *post-mortem* inspection does not differentiate food safety aspects related to the spread of zoonotic agents through the food chain from meat quality aspects, prevention of animal diseases and occupational hazards.

TOR 3: If new hazards currently not covered by the meat inspection system (e.g. *Salmonella, Campylobacter*) are identified under TOR 1, then recommend inspection methods fit for the purpose of meeting the overall objectives of meat inspection. When appropriate, food chain information should be taken into account.

CONCLUSIONS

- A comprehensive pork carcass safety assurance, combining a range of preventative measures and controls applied both on-farm and at-abattoir in a longitudinally integrated way is the only way to ensure effective control of the main hazards (*Salmonella* spp., *Yersinia enterocolitica*, *Toxoplasma gondii* and *Trichinella* spp.) in the context of meat inspection.

- A prerequisite for effective pork carcass safety assurance system is setting measurable targets in respect to the main hazards to be achieved in/on final, chilled carcasses. These would also inform what has to be achieved at earlier steps in the food chain and would focus related control measures.

- At abattoir level, the primary goal is the risk reduction for the main hazards that can be achieved through integrated programs based on GMP/GHP and HACCP, including:

    – hygienic practice- and technology-based measures aimed at avoiding direct and indirect cross-contamination with *Salmonella* spp. and *Yersinia enterocolitica*;

  - additional interventions such as surface decontamination of carcasses if considered necessary;
  - heat- or freezing-based treatments of carcass meat to inactivate intramuscular parasites *Toxoplasma gondii* and *Trichinella* spp. if considered necessary and as alternative to related laboratory testing of carcasses;
  - FCI should be used to differentiate incoming pig batches in respect to the *Salmonella* spp., *Yersinia enterocolitica*, *Toxoplasma gondii* and *Trichinella* spp. risks (based on herd status *via* sampling at farms or abattoirs), and differentiate risk-reduction capacity of abattoirs (process hygiene).

- At farm level, the primary goal is the risk reduction for the main hazards, which can be achieved through preventive measures such as herd health programs and closed breeding pyramids, GHP and GFP and finally categorisation of animals based on the carrier state of these agents.

RECOMMENDATIONS

- Systematic FCI data collection and analysis for the main hazards at herd and abattoir levels, as well as other (re-)emerging agents at EU or regional levels is a prerequisite for the proposed pork carcass safety assurance system, and it is therefore recommended. Research on the optimal ways of using the collected FCI data for risk categorisation and differentiated slaughter of pigs, as well as on the following benefit for public health is required.

- Further research on development of the hazard testing that could be used within the proposed pork carcass safety assurance system is recommended.

- The development of systematic methodologies for assessing abattoir process hygiene and related differentiation of abattoirs is recommended.

- The efficacy of various carcass treatments to be used for elimination/inactivation of the main hazards need to be validated.

TOR 4: Recommend adaptations of inspection methods and/or frequencies of inspections that provide an equivalent level of protection within the scope of meat inspection or elsewhere in the production chain that may be used by risk managers in case they consider the current methods disproportionate to the risk, e.g. based on the ranking as an outcome of terms of reference 1 or on data obtained using harmonised epidemiological criteria. When appropriate, food chain information should be taken into account.

CONCLUSIONS

- Palpation/incisions used in current *post-mortem* inspection should be omitted in pigs subjected to routine slaughter, because the risk of microbial cross-contamination is higher than the risk associated with potentially reduced detection of conditions targeted by these techniques.
- The use of these manual techniques during *post-mortem* examination should be limited to suspect pigs identified through FCI/*ante-mortem* inspection or *post-mortem* visual detection of relevant abnormalities where it would lead to risk reduction.
- *Post-mortem* examination involving palpation and incision, where necessary, should be performed separately from the slaughterline operation and accompanied with laboratory testing as required.
- Elimination of abnormalities on aesthetic/meat quality grounds can be ensured through meat quality assurance system.

RECOMMENDATIONS

- The overall public health impact of the modified pig meat inspection system, as compared to the current status, should be evaluated regularly after its implementation in practice.

General recommendations

- It is recommended that all parties involved in the proposed pork carcass safety assurance system, including official veterinarians, official auxiliaries and abattoir staff, be trained in the skills required for this system.

REFERENCES

Alban L, Pozio E, Boes J, Boireau P, Boue F, Claes M, Cook AJ, Dorny P, Enemark HL, van der Giessen J, Hunt KR, Howell M, Kirjusina M, Nockler K, Rossi P, Smith GC, Snow L, Taylor MA, Theodoropoulos G, Vallee I, Viera-Pinto MM and Zimmer IA, 2011. Towards a standardised surveillance for *Trichinella* in the European Union. Prev Vet Med, 99, 148-160.

Alban L and Stark KD, 2005. Where should the effort be put to reduce the *Salmonella* prevalence in the slaughtered swine carcass effectively? Prev Vet Med, 68, 63-79.

Alban L, Vilstrup C, Steenberg B, Jensen HE, Aalbak B, Thune-Stephensen F and Jensen S, 2008. Assessment of risk for humans associated with Supply Chain Meat Inspection – The Danish Way. Danish Ministry of Food, Agriculture and Fisheries, Danish Veterinary and Food Administration, Copenhagen, Denmark.

Alonso S, Dadios N, Gregory N, Stark K, Nigsch A, Blagojevic B, 2011. Outcomes and values of current *ante-* and *post-mortem* meat inspection tasks. Project report N.1 - Inventory of hazards to public health, animal health and animal welfare related to meat production and their related conditions. Royal Veterinary College, University of London. Project MC1003. Report for the Food Standards Agency, UK.

Aureli P, Fenica L and Franciosa G, 1999. Classic and emergent forms of botulism: the current status in Italy. Euro Surveill, 4, 7-9.

Benschop J, Spencer S, Alban L, Stevenson M and French N, 2010. Bayesian zero-inflated predictive modelling of herd-level *Salmonella* prevalence for risk-based surveillance. Zoonoses Public Health, 57 Suppl 1, 60-70.

Berends BR, Van Knapen F, Snijders JM and Mossel DA, 1997. Identification and quantification of risk factors regarding *Salmonella* spp. on pork carcasses. Int J Food Microbiol, 36, 199-206.

Bermudez LE, Petrofsky M, Kolonoski P and Young LS, 1992. An animal model of *Mycobacterium avium* complex disseminated infection after colonization of the intestinal tract. J Infect Dis, 165, 75-79.

Blagojevic B, Antic D, Ducic M and Buncic S, 2011. Ratio between carcass-and skin-microflora as an abattoir process hygiene indicator. Food Control, 22, 186-190.

Blaha T, 2004. [Up-to-date information from the German QS *Salmonella* monitoring and reduction programme]. Dtsch Tierarztl Wochenschr, 111, 324-326.

Bolton DJ, Sheridan JJ and Doherty AM 2000. HACCP for Irish Beef Slaughter. Teagasc-The National Food Centre, Dublin, Ireland.

Borch E, Nesbakken T and Christensen H, 1996. Hazard identification in swine slaughter with respect to foodborne bacteria. Int J Food Microbiol, 30, 9-25.

Bracewell AJ, Reagan JO, Carpenter JA and Blankenship LC, 1985. Incidence of *Campylobacter-jejuni-coli* on pork carcasses in the Northeast Georgia area. Journal of Food Protection, 48, 808-810.

Brett M, 1999. Botulism in the United Kingdom. Euro Surveill., 4, 9-11.

Brown J and Tollison JW, 1979. Influence of pork consumption on human infection with *Mycobacterium avian*-intracellulare. Appl Environ Microbiol, 38, 1144-1146.

Buncic S, 2006. Integrated Food Safety and Veterinary Public Health. CABI International Publishing, Wallingford, Oxfordshire, UK.

Casas M and Martin M, 2010. Hepatitis E virus and pigs: a zoonotic risk in Europe? Vet J, 186, 135-136.

Chang VP, Mills EW and Cutter CN, 2003. Reduction of bacteria on pork carcasses associated with chilling method. J Food Prot, 66, 1019-1024.

Colson P, Borentain P, Queyriaux B, Kaba M, Moal V, Gallian P, Heyries L, Raoult D and Gerolami R, 2010. Pig liver sausage as a source of hepatitis E virus transmission to humans. J Infect Dis, 202, 825-834.

Colville A, 1993. Retrospective review of culture-positive mycobacterial lymphadenitis cases in children in Nottingham, 1979-1990. Eur J Clin Microbiol Infect Dis, 12, 192-195.

Cook AJ, Gilbert RE, Buffolano W, Zufferey J, Petersen E, Jenum PA, Foulon W, Semprini AE and Dunn DT, 2000. Sources of *Toxoplasma* infection in pregnant women: European multicentre case-control study. European Research Network on Congenital Toxoplasmosis. BMJ, 321, 142-147.

Cosivi O, Grange JM, Daborn CJ, Raviglione MC, Fujikura T, Cousins D, Robinson RA, Huchzermeyer HF, de Kantor I and Meslin FX, 1998. Zoonotic tuberculosis due to *Mycobacterium bovis* in developing countries. Emerg Infect Dis, 4, 59-70.

Dalton CB, Gregory J, Kirk MD, Stafford RJ, Givney R, Kraa E and Gould D, 2004. Foodborne disease outbreaks in Australia, 1995 to 2000. Commun Dis Intell, 28, 211-224.

Daszak P, Cunningham AA and Hyatt AD, 2000. Emerging infectious diseases of wildlife--threats to biodiversity and human health. Science, 287, 443-449.

Davies PR, 2011. Intensive swine production and pork safety. Foodborne Pathog Dis, 8, 189-201.

Delhalle L, De Sadeleer L, Bollaerts K, Farnir F, Saegerman C, Korsak N, Dewulf J, De Zutter L and Daube G, 2008. Risk factors for *Salmonella* and hygiene indicators in the 10 largest Belgian pig slaughterhouses. J Food Prot, 71, 1320-1329.

Domingues, AR, Pires, SM, Lundsby, K and Hald, T. Source attribution of human salmonellosis and campylobacteriosis using a systematic review of studies of sporadic infections. Proceedings of the 5th Med Vet Net Annual Scientific Meeting, El Escorial, Madrid, Spain, June 2009.

Dubey JP, 1974. Effect of freezing on the infectivity of *Toxoplasma* cysts to cats. J Am Vet Med Assoc, 165, 534-536.

Dubey JP, 1998. *Toxoplasma gondii* oocyst survival under defined temperatures. J Parasitol, 84, 862-865.

Dubey JP, 2009. *Toxoplasmosis* in pigs--the last 20 years. Vet Parasitol, 164, 89-103.

Dubey JP, Kotula AW, Sharar A, Andrews CD and Lindsay DS, 1990. Effect of high temperature on infectivity of *Toxoplasma gondii* tissue cysts in pork. J Parasitol, 76, 201-204.

Edelhofer R, 1994. Prevalence of antibodies against *Toxoplasma gondii* in pigs in Austria--an evaluation of data from 1982 and 1992. Parasitol Res, 80, 642-644.

EFSA, 2004. Opinion of the Scientific Panel on Biological Hazards on "the suitability and details of freezing methods to allow human consumption of meat infected with *Trichinella* or *Cysticercus*". The EFSA Journal, 142, 1-50.

EFSA, 2005a. Opinion of the Scientific Panel on Biological Hazards on "*Campylobacter* in animals and foodstuffs". The EFSA Journal, 173, 1-10.

EFSA, 2005b. Opinion of the Scientific Panel on Biological Hazards on "Risk assessment of a revised inspection of slaughter animals in areas with low prevalence of *Trichinella*". The EFSA Journal, 200, 1-41.

EFSA, 2005c. Opinion of the Scientific Panel on Biological Hazards on the "Feasibility of establishing Trichinella-free areas, and if feasible on the risk increase to public health of not examining pigs from those areas for *Trichinella* spp.". The EFSA Journal, 277, 2-37.

EFSA, 2006. Opinion of the Scientific Panel on Biological Hazards on the request from the Commission related to "Risk assessment and mitigation options of *Salmonella* in pig production". The EFSA Journal, 341, 1-131.

EFSA, 2007a. Opinion of the Scientific Panel on Biological Hazards on microbiological criteria and targets based on risk analysis. The EFSA Journal, 462, 1-29.

EFSA, 2007b. Scientific Opinion of the Panel on Biological Hazards on a request from EFSA on monitoring of verotoxigenic *Escherichia coli* (VTEC) and identification of human pathogenic VTEC types. The EFSA Journal, 579, 1-61.

EFSA, 2007c. Scientific Opinion of the Panel on Biological Hazards on a request from EFSA on Surveillance and monitoring of *Toxoplasma* in humans, foods and animals. The EFSA Journal, 583, 1-64.

EFSA, 2007d. Scientific Opinion of the Panel on Biological Hazards on a request from the European Commission on food safety aspects of different pig housing and husbandry systems. The EFSA Journal, 613, 1-20.

EFSA, 2008a. Report of the Task Force on Zoonoses Data Collection on the analysis of the baseline survey on the prevalence of *Salmonella* in slaughter pigs, Part A. The EFSA Journal, 135,

EFSA, 2008b. Report of the Task Force on Zoonoses Data Collection on the Analysis of the baseline survey on the prevalence of *Salmonella* in slaughter pigs, Part B. The EFSA Journal, 206, 1-111.

EFSA, 2008c. Scientific Opinion of the Panel on Biological Hazards on a request from EFSA on Overview of methods for source attribution for human illness from food borne microbiological hazards. The EFSA Journal, 764, 1-43.

EFSA, 2008d. Scientific Opinion of the Panel on Biological Hazards on a request from the European Food Safety Authority on foodborne antimicrobial resistance as a biological hazard. The EFSA Journal, 765, 1-87.

EFSA, 2009a. Analysis of the baseline survey on the prevalence of Salmonella in holdings with breeding pigs, in the EU, 2008, Part A: *Salmonella* prevalence estimates. The EFSA Journal, 7(12). 93 pp.

EFSA, 2009b. The Community Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks in the European Union in 2007. The EFSA Journal, 233.

EFSA, 2009c. Joint Opinion on antimicrobial resistance (AMR) focused on zoonotic infections. The EFSA Journal, 7(11). 1-78.

EFSA, 2009d. Scientific Opinion of the Panel on Animal Health and Welfare (AHAW) on a request from the Commission on porcine brucellosis (*Brucella suis*). The EFSA Journal, 1144, 2-112.

EFSA, 2009e. Scientific Opinion of the Panel on Biological Hazards on a request from the European Commission on Assessment of the Public Health significance of meticillin resistant *Staphylococcus aureus* (MRSA) in animals and foods. The EFSA Journal, 993, 1-73.

EFSA, 2010a. The Community Summary Report on antimicrobial resistance in zoonotic and indicator bacteria from animals and food in the European Union in 2004-2007. The EFSA Journal, 8(4). 304 pp.

EFSA, 2010b. The Community Summary Report on antimicrobial resistance in zoonotic and indicator bacteria from animals and food in the European Union in 2008. The EFSA Journal, 8(7). 261 pp.

EFSA, 2010c. The Community Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks in the European Union in 2008. EFSA Journal, 8(1).

EFSA, 2010d. EFSA Panel on Biological Hazards; Scientific Opinion on a Quantitative Microbiological Risk Assessment of *Salmonella* in slaughter and breeder pigs. The EFSA Journal, 8(4). 80 pp.

EFSA, 2011a. The Community Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks in the European Union in 2009. The EFSA Journal, 9(3). 1-378.

EFSA Panel, 2011b. Scientific Opinion of the Panel on Biological Hazards on the public health risks of bacterial strains producing extended-spectrum β-lactamases and/or AmpC β-lactamases in food and food-producing animals. The EFSA Journal, 9(8). 95 pp.

EFSA (European Food Safety Authority), 2011c. Scientific Report on Technical specifications on harmonised epidemiological indicators for public health hazards to be covered by meat inspection of swine. EFSA Journal 2011;9(10):2371, 125 pp.

Falkinham JO, 3rd, 1996. Epidemiology of infection by nontuberculous mycobacteria. Clin Microbiol Rev, 9, 177-215.

FAO/WHO, 1998. Guidance on regulatory assessment of HACCP. FAO/WHO, Geneva, Switzerland.

Fayer R, 2004. *Sarcocystis* spp. in human infections. Clin Microbiol Rev, 17, 894-902, table of contents.

Fosse J, Seegers H and Magras C, 2008a. Foodborne zoonoses due to meat: a quantitative approach for a comparative risk assessment applied to pig slaughtering in Europe. Vet Res, 39, 1.

Fosse J, Seegers H and Magras C, 2008b. [Prioritising the risk of foodborne zoonoses using a quantitative approach: application to foodborne bacterial hazards in pork and beef]. Rev Sci Tech, 27, 643-655.

Freitas AR, Coque TM, Novais C, Hammerum AM, Lester CH, Zervos MJ, Donabedian S, Jensen LB, Francia MV, Baquero F and Peixe L, 2011. Human and Swine Hosts Share Vancomycin-Resistant *Enterococcus faecium* CC17 and CC5 and *Enterococcus faecalis* CC2 Clonal Clusters Harboring Tn1546 on Indistinguishable Plasmids. Journal of Clinical Microbiology, 49, 925-931.

Gahrn-Hansen B and Frederiksen W, 1992. Human infections with *Actinomyces pyogenes* (*Corynebacterium pyogenes*). Diagn Microbiol Infect Dis, 15, 349-354.

Galazka A and Przybylska A, 1999. Surveillance of foodborne botulism in Poland: 1960-1998. Euro Surveill, 4, 69-72.

Gambarotto K, Ploy MC, Dupron F, Giangiobbe M and Denis F, 2001. Occurrence of vancomycin-resistant *enterococci* in pork and poultry products from a cattle-rearing area of France. Journal of Clinical Microbiology, 39, 2354-2355.

Gamble HR, Bessonov AS, Cuperlovic K, Gajadhar AA, van Knapen F, Noeckler K, Schenone H and Zhu X, 2000. International Commission on Trichinellosis: recommendations on methods for the control of *Trichinella* in domestic and wild animals intended for human consumption. Vet Parasitol, 93, 393-408.

Gamble HR, Brady RC and Dubey JP, 1999. Prevalence of *Toxoplasma gondii* infection in domestic pigs in the New England states. Vet Parasitol, 82, 129-136.

Gamble HR, Zarlenga DS and Kim CW, 2007. Helminths in meat. In: Food microbiology: fundamentals and frontiers. MP Doyle, LR Beuchat. ASM Press, Washington, 629-648.

Garcia-Bocanegra I, Dubey JP, Simon-Grife M, Cabezon O, Casal J, Allepuz A, Napp S and Almeria S, 2010. Seroprevalence and risk factors associated with *Toxoplasma gondii* infection in pig farms from Catalonia, north-eastern Spain. Res Vet Sci, 89, 85-87.

Gebreyes WA, Bahnson PB, Funk JA, McKean J and Patchanee P, 2008. Seroprevalence of *Trichinella*, *Toxoplasma*, and *Salmonella* in antimicrobial-free and conventional swine production systems. Foodborne Pathog Dis, 5, 199-203.

Gill CO, Bedard D and Jones T, 1997. The decontaminating performance of a commercial apparatus for pasteurizing polished pig carcasses. Food Microbiology, 14, 71-79.

Gill CO and Bryant J, 1993. The presence of *Escherichia coli*, *Salmonella* and *Campylobacter* in pig carcass dehairing equipment. Food Microbiology, 10, 337-344.

Gill CO and Jones T, 1997. Assessment of the hygienic characteristics of a process for dressing pasteurized pig carcasses. Food Microbiology, 14, 81-91.

Gill CO, McGinnis DS, Bryant J and Chabot B, 1995. Decontamination of commercial, polished pig carcasses with hot-water. Food Microbiology, 12, 143-149.

Gottstein B, Pozio E and Nockler K, 2009. Epidemiology, diagnosis, treatment, and control of trichinellosis. Clin Microbiol Rev, 22, 127-145, Table of Contents.

Gousia P, Economou V, Sakkas H, Leveidiotou S and Papadopoulou C, 2011. Antimicrobial Resistance of Major Foodborne Pathogens from Major Meat Products. Foodborne Pathogens and Disease, 8, 27-38.

Gray JR and Rabeneck L, 1989. Atypical mycobacterial infection of the gastrointestinal tract in AIDS patients. Am J Gastroenterol, 84, 1521-1524.

Hald T, Lo Fo Wong DM and Aarestrup FM, 2007. The attribution of human infections with antimicrobial resistant *Salmonella* bacteria in Denmark to sources of animal origin. Foodborne Pathog Dis, 4, 313-326.

Hamilton DR, Gallas P, Lyall L, Lester S, McOrist S, Hathaway SC and Pointon AM, 2002. Risk-based evaluation of postmortem inspection procedures for pigs in Australia. Vet Rec, 151, 110-116.

Havelaar AH, Galindo AV, Kurowicka D and Cooke RM, 2008. Attribution of foodborne pathogens using structured expert elicitation. Foodborne Pathog Dis, 5, 649-659.

Havelaar AH, van Rosse F, Bucura C, Toetenel MA, Haagsma JA, Kurowicka D, Heesterbeek JH, Speybroeck N, Langelaar MF, van der Giessen JW, Cooke RM and Braks MA, 2010. Prioritizing emerging zoonoses in the Netherlands. PLoS One, 5, e13965.

Horsburgh CR, Metchock BG, McGowan JE and Thompson ST, 1991. Progression to disseminated infection in HIV-infected persons colonized with mycobacteria other than tuberculosis. Am Rev Respir Dis, 143, p. A279 Abstract.

Hove T, Lind P and Mukaratirwa S, 2005. Seroprevalence of *Toxoplasma gondii* infection in domestic pigs reared under different management systems in Zimbabwe. Onderstepoort J Vet Res, 72, 231-237.

Ingram PR, Bremner P, Inglis TJ, Murray RJ and Cousins DV, 2010. Zoonotic tuberculosis: on the decline. Commun Dis Intell, 34, 339-341.

Jakobsen L, Kurbasic A, Skjot-Rasmussen L, Ejrnaes K, Porsbo LJ, Pedersen K, Jensen LB, Emborg HD, Agerso Y, Olsen KEP, Aarestrup FM, Frimodt-Moller N and Hammerum AM, 2010. *Escherichia coli* Isolates from Broiler Chicken Meat, Broiler Chickens, Pork, and Pigs Share Phylogroups and Antimicrobial Resistance with Community-Dwelling Humans and Patients with Urinary Tract Infection. Foodborne Pathogens and Disease, 7, 537-547.

James C 2002. MePOSS: Review of microbial contamination during meat manufacture (WP 1). Report for Work Package 1 of the EU CRAFT project - CRAF-1999-70560: Reduction of health risks and extension of shelf life for meat products by application of oscillating saturated steam (MePOSS).

James C and James SJ, 1995. Past and future research into methods of red meat decontamination. Report-MAFF contract MH0211, UK MAFF, London.

James C, Nicolaon M and James SJ 1999. Review of microbial contamination and control measures in abattoirs. FRPERC, University of Bristol, Bristol.

Jones TF, 2003. From pig to pacifier: chitterling-associated yersiniosis outbreak among black infants. Emerg Infect Dis, 9, 1007-1009.

Kampelmacher EH, 1963. Salmonellosis in the Netherlands. Ann Inst Pasteur (Paris), 104, 647-659.

Kapperud G, Espeland G, Wahl E, Walde A, Herikstad H, Gustavsen S, Tveit I, Natas O, Bevanger L and Digranes A, 2003. Factors associated with increased and decreased risk of *Campylobacter* infection: a prospective case-control study in Norway. Am J Epidemiol, 158, 234-242.

Kapperud G, Jenum PA, Stray-Pedersen B, Melby KK, Eskild A and Eng J, 1996. Risk factors for *Toxoplasma gondii* infection in pregnancy. Results of a prospective case-control study in Norway. Am J Epidemiol, 144, 405-412.

Kapperud G, Skjerve E, Bean NH, Ostroff SM and Lassen J, 1992. Risk factors for sporadic *Campylobacter* infections: results of a case-control study in southeastern Norway. J Clin Microbiol, 30, 3117-3121.

Keessen EC, Gaastra W and Lipman LJ, 2011. *Clostridium difficile* infection in humans and animals, differences and similarities. Vet Microbiol,

Kempf I, Hellard G, Perrin-Guyomard A, Gicquel-Bruneau M, Sanders P and Leclercq R, 2008. Prevalence of high-level vancomycin-resistant *enterococci* in French broilers and pigs. International Journal of Antimicrobial Agents, 32, 463-464.

Kijlstra A, Meerburg B, Cornelissen J, De Craeye S, Vereijken P and Jongert E, 2008. The role of rodents and shrews in the transmission of *Toxoplasma gondii* to pigs. Vet Parasitol, 156, 183-190.

Kosmider RD, Nally P, Simons RR, Brouwer A, Cheung S, Snary EL and Wooldridge M, 2010. Attribution of human VTEC O157 infection from meat products: a quantitative risk assessment approach. Risk Anal, 30, 753-765.

Kotula AW, Dubey JP, Sharar AK, Andrews CD, Shen SK and Lindsay DS, 1991. Effect of freezing on infectivity of *Toxoplasma gondii* tissue cysts in pork. Journal of Food Protection, 54, 687-690.

Koutsoumanis K and Sofos JN, 2004. Microbial contamination. pp. 727-737. In: Encyclopaedia of Meat Sciences, Vol. 2. Jensen W.K., C. Devine, M Dikeman. Elsevier, Oxford,

Kruse H and Sorum H, 1994. Transfer of multiple drug resistance plasmids between bacteria of diverse origins in natural microenvironments. Appl Environ Microbiol, 60, 4015-4021.

Kuusi M, Hasseltvedt V and Aavitsland P, 1999. Botulism in Norway. Euro Surveill., 4, 11-12.

Lahti P, Heikinheimo A, Johansson T and Korkeala H, 2008. *Clostridium perfringens* type A strains carrying a plasmid-borne enterotoxin gene (genotype IS1151-cpe or IS1470-like-cpe) as a common cause of food poisoning. J Clin Microbiol, 46, 371-373.

Lappi VR, Thimothe J, Nightingale KK, Gall K, Scott VN and Wiedmann M, 2004. Longitudinal studies on *Listeria* in smoked fish plants: impact of intervention strategies on contamination patterns. J Food Prot, 67, 2500-2514.

Lee LA, Gerber AR, Lonsway DR, Smith JD, Carter GP, Puhr ND, Parrish CM, Sikes RK, Finton RJ and Tauxe RV, 1990. *Yersinia enterocolitica* O:3 infections in infants and children, associated with the household preparation of chitterlings. N Engl J Med, 322, 984-987.

Lewis HC, Wichmann O and Duizer E, 2010. Transmission routes and risk factors for autochthonous hepatitis E virus infection in Europe: a systematic review. Epidemiol Infect, 138, 145-166.

LoBue PA, Enarson DA and Thoen CO, 2010. Tuberculosis in humans and animals: an overview. Int J Tuberc Lung Dis, 14, 1075-1078.

Manero A, Vilanova X, Cerda-Cuellar M and Blanch AR, 2006. Vancomycin- and erythromycin-resistant *enterococci* in a pig farm and its environment. Environmental Microbiology, 8, 667-674.

Mataragas M, Skandamis PN and Drosinos EH, 2008. Risk profiles of pork and poultry meat and risk ratings of various pathogen/product combinations. Int J Food Microbiol, 126, 1-12.

McLauchlin J and Grant KA, 2007. *Clostridium botulinum* and *Clostridium perfringens*. In: Foodborne diseases. S S. Humana Press Inc, New Jersey, p 41.

Meerburg BG, Van Riel JW, Cornelissen JB, Kijlstra A and Mul MF, 2006. Cats and goat whey associated with *Toxoplasma gondii* infection in pigs. Vector Borne Zoonotic Dis, 6, 266-274.

Meng XJ, 2011. From barnyard to food table: The omnipresence of hepatitis E virus and risk for zoonotic infection and food safety. Virus Res,

Michel AL, Muller B and van Helden PD, 2010. *Mycobacterium bovis* at the animal-human interface: a problem, or not? Vet Microbiol, 140, 371-381.

Molbak K, Baggesen DL, Aarestrup FM, Ebbesen JM, Engberg J, Frydendahl K, Gerner-Smidt P, Petersen AM and Wegener HC, 1999. An outbreak of multidrug-resistant, quinolone-resistant *Salmonella enterica* serotype Typhimurium DT104. N Engl J Med, 341, 1420-1425.

Motarjemi Y, 2000. Regulatory assessment of HACCP: a FAO/WHO Consultation on the role of government agencies in assessing HACCP. Food Control, 11, 341-344.

Mousing J, Kyrval J, Jensen TK, Aalbaek B, Buttenschon J, Svensmark B and Willeberg P, 1997. Meat safety consequences of implementing visual postmortem meat inspection procedures in Danish slaughter pigs. Vet Rec, 140, 472-477.

Nakamura H, Hatanaka M, Ochi K, Nagao M, Ogasawara J, Hase A, Kitase T, Haruki K and Nishikawa Y, 2004. *Listeria monocytogenes* isolated from cold-smoked fish products in Osaka City, Japan. Int J Food Microbiol, 94, 323-328.

Nesbakken T, 2009. Control of human pathogenic *Yersinia enterocolitica* in the meat chain. Thesis. Norwegian School of Veterinary Science. Oslo.

Nesbakken T, Eckner K, Hoidal HK and Rotterud OJ, 2003. Occurrence of *Yersinia enterocolitica* and *Campylobacter* spp. in slaughter pigs and consequences for meat inspection, slaughtering, and dressing procedures. Int J Food Microbiol, 80, 231-240.

Nesbakken T, Eckner K and Rotterud OJ, 2008. The effect of blast chilling on occurrence of human pathogenic *Yersinia enterocolitica* compared to *Campylobacter* spp. and numbers of hygienic indicators on pig carcasses. Int J Food Microbiol, 123, 130-133.

Nesbakken T, Iversen T, Eckner K and Lium B, 2006. Testing of pathogenic *Yersinia enterocolitica* in pig herds based on the natural dynamic of infection. Int J Food Microbiol, 111, 99-104.

Nesbakken T, Iversen T and Lium B, 2007. Pig herds free from human pathogenic *Yersinia enterocolitica*. Emerg Infect Dis, 13, 1860-1864.

Nordic Council of Ministers, 2006. Risk-Based Meat Inspection in a Nordic Context. 2006:585, TemaNord, Copenhagen. 159 pp.

Offermann U, Bodmer T, Audige L and Jemmi T, 1999. Prevalence of *Salmonella*, *Yersinia* and Mycobacteria in Swiss slaughter pigs. Schweizer Archiv fur Tierheilkunde, 141, 509...515.

Oosterom J, Dekker R, de Wilde GJ, van Kempen-de Troye F and Engels GB, 1985. Prevalence of *Campylobacter jejuni* and *Salmonella* during pig slaughtering. Vet Q, 7, 31-34.

Opsteegh M, Langelaar M, Sprong H, den Hartog L, De Craeye S, Bokken G, Ajzenberg D, Kijlstra A and van der Giessen J, 2010. Direct detection and genotyping of *Toxoplasma gondii* in meat samples using magnetic capture and PCR. Int J Food Microbiol, 139, 193-201.

Ostroff SM, Kapperud G, Hutwagner LC, Nesbakken T, Bean NH, Lassen J and Tauxe RV, 1994. Sources of sporadic *Yersinia enterocolitica* infections in Norway: a prospective case-control study. Epidemiol Infect, 112, 133-141.

Pires SM, Vigre H, Makela P and Hald T, 2010. Using outbreak data for source attribution of human salmonellosis and campylobacteriosis in Europe. Foodborne Pathog Dis, 7, 1351-1361.

Pointon AM, Hamilton D, Kolega V and Hathaway S, 2000. Risk assessment of organoleptic postmortem inspection procedures for pigs. Vet Rec, 146, 124-131.

Pozio E, 2007. World distribution of *Trichinella* spp. infections in animals and humans. Vet Parasitol, 149, 3-21.

Pozio E, Kapel CM, Gajadhar AA, Boireau P, Dupouy-Camet J and Gamble HR, 2006. Trichinella in pork: current knowledge on the suitability of freezing as a public health measure. Euro Surveill, 11, E061116 061111.

Root TL, Price JT, Hall KR, Schneider SH, Rosenzweig C and Pounds JA, 2003. Fingerprints of global warming on wild animals and plants. Nature, 421, 57-60.

Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson MA, Roy SL, Jones JL and Griffin PM, 2011. Foodborne illness acquired in the United States--major pathogens. Emerg Infect Dis, 17, 7-15.

Schantz PM, Wilkins PP and Tsang VWC, 1998. Immigrants, imaging and immunoblots: The emergence of neurocysticercosis as a significant public health problem. In: Emerging infections 2. Scheld, Craig, Hughes. ASM Press, Washington DC, pp 213-242,

SCVMRPH, 2000. Opinion of the scientific committee on veterinary measures relating to public health on revision of meat inspection procedures 24 February 2000, SCVPH,

SCVMRPH, 2001. Opinion of the Scientific Committee on Veterinary Measures Relating to Public Health on Identification of Species/Categories of Meat Producing Animals in Integrated Production Systems Where Meat Inspection May be Revised.

Skjerve E, Lium B, Nielsen B and Nesbakken T, 1998. Control of *Yersinia enterocolitica* in pigs at herd level. Int J Food Microbiol, 45, 195-203.

Skjerve E, Tharaldsen J, Waldeland H, Kapperud G and Nesbakken T, 1996. Antibodies to *Toxoplasma gondii* in Norwegian slaughtered sheep, pigs and cattle. Bulletin of the Scandinavian Society for Parasitology, 6, 11-17.

Small A, James C, James S, Davies R, Liebana E, Howell M, Hutchison M and Buncic S, 2006. Presence of *Salmonella* in the red meat abattoir lairage after routine cleansing and disinfection and on carcasses. J Food Prot, 69, 2342-2351.

Smith TC, Harper AL, Nair R, Wardyn SE, Hanson BM, Ferguson DD and Dressler AE, 2011. Emerging Swine Zoonoses. Vector Borne Zoonotic Dis,

Tauxe RV, Vandepitte J, Wauters G, Martin SM, Goossens V, De Mol P, Van Noyen R and Thiers G, 1987. *Yersinia enterocolitica* infections and pork: the missing link. Lancet, 1, 1129-1132.

Tenter AM, Heckeroth AR and Weiss LM, 2000. *Toxoplasma gondii*: from animals to humans. Int J Parasitol, 30, 1217-1258.

Thevenot D, Dernburg A and Vernozy-Rozand C, 2006. An updated review of *Listeria monocytogenes* in the pork meat industry and its products. J Appl Microbiol, 101, 7-17.

Thimothe J, Nightingale KK, Gall K, Scott VN and Wiedmann M, 2004. Tracking of *Listeria monocytogenes* in smoked fish processing plants. J Food Prot, 67, 328-341.

Thoen C, Lobue P and de Kantor I, 2006. The importance of *Mycobacterium bovis* as a zoonosis. Vet Microbiol, 112, 339-345.

Van Damme and De Zutter L, 2011. Occurrence of human enteropathogenic *Yersinia* spp. in Belgian pigs and contamination of pork carcasses during slaughter. SafePork Conference, Maastricht 19-22 June 2011,

van der Giessen J, Fonville M, Bouwknegt M, Langelaar M and Vollema A, 2007. Seroprevalence of *Trichinella spiralis* and *Toxoplasma gondii* in pigs from different housing systems in The Netherlands. Vet Parasitol, 148, 371-374.

van Knapen F, 1991. Absence of trichinellosis in the Netherlands. RIVM report 18802002.

van Knapen F, 1994. Epidemiological data concerning *T. spiralis* infection in The Netherlands. Wiad Parazytol, 40, 393.

van Knapen F, Franchimont JH and van der Lugt G, 1982. Prevalence of antibodies to *Toxoplasma* in farm animals in the Netherlands and its implication for meat inspection. Vet Q, 4, 101-105.

van Knapen F, Kremers AF, Franchimont JH and Narucka U, 1995. Prevalence of antibodies to *Toxoplasma gondii* in cattle and swine in The Netherlands: towards an integrated control of livestock production. Vet Q, 17, 87-91.

Vivas Alegre L and Buncic S, 2004. Potential for use of hide-carcass microbial counts relationship as an indicator of process hygiene performance of cattle abattoirs. Food Protection Trends, 24, 24 (11) 814-820.

von Ostertag R, 1892. Handbuch der Fleischbeschau für Tierärzte, Ärzte und Richter. Editor. F. Enke, Stuttgart, Germany.

Waddell LA, Rajic A, Sargeant J, Harris J, Amezcua R, Downey L, Read S and McEwen SA, 2008. The zoonotic potential of *Mycobacterium avium* spp. *paratuberculosis*: a systematic review. Can J Public Health, 99, 145-155.

Wagner D and Young LS, 2004. Nontuberculous mycobacterial infections: a clinical review. Infection, 32, 257-270.

Walsh C, Duffy G, Nally P, O'Mahony R, McDowell DA and Fanning S, 2008. Transfer of ampicillin resistance from *Salmonella* Typhimurium DT104 to *Escherichia c*oli K12 in food. Lett Appl Microbiol, 46, 210-215.

Walsh C, Duffy G, O'Mahony R, Fanning S, Blair IS and McDowell DA, 2006. Antimicrobial resistance in Irish isolates of verocytotoxigenic *Escherichia coli* (*E. coli*)--VTEC. Int J Food Microbiol, 109, 173-178.

WHO/FAO, 2009. Guidelines of World Health Organization/Food and Agriculture Organization of the United Nations: Microbiological Risk Assessement Series 17, pp. 6-11.

Wood RL, Pospischil A and Rose R, 1989. Distribution of persistent *Salmonella* Typhimurium infection in internal organs of swine. Am J Vet Res, 50, 1015-1021.

ANNEX

EXAMPLES OF CONTROL AND MONITORING PROGRAMS OF ZOONOTIC HAZARDS IN MEMBER STATES

Salmonella and MAP in German slaughter pigs.

Salmonella monitoring system in Germany

In Germany a steadily growing, industry-driven, national quality management system (the "QS-System") from feed to retail that farmers, slaughter plants processors and retailers join on a voluntary basis has been established since 2003 (Anonymous, 2011). Farmers, which participate in the QS system let their slaughter pigs be risk categorized. The measurement is as follows: the frequency of animals with antibodies against *Salmonella* spp. in a random sample of 60 slaughtered pigs per herd and year (Anonymous, 2011) is evaluated. The samples for this serological monitoring are either meat juice samples taken at slaughter or blood serum samples taken not earlier than 14 days prior to slaughter. Normally meat juice samples are taken at the slaughterhouse because of the easier access there. Either kind of sample is analyzed *via* Enzyme Linked Immunoabsorbant Essay (ELISA). The actual cut-off of the German *Salmonella* monitoring is 40% OD (optical density)(Anonymous, 2011). In the future it may be lowered if the overall sero-prevalence at a national level is lowered as well (Blaha, 2004). Table 1 shows the number of samples taken depending on herd size.

Table 1: Number of samples taken per herd per year depending on herd size

Number of animals sent to slaughter per year	Number of pigs to be sampled
less than 45	26*
45 -100	38
101 - 200	47
more than 200	60

*if less than 26 pigs are to be slaughtered, all must be sampled

The samples must not be taken all at once, but must be spread over a 12 month period among the groups sent to slaughter in order to receive an as accurate as possible representation of the serological status of the herd, which tends to change over time.

The categorisation is made after one year of testing as follows:

Category I: less than 20% of all samples taken are *Salmonella* spp. antibody positive

Category II: 20 to 40% of all samples taken are *Salmonella* spp. antibody positive

Category III: more than 40% of all samples taken are *Salmonella* spp. antibody positive (i.e. >40% OD).

A rolling average is calculated every three months, once a herd has been risk-categorized for the first time. For this purpose at the end of each three month period, the results of the "oldest" samples are taken out of the calculation of the average, while the results of the then "newest" samples are included into the pool. Thus there are again 60 samples that are taken into account for the re-categorization.

Herds in Category III are required and herds in Category II are encouraged to find the cause of the *Salmonella* problem and implement measures against it in order to reduce the sero-prevalence of the herd (Anonymous, 2011).

The German government has made the participation in the described Salmonella monitoring system mandatory for all farmers supplying slaughter pigs in 2007. The question of how to manage an individual herd's problem often presents some difficulty. Many risk factors, such as more than three supplier herds (Lo Fo Wong et al., 2004), rodent infestation (Letellier et al., 1999) and contaminated feed (Harris et al., 1997) have been described in the literature and many reports on studies into these risk factors have been published (Funk and Gebreyes, 2004). In some cases herds are categorized into Category III although many known measures against salmonella-infections, for example a strict all-in all-out management (Farzan et al., 2006; Stege et al., 2000), acidifying of feed and/or coarsely ground feed (Visscher, 2006) and proper external biosecurity measures (Funk et al., 2001), are already in place. Experts' opinions therefore don´t agree always on which management or hygienic factors are the key to a successful prevention of salmonella-infections in pigs (Staerk et al., 2002).

Example of Monitoring Scheme

Table 2 gives an overview on a categorisation scheme for pig herds on the basis of a serological monitoring. The microbiological agent (*M. avium*) was chosen because of legal requirements of the current meat inspection legislation. It is not the result of a formal risk assessment and in this opinion MAP is not considered as posing a high or medium ranking risk. Therefore the following table is given as an example for further categorisation schemes.

Table 2: Categorisation of pig herds on the basis of a serological monitoring for *M. avium* infections

Status - *description*	**No. of serum samples analysed so far**	**No. of serum samples at next delivery**	**No. of deliveries with –ve samples needed to go to lower risk level**	**New herd category based on results of the MA-ELISA**			
				Negative test result	**Positive test result(s)**		
				New herd category	**No. of MA-positive serum samples**		**PP of +ve serum sample**	**New Herd Category**
					GE	**NL**		
'New' – *insufficient samples*	< 18 (all –ve)	6	3	'New' or 'Neutral'	1 or 2 > 2 ≥ 1	1 ≥ 2 ≥ 1	> 20 ≤ 50 > 50	'On probation' 'High' 'High'
'High' – *positive herd*	-	6	3	'High' or 'Neutral' (after 3x 6 –ve's)	≥ 1	≥ 1	> 20	'High'
'Neutral' – *negative but to few samples*	≥ 18 ≤ 36 (all –ve)	2	9	'Neutral' or 'Low'	1 or 2 > 2 ≥ 1	1 ≥ 2 ≥ 1	> 20 ≤ 50 > 50	'On probation' 'High' 'High'
'Low' – *negative herd*	36 (all –ve)	1	NA	'Low'	1 or 2 > 2 ≥ 1	1 ≥ 2 ≥ 1	> 20 ≤ 50 > 50	'On probation' 'High' 'High'
'On probation' – *herd under suspicion*	-	6	1	To previous herd category	≥ 1	≥ 1	> 20	'High'

PP = percentage positivity, -ve = negative test result, +ve = positive test result
GE = Germany, NL = The Netherlands; NA = Not Applicable

REFERENCES FOR BIOHAZ ANNEX

Anonymous, 2011. Guideline Salmonella Monitoring and Reduction Program for Pork Production (available at http://www.q-s.de/dc_agriculture_pig_production.html).

Blaha T, 2004. [Up-to-date information from the German QS *Salmonella* monitoring and reduction programme]. Dtsch Tierarztl Wochenschr, 111, 324-326.

Farzan A, Friendship RM, Dewey CE, Warriner K, Poppe C and Klotins K, 2006. Prevalence of Salmonella spp. on Canadian pig farms using liquid or dry-feeding. Prev Vet Med, 73, 241-254.

Funk J and Gebreyes WA, 2004. Risk factors associated with Salmonella prevalence on swine farms. Journal of Swine Health and Production, 12, 246-251.

Funk JA, Davies PR and Gebreyes W, 2001. Risk factors associated with Salmonella enterica prevalence in three-site swine production systems in North Carolina, USA. Berl Munch Tierarztl Wochenschr, 114, 335-338.

Harris IT, Fedorka-Cray PJ, Gray JT, Thomas LA and Ferris K, 1997. Prevalence of Salmonella organisms in swine feed. J Am Vet Med Assoc, 210, 382-385.

Letellier A, Messier S, Pare J, Menard J and Quessy S, 1999. Distribution of Salmonella in swine herds in Quebec. Vet Microbiol, 67, 299-306.

Lo Fo Wong DM, Dahl J, Stege H, van der Wolf PJ, Leontides L, von Altrock A and Thorberg BM, 2004. Herd-level risk factors for subclinical Salmonella infection in European finishing-pig herds. Prev Vet Med, 62, 253-266.

Staerk KD, Wingstrand A, Dahl J, Mogelmose V and Lo Fo Wong DM, 2002. Differences and similarities among experts' opinions on Salmonella enterica dynamics in swine pre-harvest. Prev Vet Med, 53, 7-20.

Stege H, Christensen J, Nielsen JP and Willeberg P, 2001. Data-quality issues and alternative variable-screening methods in a questionnaire-based study on subclinical Salmonella enterica infection in Danish pig herds. Preventive Veterinary Medicine, 48, 35-54.

Thevenot D, Dernburg A and Vernozy-Rozand C, 2006. An updated review of Listeria monocytogenes in the pork meat industry and its products. J Appl Microbiol, 101, 7-17.

Visscher C, 2006. Untersuchungen (Feldstudie) zur Salmonellenprävalenz bei Mastschweinen unter dem Einfluss einer gröberen Futtervermahlung sowie von Futteradditiven (organische Säuren bzw. Kaliumdiformiat) (dissertation)Tierärztliche Hochschule Hannover. Hannover, Germany. 198 pp.

APPENDIX B FROM THE PANEL ON CONTAMINANTS IN THE FOOD CHAIN (CONTAM PANEL)

TABLE OF CONTENTS

POTENTIAL CONCERNS REGARDING RESIDUES AND CONTAMINANTS IN SLAUGHTERED DOMESTIC PIGS

1. General introduction

Meat inspection in Europe is specified in Council Regulation 854/2004.[10] A detailed overview on current practices of meat inspection in Europe has been recently presented in an external report to EFSA.[14] As stated in the report, the main objective of meat inspection is to ensure that meat is fit for human consumption. Historically, meat inspection procedures have been designed to control slaughter animals for the absence of infectious diseases, with special emphasis on zoonoses and notifiable diseases. The mandate that meat needs to be fit for human consumption, however, includes also the control of chemical residues and contaminants in meat or offal that could be harmful for consumers. This aspect is not fully addressed by the current procedures.

This document aims to identify undesirable or harmful chemical residues and contaminants in slaughter pigs and their carcasses taking into account the current legislation and results from the national residue control plans. These findings, together with the characteristics of the individual substances, were used to rank chemical residues and contaminants into categories of potential concern. Four categories were established constituting a high, medium, low or negligible potential concern. In the second part the main strengths and weaknesses of the current meat inspection protocols were assessed. The ultimate aim is an overall evaluation of the current strategies for sampling and analytical testing, resulting in recommendations for amendments of the current meat inspection protocols.

1.1. Definition of slaughter pigs

Slaughter pigs are a mixed animal population. In general, two different groups of slaughter animals can be defined:

(i) pigs raised for fattening: generally a very homogeneous population in terms of age and weight of the animals. The animals originate from production holdings of different sizes, but have been raised solely for the purpose of meat production. Pigs for fattening are by far the largest group to be considered in a meat inspection system.

(ii) other pigs: animals slaughtered at different stages of life including animals raised for breeding in defined breeding holdings, animals at the end of their breeding period, and animals slaughtered for other reasons.

Regulation (EC) No 853/2004[10] specifies the relevant food safety information which should be covered by the Food Chain Information (FCI) when presenting pigs for slaughter. FCI is the animal's life history data from birth, through all stages of rearing, up to the day of slaughter. In particular, the food business operator at the slaughterhouse should receive information related to the veterinary medicinal products or other treatments administered to the animals within a relevant period prior to slaughter, together with their administration dates and their withdrawal periods. Moreover, any sampling results taken from the animals within the framework of monitoring and control of residues should also be communicated to the slaughterhouse operators before the arrival of the animals. In contrast to fattening pigs, data on the second group (non-fattening pigs) are often incomplete, as the decision to slaughter is often taken only a few days earlier.

1.2. Procedures in the current meat inspection

The current procedure of meat inspection comprises two major steps at the abattoir level that may result in identifying animals that should be subjected to sampling for the presence of residues and contaminants:

- *ante-mortem* (living animal) inspection. The *ante-mortem* visual inspection aims to identify animals with clinical signs of disease, including signs of intoxications, or of a recent medication, such as injection sites, loss of body fat or alterations at the reproductive organs.
- *post-mortem* (carcass) inspection. In the current procedure of meat inspection, neither palpation nor incisions contribute materially to the identification of abiotic hazards in pig carcasses. The visual inspection of the carcass (and offal) may allow in some cases the identification of gross alterations in the carcass composition, and organ-specific lesions in kidneys, liver or other organs that are indicative of recent drug use or acute or chronic exposure to toxic substances. This aspect is not covered in detail in the current meat inspection protocols. On the other hand, in most cases exposure to chemical compounds including substances that accumulate in the body (toxic elements, certain organic pollutants) do not result in typical organ lesions. Hence it needs to be considered that evidence for the presence of chemical residues and contaminants will in most cases not be apparent during the current visual inspection of pig carcasses. Therefore, the meat inspection approach based on "detect and immediately eliminate", used for biotic (microbiological) hazards in slaughterhouses, is generally not applicable to abiotic hazards.

While monitoring programmes (Council Directive 96/23/EC[11] which is fully described in Section 1.3) may provide a gross indication of the prevalence of undesirable chemical residues and contaminants in pig carcasses, the sole intervention at abattoir level is the isolation of a suspect carcass as potentially unfit for human consumption, pending results of residue testing.

1.3. Current legislation

Council Directive 96/23/EC[11] prescribes the measures to monitor certain substances and residues thereof in live animals and animal products. It requires that Member States adopt and implement a national residue monitoring plan, also referred to as the national residue control plan (NRCP), for defined groups of substances.[17] Member States must assign the task of coordinating the implementation of the controls to a central public body. This public body is responsible for drawing up the national plan, coordinating the activities of the central and regional bodies responsible for monitoring the various residues, collecting the data and sending the results of the surveys undertaken to the Commission each year.

The NRCP should be targeted; samples should be taken on-farm and at abattoir level with the aim of detecting illegal treatment or controlling compliance with the maximum residue limits (MRLs) for veterinary medicinal products according to the Commission Regulation (EC) No 37/2010,[18] with the maximum residue levels for pesticides as set out in Regulation (EC) No 396/2005,[19] or with the

[17] Commission Staff Working Document on the Implementation of National Residue Monitoring Plans in the Member States in 2009 (Council Directive 96/23/EC). Available from http://ec.europa.eu/food/food/chemicalsafety/residues/workdoc_2009_en.pdf. The following text has been largely taken from the Commission Staff Working Document 2010 (SEC 2010-final).

[18] Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin.OJ L 15, 20.1.2010, p. 1-72.

[19] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p.1-16.

maximum levels for contaminants as laid down in Commission Regulation (EC) No 1881/2006,[20] This means that in the national monitoring plan the Member States target the groups of animals/gender/age combinations where the probability of finding residues is the highest. This approach differs from random sampling, where the objective is to gather statistically representative data, for instance to evaluate consumer exposure to a specific substance.

For pigs, it is compulsory that samples are taken from at least 0.05 % of the total number of animals slaughtered per year. The numerical basis for calculation of the value of 0.05 % is the number of slaughter animals reported in the previous year.

1.4. Actions taken as a consequence of non-compliant results

In accordance with Article 8 of Directive 96/23/EC,[11] the Member States are requested, as a follow-up, to provide information on actions taken at regional and national level as a consequence of non-compliant results. The Commission sends a questionnaire to the Member States to obtain an overview of these actions, for example when residues of non-authorised substances are detected or when the maximum residue limits (MRLs) established in EU legislation are exceeded. The actions taken by the Member States may include:

- suspect sampling;
- modifications of the national plans;
- other actions taken as a consequence of non-compliant results.

1.4.1. Suspect sampling

Sampling as suspect includes:

- samples taken as a consequence of non-compliant results on targeted samples taken in accordance with the monitoring plan (Article 5 of Directive 96/23/EC[11]);
- samples taken as a consequence of possession or presence of prohibited substances at any point during manufacture, storage, distribution or sale throughout the food and feed production chain (Article 11 of Directive 96/23/EC[11]);
- samples taken where the veterinarian suspects, or has evidence of, illegal treatment or non-compliance with the withdrawal period for an authorized veterinary medicinal product (Article 24 of Directive 96/23/EC[11]).

In summary, this means that the term “suspect sample” applies to a sample taken as a consequence of:

- non-compliant results, and/or
- suspicion of an illegal treatment, and/or
- suspicion of non-compliance with the withdrawal periods.

[20] Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs. OJ L 364, 20.12.2006, p. 5-24.

1.4.2. Modification of the national plans

Non-compliant results for a specific substance or group of substances or a specific food commodity should result in intensified controls for this substance/group or food commodity in the plan for the following year.

1.4.3. Other actions

Article 16 and Articles 22-28 of Directive 96/23/EC[11] prescribe a series of actions (other than modifications of the residue monitoring plan) to be taken in the case of non-compliant results or infringements:

- to carry out investigations in the farm of origin, such as verification of records and additional sampling;
- to hold animals in the farm as a consequence of positive findings;
- to slaughter animals in case of confirmation of illegal treatment and to send them to a high risk processing plant;
- to intensify the controls in the farms where non-compliant results were found;
- to impound carcasses at the slaughterhouse when non-compliant results have been found;
- to declare the carcasses or products of animal origin unfit for human consumption.

It should be noted that targeted sampling as defined by the Directive 96/23/EC[11] aims at monitoring certain substances and residues thereof in live animals and animal products across EU Member States. In contrast to monitoring, under suspect sampling, a "suspect" carcass has to be detained at the abattoir until laboratory results confirm or deny conformity with legislative limits for chemical residues. Based on the test results, the carcass can be declared fit or unfit for human consumption. In the first scenario, the carcass is released into the human food chain whereas in the second case the carcass is disposed off.

2. Identification, classification and ranking of substances of potential concern

The presence of chemical residues or contaminants in slaughtered pigs may be of concern for a number of reasons. In addition to a possible direct effect on animal or human health, non-compliance indicates a failure of normal risk management procedures. Hence, the CONTAM Panel concluded that in contrast to the presence of certain pathogenic microorganisms on a pig carcass, it is unlikely that chemical residues and contaminants in slaughter animals pose an immediate or short term health risk for consumers. However, certain bioaccumulating contaminants are of potential concern because they will contribute to the overall exposure.

In addition, the presence of chemical residues of certain pharmacologically active substances is of potential concern as they are indicative either of non-compliance with existing regulations or of illicit use of non-authorized substances, with implications for risk management. Consequently, the first term of reference requesting identification and ranking of the main chemical risks was interpreted as a mandate to identify, classify and rank chemical substances according to the level of potential concern. Differentiation according to production systems and age of animals (e.g. breeding compared to fattening animals) was taken into consideration.

2.1. Identification of substances of potential concern

In the current EU legislation, chemical residues and contaminants in live animals and animal products intended for human consumption are addressed in Council Directive 96/23/EC.[11] Identification and ranking of potential concerns within this chapter includes all chemical compounds listed in this Council Directive. Annex I of Council Directive 96/23/EC[11] groups substances that may be found in animal tissues into two categories:

Group A – Substances having anabolic effects and unauthorized substances

A.1. Stilbenes, stilbene derivatives, and their salts and esters

A.2. Antithyroid agents

A.3. Steroids

A.4. Resorcyclic acid lactones, including zeranol

A.5. Beta-agonists

A.6. Compounds included in Annex IV to Council Regulation (EEC) No 2377/90 of 26 June 1990[21] (recently amended by Commission Regulation (EC) No 37/2010[18]).

Group B – Veterinary drugs (including unlicensed substances which could be used for veterinary purposes) and contaminants

B.1. Antibacterial substances, including sulphonamides, quinolones

B.2. Other veterinary drugs

a) Antihelmintics
b) Anticoccidials
c) Carbamates and pyrethroids
d) Sedatives
e) Non-steroidal anti-inflammatory drugs (NSAIDs)
f) Other pharmacologically active substances

B.3. Other substances and environmental contaminants

a) Organochlorine compounds, including PCBs
b) Organophosphorus compounds
c) Chemical elements
d) Mycotoxins
e) Dyes
f) Others

2.2. Classification of chemical substances in the food chain

As one of the objectives of this assessment of current meat inspection protocols is the identification of chemical substances of potential concern that may occur as residues or contaminants in slaughter pigs, but have not been specifically addressed in Council Directive 96/23/EC,[11] a more general grouping of chemical substances was chosen, resulting in the following three major groups:

- substances that are prohibited for use in food producing animals, corresponding to Group A substances in Council Directive 96/23/EC,[11]

[21] Council Regulation (EEC) No 2379/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin. OJ L 224, 18.8.90, p. 1-8.

- veterinary drugs, also denoted veterinary medicinal products (VMPs), corresponding to Groups B1 and B2 substances in Council Directive 96/23/EC,[11] and
- contaminants, corresponding to Group B3 substances in Council Directive 96/23/EC.[11]

The first group of chemicals that may occur in edible tissues are substances that are prohibited for use in food producing animals. The rationale for banning these substances for application to animals varied and the list of prohibited substances comprises substances that are of toxicological concern (substances for which an acceptable daily intake (ADI) could not be established), as well as anabolic substances and substances that may alter meat quality and/or affect animal health and welfare.

A second group of chemicals that may be a source of residues in animal-derived foods VMPs (including antibiotics, antiparasitic agents and other pharmacologically active substances) used in the health care of domestic animals. These substances have been subjected to assessment and pre-marketing approval by the Committee for Medicinal Products for Veterinary Use of the European Medicines Agency (EMA) according to Regulation (EC) No 470/2009.[22] For all VMPs licensed for use in food-producing animals, EMA establishes an ADI on the basis of the pharmacological and toxicological profile of the candidate drug. Compounds that are genotoxic or carcinogenic and substances for which no ADI can be established are excluded from approval. On the basis of the established ADI, MRLs are derived for the parent drug and/or its biologically active metabolites (marker metabolites)) in edible tissues and these MRL values (µg/kg tissue) are used to establish compliance. The list of allowed substances is presented as Annex 1 of Commission Regulation (EC) No 37/2010.[18]

It is important to note that only the toxicological assessment is considered here, as other effects such as antibiotic activity and antimicrobial resistance are addressed elsewhere (see Annex of the BIOHAZ Panel).

A third group of chemical substances that may occur in edible tissues of pigs are contaminants that may enter the animal's body mainly via feed and more exceptionally by drinking water, inhalation or direct (skin) contact. Feed materials can contain a broad variety of undesirable substances comprising persistent environmental pollutants, toxic metals and other elements as well as natural toxins, such as toxic secondary plant metabolites and fungal toxins (mycotoxins). Feed producers have to act in compliance with Commission Directive 2002/32/EC,[11] listing the undesirable substances in feed and feed materials and presenting maximum content in feed materials or compound feeds. In a recent re-assessment of these undesirable substances in animal feeds, the EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) re-evaluated the risk related to exposure to these substances for animals (detailed below, Table 1). Of major potential concern were toxic compounds that accumulate or persist in edible tissues or are directly excreted into milk and eggs. Subsequently, these Opinions addressed not only potential adverse effects for animal health, but also the possible transfer of the contaminants into edible tissues of slaughter animals and the potential human health risk associated with the consumption of milk, meat and eggs from exposed animals. Where appropriate, maximum levels have been set for food of animal origin (meat, milk, eggs) within the framework of Commission Regulation (EC) No 1881/2006.[20]

A summary of the statutory maximum levels and reference to the respective assessing body are given in the following Table (Table 1).

[22] Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2998 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council. OJ L 152, 16.6.2009, p. 11-22.

Table 1: Possible contaminants in pork.[23]

Contaminant	MLs	Health-based guidance values/MOE approach	Assessments: Reference
Aflatoxins	No provisions for pig meat	MOE approach	EFSA, 2004b, 2007c
Deoxynivalenol	No provisions for pig meat	TDI: 1 µg/kg b.w.	EFSA, 2004c SCF, 1999, 2002
Dioxins and dioxin-like PCBs	Dioxins: Pig meat, fat and meat products: 1.0 pg WHO-TEQ/g fat Pig liver and derived products: 6.0 pg WHO-TEQ/g fat Dioxins + DL-PCBs Pig meat, fat and meat products: 1.5 pg WHO-TEQ/g fat Pig liver and derived products: 12.0 pg WHO TEQ/g fat	TWI: 14 pg/WHO-TEQ/kg b.w.	EFSA, 2005a SCF, 2001a
Cadmium	Pig meat: 0.050 mg/kg wet weight Pig liver: 0.50 mg/kg wet weight Pig kidney: 1.0 mg/kg wet weight	TWI: 2.5 µg/kg b.w.	EFSA, 2009a, 2011b
Fumonisins	No provisions for pig meat	TDI: 2 µg/kg b.w.	EFSA, 2005b
Inorganic tin	No provisions for pig meat 250 mg/kg canned food	Not defined	
Lead	Maximum level: Pig meat: 0.10 mg/kg wet weight Pig offal: 0.50 mg/kg wet weight	MOE approach	EFSA, 2010b
Mercury/-(Methyl-)Mercury	No provisions for pig meat	pTWI for Mercury: 4 µg/kg b.w. pTWI for (Methyl-) Mercury: 1.6 µg/kg b.w	FAO/WHO, 2003, 2011
Nitrate	No provisions for pig meat	ADI: 0-3.7 mg/kg b.w. (nitrate) ADI: 0.07 mg/kg b.w./day (nitrite)	SCF, 1997 EFSA, 2009c
Nivalenol	No provisions for pig meat	tTDI: 0 - 0.7 µg/kg b.w.	SCF, 2000a
Ochratoxin A	No provisions for pig meat	TWI: 120 ng/kg b.w.	EFSA, 2004a, 2006
Patulin	No provisions for pig meat	pmTDI: 0.4 µg/kg b.w.	SCF, 2000b
Polycyclic aromatic hydrocarbons	Maximum level in smoked meats and smoked meat products: 5.0 µg/kg wet weight	MOE approach	EFSA, 2008h
T-2 and HT-2 toxin and other Trichothecenes	No provisions for pig meat	Combined tTDI of 0.06 µg/kg b.w.	SCF, 2001b
Zearalenone	No provisions for pig meat	TDI: 0.25 µg/kg b.w.	EFSA, 2004d, 2011d

ML: maximum level; b.w.: body weight; MOE: margin of exposure; TDI: tolerable daily intake; TEQ: toxic equivalent; TWI: tolerale weekly intake; ADI: acceptable daily intake; tTDI: temporary TDI; pmTDI: provisional maximum TDI, pTWI: provisional tolerable daily intake.

[23] The given data refer to the provisions in Regulation (EC) No 1881/2006 and are often based on Opinions of the previous Scientific Committee on Food (SCF), and assessment by JECFA (FAO/WHO) or in some cases on recent EFSA scientific outputs.

2.3. Ranking of the substances of potential concern

Different approaches can be used for ranking the potential concern of the three groups of substances that are presented in Section 2.1.2. These include:

- evaluation of the outcomes of the national residue monitoring plans indicating the numbers of samples that are non-compliant with the current legislation. All substances that were detected in more than 1 % of the analysed samples were considered to be of potential concern.
- evaluation of the likelihood that residues or contaminants that are not included in the current national residue plans will be present in a pig carcass.

2.3.1. Outcome of the national residue monitoring plans within the EU

The Commission publishes data from the national residue control plans (NRCPs) annually. Aggregated data regarding the outcome of the NRCPs for targeted sampling of pigs from 2005 to 2009 are presented in the following Tables (Tables 2 to 4). The grouping follows Council Directive 96/23/EC.[11] Data reported in 2005 were from the then 25 EU Member States whereas for the subsequent years (2006 - 2009) data have been gathered from 27 EU Member States. This is due to the accession of Romania and Bulgaria to the EU. Results from suspect sampling are not included, as these results are considered not to be representative of the actual occurrence of chemicals. As stated above, suspect sampling arises as (i) a follow-up to the occurrence of a non-compliant result and/or (ii) on suspicion of illegal treatment at any stage of the food chain and/or (iii) on suspicion of non-compliance with the withdrawal periods for authorised veterinary medicinal products (Articles 5, 11 and 24 of Directive 96/23/EC,[11] respectively). From 2005 to 2009, a total of 894,155 pig samples were tested for one or more substance groups listed in Annex I of the Directive 96/23/EC.[11] It should be noted that in some cases the same samples were analysed for different substance groups and therefore this number is higher than the total number of samples collected from pigs. No information was available on the nature of the positive samples (i.e. whether this refers to meat, liver, kidney or fat samples). Moreover, these aggregated results give no indication of the actual measured concentrations of residues or contaminants and therefore do not allow a reliable exposure assessment.

A non-compliant result refers solely to an analytical result exceeding the permitted limits with sufficient statistical certainty that it can be used for legal purposes.[24] As mentioned above, for veterinary medicinal products, MRLs are laid down in Council Regulation (EU) No 37/2010.[18] For pesticides, MRLs are laid down in Regulation (EC) No 396/2005.[19.] Maximum levels (ML) for contaminants are laid down in Commission Regulation (EC) No 1881/2006.[20] National tolerance levels were applied by individual Member States for contaminants where no EU maximum levels have been established. For certain substances that are not licensed within the EU, such as chloramphenicol, nitrofurans and their metabolites, medroxyprogesterone acetate and (leuco-) malachite green, Minimum Required Performance Limits (MRPLs) have been established (Commission Decision 2002/657/EC[24]) to make results of residue monitoring comparable between laboratories and Member States and these MRPLs were used in the reporting system. Monitoring data on corticosteroids are not included in the summary due to the divergence among EU Member States regarding their reporting categorisation as either group A3 (steroids) or as group B2f (other pharmacologically active substances). However, in pigs, a total of 11 non-compliant results for corticosteroids (prednisolone) have been reported in the EC reports[25] within the 5-year timeframe covered by the present summary.

[24] As laid down in Article 6 of Decision 2002/657/EC, the result of an analysis shall be considered non-compliant if the decision limit of the confirmatory method for the analyte is exceeded. Decision limit is defined in Article 6(3) as the lowest concentration at which the method can confirm with a defined statistical certainty (99 % for substances for which no permitted limit has been established, and 95 % for all other substances) that the particular analyte is present.

[25] Available from http://ec.europa.eu/food/food/chemicalsafety/residues/control_en.htm.

Table 2: Non-compliant (NC) samples[(a)] for prohibited substances (Group A) in pigs reported from National Residue Monitoring Plans, 2005-2009 (targeted sampling). Information extracted from the reports published by the European Commission.[(b)]

Sub-group	Substance	2009 (EU27)		2008 (EU27)		2007(EU27)		2006(EU27)		2005 (EU25)	
		NC	Total	NC	Total	NC	Total	NC	Total	NC	Total
A1 Stilbenes		0	6,623	0	5,741	0	6,431	0	6,502	0	6,473
	DES, etc.	0		0		0		0		0	
A2 Thyreostats		11	3,107	5	3,185	4	3,075	0	2,954	0	2,783
	Thiouracil	11		5		4		0		0	
A3 Steroids		36	11,562	14	11,081	18	12,167	26	11,751	71	11,229
	Boldenone	1		2		2		0		0	
	Nandrolone	33		12		16		24		52	
	Progesterone	1		0		0		1		0	
	Testosterone	0		0		0		0		0	
	17β-Nortestosterone	1		0		0		0		0	
	17β-Oestradiol	0		0		0		1		19	
	Medroxyprogesterone	0		0		0		0		0	
	Trenbolone	0		0		0		0		0	
	Ethinyloestradiol	0		0		0		0		0	
A4 Resorcyclic acid lactones (RALs)		0	6,237	5	5,594	6	6,234	0	6,233	48	6,558
	Zeranol	0		4		4		0		0	
	Taleranol	0		1		2		0		0	
	Zearalanone	0		0		0		0		48	
	Zearalenone	0		0		0		0		0	
A5 Beta-Agonists		0	12,064	0	11,486	2	12,753	10	13,561	8	14,924
	Mapenterol	0		0		1		0		0	
	Tulobuterol	0		0		1		0		0	
	Clenbuterol	0		0		0		10		8	
	Terbutaline	0		0		0		0		0	
A6 Annex IV compounds		18	21,000	6	18,148	16	19,880	15	18,868	10	15,910
	Chloramphenicol	10		6		15		13		4	
	Dimetridazole	1		0		0		0		0	
	Hydroxymetronidazole	3		0		0		0		0	
	Metronidazole	2		0		1		1		1	
	Ronidazole	0		0		0		1		0	
	Nitrofurazone (SEM)	2		0		0		0		1	
	Nitrofurantoin (AHD)	0		0		0		0		2	
	Furaltadone (AMOZ)	0		0		0		0		0	
	Furazolidone (AOZ)	0		0		0		0		2	

(a): One sample can be non-compliant for more than one substance.
(b): Available from http://ec.europa.eu/food/food/chemicalsafety/residues/control_en.htm

Table 3: Non-compliant (NC) samples[(a)] for Veterinary drugs (antibacterial substances and other veterinary drugs (Group B1 and B2)) in pigs reported from National Residue Monitoring Plans, 2005-2009 (targeted sampling). Information extracted from the reports published by the European Commission.[(b)]

Sub-group	Substance	2009 (EU27)		2008 (EU27)		2007 (EU27)		2006 (EU27)		2005 (EU25)	
		NC	Total	NC	Total	NC	Total	NC	Total	NC	Total
B1 Antibacterials		109	50,862	117	50,499	160	56,554	168	58,884	249	80,950
B2a Antihelmintics		8	7,649	8	6,981	5	7,853	2	8,642	5	8,630
	Avermectin B1	0		0		0		0		1	
	Avermectin B1a-22-23Dihydro	0		0		0		0		1	
	Doramectin	2		6		1		0		0	
	Eprinomectin	0		0		0		1		0	
	Levamisole	6		0		4		0		3	
	Moxidectin	0		2		0		1		0	
B2b Anticoccidials		0	5,724	7	4,612	3	5,088	1	3,078	2	1,919
	Chlopidol	0		1		0		0		0	
	Nicarbazin	0		0		0		0		0	
	Lasalocid	0		5		2		1		0	
	Salinomycin	0		0		0		0		2	
	Sulfadiazine	0		1		1		0		0	
B2c Carbamates and pyrethroids		1	2,523	0	2,641	0	2,583	0	2,115	0	1,977
	Fenvalerate	1		0		0				0	
B2d Sedatives		0	7,343	0	6,714	6	7,244	1	6,688	0	6,665
	Acepromazine	0		0		1		0		0	
	Azaperone	0		0		1		1		0	
	Xylazine	0		0		4		0		0	
B2e NSAIDs		0	3,857	6	3,688	1	3,570	6	2,348	3	2,395
	Antipyrin-4-Methylamino	0		2		1		0		0	
	Diclofen (diclofenac)	0		1		0		6		1	
	Flufenamic-Acid	0		1		0		0		0	
	Flunixin	0		1		0		0		0	
	Metamizol, Dipyron Monohydrat	0		0		0		0		1	
	Phenylbutazone	0		1		0		0		0	
	Ramifenazon, Isopyrin	0		0		0		0		1	
B2f Other		6	4,398	5	4,296	2	4,342	0	3,834	0	3,143
	Prednisolone	6		3		1		0		0	
	Prednisone	0		2		1		0			

(a): One sample can be non-compliant for more than one substance.
(b): Available from http://ec.europa.eu/food/food/chemicalsafety/residues/control_en.htm

Table 4: Non-compliant (NC) samples[a] for other substances and environmental contaminants (Group B3) in pigs reported from National Residue Monitoring Plans, 2005-2009 (Targeted Sampling). Information extracted from the reports published by the European Commission.[(b)]

Sub-group	Substance	2009 (EU27)		2008 (EU27)		2007 (EU27)		2006 (EU27)		2005 (EU25)	
		NC	Total	NC	Total	NC	Total	NC	Total	NC	Total
B3a Organochlorine compounds		3	4,285	2	4,297	0	4,241	5	4,234	0	4,748
	Dioxins	1									
	DDTs: Sum DDT, DDE, DDD	1		0		0		2		0	
	gamma-HCH Lindane)	1		1		0		1		0	
	Pentachlorphenol	0		0		0		1		0	
	Non dioxin-like PCB	0		1		0		1		0	
B3b Organophosphorous compounds		0	2,369	0	2,404	0	2,496	0	2,537	1	2,408
	Diazinon	0		0		0		0		1	
B3c Chemical elements		106	4,273	53	4,230	52	4,115	18	3,902	34	3,990
	Cadmium Cd	11		22		19		7		18	
	Chromium Cr	0		0		0		0		1	
	Lead Pb	5		5		7		7		14	
	Mercury Hg*	90		26		24		2		0	
	Zinc Zn	0		0		2		2		1	
B3d Mycotoxins		9	2,039	5	2,167	12	2,203	4	1,827	1	1,656
	Ochratoxin A	9		5		12		4		4	
B3e Dyes		0	0	0	0	0	0	0	0	0	0
B3f Other		0	1,266	0	1,294	0	1,328	0	1,035	0	1,078

(a): One sample can be non-compliant for more than one substance.
(b): Available from http://ec.europa.eu/food/food/chemicalsafety/residues/control_en.htm
* In absence of EU maximum levels for Mercury, decision on non-complaince is based on national tolerance levels.

An overall assessment of these data indicates that the percentage of non-compliant samples is of a low order of magnitude as compared to the total number of samples tested. For example, in 2008 and 2009 a total of 117 out of 50,499 and 109 out of 50,862 targeted samples (0.23 and 0.21 %), respectively, were non-compliant for group B1 antibacterial substance residues in pigs tested across EU Member States. Chemical elements had the highest number of non-compliants; their levels are listed as being non-compliant in 1.26 % of all samples tested for the period 2005 to 2009.

A direct comparison of data over the years is not entirely appropriate, as the test methods used and the number of samples tested for an individual residue varied between Member States. In addition, there are ongoing improvements in analytical methods, in terms of method sensitivity, accuracy and scope (i.e. number of substances covered by the method), which affects inter-year and inter-country comparisons. Therefore, the cumulative data from the national residue monitoring programmes provide only a broad indication of the prevalence and nature of the non-compliant samples.

In conclusion, this compilation of data clearly indicates the low prevalence of abiotic hazards (residues and contaminants) in edible tissues of pigs. Consequently, exposure of consumers to these residues from pork or pork products takes place only incidentally, as a result of mistakes, or non-compliance with known and regulated procedures.

2.3.2. Criteria for the evaluation of the likelihood of the occurrence of residues or contaminants of potential toxicological concern

Independent from the occurrence data as reported from the national residue control plans, each substance or group of chemical substances that may enter the food chain was also evaluated for the likelihood that potentially toxic or undesirable substances might occur in pig carcasses.

For prohibited substances and VMPs the following criteria were used:

- the likelihood of the substance(s) being used in an illicit or non-compliant way in pigs (suitability for pig production; commercial advantages);
- the potential availability of the substance(s) for illicit or non-compliant usage in pig production (allowed usage in Third Countries; availability in suitable form for use in pigs; non-authorised supply chain availability (“black market”); common or rare usage as a commercial licensed product);
- the likelihood of the substance(s) occurring as residue(s) in edible tissues of pigs based on the kinetic data (pharmacokinetic and withdrawal period data; persistence characteristics; special residue issues – e.g. bound residues of nitrofurans);
- toxicological profile and nature of hazard and the relative contribution of residues in pork and pork products to human exposure.

For contaminants, the following criteria were considered:

- the prevalence of occurrence of the substances in animal feeds in the EU where available;
- the level and duration of exposure of pigs (in fattening pigs as well as in breeding pigs);
- tissue distribution and deposition including accumulation in edible tissues in pigs;
- toxicological profile and nature of hazard and the relative contribution of residues in pork and pork products to overall human exposure.

2.3.3. General flow-chart used for ranking

Considering the above mentioned criteria, a flow-chart approach was used for ranking of the chemical residues and contaminants of potential concern. Both the outcome of the national residue control plans (indicating the number of samples that were non-compliant) and the evaluation of the likelihood that residues of substances of potential concern can occur in a pig carcass were considered in the development of the general flow-chart, as presented in Figure 1.

2.3.4. Outcome of the ranking of residues and contaminants of potential concern that can occur in pig carcasses.

Four categories were established resulting from the application of the general flow-chart:

Category 1 - negligible potential concern:

Substance irrelevant in pig production (no known use at any stage of production); no evidence for illicit use or abuse in pigs; not or very seldom associated with exceedances in MRL levels in national residue monitoring plans; no evidence of occurrence as a contaminant in pig feeds.

Category 2 - low potential concern:

Veterinary medicinal products which have an application in pig production, residues above MRLs are found in monitoring programmes, but substances are of low toxicological concern. Contaminants and prohibited substances with a toxicological profile that does not include specific hazards following accidental exposure of consumers, and which are generally not found above MLs in pigs.

Category 3 - medium potential concern:

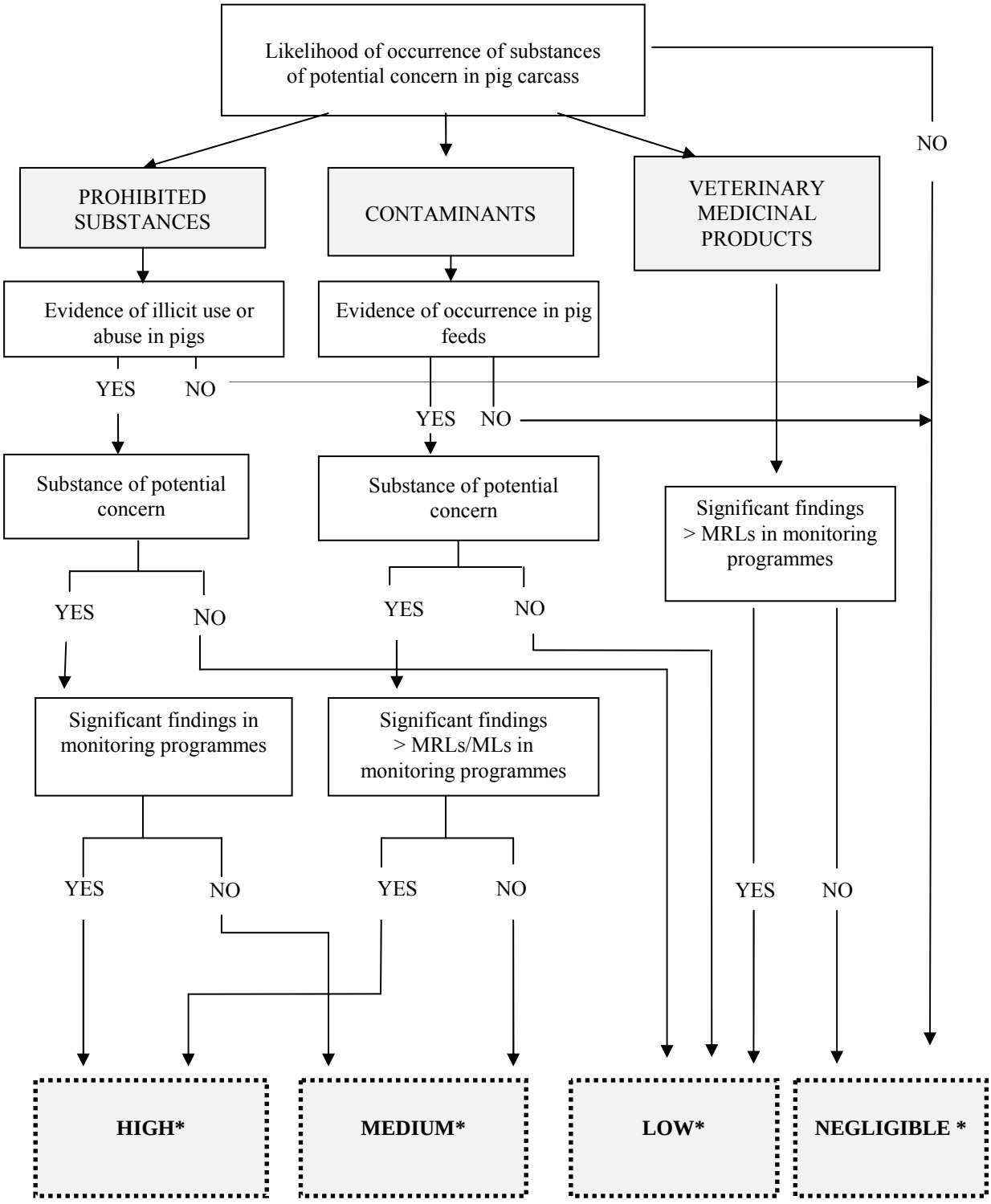
Drugs or substances known to be applied in pigs and/or history of misuse with a toxicological profile that does not entirely exclude specific hazards following accidental exposure of consumers; evidence for residues of prohibited substances being found in pigs; contaminants generally not found in concentrations above the MRL/ML values in major edible tissues of pigs.

Category 4 - high potential concern:

Drugs or substances known to be applied in pigs and with a history of misuse with distinct toxicological profile comprising a potential concern to consumers; evidence for ongoing occurrence of residues of prohibited substances in pigs; evidence for ongoing occurrence and exposure of pigs to feed contaminants.

2.3.4.1. Substances classified in the high potential concern category

In the high potential concern category are dioxins and dioxin-like polychlorinated biphenyls (DL-PCBs) as the occurrence data from the monitoring programmes show a number of incidents due to contamination of feed, such as illegal disposal of dioxin and DL-PCB containing waste materials into feed components, or open drying of feed components with dioxin-containing fuel materials.



*see definitions provided in Section 2.3.4.

Figure 1: General flow-chart used for the ranking of residues and contaminants of potential concern that can be detected in pig carcasses (MRL: maximum residues levels, ML: maximum levels; see definitions in Section 2.2.1).

2.3.4.1.1. Dioxins

Dioxins are persistent organochlorine contaminants that are not produced intentionally, have no targeted use, but are formed as unwanted and often unavoidable by-products in a number of thermal and industrial processes. Because of their low water solubility but high lipophilic properties they bioaccumulate in the food chain and are stored in fatty tissues of animals and humans. The major pathway to human dioxin exposure is via consumption of food of animal origin which generally contributes more than 80 % of the total daily dioxin intake (EFSA, 2010a). A number of dioxin incidents in the past 15 years were caused by contamination of feed with dioxins. Recent examples are an incident late in 2008 where drying of bakery products with polychlorinated biphenyl (PCBs) containing fuel led to a massive contamination of pig feed with PCBs and dioxins resulting in withdrawal from the European market of all potentially-exposed pork and pork products produced during a specific time period. More recently, in 2010-2011, contaminated fatty acids originating from the production of biodiesel from used cooking oils were illegally introduced into the feed chain. As a consequence more than 5000 farms were temporarily blocked. Mainly pigs and laying hens were affected. All these incidents were caused by grossly negligent or criminal actions and led to widespread contamination of feed and subsequently to high dioxin levels in the animals and the foodstuffs produced from them. Piglets are of importance as, due to their low body fat content, the lipophilic dioxins may reach high concentrations in the fat fraction. However, piglets are seldom presented for slaughter, with the exception of some local specialities (German Spanferkel). Regarding the toxicological profile, it is noted that based on extrapolations from animal studies and human epidemiological data (EFSA, 2005a, 2010a), there is sufficient evidence that dioxins at higher concentrations may cause cancer in several organs in humans. However, these effects are apparent only after prolonged exposure. Dioxins have a long half-life and are accumulated in various tissues. The findings of elevated levels in food are of public health concern as human dietary exposure to dioxins is considered to arise primarily from food of animal origin. The available data indicate that a substantial part of the European population is in the range of or already exceeding the tolerable weekly intake for dioxin (and DL-PCBs). Current background exposure from diverse sources is not expected to affect human health. However, due to the high toxic potential of this class of compounds, efforts need to be undertaken to reduce exposure where possible.

In summary, based on the high toxicity and the consequent low maximum levels set for meat and fat of pigs (Table 1), and in consideration that food of animal origin contributes significantly (>80 %) to human exposure, dioxins have been ranked into the category of substances of high potential concern.

2.3.4.1.2. Dioxin-like polychlorinated biphenyls (DL-PCBs)

In contrast to dioxins, PCBs had widespread use in numerous industrial applications, generally in the form of complex technical mixtures. Due to their physico-chemical properties, such as non-flammability, chemical stability, high boiling point, low heat conductivity and high dielectric constants, PCBs were widely used in industrial and commercial closed and open applications. They were produced for over four decades, from 1929 onwards until they were banned, with an estimated total world production of 1.2-1.5 million tonnes. According to Directive 96/59/EC.[26] Member States shall take the necessary measures to ensure that used PCBs are disposed off and equipment containing PCBs are decontaminated or disposed of at the latest by the end of 2010. Earlier experience has shown that illegal practices of PCB disposal may occur resulting in considerable contamination of animals and foodstuffs of animal origin.

Based on structural characteristics and toxicological effects, PCBs can be divided into two groups. One group consists of 12 congeners that can easily adopt a coplanar structure and have the ability to bind to the Ah-receptor, thus showing toxicological properties similar to dioxins (effects on liver,

[26] Council Directive 96/59/EC of 16 September 1996 on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT). OJ L 243, 24.9.1996, p. 31-35.

thyroid, immune function, reproduction and behaviour). This group of PCBs is therefore called "dioxin-like PCBs" (DL-PCBs). The other PCBs do not show dioxin-like toxicity but have a different toxicological profile, in particular with respect to effects on the developing nervous system and neurotransmitter function. This group of PCBs is called "non dioxin-like PCBs" (NDL-PCBs) (see below).

As DL-PCBs show a comparable lipophilicity, bioaccumulation, toxicity and mode of action as dioxins (EFSA, 2005a), these two groups of environmental contaminants are regulated together in European legislation and are considered together in risk assessments. Based on the high toxicity, widespread use and potential for improper disposal practices of technical PCB mixtures, DL-PCBs were added to the category of substances of high potential concern.

2.3.4.1.3. Chloramphenicol

Chloramphenicol is an antibiotic substance with broad spectrum activity which has been widely used in human and veterinary medicine. Chloramphenicol may induce blood dyscrasias in humans, particularly bone marrow aplasia, or aplastic anaemia, which may be fatal. The mechanism of induction of aplastic anaemia is not fully understood (Watson, 2004). Although the incidence of aplastic anaemia associated with exposure to chloramphenicol is apparently very low, no threshold level could be defined (EMEA, 2009a). In addition, several studies suggest that chloramphenicol and some of its metabolites are genotoxic (FAO/WHO, 1988, 2004; EMEA, 2009a). Therefore, no no-observed-adverse-effect level (NOAEL) and subsequently no ADI could be established. Based on these evaluations and in the absence of additional toxicological investigations, chloramphenicol was added to Annex II of Commission Regulation (EU) No. 37/2010[18] (previously Annex IV of Council Regulation (EEC) No. 2377/90).

Despite the fact that the use of chloramphenicol is not permitted in food producing animals, residues have been regularly found in pork in the residue monitoring programme. Indeed, a total of 48 of the 65 non-compliant samples reported during the period 2005 to 2009 for group A6 (compounds included in Annex II Reg. 37/2010[18]) concerned chloramphenicol. These positive results for chloramphenicol were found in various Member States, suggesting that chloramphenicol is still used in pigs in Europe. The proven clinical efficacy of chloramphenicol as a broad spectrum antibiotic and the fact that it is still licensed for use in many third countries may explain the relatively high number of non-compliant samples.

Considering that currently no ADI is established, and the use of chloramphenicol is prohibited in pigs, chloramphenicol was added to the category of substances of high potential concern requiring residue monitoring.

2.3.4.2. Substances classified in the medium potential concern category

In the category of substances of medium potential concern are contaminants, such as the NDL-PCBs, toxic chemical elements (metals) and the mycotoxin ochratoxin A (OTA) as they tend to accumulate in edible tissues of slaughter animals. Several of these contaminants are included in Council Regulation (EC) No 1881/2006[20] (see Table 1).

However, they have not been addressed so far in Commission Regulation (EC) No 96/23[11] and hence have also to be considered as "new" compounds in current sampling protocols.

2.3.4.2.1. Non dioxin-like PCBs (NDL-PCBs)

In contrast to DL-PCBs, the non dioxin-like PCBs (NDL-PCBs) show a different toxicological profile, in particular with respect to effects on the developing nervous system and neurotransmitter function. Because some individuals and some European (sub)-populations may be exposed to considerably

higher average intakes, a continued effort to lower the levels of NDL-PCBs in food is warranted. In 2005, the EFSA Panel on Contaminants in the Food Chain performed a risk assessment on NDL-PCBs in food (EFSA, 2005a). In the final conclusion, the CONTAM Panel stated that no health based guidance value for humans can be established for NDL-PCBs because simultaneous exposure to NDL-PCBs and dioxin-like compounds hampers the interpretation of the results of the toxicological and epidemiological studies, and the database on effects of individual NDL-PCB congeners is rather limited. There are, however, indications that subtle developmental effects, caused by NDL-PCBs, DL-PCBs, or polychlorinated dibenzo-p-dioxins/polychlorinated dibenzofurans alone, or in combination, may occur at maternal body burdens that are only slightly higher than those expected from the average daily intake in European countries.

In its risk assessment the CONTAM Panel decided to use the sum of the six PCB congeners -28, -52, -101, -138, -153 and -180 as the basis for their evaluation, because these congeners are appropriate indicators for different PCB patterns in various sample matrices and are most suitable for a potential concern assessment of NDL-PCBs on the basis of the available data. Moreover, the Panel noted that the sum of these six indicator PCBs represents about 50 % of total NDL-PCBs in food (EFSA, 2005a). Harmonized European maximum levels for NDL-PCBs in different food categories are currently under discussion.

Because of their somewhat lower toxicity compared to that of DL-PCBs, NDL-PCBs are classified in the medium potential concern category.

2.3.4.2.2. Polybrominated diphenyl ethers (PBDEs)

In 2011, EFSA performed a risk assessment on polybrominated diphenyl ethers (PBDEs) in food (EFSA, 2011a). PBDEs are additive flame retardants which are applied in plastics, textiles, electronic castings and circuitry. PBDEs are ubiquitously present in the environment and likewise in biota and in food and feed. Eight congeners were considered by the CONTAM Panel to be of primary interest: BDE-28, -47, -99, -100, -153, -154, -183 and -209. The highest dietary exposure is to BDE-47 and -209. Toxicity studies were carried out with technical PBDE mixtures or individual congeners. The main targets were the liver, thyroid hormone homeostasis and the reproductive and nervous system. PBDEs are not genotoxic. The CONTAM Panel identified effects on neurodevelopment as the critical endpoint, and derived benchmark doses (BMDs) and their corresponding lower 95 % confidence limit for a benchmark response of 10 %, the benchmark dose limit $BMDL_{10}$s, for a number of PBDE congeners: BDE-47, 309 µg/kg body weight (b.w.); BDE-99, 12 µg/kg b.w.; BDE-153, 83 µg/kg b.w.; BDE-209, 1,700 µg/kg b.w. Due to the limitations and uncertainties in the current database, the Panel concluded that it was inappropriate to use these BMDLs to establish health-based guidance values, and instead used a margin of exposure (MOE) approach for the health risk assessment. Since elimination characteristics of PBDE congeners in animals and humans differ considerably, the Panel used the body burden as starting point for the MOE approach. The CONTAM Panel concluded that for BDE-47, -153 and -209 current dietary exposure in the EU does not raise a health concern.

For BDE-99 there is a potential health concern with respect to current dietary exposure. The contribution of pig meat and offal to the total human exposure is currently not known. Therefore PBDEs, particularly BDE-99, have been allocated to the group of substances considered as being of medium potential health concern.

2.3.4.2.3. Chemical elements

Among the chemical elements, heavy metals traditionally have gained attention as contaminants in animal tissues, as they may accumulate in certain organs, particularly in kidneys over the lifespan of an animal. Exposure of animals is commonly related to contaminated feed materials, despite older reports of accidental intoxication of animals due to other sources (paints, batteries). The CONTAM Panel has issued within the framework of the re-evaluation of undesirable substances in animal feeds

according to Council Directive 2002/32/EC several opinions addressing heavy metals and arsenic in feed materials and the transfer of these elements from feed to edible tissues, milk and eggs.

Heavy metals: cadmium, mercury and lead

Cadmium (EFSA, 2009a) is a heavy metal found as an environmental contaminant, both through natural occurrence and from industrial and agricultural sources. Cadmium accumulates in humans and animals, causing concentration-dependent renal tubular damage. The highest cadmium concentrations were detected in the following food commodities: seaweed, fish and seafood, chocolate, and foods for special dietary uses.

The contribution of fattening pigs to the overall human exposure to cadmium remains very limited due to the short life-span of these animals. Older animals are expected to have higher concentrations of cadmium accumulated in the kidneys, but according to the results of the national residues control plans, the contribution of pig meat and offal to the overall human exposure to cadmium remains limited.

Mercury (EFSA, 2008b) exists in the environment as elemental mercury, inorganic mercury and organic mercury (primarily methylmercury). Methylmercury bioaccumulates and biomagnifies along the aquatic food chain. The toxicity and toxicokinetics of mercury in animals and humans depends on its chemical form. Elemental mercury is volatile and mainly absorbed through the respiratory tract, whereas its absorption through the gastrointestinal tract is limited (10 – 30 %). Following absorption, inorganic mercury distributes mainly to the kidneys and, to a lesser extent, to the liver. The critical effect of inorganic mercury is renal damage. In contrast, in animals, as in humans, methylmercury and its salts are readily absorbed in the gastrointestinal tract (>80 %) and rapidly distributed to all tissues, although the highest concentrations are also found in the kidneys.

Data from Member States indicated the presence of mercury in animal feeds, but the measured concentrations remained below the maximum content for feed materials (0.1 mg/kg feed according to Directive 2002/32/EC[12]). Human exposure is predominantly associated with fish consumption; pig meat and offal are assumed to contribute only to a minor extent to human exposure (FAO/WHO, 2011) despite the fact that data on the frequency of occurrence indicate a high number of non-compliant samples in the last two years (see Table 4). It is assumed that these data represent the analytical results of kidney samples. Due to the limited consumption of kidneys, overall human exposure to mercury from pig products is expected to remain low.

Lead (EFSA, 2010b) is an environmental contaminant that occurs naturally and, to a greater extent, from anthropogenic activities such as mining and smelting and battery manufacturing. Lead is a metal that occurs in organic and inorganic forms; the latter predominate in the environment. Human exposure is associated particularly with the consumption of cereal grains (except rice), cereal products, cereal-based mixed dishes, potatoes, leafy vegetables and tap water. The contribution of (pig) meat and offal to human exposure is very limited. More than 80 % of all pig meat samples analysed remained below the limit of detection and total exposure from pig-derived products was only approximately 3 % of overall dietary exposure. Currently the ML for pig meat is 0.10 mg/kg wet weight and for pig offal (liver and kidney): 0.50 mg/kg wet weight.

Other elements

Besides the metals that may be present in animal matrices as environmental contaminants (e.g. cadmium, lead, mercury) attention should also be given to those compounds that may be used as feed supplements (e.g. copper, selenium, zinc). The correct use of these supplements cannot be guaranteed. Especially copper seems to be a substance that might be overused, resulting in non-compliant feed samples and undesirable residues in animal organs, such as the liver. A closer communication of

results from official feed control seems essential to decide whether or not analytical monitoring of residues in slaughter animals needs to be directed to these substances that might be overused in pig feeds. This applies also to vitamin A, which has a history of overuse in poultry, resulting in undesirable high concentrations in poultry livers.

In conclusion, as the nature of the samples was not known, it cannot be concluded from the aggregated data from the national residue control programmes that all non-compliant samples for the heavy metals cadmium, mercury and lead represent kidney samples. Hence, these three elements have been allocated to the group of substances of medium potential health concern.

2.3.4.2.4. Mycotoxins

Mycotoxins comprise a chemically diverse group of secondary metabolites of moulds which may induce intoxications in humans and animals following ingestion of contaminated food or feed materials. Pigs are sensitive to the adverse effects of mycotoxins and hence the recommendations for maximum levels in feed have been issued to prevent their intoxication (Commission Recommendation 2006/576/EC).[27]

Most of the known mycotoxins have a short biological half-life and do not accumulate in animal tissues. A known exception is the mycotoxin ochratoxin A (OTA), an iso-coumarin derivative with a phenylalanine side chain that readily binds to proteins. It is produced by various fungal species of the genera *Aspergillus* and *Penicillium* invading cereals and other feed materials during storage (EFSA, 2004a). Oral bioavailability in pigs following ingestion of contaminated feeds is estimated to be approximately 65 % and its high protein binding results in an exceptionally long half life, particularly in humans and pigs. Elimination occurs mainly by renal excretion, with re-absorption and accumulation in the renal proximal tubules, where it causes progressive renal damage (porcine nephropathy). A smaller fraction is excreted in bile after glucuronidation. The highest residue concentrations have been observed in porcine blood serum (that is used for the production of various types of sausages), kidneys and liver, whereas levels in muscle tissues are general much lower. Multiple-source exposure assessment indicated that the overall contribution of animal products to human OTA exposure generally does not exceed 3-10 %. The main sources of human exposure are cereal products, pulses, coffee, beer, grape juice, dry vine fruits and wine as well as cacao products, nuts and spices (EFSA, 2006).

Considering the toxicological profile of ochratoxin A and its ability to accumulate in edible tissues of pigs, this mycotoxin was considered as of medium potential concern.

Other mycotoxins evaluated by the CONTAM Panel as undesirable contaminants in animal feeds, including aflatoxins (EFSA, 2004b), deoxynivalenol (EFSA, 2004c), fumonisins (EFSA, 2005b) and zearalenone (EFSA, 2004d), may pose a risk for animal health and productivity when present in feed materials that are used for pigs over a longer period of time, but due to their short half-life, limited transfer into edible tissues and hence the lack of substantial residues in porcine tissues, these mycotoxins have been allocated to the category of low potential concern.

In conclusion, from the group of mycotoxins, only ochratoxin A was allocated to the group of medium potential concern, due to its toxicological profile and its long biological half-life in pigs.

2.3.4.2.5. Prohibited veterinary medicinal products: nitroimidazoles and nitrofurans

Also in the medium potential concern category are nitroimidazoles and nitrofurans. Both classes of compounds have historically been legally available and used as VMPs for pigs in the EU, but were

[27] Commission Recommendation of 17 August 2006 on the presence of deoxynivalenol, zearalenone, ochratoxin A, T-2 and HT-2 and fumonisins in products intended for animal feeding (2006/576/EC). OJ L 229, 23.8.2006, p. 7-9.

banned for this purpose some years ago, because no ADI could be established due to positive results in genotoxicity testing.

Nitroimidazoles

The 5-nitroimidazoles, dimetridazole, metronidazole and ronidazole, are a group of drugs having antibacterial, antiprotozoal and anticoccidial properties. Metronidazole and ronidazole are effective against trichomonads and dimetridazole is effective against histomoniasis in poultry, while all three drugs are active against obligatory anaerobic bacteria. Nitroimidazoles have been used primarily to prevent and treat the diseases histomoniasis and trichomoniasis in turkeys, pigeons and game birds (Huet et al., 2005). In pigs, nitroimidazoles were used for the treatment and prevention of swine dysentery for many years in the EU. However, their use in food-producing animals is prohibited in the European Union (inclusion in Annex II of Commission Regulation (EC) No 37/2010), United States, and other Third Countries in consideration of the potential harmful effects on human health. Toxicological investigations suggested a risk for carcinogenic and genotoxic effects and the occurrence of residues, with an intact imidazole structure, such as hydroxymetronidazole, covalently bound to tissue macromolecules, particularly proteins (EMEA, 1997, 2009b, 2009c).

Although prohibited for use in food-producing animals in many countries, nitroimidazoles are likely to be available on the non-authorized supply chain for illicit use in pig production. A major pig disease, swine dysentery, caused by *Brachyspira hyodysenteriae* remains common and highly pathogenic in several regions of the EU. No commercial vaccines exist for this pathogen. There are many favourable reports on the clinical use of nitroimidazoles in pigs for treatment of swine dysentery and hence illicit use cannot be excluded. This applies to metronidazole, which is readily available as a human medicine throughout the EU.

Non-compliant samples for nitroimidazoles in pigs, and in other species, have been reported in most years in the results of the European national residue monitoring plans. In pigs, 10 of the 65 non-compliant samples reported during the period 2005 to 2009 for group A6 are non-compliant samples for nitroimidazoles.

In view of the availability of nitroimidazoles, the occurrence of positive residue samples in the national residue monitoring programmes, and the toxicity profile of these substances, there is a potential concern from their illicit use in pig production and consequently these substances have been allocated to the category of medium potential concern.

Nitrofurans

Nitrofurans, including furazolidone, furaltadone, nitrofurantoin and nitrofurazone, are very effective antimicrobial agents that, prior to their prohibition for use on food-producing animals in the European Union in 1995, were widely used on livestock (cattle, pigs, poultry), aquaculture and bees. A characteristic of nitrofurans is the short half-life of the parent compounds and the formation of covalently-bound metabolites which, under the acidic conditions of the human stomach, may be released as active agents. The tissue-bound metabolites of nitrofurans have been shown to be carcinogenic and mutagenic. These covalently-bound metabolites are used as marker residues for detecting the illicit use of nitrofurans in animal production.

The European Commission funded a research project in 1999 entitled “FoodBRAND” that studied methodologies for determining abuse of nitrofurans and, also, undertook a retail survey of pig meat in 15 European countries to establish the extent of abuse (O’Keeffe et al., 2004). This survey identified samples positive for AMOZ (the metabolite of furaltadone) and for AOZ (the metabolite of furazolidone) in three members states. Thereafter, non-compliant samples for nitrofurans in pigs have been rarely reported. In pigs, 7 of the 65 non-compliant samples reported during the period 2005 to 2009 for group A6 are non-compliant samples for nitrofurans. In 2009, two pig samples from different

countries were reported as positive for semicarbazide (a metabolite of nitrofurazone). However, there is some question as to whether this represents abuse of nitrofurazone or other sources of semicarbazide, such as exposure to azodicarbonamide, could explain these findings.

In view of the availability of nitrofurans, the occurrence of positive residue samples in the national residue monitoring programmes, and the toxicity profile of these substances, there is a potential concern for illicit use in pig production and hence these substances were allocated to the group of medium potential concern chemical substances.

2.3.4.3. Substances classified in the low potential concern category

Prohibited substances that might be used for growth promotion purposes in other species (stilbenes, thyreostats, steroids, resorcylic acid lactones), but for which there is no history of widespread abuse in pigs and/or which are unsuitable for such use in pigs, have been allocated to this category of substances of low potential concern. The other prohibited substances in the category of low potential concern are plant remedies containing *Aristolochia* species, as well as dapsone and chlorpromazine (a sedative), for which no residues have been found in the residue monitoring programmes over several years, indicating a very low or non-existent application in pigs.

The group of β-agonists has also been added to the group of substances of low potential concern in pigs, as in contrast to veal calves, clenbuterol does not accumulate in the liver of pigs. Clenbuterol is also licensed for use in humans for the treatment of obstructive airway diseases and considered as safe at therapeutic dose, which are much higher than the concentrations that may occur as residues in animal tissues.

In general, veterinary medicinal products (VMPs), except the substances allocated to Annex II of Regulation (EC) No 37/2010, are categorised as being of low potential concern because they have all been subjected to pre-marketing approval which specifies ADIs, and subsequently MRLs, with the aim of guaranteeing a high level of safety to the consumer. Where exceedances of MRLs are found in the residue monitoring programmes (i.e. non-compliant samples), these are typically of an occasional nature that does not constitute a concern to public health. Mutagenic substances are generally not authorized for use in food producing animals.

Organochlorine pesticides, such as dichlorodiphenyltrichloroethane (DDT) and its metabolites, hexachlorocyclohexanes (HCH), dieldrin, toxaphene and others have been added to the category of contaminants of low potential concern. Occurrence of residues of these substances has declined over the years, because of their long-standing ban, and relatively low levels in animal products can be expected as shown by results from the national residue control plans.

Some attention was given to organophosphorus compounds that are used as veterinary medicinal products (antiparasitics) in pigs (EFSA, 2011d). However, their infrequent use and short half-life in pigs results in the allocation of these compounds to the category of low potential concern, or even negligible potential concern if MRL values or not violated.

Plants used as feed materials may contain a broad variety of toxic secondary metabolites. The most commonly found toxic plant metabolites have been assessed by the CONTAM Panel within the framework of the re-evaluation of undesirable substances in animal feeds (implementation of the Directive 2002/32/EC). The evaluation addressed the major groups of toxic substances such as glucosinolates (EFSA, 2008a), saponins (EFSA, 2009b) pyrrolizidine alkaloids (EFSA, 2007b), tropane alkaloids (EFSA, 2008c) and cyanogenic compounds (EFSA, 2007a) as well as a number of individual toxic compounds such as theobromine (EFSA, 2008d), gossypol (EFSA, 2008f) and ricin (EFSA, 2008e). While for several of these substances potential concerns for animal health could be identified following ingestion with feed, none of these natural toxins appeared to accumulate in edible

tissues. Therefore, the CONTAM Panel concluded that it is unlikely that residues of these secondary plant metabolites in edible tissues constitute a potential concern for consumers. Such substances were therefore placed in the category of low potential concern within the current classification.

2.3.4.4. Substances classified in the negligible potential concern category

In the negligible potential concern category are the dyes and the prohibited substances, chloroform and colchicine, as these are not relevant to pig production.

A summary of the outcome of the ranking is presented in Table 5.

Table 5: Potential concern ranking of chemical residues and contaminants in chilled pig carcasses and pork (taking into account the findings from the NRCPs for the period 2005-2009).

Group / Potential concern category	Prohibited substances	VMPs	Contaminants
Category 1 **Negligible potential concern**	• Chloroform • Colchicine	• VMPs below MRLs	• Dyes
Category 2 **Low potential concern**	• *Aristolochia* spp. • Thyreostats • Stilbenes • Steroids • Resorcylic acid lactones • Beta-agonists • Chlorpromazine • Dapsone	• VMPs exceeding MRLs	• Organochlorines (OCs) • Organophosphates (OPs) • Perfluorinated compounds (PFCs) • Toxic secondary plant metabolites • Mycotoxins (except ochratoxin A)
Category 3 **Medium potential concern**	• Nitroimidazoles • Nitrofurans		• Non-dioxin-like polychlorinated biphenyls (NDL-PCBs) • Chemical elements (cadmium, mercury and lead) • Ochratoxin A
Category 4 **High potential concern**	• Chloramphenicol		• Dioxins and dioxin-like polychlorinated biphenyls (DL-PCBs)

VMPs: veterinary medicial products; NRCPs: National Residue Control Plans.

Future aspects:

It is important to consider that the ranking presented in this section is based on current knowledge regarding the toxicological profiles, usage in pig production, and occurrence as residues (as demonstrated by the data from the residue monitoring programmes) of prohibited substances, veterinary medicinal products and contaminants. Where changes in any of these factors occur, the ranking might need amendment.

3. Strengths and weaknesses of the current meat inspection methodology

The second term of reference requested to assess the strengths and weaknesses of the current meat inspection methodology and recommend possible alternative methods (at *ante-mortem* or *post-mortem* inspection, or validated laboratory testing within the frame of traditional meat inspection or elsewhere in the production chain) at EU level, providing an equivalent achievement of overall objectives; the implications for animal health and animal welfare of any changes suggested in the light of public health potential concerns to current inspection methods should be considered.

In the light of the existing regulation and the daily practice of the control of residues/chemical substances in pig carcasses, the strengths and weaknesses of the current meat inspection methodology can be summarized as follows:

3.1. Strengths of the current meat inspection for chemical hazards

- A mature system, well-established, coordinated, and subject to regular evaluation that is in place across EU Member States, with residue and contaminant testing that is based on common standards for method performance and interpretation of results (Commission Decision 2002/657/EC[12]), laboratory accreditation (ISO/IEC 17025) and quality assurance schemes (QAS). The residue and contaminant monitoring programmes are supported by a network of EU and National Reference Laboratories and by research in the science of residue and contaminant analysis that serves to provide state-of-the-art testing systems for control of residues and contaminants.
- Well-developed systems and follow-up mechanisms following identification of non-compliant samples. As indicated in the previous section, follow-up on non-compliant samples is typically through intensified sampling (suspect sampling), withholding of slaughter and/or of carcasses subject to positive clearance as compliant, and on-farm investigations potentially leading to penalties and/or criminal prosecutions.
- The system is well-endorsed by sector stakeholders throughout the entire food chain (national farmers' associations, feed/ meat industry, retailers).
- The regular sampling and testing for chemical residues and contaminants is a disincentive for the development of bad practices.
- The prescriptive sampling system allows for equivalence to be achieved for EU domestic pork and Third Country imports (this issue is addressed further in TOR 4).
- The current combination of food chain information (FCI), *ante-mortem* inspection and gross tissue examination has been found, in general, to be supportive to the collection of appropriate samples for residue monitoring.

3.2. Weaknesses of the current meat inspection method for chemical hazards

- Chemical hazards are not detected by current *ante-/post- mortem* meat inspection procedures and regulations, indicating the need for further harmonization of the risk reduction strategies along the entire food chain.
- According to Council Directive 96/23/EC,[11] sampling of tissue specimens for the analysis of residues or contaminants is prescriptive in terms of the number of samples that need to be taken. In addition, the choice of substances to be tested is based neither on actual feed chain information nor on species-specific information about the likelihood of animal exposure. At present, there is poor integration between the testing of feed materials for undesirable contaminants and the residue monitoring programmes in terms of communication and follow-up testing strategies or interventions. Hence, animals that would be considered at risk of being

residue-positive when based on FCI data might not be included in the current sampling and testing plans.

- Limited flexibility to adopt emerging chemical substances into residue monitoring and limited ongoing adaptation of the sampling and testing programme to the results of the residue monitoring programmes.

4. New hazards

The third term of reference states that if new hazards currently not covered by the meat inspection system are identified under TOR 1, then recommend inspection methods fit for the purpose of meeting the overall objectives of meat inspection. When appropriate, food chain information should be taken into account.

Current monitoring of chemical residues and contaminants in edible tissues of slaughter pigs is based on Council Directive 96/23/EC.[11] In turn, ranking of potential concern as presented under TOR 1 is also based largely on the chemical substances listed in Council Directive 96/23/EC.[11] The outcome of the ranking showed that only a small number of compounds are considered to constitute a potential concern for consumers.

However, considering the recent information available from the re-assessment of undesirable substances in the food chain, as reported in EFSA Opinions of the CONTAM Panel, additional compounds have been identified that require attention. Prominent examples of such substances are dioxins, DL-PCBs and NDL-PCBs, which were identified as high and medium potential concern compounds, as they bioaccumulate in the food chain, are likely to be found in pig carcasses and have a toxicological profile that points towards potential public health concerns even at low (residual) concentrations. In addition, it has been shown that these substances are found in edible tissues of pigs. Other halogenated substances such as brominated flame retardants, including polybrominated diphenylethers (PBDE), as well as hexabromocyclododecane (HBCDD) and perfluorinated compounds (PFC), such as perfluorooctanesulfonic acid (PFOS) and perfluorooctanoic acid (PFOA) have different toxicological profiles and likely present lower potential concern (EFSA 2008g, 2011a, 2011d). However, these compounds also bioaccumulate in the food chain and deserve attention, as currently knowledge about the prevalence and levels of these compounds in edible tissues of pigs is limited. Inclusion of these substances in national monitoring programmes (even as a temporary measure) should therefore be considered together with an intensified monitoring of feed materials for the presence of these compounds, to support forthcoming decisions on whether or not these substances require continued monitoring either in feed materials and/or in slaughter animals.

In addition, new technologies such as the production of bioethanol and biodiesel, and the increasing availability of new by-products suitable for inclusion in animal feeds from these technical processes, such as for example distillers dried grains (DDGs), need to be addressed in hazard identification and subsequently may require new testing strategies and methods (see also TOR 4).

5. Adaptation of inspection methods

The fourth term of reference requested to recommend adaptations of inspection methods and/or frequencies of inspections that provide an equivalent level of protection within the scope of meat inspection or elsewhere in the production chain that may be used by risk managers in case they consider the current methods disproportionate to the risk, e.g. based on the ranking as an outcome of terms of reference 1 or on data obtained using harmonised epidemiological criteria. When appropriate, food chain information should be taken into account.

The pig farming sector across the EU is diverse. As noted earlier, there are two main groups of slaughtered pigs: pigs reared only for fattening and other pigs, often from breeding farms that are slaughtered for various other reasons. Subsequently, under current prescriptive residue control plans, integrated farms delivering large numbers of animals for slaughter at one occasion, may be over-sampled, while breeding farms delivering individual animals may escape sampling.

The number of integrated pig production farms which operate by using Good Hygiene Practices (GHP), Good Farming Practices (GFP), and which offer reliable FCI information as part of the quality assurance scheme, and have fully implemented HACCP-based protocols is increasing. These integrated farms need to operate under criteria specified in the Commission Regulation (EC) No 1244/2007.[28] They deliver animals for slaughter with a low-risk profile as this homogeneous pig population is slaughtered at a young age and covered with reliable and detailed information from birth to slaughter. Therefore, it can be recommended that for these farms, residue monitoring programmes could be restricted to the emerging contaminants in the food chain, and to the incidental control of compliance with the "honour" statements regarding the use of medication and the compliance with drug withdrawal periods. Simplified meat inspection for pigs raised on integrated production systems was already proposed by the Scientific Committee on Veterinary Measures relating to Public Health in 2000 and later on 2001(SCVPH, 2000; 2001) and is supported by the outcome of the external report recently presented to EFSA on the "Overview on current practices of meat inspection in the EU".[13]

In contrast, many traditional pig breeding farms can usually provide only limited and incomplete FCI data. These farms submit different age groups of animals for slaughter, with a complex life history, which have a higher-risk profile for tissue residues and/or contaminants.

It is therefore recommended that national residue control plans should focus on these producers, with targeted sampling plans also taking into account the results from feed quality monitoring.

Moreover, there is a need for an improved integration of sampling, testing and intervention protocols across the food chain including information from environmental monitoring and predictive information relating to likely occurrence of contaminants in the feed for slaughter pigs that may be transferred into edible tissue that reach the consumer.

With regard to the potential abuse of illicit substances (Group A substances as defined by the Council Directive 96/23/EC), criteria to be applied in *ante-mortem* and *post-mortem* inspection should be defined. These include patho-physiological signs in the animal's body or organs related to the use of these compounds, changes in carcass characteristics (lean/fat ratio), and the presence of pellets, injection sites or abscesses as indicators for use of anabolic agents, thyreostats and beta-agonists. Current figures for non-compliant samples indicate that the use of these compounds occurs only incidentally in pigs (for many of the illicit compounds no non-compliant samples have been reported in the last five years), but a strategic control remains essential to discourage any use of this group of substances (see also TOR 2: strength and weaknesses of the current meat inspection methodology).

In addition, there is a need to develop new approaches to testing. Recent developments in chemical analytical techniques allow the simultaneous measurement of a broad range of substances. Application of such validated methods for multi-residue analyses comprising drugs, pesticides and natural and environmental contaminants should be encouraged. For prohibited substances testing should be directed towards the farm level. To this end, new approaches including molecular biological techniques for the identification of biomarkers of exposure may be of additional value.

[28] Commission Regulation (EC) No 1244/2007 of 24 October 2007 amending Regulation (EC) No 2074/2005 as regards implementing measues for certain products of animal origin intended for human consumption and laying down specific rules on official controls for the inspection of meat. OJ L 281, 25.10.2007, p. 12-18.

Finally, it should be noted that any measures taken to improve the efficacy of meat inspection protocols need to address also the compliance of imports to the EU with these strategies. Where EU meat inspection would move to a risk-based approach, particular attention to the achievement of equivalent standards of food safety for imported food from third countries will be required. Currently, within the prescriptive system for meat inspection and residue monitoring applying in the EU, third countries exporting food products of animal origin to the EU need to demonstrate that they have the legal controls and residue monitoring programmes capable of providing equivalent standards of food safety as pertains within the EU. The risk-ranking appropriate within the EU in relation to veterinary drugs and contaminants might not be appropriate in third countries to achieve equivalent standards of food safety. Rather than requiring that a risk-based monitoring programme applying within EU Member States should be applied similarly in the third country, an individual risk assessment for each animal product(s)/third country situation may be required, which should be frequently updated.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS CONTAM PANEL

TOR 1. To identify and rank the main risks for public health that should be addressed by meat inspection at EU level. General (e.g. sepsis, abscesses) and specific biological risks as well as chemical risks (e.g. residues of veterinary drugs and contaminants) should be considered. Differentiation may be made according to production systems and age of animals (e .g. breeding compared to fattening animals).

- Chemical residues and contaminants in slaughter animals are unlikely to pose an immediate or short term health risk for consumers. However, certain bioaccumulating contaminants are of potential concern because they will contribute to the overall exposure. In addition, the presence of chemical residues of certain pharmacologically active substances may be of potential concern as they are indicative either of non-compliance with existing regulations or of illicit use of non-authorized substances, with implications for risk management.
- As a first step in the identification and ranking of chemical substances of potential concern, the CONTAM Panel considered all substances listed in Council Directive 96/23/EC[11] and evaluated the outcome of the residue monitoring plans for the period 2005-2009. The available aggregated data indicate the numbers of samples that were non-compliant with the current legislation. However, in the absence of substance-specific information, such as the tissues used for residue analysis and the actual concentration of a residue or contaminant measured, these data do not allow a reliable assessment of consumer exposure.
- Other criteria used for the identification and ranking of chemical substances of potential concern included the identification of substances that bio-accumulate in the food chain, substances with a specific toxicological profile, and the likelihood that a substance under consideration will occur in pig carcasses. Taking into account these criteria the individual contaminants were ranked into four categories denoted as high, medium, low and negligible potential concern.
- Dioxins and dioxin-like polychlorinated biphenyls (DL-PCBs) were ranked as being of high potential concern due to their known bioaccumulation in the food chain, the risk of exceedance of maximum levels, and in consideration of their toxicological profile.
- Chloramphenicol was ranked as being of high potential concern, as residues in pig carcasses have been found in the course of the residue control programmes in various Member States, although this antibiotic is not licensed for use in food producing animals in the EU.

- Non-dioxin-like polychlorinated biphenyls (NDL-PCBs) and polybrominated diphenyl ethers (PBDEs) also bioaccumulate, but were ranked in the category of medium potential concern, because they are less toxic than dioxins and DL-PCBs.
- The chemical elements cadmium, lead and mercury were allocated to the medium potential concern category, taking into account that the aggregated data from the national residue control programmes indicate non-compliance with current maximum limits in more than 1 % of samples analysed.
- The mycotoxin ochratoxin A was allocated to the medium potential concern category due to its slow elimination in pigs and its potential to accumulate in edible tissues.
- Nitrofurans and nitroimidazoles were ranked as being of medium potential concern. These two classes of antimicrobials are prohibited for use in food producing animals. However, results from the national residue control programmes indicated the occasional presence of non-compliant samples from pigs and hence it can be assumed that these compounds are infrequently used in slaughter pigs.
- Residues originating from other substances listed in Council Directive 96/23/EC[11] were ranked in the low or negligible potential concern category due to the low toxicological profile of residues of these compounds. This category includes, among others, organochlorine pesticides, organophosphates, perfluorinated compounds, natural plant toxins, mycotoxins (others than ochratoxin A), as well as residues of veterinary medicinal products, and prohibited substances such as thyreostats, stilbenes, steroids, resorcylic acid lactones, and *beta*-agonists.
- The CONTAM Panel emphasised that this ranking into specific categories of potential concern is based on the current knowledge regarding the toxicological profiles, usage in pig husbandry and likelihood of occurrence of residues in edible tissues of pigs.
- Differentiation in sampling plans can be made according to the current production systems and the age of animals. Pigs reared for fattening are slaughtered at a young age and generally originate from farms with operational HACCP-based protocols and with full FCI data. This homogeneous animal population has a low-risk profile regarding exposure to contaminants and tissue residues. In contrast, non-specialised farms produce animals of different age groups and with different reasons for slaughter. These animals are generally not accompanied by complete FCI data. Therefore, this group has a higher-risk profile for exposure to contaminants and for tissue residues.

TOR 2. To assess the strengths and weaknesses of the current meat inspection methodology and recommend possible alternative methods (at *ante-mortem* or *post-mortem* inspection, or validated laboratory testing within the frame of traditional meat inspection or elsewhere in the production chain) at EU level, providing an equivalent achievement of overall objectives; the implications for animal health and animal welfare of any changes suggested in the light of public health risks to current inspection methods should be considered.

Strengths

- The current meat inspection system facilitates tissue sampling for the analysis of residues of contaminants, veterinary medicinal products and non-authorized substances as listed in Council Directive 96/23/EC.[11]
- The current procedures of sampling and testing are well-established and involve a regular evaluation of analytical procedures in all EU Member States addressing the performance of analytical methods (Commission Decision 2002/657/EC[12]), laboratory accreditation (ISO/IEC 17025) and quality assurance schemes (QAS).

- There are well-developed systems and follow-up mechanisms following identification of non-compliant samples. Follow-up on non-compliant samples is typically through intensified sampling (suspect sampling), withholding of carcasses or pigs with the same history for slaughter, subject to positive clearance as compliant, and on-farm investigations potentially leading to intervention, penalties and/or prosecutions.
- The prescribed regular sampling and testing for chemical residues is a proven disincentive for the development of bad practices.
- The prescriptive sampling system of the current methodology allows for equivalence between EU domestic pork and Third Country imports.

Weaknesses

- The presence of residues and contaminants cannot be determined by the current *ante*- and *post- mortem* meat inspection procedures at the abattoir and hence no immediate measures can be taken.
- According to Council Directive 96/23/EC,[11] sampling of tissue specimens for the analysis of residues or contaminants is prescriptive in terms of the number of samples that need to be taken. In addition, the choice of substances to be tested is based neither on actual feed chain information nor on species-specific information about the likelihood of animal exposure Hence, animals that would be considered at risk of being residue-positive when based on FCI data, might not be included in the current sampling and testing plans.
- There is limited flexibility to amend sampling plans and to include emerging substances or actual findings from feed monitoring or other actual food chain information into the national sampling and testing programmes.

TOR 3. If new hazards currently not covered by the meat inspection system (e.g. Salmonella, Campylobacter) are identified under TOR 1, then recommend inspection methods fit for the purpose of meeting the overall objectives of meat inspection. When appropriate, food chain information should be taken into account.

- Polychlorinated substances such as dioxins and DL-PCBs have been ranked as being of high potential concern. They are not yet included in the Council Directive 96/23/EC. Therefore, these compounds have to be considered as "new" hazards.
- A number of other contaminants also bioaccumulate in the food chain. However, current knowledge on their prevalence and their actual levels in edible tissues of slaughter pigs is limited. In spite of their likelihood of being of medium or low concern, they should be monitored. This is the particular case of (i) non dioxin-like polychlorinated biphenyls (NDL-PCBs), (ii) brominated flame retardants, including polybrominated diphenylethers (PBDEs) as well as hexabromo-cyclodocecane (HBCDD) and, (iii) perfluorinated compounds (PFC) such as perfluorooctanesulfonic acid (PFOS) and perfluorooctanoic acid (PFOA).

TOR 4. To recommend adaptations of inspection methods and/or frequencies of inspections that provide an equivalent level of protection within the scope of meat inspection or elsewhere in the production chain that may be used by risk managers in case they consider the current methods disproportionate to the risk, e.g. based on the ranking as an outcome of terms of reference 1 or on data obtained using harmonised epidemiological criteria. When appropriate, food chain information should be taken into account.

- Considering that pig farming in the EU is diverse, it is suggested to develop tailored sampling plans taking into account these differences. National residue control plans have the potential to distinguish between farms producing only pigs for fattening under conditions of fully

implemented HACCP-based protocols providing professional and reliable FCI, from those other farms that have a mixed pig population without HACCP-based quality control protocols.

- In line with the development of tailored sampling plans, all information from national quality controls of feedstuffs should be integrated into the residue control plans. Moreover, animal species (i.e. pig-specific) information that is not considered in current sampling strategies and testing procedures deserves more consideration.
- The currently limited flexibility to amend sampling plans hinders the inclusion of emerging substances in national sampling plans. The possibility for *ad hoc* amendments should be incorporated in forthcoming sampling strategies.
- Any amendments in the EU meat inspection procedures need to include provisions for the control of imports from Third countries.

RECOMMENDATIONS

TOR 1. To identify and rank the main risks for public health that should be addressed by meat inspection at EU level. General (e.g. sepsis, abscesses) and specific biological risks as well as chemical risks (e.g. residues of veterinary drugs and contaminants) should be considered. Differentiation may be made according to production systems and age of animals (e .g. breeding compared to fattening animals).

- Regular updates of sampling plans should take into account any new information regarding the toxicological profile of residues and contaminants, usage in pig production, and actual occurrence of individual substances in pigs.
- Any amendments in the EU meat inspection procedures need to include provisions for the control of imports from Third countries.

TOR 2. To assess the strengths and weaknesses of the current meat inspection methodology and recommend possible alternative methods (at *ante-mortem* or *post-mortem* inspection, or validated laboratory testing within the frame of traditional meat inspection or elsewhere in the production chain) at EU level, providing an equivalent achievement of overall objectives; the implications for animal health and animal welfare of any changes suggested in the light of public health risks to current inspection methods should be considered.

- Considering that a major weakness of the current sampling protocol is its prescriptive nature and the lack of flexibility towards emerging contaminants in the food chain, improvement of flexibility and differentiation of sampling plans according to the animal history, species-specific and food chain information data, particularly the results from quality programmes for feedstuffs are recommended.
- Considering that the current procedure of data aggregation at the Community level does not allow any reliable exposure assessment linked to the occurrence of non-compliant samples, it is recommended that a database collecting the results from the individual national residue monitoring programmes is established at the Community level.
- Considering that certain non-authorized substances exert specific patho-physiological alterations in the animal, forthcoming meat inspection protocols should include appropriate *ante-/post-mortem* inspection criteria indicative of the illicit use of non-authorized substances.

TOR 3. If new hazards currently not covered by the meat inspection system (e.g. Salmonella, Campylobacter) are identified under TOR 1, then recommend inspection methods fit for the purpose of meeting the overall objectives of meat inspection. When appropriate, food chain information should be taken into account.

- Control programmes for residues and contaminants should consider all substances ranked in the categories of substances of high and medium concern. This may involve an amendment of Council Directive 96/23/EC.[11] Regular updates of these categories are recommended as the profile of residues and contaminants in pig carcasses can change.

TOR 4. To recommend adaptations of inspection methods and/or frequencies of inspections that provide an equivalent level of protection within the scope of meat inspection or elsewhere in the production chain that may be used by risk managers in case they consider the current methods disproportionate to the risk, e.g. based on the ranking as an outcome of terms of reference 1 or on data obtained using harmonised epidemiological criteria. When appropriate, food chain information should be taken into account.

- Information-based sampling strategies for the control of residues and contaminants taking into account the origin of slaughtered pigs and the available food chain information should be implemented. This includes differentiated sampling plans for pigs reared for fattening on specialised farms and pigs from other farms slaughtered for different reasons.
- For pigs raised for fattening on farms with operational HACCP-based protocols and with full FCI data, a tailored sampling plan directed primarily to the emerging contaminants in the food chain and/or to other substances not covered by FCI data should be implemented, taking into account also the farm size (i.e. sampling of a defined percentage of animals from the same farm rather than a given percentage of all slaughter pigs).
- For pigs raised on farms without an operational quality control system, prescriptive sampling remains recommended, but should also incorporate emerging contaminants in the food chain. Sampling strategies also need to take into account the farm size (i.e. sampling of a defined percentage of animals from the same farm rather than a given percentage of all slaughter pigs).
- Analytical techniques covering multiple analytes should be encouraged and incorporated into national residue control programmes.
- Measures to identify the illicit use of non-authorized substances at the farm level, prior to transport and slaughter, should be promoted.
- Any measures taken to improve the efficacy of meat inspection protocols need to address also the compliance of imports into the EU with these strategies.

REFERENCES

EFSA (European Food Safety Authority), 2004a. Scientific opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission related to ochratoxin A (OTA) as undesirable substance in animal feed. The EFSA Journal, 101, 1-36.

EFSA (European Food Safety Authority), 2004b. Scientific opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission related to Aflatoxin B as undesirable substance in animal feed. The EFSA Journal, 39, 1-27.

EFSA (European Food Safety Authority), 2004c. Scientific opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission related to Deoxynivalenol (DON) as undesirable substance in animal feed. The EFSA Journal, 73, 1-42.

EFSA (European Food Safety Authority), 2004d. Scientific opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission related to Zearalenone as undesirable substance in animal feed. The EFSA Journal, 89, 1-35.

EFSA (European Food Safety Authority), 2005a. Scientific opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission related to the presence of non dioxin-like polychlorinated biphenyls (PCB) in feed and food. The EFSA Journal, 284, 1-137.

EFSA (European Food Safety Authority), 2005b. Scientific opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission related to fumonisins as undesirable substances in animal feed. The EFSA Journal, 235, 1-32.

EFSA (European Food Safety Authority), 2006. Scientific opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission related to ochratoxin A in food. The EFSA Journal, 365, 1-56.

EFSA (European Food Safety Authority), 2007a. Scientific opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission related to cyanogenic compounds as undesirable substaces in animal feed. The EFSA Journal, 434, 1-67.

EFSA (European Food Safety Authority), 2007b. Scientific opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission related to Pyrrolizidine alkaloids as undesirable substaces in animal feed. The EFSA Journal, 447, 1-51.

EFSA (European Food Safety Authority), 2007c. Scientific opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission related to the potential increase of consumer health risk by a possible increase of the existing maximum levels for aflatoxins in almonds, hazelnuts and pistachios and derived products. The EFSA Journal, 446, 1-127.

EFSA (European Food Safety Authority), 2008a. Scientific opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission on Glucosinolates as undesirable substances in animal feed. The EFSA Journal, 590, 1-79.

EFSA (European Food Safety Authority), 2008b. Scientific Opinion of the Panel on Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission on Mercury as undesirable substance in animals feed. The EFSA Journal, 654, 1-74.

EFSA (European Food Safety Authority), 2008c. Scientific opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission on Tropane alkaloids (from *Datura* sp.) as undesirable substances in animal feed. The EFSA Journal, 691, 1-55.

EFSA (European Food Safety Authority), 2008d. Scientific opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission on Theobromine as undesirable substances in animal feed. The EFSA Journal, 725, 1-66.

EFSA (European Food Safety Authority), 2008e. Scientific opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission on Ricin (from *Ricinus communis*) as undesirable substances in animal feed. The EFSA Journal, 726, 1-38.

EFSA (European Food Safety Authority), 2008f. Scientific opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission on Gossypol as undesirable substances in animal feed. The EFSA Journal, 908, 1-55.

EFSA (European Food Safety Authority), 2008g. Scientific opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission on Perfluotooctane sulfonate (PFOS), perfluorooctanoic acid (PFOS) and their salts. The EFSA Journal, 653, 1-131.

EFSA (European Food Safety Authority), 2008h. Polycyclic Aromatic Hydrocarbons in Food. Scientific Opinion of the Panel on Contaminants in the Food. The EFSA Journal, 724, 1-114.

EFSA (European Food Safety Authority), 2009a. Scientific opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission on Cadmium in food. The EFSA Journal, 980, 1-139.

EFSA (European Food Safety Authority), 2009b. Scientific opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission on Saponins in *Madhuca longifolia* L. as undesirable substances in animal feed. The EFSA Journal, 979, 1-36.

EFSA (European Food Safety Authority), 2009c. Scientific opinion of the Panel of Contaminants in the Food Chain (CONTAM Panel) on request from the European Commission on Nitrite as undesirable substances in animal feed. The EFSA Journal, 1017, 1-47.

EFSA (European Food Safety Authority), 2010a. Scientific report of EFSA. Results of the monitoring of dioxin levels in food and feed. EFSA Journal, 8(3):1385, 36 pp.

EFSA Panel on Contaminants in the Food Chain (CONTAM), 2010b. Scientific Opinion on Lead in Food. EFSA Journal, 8(4):1570, 147 pp.

EFSA Panel on Contaminants in the Food Chain (CONTAM), 2011a. Scientific Opinion on Polybrominated Diphenyl Ethers (PBDEs) in Food. EFSA Journal, 9(5):2156, 274 pp.

EFSA Panel on Contaminants in the Food Chain (CONTAM), 2011b. Scientific Opinion on tolerable weekly intake for cadmium. EFSA Journal, 9(2):1975, 19 pp.

EFSA Panel on Contaminants in the Food Chain (CONTAM), 2011c. Scientific Opinion on the risks for public health related to the zearalenone in food. EFSA Journal, 9(6):2197, 124 pp.

EFSA Panel on Contaminants in the Food Chain (CONTAM), 2011d. Scientific Opinion on Hexabromocyclododecanes (HBCDDs) in Food in food. Opinion adopted on the 5 July 2011. EFSA Journal, 9(7):2296, 118 pp.

EMEA (The European Agency for the Evaluation of Medicinal Products), 1997. Committee for Veterinary Medicinal Products. Metronidazole. Summary report. Available from http://www.ema.europa.eu/docs/en_GB/document_library/Maximum_Residue_Limits_-_Report/2009/11/WC500015087.pdf.

EMEA (The European Agency for the Evaluation of Medicinal Products), 2009a. Committee for Veterinary Medicinal Products. Chloramphenicol. Summary report. Available from http://www.ema.europa.eu/docs/en_GB/document_library/Maximum_Residue_Limits_-_Report/2009/11/WC500012060.pdf.

EMEA (The European Agency for the Evaluation of Medicinal Products), 2009b. Committee for Veterinary Medicinal Products. Ronidazole. Summary report. Available from http://www.ema.europa.eu/docs/en_GB/document_library/Maximum_Residue_Limits_-_Report/2009/11/WC500015834.pdf.

EMEA (The European Agency for the Evaluation of Medicinal Products), 2009c. Committee for Veterinary Medicinal Products. Dimetridazole. Summary report. Available from http://www.ema.europa.eu/docs/en_GB/document_library/Maximum_Residue_Limits_-_Report/2009/11/WC500013885.pdf.

Huet AC, Mortier L, Saeseleire E, Fodey T, Elliott C and Delahaut P, 2005. Screening for the coccidiostats halofuginone and nicarbazin in egg and chicken muscle: development of an ELISA. Food Additives & Contaminants, 22, 128-134.

FAO/WHO (Food and Agriculture Organization of the United Nations/World Health Organization Expert Committee on Food Additives), 1988. Chloramphenicol - toxicological evaluation of

certain veterinary drug residues in food, WHO Food Additives Series 23, WHO, Geneva, 1-71. Available from http://www.inchem.org/documents/jecfa/jecmono/v23je02.htm.

FAO/WHO (Food and Agriculture Organization of the United Nations/World Health Organization Expert Committee on Food Additives) 2003. Safety evaluation of certain food additives and contaminants Prepared by the Sixty-first meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), Rome, Italy. WHO Food Additives Series 23, WHO, Geneva. Available from http://www.inchem.org/documents/jecfa/jecmono/v52je01.htm.

FAO/WHO (Food and Agriculture Organization of the United Nations/ World Health Organization Expert Committee on Food Additives) 2004. Evaluaion of certain veterinary drug residues in food. Sixty-second meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), Rome, Italy, 4-12 February 2004. WHO Technical Report Series 925, WHO, Geneva. Available from http://whqlibdoc.who.int/trs/WHO_TRS_925.pdf

FAO/WHO (Food and Agriculture Organization of the United Nations/World Health Organization Expert Committee on Food Additives), 2011. Safety evaluation of certain contaminants in food; WHO Food Additives Series, 63. WHO/JECFA monographs 8, WHO, Geneva, 1-799. Available from http://whqlibdoc.who.int/publications/2011/9789241660631_eng.pdf.

O'Keeffe M, Conneely A, Cooper KM, Kennedy DG, Kovacsics L, Fodor A, Mulder PPJ, van Rhijn JA and Trigueros G, 2004. Nitrofuran antibiotic residues in pork: the FoodBRAND retail survey. Analytica Chimica Acta, 520, 125-131.

SCF (Scientific Committee for Food), 1997. Opinion on nitrates and nitrites. Reports of the Scientific Committee for Food, 38th Series, 1-33.

SCF (Scientific Committee on Food), 1999. Opinion on Fusarium toxins, Part 1: Deoxynivalenol (DON) (expressed on 2 December 1999). Available from http://ec.europa.eu/food/fs/sc/scf/out44_en.pdf.

SCF(Scientific Committee on Food), 2000a. Opinion on Fusarium toxins, Part 4: Nivalenol. (expressed on 19 October 2000). Available from http://ec.europa.eu/food/fs/sc/scf/out74_en.pdf.

SCF (Scientific Committee on Food), 2000b. Minute Statement on Patulin. Expressed by the Scientific Committee on Food during the plenary meeting on 8th of March, 2000. Available from Available from http://ec.europa.eu/food/fs/sc/scf/out55_en.pdf.

SCF (Scientific Committee on Food), 2001a. Opinion on the Risk Assessment of Dioxins and Dioxins-like PCBs in Food. Update based on new scientific information available since the adoption of the SCF opinion of 22nd November 2000. Adopted on 30 May 2001. Available from http://ec.europa.eu/food/fs/sc/scf/out90_en.pdf.

SCF (Scientific Committee on Food), 2001b. Opinion on Fusarium toxins. Part 5: T-2 toxin and HT-2 toxin, adopted on 30 May 2001. Available from http://ec.europa.eu/food/fs/sc/scf/out88_en.pdf.

SCF (Scientific Committee on Food), 2002. Opinion of the Scientific Committee on Food on *Fusarium* toxins. Part 6: group evaluation of T-2 toxins, HT-2 toxins, nivalenol and deoxynivalenol (adopted on 26 February 2002). Available from http://ec.europa.eu/food/fs/sc/scf/out123_en.pdf.

SCVPH (Scientific Committee on Veterinary Measures relating to Public Health), 2000. Revision of meat inspection procedures. 24 February 2000. Available from http://ec.europa.eu/food/fs/sc/scv/out30_en.pdf.

SCVPH (Scientific Committee on Veterinary Measures relating to Public Health), 2001. Opinion on Identification of species/categories of meat-producing animals in integrated production systems where meat inspection may be revised. Adopted on 20-21 June 2001. Available from http://ec.europa.eu/food/fs/sc/scv/out42_en.pdf.

Watson DH, 2004. Pesticide, veterinary and other residues in food. Woodhead Publishing Ltd., UK, 686 pp.

ABBREVIATIONS

ADI	Acceptable daily intake
AHAW	EFSA's Panel on Animal Health and Welfare
AHD	Nitrofurantoin
AMOZ	Metabolite of Furaltadone
AOZ	Metabolite of Furazolidone
BIOHAZ	EFSA's Panel on Biological Hazards
BIOMO	EFSA's Unit on Biological Monitoring
BMD	Benchmark dose
BMDL	Benchmark dose limit
b.w.	Body weight
CONTAM Panel	EFSA's Panel on Contaminants in the Food Chain
DCM	EFSA's Unit on Dietary and Chemical Monitoring
DDG	Distillers dried grains
DDT	Dichlorodiphenyltrichloroethane
DL-PCBs	Dioxin-like polychlorinated biphenyls
EFSA	European Food Safety Authority
EMA/EMEA	European Medicines Agency
EU	European Union
FAO	Food and Agriculture Organization
FCI	Food chain information
GFP	Good Farming Practice
GHP	Good Hygiene Practice
HACCP	Hazard Analysis and Critical Control Points
HBCDD	hexabromo-cyclododecane
HCH	Hexachlorocyclohexane
JECFA	The Joint FAO/WHO Expert Committee on Food Additives
ML	Maximum limit
MOE	Margin of exposure
MRL	Maximum residue limit
MRPL	Minimum Required Performance Limit
MS	Member State
NC	Non-compliant
NDL-PCBs	Non-dioxin-like polychlorinated biphenyls
NOAEL	No-observed-adverse-effect level
NRCP	National Residue Control Plan
NSAID	Non-steroidal anti-inflammatory drug
OC	Organochlorine
OIE	Terrestrial Animal Health Code of the World Organization for Animal Health
OP	Organophosphate
OTA	Ochratoxin A
PBDEs	Polybrominated diphenyl ethers
PCBs	Polychlorinated biphenyls
PFC	Perfluorinated compound
PFOA	Perfluorooctanoic acid
PFOS	Perfluorooctanesulfonic acid
pmTDI	Provisional maximum TDI
pTWI	Provisional tolerable daily intake
QAS	Quality assurance scheme
SAS	EFSA's Unit on Scientific Assessment Support

SCF	Scientific Committee on Food
SCVPH	Scientific Committee on Veterinary Measures relating to Public Health
SEM	Nitrofurazone
TDI	Tolerable daily intake
TEQ	Toxic equivalent
tTDI	Temporary tolerable daily intake
TWI	Tolerable weekly intake
VMP	Veterinary medicinal product
WHO	World Health Organization

APPENDIX C FROM THE PANEL ON ANIMAL HEALTH AND WELFARE (AHAW PANEL)

TABLE OF CONTENTS

1. OVERVIEW

1.1. Introduction and scope

In this mandate, for each of the six species in turn, the AHAW working group focused on the implications for animal health and welfare of any changes to the current meat inspection system, as proposed by the Biological Hazards (BIOHAZ) and Contaminants (CONTAM) Panels. 'Implications for animal health and welfare' relates principally to monitoring and surveillance of animal health and welfare during meat inspection (that is, inspection at the abattoir before and after slaughter, which is referred to in this document as ante- and post-mortem inspection, respectively). The Opinion also considers the impact of the proposed changes on the health and welfare of animals during transport, lairage and ante-mortem inspection, prior to slaughter.

> This opinion focuses on the implications for animal health and welfare of any changes to the current meat inspection system. 'Implications for animal health and welfare' relates principally to *monitoring and surveillance* of animal health and welfare during meat inspection. The opinion also considers the impact of the proposed changes on the health and welfare of animals during transport, lairage and ante-mortem inspection, prior to slaughter.

Monitoring and surveillance mainly concerns 'early detection', 'case-finding' and 'esti*mating prevalence'*. The effectiveness of monitoring and surveillance is measured in terms of:

- *'Probability of detection'* (surveillance sensitivity), primarily, with
- *'Validity' (bias associated with animals sampled) and 'precision' (the number of animals sampled), also playing a role.*

The use of data subsequent to collection (for example, by government, by industry and farming organisations etc.), is outside the scope of the Opinion.

The Working Group (WG) members were cognisant that meat inspection is an important component of the overall monitoring and surveillance system of animal welfare and diseases/conditions of interest, and considered this further during stage 3 modelling (see later).

> Meat inspection is an important component of *the overall monitoring and surveillance system* of animal welfare and diseases/conditions of interest.

1.2. Abattoir surveillance for animal health and welfare

1.2.1. Introduction

Until relatively recently, meat inspection was mainly used to detect major zoonotic diseases such as tuberculosis, and parasites such as *Trichinella*. Increasingly, however, the role of meat inspection has broadened to include surveillance for epidemic diseases, such as classical swine fever, a range of endemic diseases, and animal welfare concerns. The above-mentioned zoonotic diseases and animal diseases remain an important aspect of meat inspection, but some of these, including trichinellosis, are now under improved control.

Ante-mortem and *post-mortem* inspection results can be used for improvements in the overall welfare of farm animal populations. Clinical disease is always associated with poor welfare (Slauson and

Cooper, 2002; Broom, 2006; therefore, detection of infectious disease as a result of meat inspection, and the consequent reduction of disease among in-contact animals, is also of major importance for farm animal welfare. As examples, detection during ante- or *post-mortem* meat inspection of endemic diseases, such as lung abscesses, arthritis or bursitis is indicative of on-farm welfare problems and economic losses. These measures of injuries, behaviour, etc., are examples of welfare-outcome indicators that can be used by governments to enforce control measures or by organisations to manage product quality programmes. In each situation, animals and carcasses need to be adequately traced. The use of welfare outcome indicators for dairy cows and pigs on farms and at the abattoir is the subject of two EFSA Opinions in preparation.

1.2.2. Surveillance concepts

The concepts and elaborations outlined below are general, and could equally be applied to meat inspection and to efforts to protect public health and to detect the presence of chemical residues and contaminants.

There is a wide variety of surveillance activities and approaches available to collect information about the welfare and disease status of animal populations. *'Abattoir surveillance'* defines the location of surveillance activities, but not necessarily the nature of those activities. This discussion will be limited to routine surveillance for animal welfare and disease conditions (by definition, an ongoing process), and excludes special studies or surveillance activities of limited duration. Broadly, these activities include:

- *Ante-mortem* inspection (pre-slaughter),
- *Post-mortem* inspection (post-slaughter),
- Specific legislated screening tests for priority disease conditions (applied at different points along the slaughter chain, for example, serological tests or bacterial swabs).

Abattoir surveillance is an ongoing process, with the potential to provide continuous insights into animal health and welfare over the long term. This is in contrast to active surveillance, which may only be conducted for a defined time period.

There are a number of different possible general purposes for surveillance.

For endemic diseases, including conditions important for welfare, surveillance has two major goals, including:

- *Measuring the level of a disease or welfare condition* (estimating the prevalence or incidence). Prevalence and incidence data may be required for priority setting, monitoring farm performance and interventions, detecting changes in the disease distribution that may trigger a control programme, monitoring the effectiveness of an existing control programme, or providing data for risk analysis,
- *Identifying individual cases of a specified disease or welfare condition in order to implement some response* (case-finding). The response to case-finding will vary, depending on the disease/condition. For non-infectious diseases without regulatory implications, the animal may be removed. For welfare conditions, a regulatory response may be triggered. For example, a pig with extensive bruising or with dark firm dry meat (DFD) indicates that the transport or lairage conditions did not comply with legislation or with codes of practice. For diseases that are the subject of either an official or industry-based control programme, the response may be to remove the animal from the population, or to identify the farm of origin and undertake disease control activities on that farm.

For epidemic diseases that are either absent or occur sporadically in a country, the main purpose of surveillance is early detection in order to implement effective control/eradication measures. Abattoir surveillance may also be used to provide evidence of freedom from infection or disease, however, this is usually undertaken as a time-limited exercise to meet a specific trade or other requirement, and will therefore not be considered further as one of the purposes of routine abattoir surveillance.

> For endemic diseases, surveillance can be used to *estimate prevalence* or *incidence* and for *case-finding*. For epidemic diseases, the main purpose of surveillance is *early detection.*

1.2.3. Assessing the quality and value of surveillance

1.2.3.1. The quality of surveillance

Changes in the meat inspection procedure have the potential to affect the quality of surveillance for animal welfare and disease conditions. In the current Opinion, it has been necessary to quantify surveillance quality in two situations: current surveillance and surveillance following recommended changes. It is important to note that quantitative measurements of the quality of surveillance differ according to the purpose of surveillance (early detection, case-finding, or estimating prevalence or incidence), as explained below.

a. Early detection

The quality of surveillance for the purpose of early detection of exotic or sporadic epidemic diseases can be quantified using the sensitivity of the surveillance system; that is, the probability that the system will detect at least one infected animal, given that the disease is present in the population at a specified prevalence. *The sensitivity of surveillance is primarily influenced by the number of animals included in the surveillance system, the design prevalence (assumed or detectable level of disease in the population), and the sensitivity of the screening test*. As with case-finding (below), risk-based approaches may be used to increase the sensitivity of surveillance by targeting high-risk populations.

> The quality of surveillance for early detection can be quantified by estimating the sensitivity of the surveillance system.

b. Case-finding

The quality of surveillance for case-finding is measured by the detection fraction (the proportion of cases in the population that are detected by the surveillance). This is influenced primarily by *the sensitivity of the screening test* (proportion of truly positive animals that give a positive test result), and *the population coverage* of the surveillance activity (proportion of the population that is included in the surveillance). Risk-based approaches may be used to increase the efficiency of case-finding by targeting sub-populations with a higher prevalence of infection or the welfare condition.

> The quality of surveillance for case-finding can be quantified by estimating the detection fraction.

c. Estimating prevalence or incidence

During surveillance for endemic conditions, which aims to measure the level of disease (e.g. prevalence) and welfare problems, the quality of surveillance may be quantified by assessing the

errors associated with the estimate. The level of random error is described by the precision of an estimate, and depends primarily on the sample size, but also the variance of the characteristic being measured in the population (which in turn can be described using the estimated population prevalence). Precision or random error is expressed quantitatively in terms of a (normally 95 %) confidence interval around an estimate.

There may be a variety of reasons for systematic error, or bias, including selection bias (due to non-representative sampling), measurement bias (due, for instance, to imperfect sensitivity and specificity), and analysis bias (due to the use of inappropriate statistical techniques to estimate prevalence from the data). Bias is quantified as the difference between the true value and the expected value from the surveillance (i.e. once the effect of random error has been removed).

> The quality of surveillance when estimating prevalence or incidence can be quantified by assessing precision (random error) and bias (systematic error).

1.2.3.2. Value of surveillance

The value of abattoir surveillance depends on:

- The quality of the measurements derived from the surveillance (as described in 1.2.3.1) and the traceability,
- The use of the surveillance for decision-making, and
- The availability, quality and efficiency of alternative sources of surveillance data.

In other words:

- How good are the results?
- Once generated, are the results available and are they actually used to help improve the health and welfare of animal populations? and,
- Are there other sources of surveillance data that could achieve the same objectives more efficiently?

The last two of these three questions are discussed further below.

1.2.4. Populations and samples

In order to understand the quality and value of surveillance, it is important to understand clearly the differences in target populations, sampling, representativeness and coverage. In this discussion, the following terms will be used:

- *Population of interest*: the results of surveillance are intended to reflect the health or welfare of this population,
- *Surveillance population*: this is the population from which the animals included in surveillance are drawn,
- *Sample*: the animals that are actually examined as part of the surveillance system, drawn from the surveillance population,

- *Representative sample*: a representative sample is a sample drawn from a population in such a way as to ensure that the prevalence of the character of interest in the sample is the same as that in the surveillance population (i.e. there is no sampling bias).

When the objective of surveillance is to measure *the level of disease or welfare problem*, a representative sample of the population is required in order to avoid bias. However, the concept of representativeness is relative to the population of interest:

- If the population of interest is the entire live animal population (for instance, when trying to assess the national prevalence of a given disease), the abattoir population (surveillance population) cannot be considered to be representative of this population. Biases inherent in the use of abattoir surveillance include:
  - Underrepresentation of *very young animals*,
  - Underrepresentation of *breeding animals*, and,
  - Underrepresentation of animals showing signs of disease (as these are not considered to be fit for transportation or slaughter),
- However, for some conditions, the population of interest is the slaughter population, in which case the surveillance population is identical and may be considered completely representative. This is the case for welfare conditions related to transportation (but not for those conditions caused by on-farm conditions or practices).

Three approaches to sampling in abattoir surveillance can be used:

- Census: no sampling is applied and *the entire surveillance population* is examined. Typically this is the case with ante- and *post-mortem* inspection. By definition, a census is representative of the population as it contains all members of the population and therefore cannot suffer from selection bias,
- Representative sampling: a representative sample is drawn from the abattoir population (using, for example, random or systematic sampling),
- Risk-based sampling: a sample is drawn from the abattoir population with the intention that the prevalence or risk of a disease or welfare condition in the sample is greater than in the surveillance population.

In order to produce valid estimates, surveillance to measure the level of disease or welfare problem should avoid bias, and therefore needs to be based either on a census or representative sample of the appropriate population. In contrast, surveillance for early detection or case-finding can benefit from risk-based approaches which, for a given sample size, can increase the sensitivity or detection fraction, respectively.

In order to produce valid estimates, surveillance *to measure the level of disease or welfare problem* should avoid bias, and therefore needs to be based either on a census or representative sample of the appropriate population. In contrast, surveillance for *early detection* or *case-finding* can benefit from risk-based approaches which, for a given sample size, can increase the sensitivity or detection fraction, respectively.

1.2.5. Tests used in abattoir surveillance

The value of abattoir surveillance is influenced by the sensitivity and specificity of the tests used. The main screening tests applied in abattoir surveillance are visual inspection (a form of clinical examination) in *ante-mortem* inspection, and meat inspection (a form of necropsy examination) in *post-mortem* inspection. Further specific tests may be used to screen for other conditions of public health importance (such as the digestion test for trichinellosis) or animal health importance (e.g laboratory tests, whenever considered necessary to reach a definitive diagnosis or to detect an animal disease (see Annex I, section D (2), Regulation (EC) 854/2004[29]). If abnormalities are detected on ante- or *post-mortem* inspection, they may be followed up by more detailed diagnostic and confirmatory tests.

1.2.5.1. *Ante-mortem* inspection

Visual ante-mortem inspection has the advantages of being rapid and inexpensive. It has fair to moderate sensitivity for diseases and welfare conditions that manifest obvious clinical signs, which is further improved if a number of animals are affected. Examples include severe wounds or traumatic injury, obvious behavioural abnormalities, severe lameness or recumbency. *Sensitivity is limited by the duration of examination of each animal, and is affected by the skill and experience of the examiner*. A range of other welfare conditions or diseases may also be detected if signs are severe enough, including pneumonia with coughing or severe dyspnoea, and diarrhoea. A range of diseases with skin manifestations may also be detected.

In some cases, visual inspection may be able to detect an abnormal state but may not be able to make a definitive diagnosis in the absence of follow-up testing (e.g. pneumonia or diarrhoea). In other cases, the specificity may be good (e.g. welfare conditions manifested by injury or behavioural changes).

1.2.5.2. *Post-mortem* inspection

As *with ante-mortem inspection, the sensitivity of post-mortem inspection is limited by the duration of examination of each animal, and is affected by the skill and experience of the examiner*. The sensitivity *of post-mortem* meat inspection depends on the degree of pathological change associated with the disease or welfare condition, and the skill and experience of the examiner. In optimal situations, the *post-mortem* meat inspection can detect a wide range of diseases, disease syndromes and welfare conditions that are not readily detectable in *ante-mortem* inspection. However, commonly, the outcomes from the whole meat inspection (*ante-* and *post-mortem* inspection) may also be that the aetiology of occurring signs cannot be specified because more than one condition or agent is able to result in a given pathological presentation. In these cases, specific tests are required to make a definitive diagnosis (e.g. granulomas in lymph nodes, pneumonia).

> During both *ante-* and *post-mortem* inspection, sensitivity is limited by duration of examination of each animal, and is affected by the degree of pathological change and the skill and experience of the examiner. There is a spectrum of potential outcomes, from non-specific findings (requiring further examination before a definitive diagnosis can be made) through to the detection of specific diseases, syndromes or welfare conditions.

[29] Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption

1.2.6. The value of abattoir surveillance

1.2.6.1. Early detection of epidemic diseases

Abattoir surveillance has successfully detected a number of epidemic diseases in Europe when other surveillance systems had failed (e.g. UK FMD 2001) and has been used as part of tracking and tracing systems during epidemic situations (e.g. CSF in the Netherlands from 1997 to 1998; Elbers et al., 2001). For diseases with typical lesions, such as FMD, the sensitivity of both ante- and post-mortem inspection is generally high.

Early detection of an epidemic disease in a region or country requires high coverage and continuous investigation of the susceptible population. The probability of detection is increased if there are a high number of cases present at slaughter (as might occur with highly contagious diseases) and if there are cases present with detectable lesions.

Early detection systems are not generally relevant to welfare conditions although they could be applied for the detection of evidence of banned practices.

> *Early detection of an epidemic disease* in an abattoir requires high coverage and continuous investigation of the susceptible population.

1.2.6.2. Case-finding

The value of abattoir surveillance for case-finding of welfare conditions or disease is often limited, again due to the biased nature of the abattoir population with respect to the total animal population. For most diseases or welfare conditions manifesting clinical signs, the abattoir population is likely to have a lower prevalence than the rest of the population. Note, however, that many welfare outcome indicators relating to on-farm problems are much more likely to be detected accurately at the abattoir than on-farm. Examples include broken bones, breast blisters and pododermatitis in poultry, joint abscesses in pigs, and walking difficulties in dairy cows. Poor welfare during transport of a wide range of animals is almost exclusively detected at ante- and *post-mortem* inspection at the abattoir. Individuals dead on arrival, skin lesions and bruising during transport, severe respiratory distress on arrival, PSE and DFD meat, and bone breakages during transport are all detected during meat inspection. In addition, on arrival at a slaughterhouse, it may be apparent that the animal was not fit for travel, for example because of an injury or a disease condition that would have existed prior to transport. The condition would have affected the welfare of the animal before transport, so information is provided about welfare and the quality of management at this time. The welfare during transport would have been poor, and very poor if there was a condition such as a broken bone. Information about welfare during transport can only be detected at the slaughterhouse, except on the rare occasions where animals in vehicles are checked by the competent authority during transit.

The sensitivity of detection of welfare conditions for the purposes of case-finding will generally be higher in abattoir surveillance than, for example, passive farmer reporting. In general, abattoir surveillance may provide a useful adjunct to case-finding surveillance systems, but limited coverage and potential biases will usually require other surveillance approaches to be used as well.

The value of abattoir surveillance for *case-finding of welfare conditions or disease* is often limited, due to the biased nature of the abattoir population with respect to the total animal population. The sensitivity of detection of welfare conditions for the purposes of case-finding will generally be higher during abattoir surveillance in comparison with farmer reporting.

1.2.6.3. Measuring the level of endemic disease and welfare conditions

When the population of interest is the entire population of a given species, the value of abattoir surveillance is limited due to the biased abattoir population. However, *if it is assumed that these biases are approximately constant*, abattoir surveillance may be used as a tool to detect changes in the level of disease or welfare conditions over time. The biases are most important for diseases or welfare conditions that occur in age groups other than those most commonly slaughtered, and for those that produce signs that render them unsuitable for transport or slaughter. The biases are more limited when considering subclinical disease or welfare states, and those that affect all age classes roughly equally, but in this case, the sensitivity of screening tests will often be lower, again limiting the value of abattoir surveillance.

When the population of interest is the slaughter population (for instance when considering welfare conditions associated with transportation and pre-slaughter handling), the abattoir population is ideal and measurements of the level of conditions or disease may be considered unbiased.

When the population of interest is the entire population under consideration of a given species, the value of abattoir surveillance *to measure the level of endemic disease and welfare conditions* is limited due to the biased abattoir population. However, if it is assumed that these biases are approximately constant, abattoir surveillance may be used as a tool to detect changes in the level of disease or welfare conditions over time.

1.2.6.4. Use of abattoir surveillance data

To provide value, abattoir surveillance data must be made available to decision makers, and used for making decisions. There is a range of potential users of abattoir surveillance data at different levels, including: global (OIE and its members), regional (e.g. the European Union), national veterinary authorities, abattoir operators, producers, and service providers such as livestock transporters and local veterinarians. There is currently little to no systematic aggregation of data on meat inspection data, relating to pig health and welfare, either nationally or at the EU level but in some Member States (MS) industry-based systems are in place for surveillance of meat inspection data for the improvement of animal health and welfare.

The following list outlines the requirements for effective use of abattoir surveillance by any of these groups:

- *The observation or test is performed*. There may be circumstances in which standards require certain inspections or other tests to be carried out, but due to failures in training or quality assurance systems, they are not conducted as required (or in the worst case, not conducted at all),
- *The results of the observations are captured*. The level of detail of data capture required depends on the needs of the different users of the surveillance data. For instance, a producer

may be interested in knowing the proportion of animals from their farm with a particular welfare condition (for example, to measure the effectiveness of a particular intervention), requiring capture of information on the origin of animals, the number of animals with the welfare condition, the number of animals examined and, possibly, further information such as identification of the transporter,

- *The captured data are traceable to farm of origin* and, where necessary, to relevant transporters,
- *The captured data are analysed in such a way as to facilitate decision-making*,
- *The results are communicated to relevant decision makers*,
- *Decision makers use the results to inform their decisions*.

Key current weaknesses that frequently limit the value of abattoir surveillance relate to the capture, analysis and communication of surveillance data, although the situation varies significantly between MS and abattoirs.

> Existing data from pig health and welfare abattoir system records are currently being greatly underutilised. To provide value, abattoir surveillance data must be utilised through analysis to support future direction in the decision-making process.

1.3. Methodologies

1.3.1. Overview, including general assumptions

Two methodologies have been used for each species:

- *A qualitative approach*, informed by both a literature review and expert opinion, to gain an understanding of the direction of change, and,
- *A quantitative approach,* using a defined number of diseases and conditions, to provide an estimate of both the magnitude and direction of change.

The scope of the former was broad, with the potential to encompass all diseases and conditions, whereas the latter considered only a defined number of diseases and conditions. Both approaches were considered critical to the Opinion, noting that the role of AHAW was to identify '*the implications to animal health and welfare of any changes to the current meat inspection system as proposed by the BIOHAZ and CONTAM Panels'*.

> In this Opinion, both qualitative and quantitative approaches were used to assess surveillance quality following the recommended changes. Both were considered important. The two approaches each provide insights into the direction of change. Information about the magnitude of the change is available as an output from the quantitative assessment only.

In this mandate, for each species in turn, the work of AHAW is underpinned by a number of general assumptions:

- All aspects of meat inspection were assumed to have been conducted in *full compliance with relevant EU legislation,*
- Meat inspection was assumed *to specifically exclude* non-routine surveillance, including special studies initiated for a specific purpose,
- In this Opinion, only some aspects of sampling for chemical residues and contaminants are considered. Specifically, in this study, the impact of changes *to suspect sampling (*a form of *'case-finding')* for chemical compounds is considered, which is undertaken when suspicion about the health of individual animals and samples is raised at the abattoir, and samples are collected specifically to identify abnormal levels of pharmacological products or illegal drugs as well as contaminants, which renders the slaughtered animal unsuitable for human consumption. In this Opinion, changes to sampling schemes *for prevalence estimation* of residues and contaminants, which is undertaken in a strategic manner to gain an understanding of chemical load in the broader farmed animal population, have not been considered,
- *This report*[30] *does not seek to represent specific situations, nor does it seek to measure variation in meat inspection practices between MS.* Rather, hypothetical examples ('typical cases') are used to illustrate particular points, drawing, as appropriate, on parameters representing the 25th, median and 75th percentile among MS,
- Within any jurisdiction, all surveillance activities are assumed to have been implemented *in a uniform manner, and,*
- Diseases have each been considered on the basis of aetiological diagnoses (for example, infection with foot and mouth disease virus), whereas welfare conditions have been considered on the basis of morphological diagnoses or welfare outcomes (for example, lameness).

The methodologies used in this opinion are underpinned by a number of general assumptions, as outlined in the text.

1.3.2. Qualitative assessment

The qualitative assessment is presented separately for each animal species, and is not considered further here.

1.3.3. Quantitative assessment

The quantitative assessment was conducted in stages:

- *Stage 1 (selecting diseases and other welfare issues)*, leading to the identification of approximately 20 diseases/conditions for stage 2 modelling and approximately 5 diseases/conditions for stage 3 modelling,
- *Stage 2 (modelling the meat inspection system)*, leading to an assessment of surveillance quality during meat inspection for the 20 above-mentioned diseases/conditions,
- *Stage 3 (modelling the overall surveillance system)*, leading to an assessment of surveillance quality during meat inspection for the 20 above-mentioned diseases/conditions.

[30] External scientific report: Contribution of meat inspection to animal health surveillance in swine. Available from www.efsa.europa.eu

The quantitative assessment was conducted over three stages:

- Stage 1, selecting diseases and other welfare issues,
- Stage 2, modelling the meat inspection system, and
- Stage 3, modelling the overall surveillance system.

1.3.3.1. Stage 1: Selecting diseases and other welfare issues

a. A definitive list of diseases and other welfare conditions

For each species, a definitive list of diseases and other welfare conditions was developed, following reference to recognized textbooks and expert opinion. Diseases were defined on the basis of *aetiological diagnoses*, and welfare conditions on the basis of *welfare outcomes*. Microsoft Excel was used for data management at all stages of the prioritisation process.

b. Prioritisation

The prioritisation process varied between species, and is presented in section 2.4. Nonetheless, in all cases prioritisation was conducted with three key issues in mind:

i. The AHAW work has focused on the implications to animal health and welfare of any changes to the current meat inspection system as proposed by the BIOHAZ and CONTAM Panels. In this context, 'implications for animal health and welfare' relates specifically to monitoring and surveillance of animal health and welfare during meat inspection (that is, inspection at the abattoir before and after slaughter, in this document referred to as ante- and *post-mortem* inspection, respectively). *Therefore, there was a particular interest in diseases and conditions*:

  – *Where meat inspection is an important component of the overall surveillance system, and,*

  – *Where changes to meat inspection have the potential to adversely impact on surveillance quality (in particular, detection probability).*

ii. Throughout the mandate, the BIOHAZ and AHAW Panels each considered zoonoses very differently:

  – The BIOHAZ Panel from the perspective of *implications for public health* ('how can the meat inspection system be changed to better address key public health hazards?'), and,

  – The AHAW Panel from the perspective of *implication for animal health and welfare* ('what are the implications of the proposed system changes on the effectiveness of monitoring and surveillance for animal health and welfare?').

The BIOHAZ Panel considered some, but not all, zoonoses during their work. During the prioritisation process, therefore, the AHAW Panel have considered all animal diseases (zoonotic and otherwise), with prioritisation being based on the relevance of each to animal health and welfare.

iii. The quantitative modelling stages (Stages 2 and 3) are very resource-intensive. *Therefore, only a defined number of diseases and welfare conditions were listed, following prioritisation, for consideration in the stage 2 model* (20 diseases/conditions for stage 2

modelling, and a subset of 5 of these for stage 3 modelling). Stage 2 focused solely on the meat inspection process. However, meat inspection is only part of the overall surveillance system, which may include other surveillance components, such as passive on-farm surveillance and active serological surveillance. For this reason, during stage 3, the focus was on the overall surveillance system, of which meat inspection is a part.

1.3.3.2. Stage 2: Modelling the meat inspection system

The stage 2 modelling was undertaken *to evaluate surveillance quality during meat inspection for animal diseases and other welfare conditions*, both currently and following changes to meat inspection as recommended by the BIOHAZ and CONTAM Panels. The impact of these changes was quantified and assessed following comparison of these two measurements of surveillance quality.

> Stage 2 modelling was undertaken to evaluate the quality of surveillance, *both prior to and following the BIOHAZ/CONTAM recommended changes*, focusing solely on the meat inspection process.

The stage 2 model quantifies *the quality of abattoir surveillance* for animal health and welfare conditions in terms of:

- Surveillance sensitivity *(for early detection),*
- Detection fraction *(for case-finding)*, and,
- Bias and precision *(for prevalence estimation)*.

Further details are available in *Annex II*.

1.3.3.3. Stage 3: Modelling the overall surveillance system

The value of surveillance is related not only to the quality of the surveillance measurements, but also to the use of the data, and the availability and efficiency of alternative surveillance data sources. To understand fully the value of abattoir surveillance, therefore, it was necessary to evaluate its contribution *when compared to* other existing sources of surveillance information. Therefore, stage 3 involved the development of a number of models with the purpose of quantifying the relative contribution of abattoir surveillance for a number of example diseases and welfare conditions, *in the context of other existing surveillance activities*.

Stage 3 modelling was conducted on a subset of diseases/conditions produced from stage 2. In general terms, this included:

- Those diseases/conditions where gross inspection at *post-mortem* is particularly important, and,
- Those diseases/conditions with a strong animal welfare component (and where farmer-based reporting is most unlikely.

> Stage 3 modelling was undertaken to evaluate the quality of surveillance, *both prior to and following the BIOHAZ/CONTAM recommended changes* focusing on the overall surveillance system, of which meat inspection is a part.

Further details are available in Annex III.

2. Domestic pigs

2.1. A description of the meat inspection process

The procedures during *ante-mortem* and *post-mortem* meat inspection are described by in an external report to EFSA entitled 'Overview on current practices on meat inspection in the EU'[31], and are not repeated here.

2.2. The changes to meat inspection, as recommended by BIOHAZ and CONTAM

The proposed changes to the meat inspection system are presented elsewhere, in the appendices from the BIOHAZ and CONTAM Panels, but they include proposals to shorten the duration of transport and lairage, removal of palpation and incision from *post-mortem* inspection, and introduction of risk categorisation. Although there are no proposals for changes, the BIOHAZ Panel commented that *ante-mortem* inspection is of limited value for public health protection. As stated by the BIOHAZ Panel, it does not currently contribute to detection of any of the main pork-borne public health hazards (*Salmonella*, *Y. enterocolitica*, *Toxoplasma* and *Trichinella*), as none produce observable signs in pigs. Indeed, from a public health perspective, the only aspect of *ante-mortem* inspection that has some relevance for *Salmonella*- and *Y. enterocolitica*-related pork safety assurance is assessment of visual cleanliness of pigs (Section 5.1 BIOHAZ Appendix A).

> The proposed changes to the meat inspection system include proposals to shorten the duration of transport and lairage, changes to the location of *ante-mortem* inspection, removal of palpation and incision from *post-mortem* inspection, and introduction of risk categorisation. As stated by the BIOHAZ Panel, *ante-mortem* inspection is of limited value for protection against food-borne human health hazards.

2.3. Qualitative assessment

The proposed modifications for the meat inspection system may have implications for animal health and welfare, relating to:

- *Shortened transport and lairage (Section 5.1 BIOHAZ Appendix A),*
- *Removal of palpation and incision from post-mortem inspection (Sections 5.3; 5.3.1, 5.3.2 BIOHAZ Appendix A)* and,
- *Introduction of risk categorisation (Sections 4.2; 4.3 BIOHAZ Appendix A).*

The importance of *ante-mortem* inspection for public health is also questioned (for further details refer to the c*onclusions to* ToR2 BIOHAZ Panel and CONTAM Panel, and *Section 5.1* in *Appendix A,* and *Section 3.2* in *Appendix B).*

[31] External scientific report: Overview of current practices of meat inspection in the European Union. Available at www.efsa.europa.eu

2.3.1. Proposed shortened duration of transport and lairage

2.3.1.1. Changes proposed

The BIOHAZ Panel proposes a reduction in the duration of transport and lairage.

Previous EFSA Opinions on the welfare of animals during transport (EFSA, 2004, 2011) presented a detailed discussion of the possible effects of duration of transport on both disease detection and transmission of infection. In broad terms, stressful conditions during transport may exacerbate existing disease conditions, resulting in increases in pathogen shedding, transmission of infection and disease detection.

2.3.1.2. Impact on pig health and welfare

a. Literature review

The impact of transport on the health and welfare of individual animals has been reviewed in detail in an earlier EFSA report (EFSA, 2011). Key factors that may adversely affect animal welfare include animal fitness, fasting, vehicle design, driving style, stocking density, weather condition and ventilation. Reductions in the duration of transport and lairage, without adverse changes to other key variables (in particular, the quality of transport) are likely to lead to improvement in the health and welfare of individual animals. Note that training and education for drivers to promote careful driving would also improve the welfare of animals in transport (Cockram et al., 2004).

> Key factors that may adversely affect animal welfare include animal fitness, fasting, vehicle design, driving style, stocking density, weather condition, ventilation, etc.

b. Expert opinion

Pig health and welfare			
POSSIBLE CHANGE	POSITIVE CONSEQUENCES	NEGATIVE CONSEQUENCES	IMPACT (magnitude, direction) *[based on WG opinion]*
Reduce duration of transport	Reduction in stress, fatigue, injuries, general animal disturbance, clinical disease, PSE or DFD meat. Reduced opportunity for pathogen shedding and transmission of infection during transport.	None expected, assuming high standards of transport quality	High (*magnitude depends on duration of transport*), positive
Reduce duration of lairage	Lower probability of aggression, reduction in stress, fatigue, injuries, general animal disturbance, clinical disease, PSE or DFD meat. Reduced opportunity for pathogen shedding and transmission of infection during lairage.	None	High, positive

The welfare of animals is better when the periods of transport and lairage are short. The effects on welfare of a lengthy transport period, and of extending the lairage period, can be severe, especially for pigs where stress is associated with handling, human contact and aggressive interactions.

Consequently, the proposed reduced duration of both transport and lairage will have a substantial positive consequence for the welfare of the animals. In addition, transport may exacerbate existing disease conditions, resulting directly in a worsening of animal welfare as well as in greater potential for disease spread. There is the potential to ignore harmful effects on animals during transportation if the observation of the animals at the slaughter facilities is too short for efficient detection of problems. The time required for ante-mortem inspection is the same whatever the length of lairage.

2.3.1.3. Impact on surveillance and monitoring of pig health and welfare

a. Literature review

Lairage is conducted to provide a reservoir of pigs for the slaughter line. Relevant to pig health and welfare, lairage is known to act as a reservoir of infection by pathogenic bacteria, with longer holding times being associated with increasing risk of cross-contamination (Warriss, 2003). Some authors (Swanenburg et al., 2001, cited by Warriss 2003) concluded that pigs held for two or three hours are less likely to become infected than pigs held for six hours in lairage. Animals may carry some pathogens (e.g. Actinobacillus pleuropneumoniae) without obvious ill effects on their health. However, in times of stress, these organisms can cause disease. However, Hartley et al. (1988; cited by Warriss, 2003) could find no evidence of higher lesion prevalence in pigs held for an average period of 20.5 hours compared with pigs held for 3 hours. A lairage time of 2-3 hours leads to a reduction in skin temperature in live pigs and muscle temperature during the early post-slaughter period (Warriss, 1998, Milligan et al., 1998; cited in Warriss, 2003).

b. Expert opinion

Surveillance and monitoring of pig health and welfare			
POSSIBLE CHANGE	POSITIVE CONSEQUENCES	NEGATIVE CONSEQUENCES	IMPACT (magnitude, direction) *[based on WG opinion]*
Reduced duration of transport	None	Minor reduction in the probability of disease detection	Low, negative
Reduced duration of lairage	None	Minor reduction in the probability of disease detection	Low, negative

A reduction in duration of both transport and lairage, leading to a minor reduction in the probability of disease detection, is likely to have a low, but negative, impact on surveillance and monitoring for pig health and welfare.

> A reduction in the duration of transport and lairage may influence disease detection, with a minor negative impact on surveillance and monitoring for pig health and welfare conditions.

2.3.1.4. Conclusions

> The impact of a reduction in the duration of transport and lairage on pig health and welfare is likely to be high (magnitude depends on duration of transport) and positive. There will be a minor negative impact on animal health and welfare surveillance and monitoring (including early detection of epidemic diseases).

2.3.2. Importance of *ante-mortem* inspection for animal health and welfare

2.3.2.1. Changes proposed

In producing this report, the possibility was considered that removal and/or modification of *ante-mortem* inspection at the slaughterhouse might be proposed. As noted previously, *ante-mortem* inspection is seen by BIOHAZ to be of limited value for protection against food-borne human health hazards.

2.3.2.2. Direct impact on pig health and welfare

The location of *ante-mortem* inspection, either on-farm or at the abattoir is unlikely to substantially influence pig health. Data collected during inspection does allow, when welfare concerns are highlighted, appropriate action to be taken to address problems. However, welfare problems related to transport and lairage will not be detected if the inspection is done only at farm.

2.3.2.3. Impact on surveillance and monitoring of pig health and welfare

a. Literature review

With many animal diseases, infected animals are likely to present clinical signs, detectable either on-farm or during pre-slaughter inspection at the slaughterhouse (Petersen et al., 2002; Schemann et al., 2010). For this reason, *ante-mortem* inspection is an important component of the broader system of pig health and welfare surveillance and monitoring. The foot and mouth disease epidemic in the UK in 2001 was first identified (by authorities) following suspicion of lameness in sows during *ante-mortem* inspection at an abattoir in Essex (Gibbens et al., 2001).

> Ante-mortem inspection is an important component of the broader system of pig health and welfare surveillance and monitoring.

Several studies have investigated the effectiveness of *ante-mortem* inspection of pigs. In a study from Australia, Schemann et al. (2010) noted that effective *ante-mortem* inspection was hampered by several factors, including time constraints, overcrowded conditions, poor lighting, soiled hides, and pig smell and noise. The sensitivity of detection was almost invariably greater when inspection was conducted as animals are moved past an inspector ('in-movement' inspection) versus inspection whilst animals are stationary ('pen-side' inspection), with detection probability of infectious and suspect cases during 'pen-side' inspection being as low as 30 %. Jackowiak et al. (2006) also highlight concerns about detection probability during routine *ante-mortem* inspection, based on results following a comparison of on-farm versus abattoir *ante-mortem* inspection (see below). In a study to assess pen-level prevalence of clinical signs in finishing pigs, Petersen et al. (2004) found that agreement between trained observers was variable, being higher for tail biting and umbilical hernias, but only fair to moderate when identifying pens holding one or more lame pigs. These differences remained, despite training.

> For some infectious conditions, the sensitivity of detection during ante-mortem inspection is low. Nevertheless, *ante-mortem* inspection is essential for identifying specific clinical signs as indicators for diseases important to both human and animal health. A range of factors can hamper detection probability during *ante-mortem* inspection, including time constraints, and inspection conditions. In addition, agreement between trained observers can be quite variable.

Several studies have investigated the impact of location on the quality of *ante-mortem* inspection. In a Dutch study, Harbers et al. (1992c) examined the impact of on-farm preselection of finishing pigs as an aid to meat inspection. The results of this work indicated that this approach offered promise as a means to facilitate (rather than replace) abattoir-based *ante-mortem* inspection by separating pigs prior to slaughter into groups with and without visible lesions. There is an increased probability that the animals will show *post-mortem* abnormalities, if abnormalities were previously identified on-farm. In a later Australian study, Jackowiak et al. (2006) evaluated the efficacy of on-farm *ante-mortem* inspection (detection of high-risk animals, impact on food safety and potential for improvement of animal welfare). The results supported the earlier work by Harbers et al. (1992c), indicating that on-farm inspection may be more effective than abattoir-based *ante-mortem* inspection in identifying some categories of suspect pigs, particularly those with pre-existing locomotor problems that were susceptible to transport injury. The authors concluded that the use of farmer inspections may have benefits for animal welfare and chain efficiency, but not for food safety.

> The scientific literature highlights the potential value of on-farm inspection, but in the context of supplementing, not replacing, abattoir-based ante-mortem inspection. The use of farmer inspections may have benefits for animal welfare and chain efficiency, but not for food safety.

b. Expert opinion

Surveillance and monitoring of pig health and welfare			
POSSIBLE CHANGE	POSITIVE CONSEQUENCES	NEGATIVE CONSEQUENCES	IMPACT (magnitude, direction) *[based on WG opinion]*
On-farm inspection *to replace* abattoir-based *ante-mortem* inspection	May provide additional information about farm-based factors that adversely affect animal health and welfare.	Diseases and welfare conditions relating to transport will not be detected. It may be difficult to establish a harmonized farm-based *ante-mortem* inspection. It may be difficult to achieve independence and quality, given the involvement of para-professionals or farm-associated veterinarians. Consistence of on-farm awareness and compliance may be difficult to achieve.	Medium-high, negative
On-farm inspection *to supplement* abattoir-based *ante-mortem* inspection	May provide additional information about farm-based factors that adversely affect animal health and welfare. Can identify animals at increased risk of injury during transport. Can increase the overall sensitivity of *ante-mortem* inspection. Can contribute to improved chain efficiency.	It may be difficult to establish a harmonized farm-based *ante-mortem* inspection It may be difficult to achieve independence and quality, given the involvement of para-professionals or farm-associated veterinarians. Consistence of on-farm awareness and compliance may be difficult to achieve.	Medium, positive

Currently, *ante-mortem* inspection is conducted when animals are delivered at an abattoir prior to slaughter. If the location of *ante-mortem* inspection were to be altered and conducted on-farm, it is likely this will be conducted by paraprofessionals or farm-associated veterinarians. On-farm inspection would offer an opportunity to gather information about farm-based factors that adversely affect animal health and welfare. Sick animals and animals with impaired welfare could be detected, with the potential to prevent animals being sent to the abattoir that are not fit for slaughter. However, a harmonised system of on-farm *ante-mortem* inspection would be required to ensure consistency, quality and independence of inspection. It is likely that increased resources would be needed, in comparison to *ante-mortem* inspection at the abattoir, to inspect each batch of pigs adequately prior to their departure for slaughter, particularly if this were conducted in the absence of further inspection by an independent and trained veterinarian immediately prior to slaughter. Further, on-farm inspection, by definition, will not allow any assessment of welfare issues caused during transport. As highlighted in the table above, the overall impact of a shift towards on-farm *ante-mortem* inspection will vary, depending on whether on-farm inspection is conducted *as a replacement for* or *as a supplement to* abattoir-based *ante-mortem* inspection.

2.3.2.4. Conclusions

The impact of a potential change in location of ante-mortem inspection on pig health and welfare surveillance and monitoring will vary depending on whether on-farm inspection is intended as a replacement for, or a supplement to, abattoir-based ante-mortem inspection:

- If on-farm inspection is intended *as a replacement*, the change in the location of ante-mortem inspection, from abattoir to on-farm, is likely to have a medium-high and negative impact on surveillance and monitoring.
- If on-farm inspection is intended *as a supplement*, the change is expected to be medium and positive.

In each case, it is assumed that the system of ante-mortem inspection will be harmonised, as well as underpinned by consistency, quality and independence.

2.3.3. Proposed removal of palpation and incision from *post-mortem* inspection

2.3.3.1. Changes proposed

The BIOHAZ Panel proposes omission of palpation and incision during *post-mortem* inspection.

2.3.3.2. Direct impact on pig health and welfare

No impact is envisaged.

2.3.3.3. Impact on surveillance and monitoring of pig health and welfare

a. Literature review

A shift towards visual inspection, without incision and palpation, has been considered in detail previously (for example: Murray, 1986; Hathaway and Richards, 1993, including later discussion on methodologies by Willeberg et al., 1994 and Hathaway and Richards, 1994; Edwards et al., 1997; Mousing et al., 1997; Willeberg et al., 1997; Hamilton et al., 2002). In each of these papers, a number of broad issues were considered, including microbial cross-contamination, resource implications, etc.

In the current review, however, only those results relevant to pig health and welfare surveillance and monitoring were considered further.

Several authors have commented on the initial context of meat inspection. When the traditional meat inspection system was introduced in the late 19th century, its primary focus was the detection of animal diseases then endemic in Europe, including trichinellosis, tuberculosis and taeniasis (Edwards et al., 1997; Mousing et al., 1997; Uzal et al., 2002). Throughout the literature, there is general agreement of the need for system adaptation, focusing on contemporary public health concerns (Willeberg et al., 1994; Sørensen and Petersen, 1999; Pointon et al., 2000), and most research has focused on this issue. There are limited insights, from the available research, on the impact of *post-mortem* inspection changes on pig health and welfare surveillance and monitoring.

> When considering a change from current to proposed modified post-mortem inspection, published research has primarily focused on the impact on public health. Limited insights are available on the impact of this change on pig health and welfare surveillance and monitoring.

Several studies have been conducted comparing the current and modified (visual only) systems of *post-mortem* inspection of slaughter pigs, from Denmark (Mousing et al., 1997; Willeberg et al., 1997), the Netherlands (Harbers et al., 1992b) and Australia (Pointon et al., 2000; Hamilton et al., 2002). In Denmark, current and modified (visual only) meat inspection systems were compared, based on modified (visual only) then current inspection of approximately 183,000 animals during a 6-month period at a single abattoir. In this study, inspectors did not incise or palpate the tissues during modified (visual only) inspection. In comparison to the current system, modified (visual only) procedures were associated with higher non-detection rates in all categories under study, which, of relevance to pig health and welfare surveillance and monitoring, included aesthetic (healed) lesions, active pathological lesions (in both non-edible and edible tissue), and abscesses or pyaemic lesions. In the Netherlands, the sensitivity and specificity of the modified (visual only) and current inspection methods did not differ significantly for most abnormalities, and, in both cases, the sensitivity was relatively low. In addition, the reproducibility of both modified (visual only) and current meat inspection was poor to fair (Cohen's kappa: 0.14-0.64 and 0.24-0.73, respectively). In Australia, Hamilton et al. (2002) compared these two methods during alternate fortnights throughout a 12-month period, for approximately 60,000 pigs in total. Modified (visual only) inspection was deemed to include both routine tasks (visual inspection of head, viscera and carcass) and additional tasks (palpation/incision if warranted, based on visual inspection). The study reported a range of performance criteria, but only some are relevant to pig health and welfare monitoring and surveillance, including apparent non-detection rates for grossly detectable abnormalities (abscesses, arthritis, pleuritis, bursitis and dermatitis) and detection rates for reactive lymph nodes. In agreement with other studies (Mousing et al., 1997; Willeberg et al., 1997), neither system of meat inspection was completely effective in detecting abnormalities. Nonetheless, in comparison with current methods, a modified (visual only) system was associated with significant increases in non-detection rates for some pathologies [abscesses (P=0.045), arthritis (P=0.05) and bursitis (P=0.002)], but not for others (pleuritis, dermatitis, other including scars, blackspot bruising, melanoma, bile stain, fever and wounds). Current methods were also more effective in identifying reactive lymph nodes and modified (visual only) inspection was associated with an increase in non-detection rates for reactive submaxillary and superficial inguinal nodes of 0.31 and 0.03 %, respectively).

Several studies have been conducted comparing the current and visual only systems of pig meat inspection. These studies have focused on organoleptic changes, rather than specific aetiological agents. Therefore, the results are more easily extrapolated to infections that affect one compared with a greater number of organs. Compared with current meat inspection, visual only inspection was associated with higher non-detection rates in a number of condition categories, including aesthetic lesions, active pathological lesions in both non-edible and edible tissue, and abscesses or pyaemic lesions. Differences in some categories tended to disappear if modified (visual only) inspection was supplemented with palpation and incision in response to suspected lesions.

Westhead (1991; cited by Edwards et al., 1997) has indicated that a number of kidney lesions can occur without associated lymph node involvement or surface features, thereby necessitating kidney incision and pelvic mucosa examination. Indeed, it is suggested that kidney incision be increased, to enable better detection of systemic infections (Edwards et al., 1997).

Several studies have been conducted to quantify the effectiveness of current meat inspection. In an assessment of routine inspection methods for porcine cysticercosis in Zambian village pigs, Phiri et al. (2006) highlighted the poor sensitivity of current methods, with tongue palpation and routine meat inspection failing to detect 83.9 % and 61.3 %, respectively, of infected animals. The sensitivity of detection was also low (range 0-76 %) in a study conducted in the Netherlands (Harbers et al., 1992b). Latent class analysis has been used on several occasions to determine the sensitivity and specificity of routine meat inspection of Danish slaughter pigs, in the absence of a gold standard. Using data recorded by both meat inspectors and researchers during routine (current) meat inspection, Bonde et al. (2010) found that the sensitivity of meat inspection (by meat inspectors) was low for many abnormalities (0.24, 0.49 and 0.16 for intestinal, heart and parasitic disorders, respectively) but higher for respiratory disorders (0.92). In an earlier study from Enøe et al. (2003), the estimated sensitivity of current meat inspection in four abattoirs was 28.8 to 61.4 % in 1993-94 and 39.2 to 87.3 % in 1997-98. Bonde et al. (2010) found that specificity was high for all disease complexes, suggesting that meat inspectors may be looking for 'typical cases' before declaring an animal positive.

The reproducibility of both traditional and visual meat inspection was poor to fair. Neither the traditional nor the visual systems are effective in detecting all abnormalities. Indeed, the sensitivity of traditional meat inspection is relatively low for many abnormalities (including intestinal, heart and parasitic disorders), but is higher for respiratory disorders.

b. Expert opinion

Surveillance and monitoring of pig health and welfare			
POSSIBLE CHANGE	POSITIVE CONSEQUENCES	NEGATIVE CONSEQUENCES	IMPACT (magnitude, direction) *[based on WG opinion]*
Omission of palpation	None	Reduced detection likelihood for alterations that change the consistency of organs (including subacute toxic liver damage and interstitial pneumonia)	Low, negative
Omission of incision	None	Reduced detection likelihood for diseases and lesions that occur inside organs and are of small-medium size (that is, small enough not to alter the shape and regular form of organs and tissues). Examples include: Endocarditis (erysipela, staph, strep, others) Lung, liver abscesses Granulomas in lymph nodes and other organs (tuberculosis) Cysticercosis caused by *Taenia solium* Cysticercosis Lung alveolar oedema and scald water will not be detected without incision of trachea and main bronchi.	Medium-high, negative

Omission of palpation and incision may have a variable negative effect on the sensitivity for detection of lesions in organs. If palpation is omitted, the sensitivity of detection of any condition causing slight changes in consistency of organs, without changing colour or morphology, will be reduced. Omission of incision will have the same effect on reducing the sensitivity of detection for those conditions localised in the inner parts of organs (those that are only detectable by incision and visualization of the cut surface. The most probable impact would be in organs like heart, lymph nodes (some early cases of tuberculosis could be localised in a single lymph node), liver, and lungs.

Head (e.g. including submandibular lymph nodes). Abscesses and granulomas may go undetected if affected lymph nodes are not enlarged. There is the potential for reduced sensitivity of detection of tuberculosis (noting, however, that most cases of tuberculosis in pigs also involve the liver, with multifocal granulomas) and bacterial abscesses.

Lungs (e.g. pneumonia: lung abscesses, lung parasites). Major forms of pneumonia would not be affected by omitting palpation and incision, as in most cases there is a sharp change of colour visible at the lung surface. Consistency (palpation) may be necessary for detection of some subacute pneumonia caused by viruses, which do not alter substantially the colour of the organ. Lung oedema and scald water may not be detected without incision of trachea and bronchi.

Heart (e.g. endocarditis, cysticercosis). Omitting incision of the heart will greatly reduce the probability of detection of bacterial endocarditis and *Taenia solium* cysticercosis. Adverse consequences may be high, as endocarditis may be taken as synonymous of bacteraemia. In the case of cysticercosis, meat inspection is the only way of detecting this parasitic infection. There is a very low risk of cysticercosis in Europe in industrialised indoor pork production, but the risk in outdoor pigs may be higher.

Liver (e.g. Ascaris suum*, Echinoccocus, abscesses, other non-specific changes)*. Subacute liver damage is best detected by palpation and/or incision. This is a non-specific lesion, unrelated to infectious agents, resulting from exposure to agents causing hepatocyte injury. It usually causes hardening of the liver. Prevalence of this kind of lesion is probably low. Its significance for public health is uncertain and probably will depend on the nature of the damaging agent. Liver abscesses and granulomas, in low numbers, may be undetected if palpation and incision are omitted.

2.3.3.4. Conclusions

There will be some reduction in detection probability with a shift from the current to the proposed modified (visual only) systems of pig meat inspection. The magnitude of this reduction will vary, depending on the disease/condition. A substantial reduction is likely for conditions (such as *Taenia solium* cysticercosis or early cases of tuberculosis) where pathology is limited to one or a limited number of organs and detection is reliant on palpation and/or incision. For diseases/conditions affecting several organs simultaneously or progressively, however, the impact is likely to be less. By definition, the proposed modified (visual only) inspection will not detect conditions where palpation and/or incision is required for detection. Any adverse impacts would be lessened if palpation and incision are conducted as a follow-up to visual inspection when abnormalities are detected. Neither the current nor proposed (visual only) systems are effective in detecting all abnormalities.

2.3.4. Proposed risk categorisation of pigs and abattoirs

2.3.4.1. Changes proposed

The BIOHAZ Panel proposes the introduction of a differential approach to meat inspection, following risk categorisation of both pigs and abattoirs.

2.3.4.2. Direct impact on pig health and welfare

At this point, it is uncertain whether risk categorisation would lead to increased journey times from farm to slaughter. As highlighted previously (section 2.3.1.2), increased duration of transport will adversely impact on the health and welfare of individual animals.

2.3.4.3. Impact on surveillance and monitoring on pig health and welfare

a. Literature review

The concept of risk-based meat inspection has been raised by several authors, including Edwards et al. (1997). Using this approach, farms (and their animals) are differentiated on the basis of disease risk (Edwards et al., 1997). Work has been undertaken, in several countries, to evaluate the use of farm-level health information for meat inspection purposes. In the Netherlands (Snijders et al., 1989; Harbers et al., 1992a), a study was conducted evaluating the utility of Quality Information Cards (QUIC; capturing data on health and drug use problems) accompanying shipments of pigs to slaughter. Their value was relatively limited, with a low predictive value for abnormalities such as arthritis, liver condemnation and lung lesions. Higher levels of abnormalities were found with shipments with no, or a faulty, QUIC. In Finland, farms are assigned a health classification, based on

a range of criteria including freedom from certain diseases (such as enzootic pneumonia, progressive atrophic rhinitis etc). In a detailed study, however, health classification did not have any effect on the prevalence of whole-carcass condemnations, arthritis or abscesses (Heinonen et al., 2001).

> Farm-level pig health information has been used in several countries for meat inspection purposes. Based on available literature, its value has been limited.

b. Expert opinion

Surveillance and monitoring of pig health and welfare			
POSSIBLE CHANGE	POSITIVE CONSEQUENCES	NEGATIVE CONSEQUENCES	IMPACT (magnitude, direction) *[based on WG opinion]*
Risk categorisation of pigs and abattoirs (*based on public health criteria*)	Implementation of the systems in the abattoir with differential handling of animals based on food chain information may provide opportunity for improved AHAW surveillance. Routine processes will be conducted on all pigs, regardless of risk categorisation.	The slaughter animals may be a biased, rather than a representative, sample of the entire population. With increased movement (which is *a possible outcome of risk categorisation*), there is the potential for increased dissemination of infectious agents.	Medium, positive (*would be less beneficial if there was increased journey time from farm to the abattoir*)

Currently, each carcass is subjected to the same inspection procedure, regardless of origin (Regulation (EC) 854/2004[32]). The meat inspection changes, as proposed by the BIOHAZ Panel, include a suggestion of a differential approach to meat inspection, depending on the risk category assigned to pigs and to the abattoir. Details of these BIOHAZ proposals were available at the very final stage of AHAW assessment, and the following comments are based on the assumption that slaughterhouses are able to manage pigs of different risk profiles. It is envisaged that routine processes would be applied to 'lower-risk' pigs, with 'higher-risk' pigs being subjected to additional process-based controls. Risk categories are yet to be defined by the BIOHAZ Panel, however, it is important to note that these solely relate to the four above-mentioned public health hazards, namely *Yersinia*, *Trichinella*, *Toxoplasma* and *Salmonella*. Since routine processes will be conducted on all pigs, regardless of risk status, it is unlikely that proposed risk categorisation will substantially impact on current levels of quality for animal health and welfare surveillance.

If slaughterhouses are not able to process pigs of differing risk profiles (for example, with lower-risk pigs being consigned to one abattoir and high risk pigs to another), it is probable that pigs would be shipped to abattoirs on the basis of risk, rather than proximity. Such a change would lead to increased journey times from farm to slaughter.

[32] Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption

The proposed changes include a differential approach to meat inspection, depending on the risk category assigned to pigs and to the abattoir. Risk categories have yet to be assigned, but relate solely to public (rather than animal) health hazards, namely *Yersinia*, *Trichinella*, *Toxoplasma* and *Salmonella*. If journey times from farm to slaughter were increased, this would have an adverse impact on the health and welfare of individual animals.

2.3.4.4. Conclusions

Categorisation based on public health risks will likely have medium positive impact on pig health and welfare surveillance. This would be less beneficial if there was increased journey time from farm to the abattoir.

Risk categorisation, based on increased usage of food chain information on pig health and welfare, may provide opportunities for improved surveillance and monitoring. However, it may result in surveillance being conducted on biased samples that are not representative of the entire population with respect to animal health and welfare.

2.4. Quantitative assessment

2.4.1. Methodology

2.4.1.1. Stage 1

A comprehensive list of porcine diseases was developed based on material presented in *Diseases of Swine, 9th edition* (B. Straw, J. Zimmerman, S. D'Allaire, D. Taylor (eds), Blackwell Publishing, 2006). Additional welfare concerns were identified based on expert opinion.

As illustrated in Figure 1, the following steps were used during the filtering process of pig diseases and other welfare conditions:

- Animal diseases (*listed by aetiological diagnosis*):
  - What is the likelihood of detection[33], at ante- and/or post-mortem inspection?
    - [based on expert opinion, only 'high' or 'medium' were considered further]
  - Is the disease of animal health and welfare importance (regardless of zoonotic potential)?
    - [if yes, considered further]
  - Is the disease/condition infectious
    - If yes, is it highly contagious?
      - *If yes,* is it of concern to EU MS*?*
        - *[if yes, retain]*

[33] For affected animals of slaughter age

- *If no, are there other, more effective surveillance tools available?*
  - *[if no, retain]*

- Animal welfare conditions (listed by welfare outcome):
  - A definitive list was initially developed
  - 'Example conditions' were chosen, after considering:
  - The likelihood of detection, at ante- and/or post-mortem inspection [based on expert opinion, only 'high' or 'medium' were considered further]
  - The stages of the meat inspection process (ante- and post-mortem inspection) where detection occurred (see Annex I Table A1)

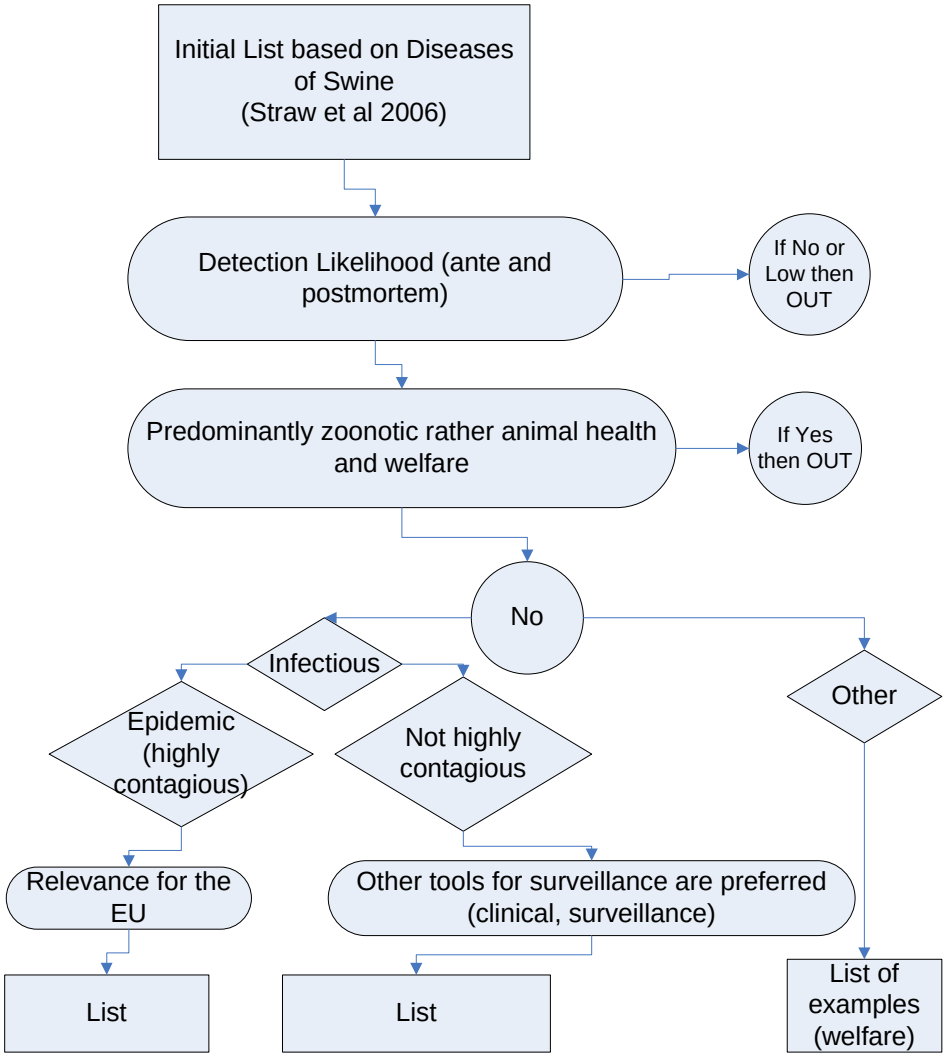


Figure 1: A schema of the filtering process used during Stage 1

2.4.1.2. Stage 2

Detailed generic information about the stage 2 methodology is presented in Appendices A and B. The methodology was adapted for use with pigs, as outlined in the accompanying COMISURV report[34]. A brief outline is included below.

a. A typical case

The quantitative assessment was undertaken with a focus on typical cases. These cases included animals considered fit to travel to the slaughterhouse but with later-stage disease, presenting a broad range of clinical signs and associated pathology. To illustrate, the following case definition for classical swine fever (CSF) was used (see COMISURV report):

> *The typical case of CSF was assumed to present itself at ante mortem inspection with apathy, dyspnoea, signs of hyperaemia and haemorrhage on the skin, signs of diarrhoea, signs of fever, conjunctivitis and non-specific central nervous system signs such as ataxia or convulsion. The typical case of CSF was assumed to present itself at post mortem inspection with swollen, blood-shot lymph nodes, congested kidneys and petechial bleeding in various organs and tissues (i.e. fat tissue, pleura, lung, epicardium, peritoneum, mucosa of the throat, trachea, stomach and bladder).*

For each disease/condition of interest, typical cases are a small subset of all cases (animals either infected [for diseases] or affected [for welfare conditions]). As illustrated in the COMISURV report , all infected/affected cases can be subdivided into those either detectable or not during routine meat inspection (that is, during ante- and/or post-mortem inspection), with detectable cases being further subdivided into typical and non-typical cases; the latter would primarily include early cases. Relevant definitions are presented in the Glossary.

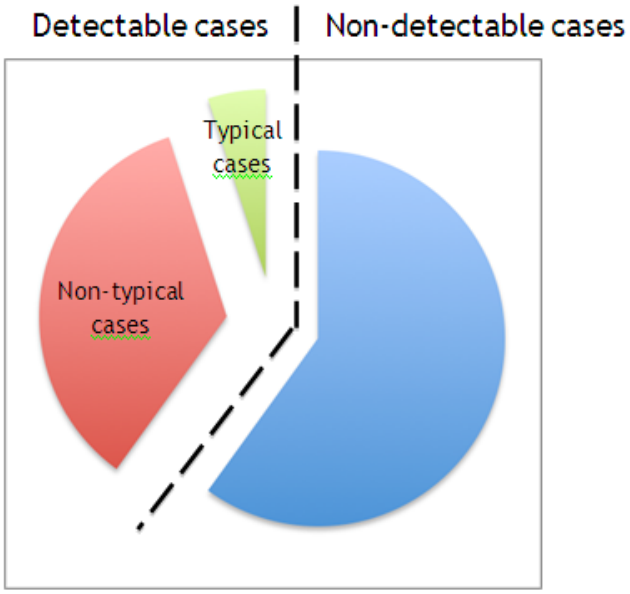


Figure 2: Detectable and non-detectable cases

[34] External scientific report: Contribution of meat inspection to animal health surveillance in swine. Available at www.efsa.europa.eu

The quantitative assessment focuses on typical cases, essentially animals with later-stage disease (presenting a broad range of clinical signs and associated pathology). Typical cases are only a subset of all cases that might be present during meat inspection.

b. Data collection

Elicitation of expert opinion

Data on the parameters needed for the stage 2 model were obtained primarily through elicitation of expert opinion. Experts were selected on the basis of their professional expertise in meat inspection in relation to the pig production chain in Europe. A protocol based on a modified Delphi technique (Hecht, 1977; Hsu, 2007; Knol, 2010) was developed, consisting of five steps: (i) questionnaire development; (ii) first elicitation round; (iii) data collation; (iv) second elicitation round; and (v) final estimates.

Questionnaire development

A case definition was developed for each disease/condition, based on a typical case. The outline of the questionnaire was the ante- and *post-mortem* inspection procedures for swine as defined under the Regulation (EC) 854/2004 currently implemented in European Union Member States (see COMISURV report Annex B). The different inspection tasks that make up the full inspection were considered individually:

- *Ante-mortem inspection* was considered to consist of visual inspection when animals are unloaded from vehicles, and inspection of the animals in the lairage ("Live animal" in Annex B of COMISURV report), and the information provided by the farmer regarding the disease status gathered in the Food Chain Information (FCI).
- *Post-mortem inspection* procedures were divided into carcass inspection, organ inspection and tissue inspection as defined by the legislation (Regulation (EC) 854/2004). For each of these, a list of one or more inspection tasks was included, with their current mode of inspection (i.e. visual inspection, palpation and/or incision with a knife) (Table 1). Furthermore, evaluation of visual *post-mortem* inspection as an alternative mode of inspection was included for those inspection tasks that currently include palpation and/or incision, in order to assess the effect of changes in *post-mortem* inspection proposed by the EFSA BIOHAZ Panel.

During stage 2 modelling, data collection relied on the opinion of experts, selected on the basis of their professional expertise in meat inspection in relation to the pig production chain in Europe. A questionnaire was used to gather data relevant to ante-mortem inspection and to relevant inspection tasks during post-mortem inspection.

The final questionnaire contained 7 questions for each of the 16 conditions/diseases. An assessment of the prevalence of typical cases was sought, as well as a qualitative assessment of the expected direction of any change in occurrence of typical cases (more/fewer) in younger and older age groups (i.e. suckling pigs and sows). The experts were asked to provide most likely, minimum and maximum estimates for the probability of detection of symptoms associated with the disease/condition at individual inspection tasks using current meat inspection practices. For inspection steps, where the

current practices include incision and/or palpation, the probability of detection using visual inspection only was also elicited. In addition, the experts were asked to assess qualitatively the impact on their estimates if the animals considered would be younger or older (i.e. suckling pigs and sows). Finally, experts were consulted on the frequency of subclinical cases that they would expect. Elicitation was conducted over several rounds.

Table 1: List of ante-mortem and post-mortem inspection tasks in swine according to Regulation (EC) 854/2004 (Conventional) and according to a change in procedures leading to a procedure primarily based on visual inspection (Visual-only). (V= visual inspection; I= incision; P= palpation). Grey lines indicate inspection points where the visual-only scenario implies a change to current procedures.

Inspection step			Inspection procedure	
			Conventional	**Visual-only**
***ANTE-MORTEM* INSPECTION**	FOOD CHAIN INFORMATION	Diseases, morbidity and mortality on farm	V	V
	LIVE ANIMAL	General health	V	V
POST - MORTEM INSPECTION	WHOLE CARCASS	External surface	V	V
	HEAD	Head, mouth, throat, etc.	V	V
		Submaxillary LNN	I	-[1]
		Tongue	V	V
	LUNGS	Parenchyma	V+P+I[2]	V
		Trachea	V+I[2], V[3]	V
		Major bronchi	I[2]	-[1]
		Mediastinal LNN	P	-[1]
		Bronchial LNN	P	-[1]
	OESOPHAGUS		V	V
	HEART	Heart	V+I	V
		Pericardium	V	V
	DIAPHRAGM		V	V
	LIVER	Parenchyma	V+P	V
		Hepatic LNN (=portal)	V+P	V
		Pancreatic LNN	V	V
	GI TRACT	Stomach and intestines	V	V
		Mesentery	V	V
		Gastric LNN	V+P	V
		Mesenteric LNN	V+P	V
	SPLEEN		V	V
	KIDNEYS	Parenchyma	V	V
	UTERUS and MAMMARY GLANDS	Uterus	V	V
		Udder	V	V
		Supramammary LNN	V+I[3]	V
	PLEURA		V	V
	PERITONEUM		V	V
	UMBILICAL AREA		V+P[4]	V
	JOINTS		V+P[4]	V

[1]Visual inspection deemed impossible for the inspection point in question; [2]If organs are destined for human consumption; [3]Sows only; [4]Suckling animals only

c. Adaptation and implementation of the generic meat inspection system model

A quantitative stochastic model was developed for each of the sixteen diseases/conditions considered in stage 2, in order to assess the sensitivity of ante- and *post-mortem* inspection procedures for each pig diseases and welfare conditions. The models followed the structure given in Table 1 and considered both the current and visual-only inspection scenarios. The methodology relating to model structure, inputs and implementation is presented in the accompanying COMISURV report. Model outputs include:

- *detection probability for typical cases*, and,
- an approximation of detection probability for *detectable cases*, based on calculation of a weighted value, being the @Risk mode output for typical cases multiplied by the estimates of the proportion of typical cases. Using this approach, all non-typical cases were assumed to have a probability of detection equal to zero. Consequently, with this interpretation the figures should be regarded as being conservative.

> The purpose of the stage 2 model for pigs was, for each of the 16 diseases/conditions, *to estimate the probability of detection of typical cases* through ante- and post-mortem inspection at the unit (animal) level. An approximation of detection probability for a detectable case was also calculated.

The results of the model provide the probability of a typical case being detected (as defined by the experts) at various stages of the meat inspection procedure. It is important that this probability estimate is not confused with the unit sensitivity of the surveillance system (the probability that an infected animal in the population would be identified and result in an official notification). Factors contributing to the official notification of disease include, among others, the probability that a diseased animal will be sent to slaughter, the probability that an infected animal displays clinical signs, or the probability of diagnostic tests being used and the probability of detection an infected animal. In this study, only the probability that an infected animal would be recognised as abnormal during meat inspection was estimated.

> The results of the stage 2 model provide the probability of a typical case being detected at various stages of the meat inspection procedure. This probability is not equivalent to the unit sensitivity of the surveillance system.

2.4.1.3. Stage 3

Five exotic diseases in pigs were selected for inclusion in stage 3 modelling. Detailed information about the model structure, inputs and implementation, and calculations of the sensitivity of the overall surveillance system are presented in detail in the accompanying COMISURV report.

2.4.2. Results and discussion

2.4.2.1. Stage 1

Detailed information about the outputs from the stage 1 screening is presented in *Annex I.* In summary, the following diseases and other welfare conditions were identified during stage 1 (for stage 2 modelling):

a. Highly infectious diseases (5)

- African swine fever
- Classical swine fever
- Foot and mouth disease
- Swine vesicular disease
- Vesicular stomatitis

b. Other diseases/conditions (6)

- Enzootic pneumonias (*Mycoplasma* spp., *Pasteurella* spp.)
- The pleuropneumonias (*Actinobacillus pleuropneumonia*, *A. suis*)
- Atrophic rhinitis
- *Arcanobacterium pyogenes*
- *Ascaris suum*
- Tuberculosis

c. Other welfare conditions (5)

- Arthritis and bursitis
- Bruising and skin lesions
- Dark Firm Dry (DFD) meat
- Lameness
- Tail biting

A total of 16 diseases/conditions were selected for stage 2 modelling.

2.4.2.2. Stage 2

Detailed information about the stage 2 modelling results is presented in the accompanying COMISURV report.

a. Proportion of typical cases

Among the 11 diseases/conditions of an infectious nature, the estimated proportion of detectable, typical and non-typical cases is presented in Table 2:

Table 2: Percentage of detectable, typical and non-typical cases by disease/condition, based on expert opinion

Diseases and conditions	Of all cases, % detectable	Of all detectable cases:	
		% typical cases	% non-typical cases
Classical Swine Fever (CSF)	35[a]	50[a]	50[a]
African Swine Fever (ASF)	90	55	45
Foot and Mouth Disease (FMD)	60	35	65
Swine Vesicular Disease (SVD)	30	30	70
Vesicular Stomatitis (VS)	30	10	90
Pneumonia	40	80	20
Pleuropneumonia	70	65	35
Arcanobacterium pyogenes	60	50	50
Ascaris suum	30	20	80
Atrophic Rhinitis	70	60	40
Tuberculosis (TB)	40	60	40

a. That is, of 100 CSF-infected pigs sent for slaughter, based on expert opinion, it is estimated that 35 would be detectable and 65 non-detectable. Of the 35 detectable cases, 50 % were estimated to present as typical cases and 50 % as non-typical cases.

Typical cases represent only a subset of all cases detectable during meat inspection.

b. Detection probability (for typical cases, for non-typical cases, for detectable cases)

Typical cases

Table 4 presents the output from the stage 2 modelling for typical cases, being the overall probability of detection during *ante-* and *post-mortem* inspection. For each of the diseases/conditions under investigation, the results from expert opinion indicated that detection probability was very high. Further, for most diseases/conditions, the experts did not anticipate any changes in detection probability as a result of changing from conventional to proposed modified (visual only) inspection (Table 4). For several tasks and conditions, experts assumed a 'visual only' approach to meat inspection to be slightly more sensitive as there would be more time available to conduct this task when palpation and/or incision did not have to be carried out.

The detection probability at individual inspection steps, for both the current and proposed modified (visual only) methods, is presented in Table 5. This table only includes those inspection steps where change would occur, as a consequence of the shift from the current to the proposed modified method. Based on these results, there was limited change in detection probability with a shift to a visual only approach. It should be noted that detection probability will drop to zero at several inspection tasks where inspection is currently solely reliant on palpation and/or incision. These include incision of the submaxillary lymph nodes and major bronchi, as well as palpation of the mediastinal and bronchial lymph nodes. Diseases in which lesions may be restricted to these inspection points (at some stage of the infection) will have a reduced probability of detection.

> For typical cases of a range of diseases/conditions, detection probability is very high during a*nte-* and *post-mortem* inspection. These results are based on expert opinion. The experts do not anticipate any substantive changes in detection probability as a result of changing from conventional to proposed modified (visual only) inspection.

Non-typical cases

Based on expert opinion, non-typical cases would likely be mild, expressing only a subset of the full range of abnormalities exhibited by a typical case. *Ante mortem* inspection and the inspection of the whole carcass/skin were considered to be most critical to detect early cases. For many diseases/conditions, the experts stated that early cases would not be detectable by either current or proposed modified (visual only) meat inspection. Detection probabilities with visual only inspection will therefore generally be lower in early cases, but will not differ from the values achieved with current meat inspection practices.

> *Ante mortem* inspection and the inspection of the whole carcass/skin were considered to be most critical to detect early cases. For many diseases/conditions, early cases would not be detectable by either current or proposed modified (visual only) meat inspection.

All detectable cases (typical and non-typical)

In comparison to typical cases, much lower detection probabilities were calculated when considering detectable cases (Table 4). As highlighted previously, these estimates were conservative, noting the assumption (for the purposes of the weighting calculations) of a detection probability of zero among the non-typical cases. As with the typical cases, for most diseases/conditions, the experts did not anticipate any changes in detection probability as a result of changing from conventional to proposed modified (visual only) inspection. Any suspicious lesions detected during visual inspection would be clarified by further examination (including palpation and incision).

> In comparison to typical cases, much lower detection probabilities were calculated, when considering detectable cases, both for current and proposed modified (visual only) meat inspection systems.

c. Detection probability, the impact of age

The impact of age (for suckling pigs and sows, i.e. the younger and older age groups of pigs), relative to pigs at normal slaughter age, on the proportion of typical cases in a batch of 100 % infected animals and on the probability of detection at meat inspection was also elicited from the experts (Table 3). The assessment was qualitative, since the experts were only asked to indicate if there would be more or fewer typical cases, and if it would be more or less likely to detect them. The results indicated a very limited effect of age on detection probability for epidemic diseases. For non-epidemic diseases, cases of pleuropneumonia, atrophic rhinitis, *Ascaris suum* and tuberculosis in suckling pigs were either considered less typical or had a lower probability of detection, whereas the opposite was seen for sows with atrophic rhinitis and tuberculosis. Also, for welfare conditions, an effect of age was seen with arthritis/bursitis as well as tail biting, with the former being less, and the latter being

more likely to be seen/detected in younger pigs. For both these conditions, the relationship was assessed to be the opposite for sows.

> For epidemic diseases, there is a very limited effect of age on detection probability. For endemic diseases and welfare conditions, detection probability is likely to be less in younger pigs and greater in older pigs, in comparison with slaughter age pigs.

Table 3: Impact of age, relative to pigs at normal slaughter age, on the percentage of typical cases in a batch of infected animals and on the probability of detection at meat inspection, for sixteen diseases/conditions considered in an expert assessment of the contribution of meat inspection to animal health surveillance.

Disease/Condition	Sucklers		Sows	
	% typical cases	P(detection)	% typical cases	P(detection)
Classical Swine Fever	More	-[a]	-	-
African Swine Fever	-	-	-	-
Foot and Mouth Disease	-	-	-	-
Swine Vesicular Disease	-	-	-	-
Vesicular Stomatitis	-	-	-	-
Pneumonia	More	-	-	-
Pleuropneumonia	Fewer	-	-	-
Arcanobacterium pyogenes	-	-	-	-
Ascaris sum	More	Less likely	Fewer	-
Atrophic Rhinitis	-	Less likely	-	More likely
Tuberculosis	Fewer	-	More	More likely
Lameness	-	-	-	-
Arthritis and Bursitis	Fewer	Less likely	More	More likely
Tail Biting/Tail Amputation	More	More likely	Fewer	-
Bruising and Skin lesions	Fewer	-	-	-
Dark, Firm and Dry Meat	-	-	-	More likely

a. '-' indicates no change in the frequency or probability of detection relative to estimates for pigs of normal slaughter age.

d. Methodological issues and points of caution

It is important to consider these results within the context within which the modelling was conducted:

- *There remains uncertainty regarding the input variables*, which were derived from expert opinion.
- *Certain standards in meat inspection practice were assumed*, including:
  - all inspection tasks were performed as required by current legislation (Regulation (EC) 854/2004),
  - that inspection was performed by fully trained Official Veterinarians (OVs) and/or Meat Inspectors (MIs) with sufficient knowledge of infectious, non-infectious diseases and welfare conditions in animals, and
  - these were performed in an adequate environment (i.e. good lighting, adequate speed of slaughter line to perform inspection, good facilities).

- *The study assumes independence between each inspection task*. The validity of this assumption depends on the procedures in place within different abattoirs. For some abattoirs, separate meat inspectors are responsible for each individual step, and are not provided with any prior information about the findings of other meat inspectors. In this situation, each probability may be thought to be completely independent. In smaller abattoirs, a single inspector may be responsible for multiple inspection points, in which case observations are unlikely to be independent.
- *The expected number of inspection tasks at which abnormalities are detected will have an impact on model outputs*. For a disease in which the typical case exhibits abnormalities at a large number of detection points, the overall sensitivity of detection will be higher than for a disease with abnormalities at fewer detection points. For example, some welfare conditions, such as lameness, can only be detected at *ante-mortem* inspection (a single point), but are very easily detected (relatively high sensitivity at this inspection point). The result of this phenomenon is that diseases that may be intuitively considered to be difficult to detect may have a higher estimated overall sensitivity than those that are considered easier to detect.
- *The results of the model provide the detection probability for a typical case*, as defined previously. However, typical cases represent only a subset of all infected/affected animals, with this proportion depending on factors such as the pathogenicity of the strain involved in infectious diseases and the degree of welfare issues in a holding. Detection probability will be lower with non-typical (early and milder) cases. However, it should be noted that inspection tasks where visual inspection is not possible will be completely eliminated in a visual-only scenario. These include incision of the submaxillary lymph nodes and major bronchi, as well as palpation of the mediastinal and bronchial lymph nodes. Consequently, diseases where lesions are restricted to these inspection points have either substantially reduced probability of detection, or will not be detected at all. The most severe cases will not reach the slaughterhouse, as they will not be fit to travel.
- *Detection of typical pathological signs is only the first step in raising an alarm*. A high awareness of meat inspectors is likely to be an important factor influencing overall sensitivity of the meat inspection system, regardless of the probability of detection at individual inspection tasks.
- Although most values are high, *this does not directly imply that the cases will be notified*. The results only indicate the probability that a suitably trained and experienced meat inspector will observe the lesions, as described in the case definitions. Whether this will lead to a suspicion and subsequent notification will depend on other factors such as disease awareness. Also, the proportion of typical cases among all animal cases (detectable and non-detectable) will depend on factors such as the pathogenicity of the strain involved in infectious diseases, or the degree of welfare issues in a holding. If cases are milder, the probability of detection is lower.

A range of methodological issues and points of caution were raised:

- There remains uncertainty regarding the input variables,
- Certain standards in meat inspection were assumed,
- The study assumes independence between each inspection task,
- The expected number of inspection tasks at which abnormalities are detected will have an impact on model outputs,
- The model focuses on a typical case, noting that these represent only a subset of all infected animals,
- Detection of typical pathological signs is only the first step in raising an alarm, and,
- A high detection probability does not directly infer that cases will be notified.

2.4.2.3. Stage 3

As highlighted previously, stage 3 modelling is only justified following the detection of a substantial change in detection probability, when comparing the current and proposed modified (visual only) systems of meat inspection. During the stage 2 modelling, however, no substantial changes were observed. For this reason, stage 3 modelling was not considered further with pigs.

It should be noted, however, that the theoretical structure is presented in the accompanying COMISURV report, and could be used further by Member States interested in evaluating the performance of their surveillance systems in pigs.

Stage 3 modelling was not conducted in pigs. However, the theoretical structure of stage 3 modelling is available, and could be used by Member States that wish to evaluate the performance of their surveillance systems in pigs.

2.5. Reflection on the qualitative and quantitative results

The results of the qualitative and quantitative assessments are not directly comparable. One component of the qualitative assessment (the review of the literature) focuses on organoleptic changes, rather than specific aetiological agents. Therefore, the results are more easily extrapolated to single-system diseases (those generally affecting one or a small number of organs) rather than multi-systemic diseases (where many organs may be affected). In contrast, another component of the qualitative assessments (expert opinion) and the quantitative assessment is that each provides insights into a number of defined diseases/conditions, which generally affect several organs. The quantitative assessment also focuses principally on typical cases.

The following conclusions can be drawn, after assimilating the results from the two assessments:

- During current systems of meat inspection, the probability of detection is often low, particularly for non-typical cases. Detection probability is substantially higher with typical cases. It is also higher for respiratory disorders in comparison to intestinal, heart and parasitic disorders.
- Typical cases represent only a subset of all detectable cases, for any disease/condition.
- Neither the traditional nor the proposed modified (visual only) systems of meat inspection are effective in detecting all abnormalities.

- There will be some reduction in detection probability with a shift from the current to the proposed modified (visual only) system of pig meat inspection. The magnitude of this difference will vary, depending on the disease/condition:
  - For typical cases of multi-systemic diseases, the difference is likely to be minimal.
  - For early cases of a range of diseases, the difference may be substantial.
  - For conditions (such as *Taenia solium* cysticercosis or early cases of tuberculosis) where pathology is limited to one or a small number of systems with detection reliant on palpation and/or incision, there will be either a substantially reduced probability of detection or the disease will not be detected at all.
- By definition, the proposed modified (visual only) inspection will not detect conditions where palpation and/or incision is required for detection. Detection probability for the proposed modified (visual only) system of meat inspection would increase if palpation and/or incision is conducted as a follow-up to visual inspection when abnormalities are detected.
- *Ante-mortem* inspection is an important component of the meat inspection system for animal health and welfare surveillance and monitoring, particularly in the detection of early cases.

The qualitative and quantitative results are generally comparable. During current systems of meat inspection, the probability of detection is often low, particularly for non-typical cases. There will be some reduction in detection probability with a shift to the proposed modified (visual only) systems of pig meat inspection, however, the magnitude of this difference will vary, depending on the disease/condition. For typical cases of multi-systemic diseases, this difference is likely to be minimal. With the proposed modified system, detection probability would increase if palpation and/or incision were conducted as a follow-up to visual inspection when abnormalities are detected. Ante-mortem inspection is an important component of the meat inspection system, particularly in the detection of early cases.

Table 4: Detection probability (mode, 5th and 95th percentiles) for 16 diseases/conditions, based on the results of stage 2 modelling. The detection probabilities are presented separately for ante- and post-mortem inspection, and for the latter by case (typical or detectable) and inspection method (current method, proposed modified method based on visual only). The detection probabilities for detectable cases (of which typical cases are a subset) was calculated using weighted values, calculated based on the probabilities obtained through @Risk models and the estimates obtained by expert elicitation of the proportion of typical cases in a batch of 100 % infected animals sent for slaughter.

Diseases and conditions		*Ante-Mortem*	*Post-Mortem* inspection			
			Typical case		Detectable case	
			Current system	Proposed modified system (visual only)	Current system	Proposed modified system (visual only)
Exotic diseases	Classical Swine Fever (CSF)	0.74 (0.59; 0.81)	1.00 (1.00; 1.00)	1.00 (1.00; 1.00)	0.50	0.50
	African Swine Fever (ASF)	0.70 (52; 0.77)	1.00 (1.00; 1.00)	1.00 (1.00; 1.00)	0.55	0.55
	Foot and Mouth Disease (FMD)	0.72 (0.50; 0.78)	1.00 (1.00; 1.00)	1.00 (1.00; 1.00)	0.35	0.35
	Swine Vesicular Disease (SVD)	0.67 (0.54; 0.72)	1.00 (1.00; 1.00)	1.0000 (1.00; 1.00)	0.30	0.30
	Vesicular Stomatitis (VS)	0.34 (0.21; 0.39)	0.93 (0.91; 0.96)	0.89 (0.85; 0.92)	0.09	0.09
Endemic diseases	Pneumonia	0.59 (0.50; 0.71)	1.00 (1.00; 1.00)	1.00 (1.00; 1.00)	0.80	0.80
	Pleuropneumonia	0.75 (0.63; 0.79)	1.00 (1.00; 1.00)	1.00 (1.00; 1.00)	0.65	0.65
	Arcanobacterium pyogenes	0.75 (0.63; 0.88)	0.82 (0.73; 0.91)	0.86 (0.72; 0.90)	0.41	0.42
	Ascaris suum	0.82 (0.71; 0.90)	0.97 (0.96; 0.98)	0.98 (0.97; 0.99)	0.19	0.20
	Atrophic Rhinitis	0.90 (0.83; 0.94)	1.00 (1.00; 1.00)	1.00 (1.00; 1.00)	0.60	0.60
	Tuberculosis (TB)	0.34 (0.26; 0.43)	1.00 (1.00; 1.00)	1.00 (1.00; 1.00)	0.60	0.60
Welfare conditions	Lameness	0.87 (0.72; 0.93)	0.69 (0.55, 0.83)	0.71 (0.52; 0.82)	0.48	0.50
	Arthritis and Bursitis	0.81 (0.67; 0.86)	0.71 (0.55; 0.79)	0.68 (0.54; 0.79)	0.36	0.34
	Tail Biting/Tail Amputation	0.86 ().67; 0.93)	0.71 (0.50; 0.84)	0.71 (0.56; 0.86)	0.50	0.50
	Bruising and Skin lesions	0.89 (0.81; 0.94)	0.86 (0.76; 0.90)	0.84 (0.75; 0.89)	0.60	0.59
	Dark, Firm and Dry (DFD) Meat	0.02 (0.01; 0.03)	1.00 (0.99; 1.00)	0.99 (0.98; 0.99)	0.45	0.45

Table 5: Detection probabilities at each of a series of *post-mortem* inspection tasks, based on the current (according to Regulation (EC) 854/2004) and proposed modified (visual only) systems of meat inspection, by disease/condition for pigs of slaughter age. The table only includes those inspection steps where change would occur, as a consequence of the shift from the current to the proposed modified (visual only) method. I= incision; P= palpation; V= visual.

Inspection tasks		**Diseases and conditions**										
		Epidemic					**Non-epidemic**					
		CSF	ASF	FMD	SVD	VS	Pneumonia	Pleuro-pneumonia	*Arcanobacterium pyogenes*	*Ascaris suum*	Atrophic rhinitis	TB
HEAD	Submaxillary lymph nodes *I (V)*	0.72 (*)	0.72 (*)	0.78 (*)	0.70 (*)	0.05 (*)	0.50 (*)	0.50 (*)	0.01 (*)	0.01 (*)	0.20 (*)	0.32 (*)
LUNGS	Parenchyma *V+P+I (V)*	0.78 (0.78)	0.78 (0.78)	0.33 (0.33)	0.70 (0.70)	0.05 (0.05)	0.50 (0.75)	0.50 (0.75)	0.01 (0.01)	0.01 (0.01)	0.68 (0.68)	0.48 (0.48)
	Trachea *V+I (V)*	0.78 (0.78)	0.78 (0.78)	0.67 (0.67)	0.70 (0.70)	0.05 (0.05)	0.60 (0.60)	0.60 (0.60)	0.01 (0.01)	0.01 (0.01)	0.58 (0.58)	0.48 (0.48)
	Major bronchi *I (V)*	0.78 (*)	0.78 (*)	0.67 (*)	0.70 (*)	0.05 (*)	0.60 (*)	0.78 (*)	0.01 (*)	0.01 (*)	0.58 (*)	0.58 (*)
	Mediastinal lymph nodes *P (V)*	0.78 (*)	0.78 (*)	0.67 (*)	0.70 (*)	0.05 (*)	0.60 (*)	0.78 (*)	0.01 (*)	0.01 (*)	0.58 (*)	0.78 (*)
	Bronchial lymph nodes *P (V)*	0.78 (*)	0.78 (*)	0.67 (*)	0.70 (*)	0.05 (*)	0.60 (*)	0.78 (*)	0.01 (*)	0.01 (*)	0.58 (*)	0.78 (*)
HEART	Heart *V+I (V)*	0.78 (0.78)	0.78 (0.78)	0.67 (0.67)	0.60 (0.60)	0.05 (0.05)	0.60 (0.60)	0.60 (0.60)	0.01 (0.01)	0.01 (0.01)	0.33 (0.33)	0.20 (0.20)
LIVER	Parenchyma *V+P (V)*	0.78 (0.78)	0.78 (0.85)	0.67 (0.67)	0.60 (0.60)	0.05 (0.05)	0.50 (0.50)	0.50 (0.50)	0.01 (0.01)	0.52 (0.68)	0.33 (0.33)	0.48 (0.48)
	Hepatic lymph nodes (=portal) *V+P (V)*	0.79 (0.80)	0.80 (0.80)	0.33 (0.33)	0.60 (0.60)	0.05 (0.05)	0.50 (0.50)	0.50 (0.50)	0.01 (0.01)	0.70 (0.70)	0.33 (0.33)	0.48 (0.48)
GI TRACT	Gastric lymph nodes *V+P (V)*	0.80 (0.80)	0.80 (0.80)	0.33 (0.33)	0.50 (0.50)	0.05 (0.05)	0.20 (0.20)	0.20 (0.20)	0.01 (0.01)	0.01 (0.01)	0.30 (0.30)	0.48 (0.48)
	Mesenteric lymph nodes *V+P (V)*	0.80 (0.80)	0.80 (0.80)	0.33 (0.33)	0.50 (0.50)	0.05 (0.05)	0.20 (0.20)	0.20 (0.20)	0.01 (0.01)	0.01 (0.01)	0.30 (0.30)	0.48 (0.48)
MAMMARY GLANDS	Supramammary lymph nodes *V+I (V)*	0.58 (0.58)	0.58 (0.58)	0.33 (0.33)	0.50 (0.50)	0.05 (0.05)	0.10 (0.10)	0.10 (0.10)	0.01 (0.01)	0.01 (0.01)	0.30 (0.30)	0.47 (0.47)
UMBILICAL AREA	Umbilical area *V+P (V)*	0.58 (0.58)	0.58 (0.58)	0.60 (0.60)	0.50 (0.50)	0.05 (0.05)	0.10 (0.10)	0.10 (0.10)	0.01 (0.01)	0.01 (0.01)	0.19 (0.19)	0.47 (0.47)
JOINTS	Joints *V+P (V)*	0.58 (0.58)	0.58 (0.58)	0.60 (0.60)	0.50 (0.50)	0.05 (0.05)	0.10 (0.10)	0.10 (0.10)	0.77 (0.75)	0.01 (0.01)	0.19 (0.19)	0.47 (0.47)

* Estimates for the proposed modified (visual only) system were not elicited from experts for these inspection steps.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

Meat inspection

- Meat inspection, both ante- and *post-mortem*, is a key component of the overall surveillance system for pig health and welfare.
- There have been several occasions within the EU where outbreaks of epidemic diseases have first been detected during meat inspection.
- Pig health and welfare surveillance information is currently being greatly underutilised.
- The sensitivity of detection of welfare conditions for the purposes of case-finding will generally be higher during abattoir surveillance in comparison to passive farmer reporting.
- The use of welfare-outcome indicators at the slaughterhouse is valuable for monitoring welfare on-farm and during transport and pre-slaughter handling.

On the proposed modifications (as per terms of references 3 and 4)

- By definition, the proposed modified (visual only) inspection will not detect conditions where palpation and/or incision are required for detection.
- There will be some reduction in detection probability with a shift from the current to the proposed modified (visual only) systems of pig meat inspection. The magnitude of this difference will vary, depending on the disease/condition:
  - For typical cases of diseases/conditions that generally affect several organs, the difference is likely to be minimal.
  - For early cases of a range of diseases, the difference may be substantial.
  - For conditions (such as *Taenia solium* cysticercosis or early cases of tuberculosis) where pathology is limited to one or a small number of organs with detection reliant on palpation and/or incision, there will be either a substantially reduced probability of detection or the disease will not be detected at all .
- Transport-related welfare cases would not be detected if abattoir-based *ante-mortem* inspection were removed.
- To mitigate the reduced disease/condition detection probability of the proposed modified (visual only) system, it is emphasised that palpation and/or incision should be conducted as a follow-up to visual inspection whenever relevant abnormalities are seen.
- A shortening of transport and lairage would improve pig welfare, without adversely affecting pig health, based on the assumption that transport quality is equivalent.

Current and proposed meat inspection

- The sensitivity of both the current and the proposed modified component of the surveillance systems is low.
- The role of meat inspection for early detection of epidemic diseases of pigs is well-recognised. Its potential role in surveillance of welfare and endemic disease of pigs (with case-finding and estimating prevalence) is equally important.

- Risk categorisation, based on increased usage of food chain information on pig health and welfare, may provide opportunities for improved surveillance and monitoring. However, risk categorisation may result in surveillance being conducted on biased samples that are not representative of the entire population with respect to animal health and welfare.
- Categorisation based on food-borne human health risks will likely have medium positive impact on pig health and welfare surveillance. This would be less beneficial if journey times from the farm to the abattoir were increased.

RECOMMENDATIONS

- There should be an assessment of the relative contribution of meat inspection to the overall system of surveillance and monitoring of pig health and welfare.
- There should be a critical evaluation of the efficiency and utility of risk-based approaches to meat inspection of pigs, using risk categorisation from the perspective of pig health and welfare.
- There should be development and application of standards (including indicators of welfare outcomes and major endemic diseases) to enable ongoing evaluation of the quality of pig health and welfare surveillance during meat inspection.
- Options should be examined to better utilise existing abattoir data and records on pig health and welfare.

REFERENCES

Bonde M, Toft N, Thomsen PT and Sørensen JT, 2010. Evaluation of sensitivity and specificity of routine meat inspection of Danish slaughter pigs using Latent Class Analysis. Preventive Veterinary Medicine, 94, 165-169.

Broom DM, 2006. Behaviour and welfare in relation to pathology. Applied Animal Behaviour Science, 97, 71-83.

Cameron AR, and Baldock FC, 1998a. A new probability formula for surveys to substantiate freedom from disease. Preventive Veterinary Medicine, 34, 1-17.

Cameron AR and Baldock FC, 1998b. Two-stage sampling in surveys to substantiate freedom from disease. Preventive Veterinary Medicine, 34, 19-30.

Cockram MS, Baxter EM, Smith LA, Bell S, Howard CM, Prescott RJ and Mitchell MA, 2004. Effect of driver behaviour, driving events and road type on the stability and resting behaviour of sheep in transit. Animal Science, 79(1), 165-176.

Edwards DS, Johnston AM and Mead GC, 1997. Meat inspection: an overview of present practices and future trends. The Veterinary Journal, 154, 135-147.

EFSA (European Food Safety Authority), 2004. Opinion of the Scientific Panel on Animal Health and Welfare related to the welfare of animals during transport. EFSA Journal 44, 1-36.

EFSA Panel on Animal Health and Welfare (AHAW), 2011. Scientific opinion concerning the welfare of animals during transport. EFSA Journal 9, 1966.

Elbers AR, Moser H, Ekker HM, Crauwels PA, Stegeman JA, Smak JA and Pluimers FH, 2001. Tracing systems used during the epidemic of classical swine fever in the Netherlands, 1997-1998. Revue Scientifique et Technique, 20, 614-629.

Enøe C, Christensen G, Andersen S and Willeberg P, 2003. The need for built-in validation of surveillance data so that changes in diagnostic performance of post-mortem meat inspection can be detected. Preventive Veterinary Medicine 57, 117-125.

Gibbens JC, Wilesmith JW, Sharpe CE, Mansley LM, Michalopoulou E, Ryan JBM and Hudson M, 2001. Descriptive epidemiology of the 2001 foot-and-mouth disease epidemic in Great Britain: the first five months. Veterinary Record, 149, 729-743.

Hamilton DR, Gallas P, Lyall L, Lester S, McOrist S, Hathaway SC and Pointon AM, 2002. Risk-based evaluation of postmortem inspection procedures for pigs in Australia. Veterinary Record, 151, 110-116.

Harbers AHM, Elbers ARW, Geelen AJ, Rambags PGM and Snijders JMA, 1992a. Preselection of finishing pigs on the farm as an aid for meat inspection. Veterinary Quarterly, 14, 46-50.

Harbers THM, Smeets JFM, Faber JAJ, Snijders JMA and van Logtestijn JG, 1992b. A comparative study into procedures for postmortem inspection for finishing pigs. Journal of Food Protection, 55, 620-626.

Harbers AHM, Snijders JMA, Smeets JFM, Blocks GHM and van Logtestinjn JG, 1992c. Use of information from pig finishing herds for meat inspection purposes. Veterinary Quarterly, 14:2, 41-45.

Hartley PE, Done SH, Wilesmith JW & Bradley R, 1988. A study to investigate lairage time and acute pleurisy in pigs. Veterinary Record 122, 564.

Hathaway SC and Richards MS, 1993. Determination of the performance attributes of post-mortem meat inspection procedures. Preventive Veterinary Medicine, 16, 119-131.

Hathaway SC and Richards MS, 1994. Different trial designs for performance attributes of meat inspection procedures: a response to Willeberg et al. Preventive Veterinary Medicine 21, 196-199.

Hecht AR, 1977. A modified Delphi Technique for obtaining consensus on institutional research priorities. Paper presented at the Annual Meeting of the North Central Region AERA Special Interest Group on Community College Research, July 77.

Heinonen M, Gröhn YT, Saloniemi H, Eskola E and Tuovinen VK, 2001. The effects of health classification and housing and management of feeder pigs on performance and meat inspection findings of all-in-all-out swine-finishing herds. Preventive Veterinary Medicine, 49, 41-54.

Hsu CC and Sandford BA, 2007. The Delphi Technique: Making sense of consensus. Practical Assessment Research and Evaluation, 12(10), 1-8.

Jackowiak J, Kiermeier A, Kolega V, Missen G, Reiser D and Pointon AM, 2006. Assessment of producer conducted antemortem inspection of market pigs in Australia. Australian Veterinary Journal, 84, 351-357.

Knol AB, Slottje P, Van der Sluijs JP and Lebret E, 2010. The use of expert elicitation in environmental health impact assessment: a seven step procedure. Environmental Health, 9, 19.

Martin PAJ, Cameron AR and Greiner M, 2007a. Demonstrating freedom from disease using multiple complex data sources. 1: A new methodology based on scenario trees. Preventive Veterinary Medicine, 79, 71-97.

Martin PAJ, Cameron AR, Barfod K, Sergeant ESG and Greiner M, 2007b. Demonstrating freedom from disease using multiple complex data sources. 2: Case study – Classical swine fever in Denmark. Preventive Veterinary Medicine, 79, 98-115.

Martin PAJ, 2008. Current value of historical and ongoing surveillance for disease freedom: Surveillance for bovine Johne's disease in Western Australia. Preventive Veterinary Medicine, 84, 291-309.

Milligan SD, Ramsey CB, Miller MF, Kaster CS & Thompson LD, 1998. Resting of pigs and hot fat trimming and accelerated chilling of carcasses to improve pork quality. Journal of Animal Science 76, 74-86.

Mousing J, Kyrval J, Jensen TK, Aalbaek B, Buttenschøn J, Svensmark B and Willeberg P, 1997. Meat safety consequences of implementing visual postmortem meat inspection procedures in Danish slaughter pigs. Veterinary Record, 140, 472-477.

Murray G, 1986. Ante-mortem and post-mortem meat inspection: an Australian Inspection Service perspective. Australian Veterinary Journal, 63, 211-215.

Office International des Epizooties (OIE) [World Organisation for Animal Health] 2011 Terrestrial code, Glossary, accessed online on 14 June 2011 http://www.oie.int/index.php?id=169&L=0&htmfile=glossaire.htm#terme_surveillance

Petersen HH, Enøe C and Nielsen EO, 2004. Observer agreement on pen level prevalence of clinical signs in finishing pigs. Preventive Veterinary Medicine, 64, 147-156.

Petersen JV, Andersen JK, Sørensen F and Knudsen H, 2002. Food safety on the slaughterline: inspection of pig heads. Veterinary Record, 150, 782-784.

Phiri IK, Dorny P, Gabriel S, Willingham III AL, Sikasunge C, Siziya S and Vercruysse L, 2006. Assessment of routine inspection methods for porcine cysticercosis in Zambian village pigs. Journal of Helminthology, 80, 69-72.

Pointon AM, Hamilton D, Kolega V and Hathaway S, 2000. Risk assessment of organoleptic postmortem inspection procedures for pigs. Veterinary Record, 146, 124-131.

Schemann AK, Hernández-Jover M, Hall W, Holyoakec PK and Toribioa J-ALML, 2010. Assessment of current disease surveillance activities for pigs post-farmgate in New South Walesavj. Australian Veterinary Journal, 88 (3), 75-83.

Slauson DO and Cooper BJ, 2002. Mechanisms of Disease: a Textbook of Comparative General Pathology, 3rd edn. Williams and Wilkins, Baltimore, USA, 445 pp.

Snijders JMA, Smeets JFM, Harbers AHM and van Logtestijn JG, 1989. The evolution of meat inspection of slaughter pigs. Fleischwirtsch, 69, 1422-1424.

Sørensen F and Petersen JV, 1999. Survey of numbers and types of lesions detectable in pig heads and implications for human and animal health. Veterinary Record, 145, 256-258.

Straw B, Zimmerman J, D'Allaire S and Taylor D (eds), 2006. Diseases of Swine, 9th edition, Blackwell Publishing, Ames, Iowa, USA, 1155 pp.

Swanenburg M, Urlings HAP, Keuzenkamp DA & Snijders JMA, 2001. Salmonella in the lairage of pig slaughterhouses. Journal of Food Protection 64, 12-16

Toma B, Vaillancourt J-P, Dufour B, Eloit M, Moutou F, Marsh W, Bénet J-J, Sanaa M and Michel P, (eds), 1999. Dictionary of Veterinary Epidemiology, Iowa State University Press, Ames, USA, 284 pp.

Uzal FA, More SJ, Dobrenov B and Kelly WR, 2002. Assessment of organoleptic postmortem inspection techniques for bovine offal. Australian Veterinary Journal, 80, 70-74.

Warriss PD, Brown SN, Edwards JE & Knowles TG, 1998. Effect of lairage time on levels of stress and meat quality in pigs. Animal Science 66, 255-261.

Warriss PD, 2003. Optimal lairage times and conditions for slaughter pigs: a review. Veterinary Record, 153, 170-176.

Westhead S, 1991. Examination of kidneys at post-mortem inspection: are current inspection requirements adequate? With a study and comparison of the incidence of kidney lesions seen at two abattoirs. (Unpublished). Elective Study Report, The Royal Veterinary College, University of London.

Willeberg P, Gardner I, Zhou H and Mousing J, 1994. On the determination of non-detection rates at meat inspection. Preventive Veterinary Medicine, 21, 191-195.

Willeberg P, Wedam JM, Gardner IA, Holmes JC, Mousing J, Kyrval L, Enøe C, Andersen S and Leontides L, 1997. A comparative study of visual and traditional post-mortem inspection of slaughter pigs: estimation of sensitivity, specificity and differences in non-detection rates. Epidémiolgie et Santé Animale, 31/32, 04.20.1–04.20.3.

ANNEX I. STAGE 1 PRIORITISATION (PIGS)

Table A1: Results of the stage 1 filtering process conducted on disease/conditions of pigs

Adapted list of pig diseases/conditions (Based on Straw et al., 2006)	**Potential for detection at either ante- and/or post mortem) (If estimated as No or Low, not considered further)**	**Predominantly zoonotic rather than animal health and welfare (If yes, not considered further)**	**Highly infectious diseases**		**Other diseases**		**Other welfare conditions [choose examples and list for modelling] (Account taken of detection stage, pathological signs [group], similar detection likelihood)**
			Not known to be relevant in any of the EU MS	***List for modelling***	**Other tools for surveillance are preferred *(e.g. clinical surveillance)***	***List for modelling***	
Viral diseases							
African swine fever				List			
Porcine circovirus disease 1 (PMWS)					Out		
Circovirus disease 2 (PDNS)					Out		
Classical swine fever				List			
Encephalomyocarditis virus					Out		
Porcine enteric picornaviruses teschovirus encephalomyelitis (Enterovirus encephalomyelitis, Teschen/Talfan disease)					Out		
Japanese encephalitis (JEV) and West Nile Viruses	Out						
Porcine epidemic diarrhoea	Out						
Porcine parvoviruses	Out						
Porcine reproductive and respiratory syndrome virus (Porcine arterivirus)	Out						
Aujezky's diseases (Pseudorabies)					Out		
Menangle virus	Out						
Nipah virus infection			Out				
Swine influenza	Out						

Adapted list of pig diseases/conditions (Based on Straw et al., 2006)	Potential for detection at either ante- and/or post mortem) (If estimated as No or Low, not considered further)	Predominantly zoonotic rather than animal health and welfare (If yes, not considered further)	Highly infectious diseases		Other diseases		Other welfare conditions [choose examples and list for modelling] (Account taken of detection stage, pathological signs [group], similar detection likelihood)
			Not known to be relevant in any of the EU MS	*List for modelling*	Other tools for surveillance are preferred *(e.g. clinical surveillance)*	*List for modelling*	
Swine pox					Out		
Transmissible gastroenteritis and Porcine respiratory corona virus					Out		
Foot and mouth disease				List			
Vesicular stomatitis				List			
Swine vesicular disease				List			
Rabies		Out					
Bacterial diseases							
The pleuropneumonias - *Actinobacillus pleuropneumoniae, Actinobacilus suis* [expert decision to group]						List	
Atrophic rhinitis						List	
Brucellosis	Out						
Clostridial infections (various)					Out		
Tetanus					Out		
Botulism					Out		
Erysipelas					Out		
Exudative epidermitis					Out		
Edema Disease					Out		
Mastitis, Staphylococcal mastitis [expert decision to group]					Out		
Urinary tract infection	Out						

Adapted list of pig diseases/conditions (Based on Straw et al., 2006)	Potential for detection at either ante- and/or post mortem) (If estimated as No or Low, not considered further)	Predominantly zoonotic rather than animal health and welfare (If yes, not considered further)	Highly infectious diseases		Other diseases		Other welfare conditions [choose examples and list for modelling] (Account taken of detection stage, pathological signs [group], similar detection likelihood)
			Not known to be relevant in any of the EU MS	*List for modelling*	Other tools for surveillance are preferred *(e.g. clinical surveillance)*	*List for modelling*	
Haemophilus parasuis	Out						
Leptospirosis		Out					
Enzootic pneumonias - Mycoplasmal diseases, Pneumonic pasteurellosis [expert decision to group]						List	
Proliferative enteropathies	Out						
Salmonellosis for certain serovars (incl. *S. cholerae suis*)	Out						
Porcine colonic spirochetosis/ intestinal spirochetosis	Out						
(*Strep. suis*) infection	Out						
Swine dysentery					Out		
Tuberculosis						List	
Anthrax		Out					
Melioidosis (*Burkholderia pseudomallei*)					Out		
Chlamydiae	Out						
Yeasts	Out						
Yersinioses	Out						
Rhodococcus equi					Out		
Arcanobacterium pyogenes						List	
Miscellaneous disease conditions (parasitic, toxicants, other conditions)							
Sarcoptic Mange					Out		

Adapted list of pig diseases/conditions (Based on Straw et al., 2006)	Potential for detection at either ante- and/or post mortem) (If estimated as No or Low, not considered further)	Predominantly zoonotic rather than animal health and welfare (If yes, not considered further)	Highly infectious diseases		Other diseases		Other welfare conditions [choose examples and list for modelling] (Account taken of detection stage, pathological signs [group], similar detection likelihood)
			Not known to be relevant in any of the EU MS	*List for modelling*	Other tools for surveillance are preferred *(e.g. clinical surveillance)*	*List for modelling*	
Demodectic Mange	Out						
Lice	Out						
Fleas					Out		
Ticks					Out		
Hyostrongylus rubidus	Out						
Strongyloides ransomi	Out						
Ascaris suum						List	
Trichinellosis	Out						
Metastrongylus spp.	Out						
Stephanurus dentatus					Out		
Porcine cysticercosis		Out					
Echinococcosis/hydatidosis		Out					
Fasciola hepatica		Out					
Mycotoxicoses	Out						
Toxic Minerals, Chemicals, Plants, and Gases					Out		
Gastric Ulcers	Out				Out		
Nutrient deficiencies					Out		
Welfare (indicators)							
Signs of Aggression	Out						
Signs of Fear of Humans (pig reluctant to move when human is close or strongly avoids human)	Out						
Tail biting, bitten tail							List
Ear and flank biting, Characteristic bite marks and							

Adapted list of pig diseases/conditions (Based on Straw et al., 2006)	Potential for detection at either ante- and/or post mortem) (If estimated as No or Low, not considered further)	Predominantly zoonotic rather than animal health and welfare (If yes, not considered further)	Highly infectious diseases		Other diseases		Other welfare conditions [choose examples and list for modelling] (Account taken of detection stage, pathological signs [group], similar detection likelihood)
			Not known to be relevant in any of the EU MS	*List for modelling*	Other tools for surveillance are preferred *(e.g. clinical surveillance)*	*List for modelling*	
lesions, usually on front, flank or ear.							
Belly nosing	Out						
Pen fouling	Out						
Stereotypies	Out						
Maternal behaviour	Out						
Low levels of sexual behaviour	Out						
Signs of porcine stress syndrome (PSE pork)							
Pale Soft Exudative (PSE) meat							Out *[Similar pattern of detection likelihood with listed items]*
High blood cortisol at slaughter	Out						
High blood lactate dehydrogenase isoenzyme at slaughter	Out						
High blood creatine kinase at slaughter	Out						
High blood osmolality at slaughter	Out						
Elevated body temperature							Out *[Common element of detection of many other diseases/conditions already in the list]*

Adapted list of pig diseases/conditions (Based on Straw et al., 2006)	Potential for detection at either ante- and/or post mortem) (If estimated as No or Low, not considered further)	Predominantly zoonotic rather than animal health and welfare (If yes, not considered further)	Highly infectious diseases		Other diseases		Other welfare conditions [choose examples and list for modelling] (Account taken of detection stage, pathological signs [group], similar detection likelihood)
			Not known to be relevant in any of the EU MS	*List for modelling*	Other tools for surveillance are preferred *(e.g. clinical surveillance)*	*List for modelling*	
Dark Firm Dry (DFD) meat							List
Signs of different pathologies (e.g. pneumonia, lung lesions)							Out *[Overlapped (similar signs) with listed items]*
Prolapses							Out *[Similar pattern of detection likelihood with listed items]*
Bruising and skin lesions							List
Arthritis and bursitis							List
Lameness							List
Slipping, falling, foaming at mouth							Out *[Overlapped (similar signs) with already listed items]*

ANNEX II. STAGE 2 MODELLING (ALL SPECIES)

a. Overview

A model was developed, focusing on the following two parts:

- The first part described an approach to surveillance for a public health hazard and identified the particular disease, sampling and testing strategies;
- The second part evaluated the quality of animal health and welfare surveillance based on the approach defined in the first part.

The current model considered two main aspects of surveillance with a number of alternatives for each aspect: *sampling and testing. The unit of interest/study* was a slaughtered animal, with *sampling* referring to a subset of animals slaughtered. *The reference population* was all animals going to slaughter, and *the grouping level* was a batch of animals being slaughtered. The definition of batch will need to be refined for different species and slaughter systems. The *alternative sampling approaches* included in the model were:

- Census: the entire slaughtered population is examined,
- Representative sample: a number of animals from the batch is sampled using a sampling technique that produces a representative sample (e.g. random sampling),
- Risk-based sampling: non-representative sampling is used, such that the population is divided into different sub-populations, each with a different probability of being infected (or prevalence). The sub-populations are sampled at different proportions. The effect of risk-based sampling is quantified using three parameters:
    - The relative risk of animals being affected/infected between the different sub-populations. This is a measure of the importance of the risk factor or the efficiency of targeting,
    - The proportion of animals in each of the sub-populations,
    - The number of animals sampled from each of the sub-populations,
    - The difference between the population proportion and the sample proportion describes the degree to which the high-risk sub-population was targeted in the sampling strategy.

The 'quality' of surveillance for animal health is described in a number of ways, reflecting a number of possible different purposes for surveillance:

- Sensitivity
    - Used when the purpose of surveillance *is to detect disease or demonstrate freedom from disease*,
    - This is the probability that the meat inspection surveillance system will detect at least one affected/infected animal in a batch or lot, based on the assumption that the condition/disease is present at a defined prevalence (the design prevalence).
- Bias and precision
    - Used when the purpose of surveillance *is to estimate the level of disease* (e.g. the prevalence or incidence),

  - In the model, the bias is calculated as the difference between the estimated prevalence (based on the defined meat inspection surveillance system) and the true prevalence. This is a measure of systematic error, due to sampling bias created by risk-based sampling,
  - The precision is a measurement of the random error due to sampling from the population, and is defined as half the width of the 95 % confidence interval. In the model this is estimated using a normal approximation.

- Fraction detected
  - Used when the purpose of surveillance *is to remove affected/infected animals from the food chain*, in order to achieve an acceptable maximum prevalence in the final meat product,
  - This is calculated as the number of affected/infected animals that would be detected in the batch by the defined surveillance system, as a proportion of the assumed total number of affected/infected animals in the population.

The generic model was developed to allow for:

- *Changes in the number/type of animals being inspected*, based on the risk profile of the batch, farm, region or country. For example, the changes to the meat inspection process could include a move from 'census' sampling (that is, all animals inspected) to either representative sampling (an unbiased subset of all these animals) or risk-based sampling (focusing on those animals considered at highest risk of the public health condition of interest).
- *Changes to the inspection methods, among those animals that are inspected.* This might include eliminating or reducing the intensity of some inspection methods, introducing new interventions, or modifying existing interventions (for example, using less sensitive tests with a greater number of animals, using more sensitive tests with a small number of animals, or using multiple tests).
- The final model used for analysis of surveillance for different species was based on this generic model, but it was simplified to take into account the specific changes to meat inspection recommended by BIOHAZ. In cases where recommendations result only in changes to the sensitivity and specificity of detection (i.e. no change in processes for the selection of animals undergoing meat inspection), the model is significantly simplified.

> A generic stage 2 model was developed, with the capacity to accommodate a number of potential changes to the meat inspection system, including:
>
> - Changes in the number/type of animals being inspected,
> - Changes in the inspection methods.

b. Model structure

The model was implemented in an Excel spreadsheet that currently consists of three sheets:

- *Parameters*, containing the input parameters and the results,
- *The model*, containing the calculations,
- An alternative model layout, for model validation.

This description will focus on the practical use of the model, by entering parameters into the Parameters sheet, and the interpretation of the results in the Parameters sheet, as well as a brief description of the calculations contained within the Model sheet.

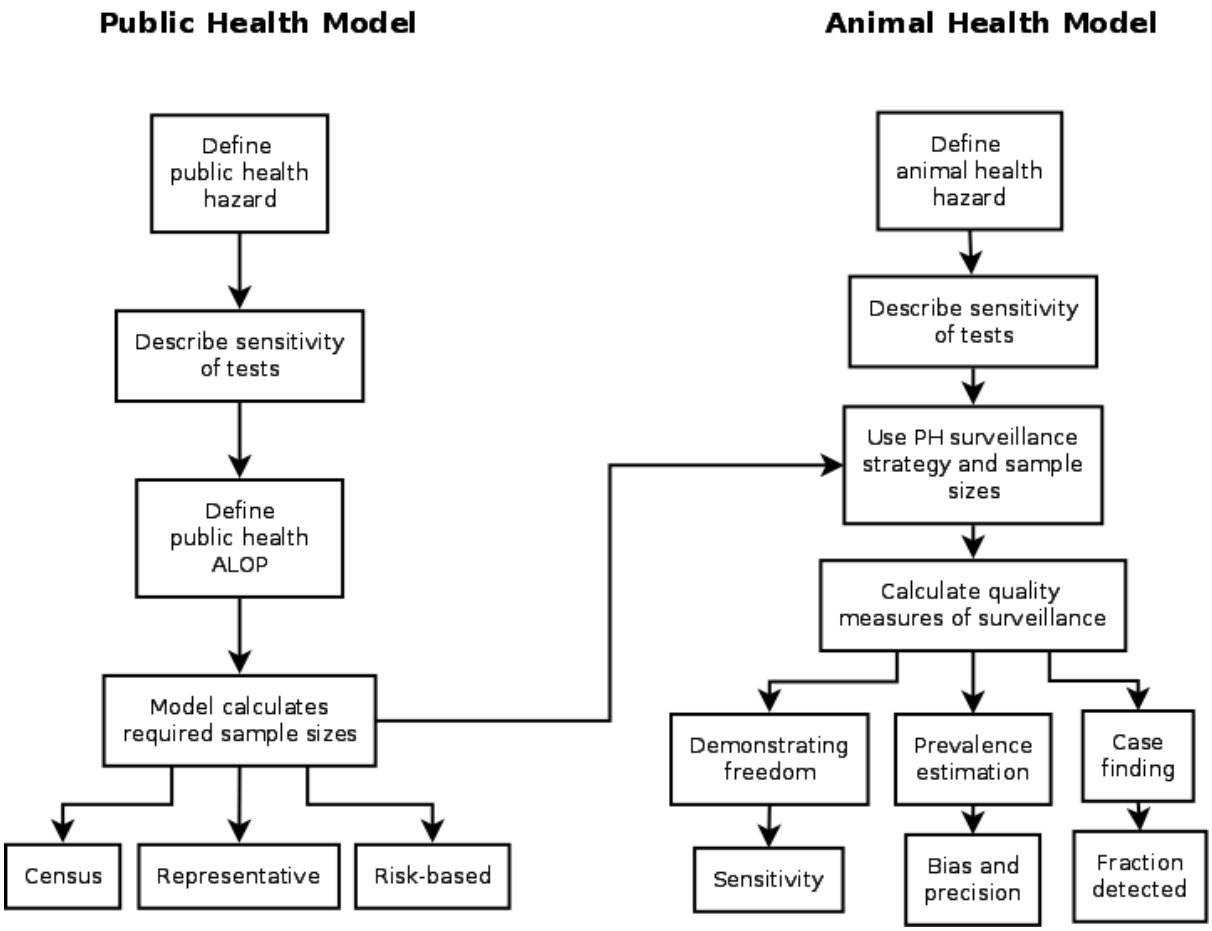


Figure 3: The capacity to model changes affecting both public and animal health

> The generic stage 2 model has the capacity to model changes affecting both public and animal health. In this opinion, only the animal health model was considered further.

c. Model parameters

As the model is divided into two parts (one describing the surveillance strategy used for public health purposes, and the other describing the impact of this strategy on animal health surveillance), the model parameters are also divided into public health and animal health sections.

Common parameters

Batch size	The number of animals in a batch or lot. Most calculations are performed in terms of proportions or percentages, in which case this parameter has little effect. However, where the numbers of animals are expressed as integers, and when the calculation type (see below) is set as integer, integer calculations are performed based on whole numbers of animals as determined by this batch size setting. The definition of a batch may vary for the slaughter system and species, however, for pigs, it may represent all the animals from a single farm that are slaughtered on the same day.

Public health parameters

Condition of interest	Text to describe the public health disease or condition of interest, on the basis of which changes are made to the meat inspection system. This has no effect in the model as it is only a label.
Prevalence or P*	When the disease/condition of interest is endemic, this value expresses the assumed prevalence of the disease in the abattoir population. When the disease is exotic, this value represents the design prevalence (P*), a hypothetical prevalence used as a standard upon which sensitivity estimates are based. It is also referred to as the minimum expected or the maximum acceptable prevalence.
Risk factor	If risk-based sampling is used, this is a label describing the risk factor upon which the sampling is based. For instance, with *Trichinella*, the risk factor may be a free-range production system, which would mean that the population has been divided into free-range animals (high-risk) and non-free-range (low-risk)
Relative risk	This is the relative risk of infection between the two defined sub-populations for risk-based sampling. It is calculated as the risk of being infected in the high-risk group divided by the risk in the low-risk group, which is also known as the risk ratio. The current model only allows for two risk groups but this may be extended in future versions if required. This value is only used when risk-based sampling is applied.
Proportion of population in high-risk group	This indicates the distribution of the risk factor in the population, by describing what proportion of the population falls into the high-risk group.
Sensitivity of tests	
Ante-mortem inspection	The sensitivity (proportion of truly affected/infected animals that yield a positive test result) based on *ante-mortem* examination (usually visual inspection). For many microbiological hazards, the sensitivity may be very low or zero as they are not detectable by visual inspection.
Post-mortem inspection	The sensitivity of *post-mortem* inspection. *Post-mortem* inspection consists of a complex series of individual examinations, which may be modified as part of the recommendations under the mandate. Any changes in procedures (e.g. stopping the incision of lymph nodes) are likely to have an impact on the sensitivity of detection of different conditions or diseases.

Specific tests	Some meat inspection procedures involve the application of specific laboratory tests, separate from *post-mortem* inspection. Examples include *Trichinella* digestion tests or BSE tests. This is currently entered as a single value, so if multiple tests are used in series or parallel, the combined sensitivity should be calculated and entered.
Sampling strategies	
Representative sampling proportion	For representative sampling, the proportion of the slaughtered population sampled. Users may enter that actual number sampled, or enter "Auto" to have the model automatically calculate the minimum sample size required to achieve the specified MAP (see below).
Risk-based sampling	
Number sampled from high-risk group	For risk-based sampling, the number of animals in the high-risk group that are included in the sample. This is expressed in terms of an integer and converted to a proportion in the model if required. Enter "Auto" to calculate the sample size automatically based on the MAP (see below).
Number sampled from low-risk group	For risk-based sampling, the number of animals in the low-risk group that are included in the sample. This is expressed in terms of an integer and converted to a proportion in the model if required. Enter "Auto" to calculate the sample size automatically based on the MAP (see below).
MAP	Maximum Acceptable Prevalence. This is expressed in terms of the maximum acceptable proportion of animals with the disease/condition of interest that remains undetected in the population after meat inspection. This is used to automatically calculate required sample sizes to achieve a target level of protection in public health surveillance.
Animal health parameters	
Condition of interest	A text label describing the animal disease or condition of interest (e.g. pneumonia)
Prevalence or P*	The prevalence or design prevalence as described above, applied to the animal health disease or condition of interest. This may be different to the value used for the public health condition.
Relative risk	When a risk-based sampling strategy has been defined for the public health hazard, this indicates that animals in the high-risk group will be sampled at a greater frequency than animals in the low-risk group. For animal health, the relative risk describes the risk that animals will be affected/infected with the animal disease/condition of interest in the defined *public health* high-risk group, divided by the risk for animals in the public health low-risk group. Using the example of *Trichinella* (public health hazard) and pneumonia (animal health hazard), and using a risk factor of free-range production, the relative risk describes the risk that animals will have pneumonia in a free-range system, divided by the risk for animals not in a free-range system. In this example, the relative risk is less than 1, indicating that the risk-based sampling strategy, designed to improve the efficiency of *Trichinella* detection, would have the effect of *decreasing* the likelihood of detecting animals with pneumonia.
Sensitivity of tests	
Ante-mortem inspection	The sensitivity of *ante-mortem* inspection for the detection of the animal disease/condition of interest.

Post-mortem inspection	The sensitivity of *post-mortem* inspection for the detection of the animal disease/condition of interest.
Specific tests	The sensitivity of specific tests for the detection of the animal disease/condition of interest.
Calculation type	Select from the drop down list. Exact calculations are based on real numbers, and may deal with fractions of animals. Integer calculations are based on the fact that it is not possible that a fraction of an animal is infected/affected.

Inputs into the stage 2 model included:

- Common parameters,
- Public health parameters (not considered further), and
- Animal health parameters.

d. Model outputs

The results are presented in the following table:

- Rows contain the different sampling strategies (census, representative sample or risk-based sample) for each of the two sections of the model (public health and animal health).
- The columns contain the different quality measurements for the surveillance, as illustrated below:

Table 6: Model outputs

Sample size	This is the sample size applied to different sampling strategies. • For the census option, the sample size is always the same as the batch size (all animals are inspected) • For representative and risk-based sampling, if "Auto" is used in the Parameters section, the sample size is automatically calculated; otherwise the values entered are used. Sample size for animal health is always the same as for public health (as the surveillance system is defined by public health considerations).
Sensitivity	The sensitivity of the surveillance for the different hazards and sampling strategies. This is the *surveillance sensitivity*, or the probability that the meat inspection system would detect at least one infected/affected animal if the population were infected at the defined design prevalence.
Absolute bias	The difference between the estimated prevalence and the actual prevalence, due to risk-based sampling. The bias for census and representative sampling is always zero.
Proportional bias	The calculated bias, divided by the true prevalence
Precision	Half the width of the 95 % confidence interval (as estimated using a normal approximation). Precision is 0 for census, as there is no sampling error.
Fraction detected	The proportion of animals detected by the surveillance system, divided by the total number of affected/infected animals in the batch.
Detection efficiency	1000 times the fraction detected divided by the sample size. This indicates the efficiency of detection.

Outputs from the stage 2 model included different surveillance quality measures relevant to early detection *(surveillance sensitivity)*, case-finding *(detection fraction)* and estimating prevalence *(bias and precision)*, given different sampling strategies.

e. Model formulae

Formulae for calculation of key values are included in an Excel spreadsheet. The key formulae, presented below, are based on those presented in Martin et al. (2007a).[35]

i. Combined sensitivity of tests

The combined sensitivity of *ante-mortem*, *post-mortem* and specific tests is calculated as:

$$Se_c = 1 - \left[(1 - Se_{am}) \times (1 - Se_{pm}) \times (1 - Se_{st})\right]$$

Where:

- Se_c is the combined sensitivity of all tests,
- Se_{am} is the ante-mortem test sensitivity,
- Se_{pm} is the post-mortem test sensitivity, and
- Se_{st} is the sensitivity of any specific tests.

Note that this formula assumes independence between the three test systems.

ii. Adjusted risk

The relative risk is used to adjust the design prevalence for the two risk groups, effectively increasing the probability of animals being infected in the high-risk group and decreasing it in the low-risk group, while keeping the average risk in the population equal to the defined design prevalence. Relative risk is first transformed into adjusted risk (AR), which is then multiplied by the design prevalence to give the effective probability of infection for the different risk groups.

$$AR_{hr} = \frac{RR_{hr}}{\left[(PP_{hr} \times RR_{hr}) + (PP_{lr} \times RR_{lr})\right]}$$

Where:

- AR_{hr} is the adjusted risk in the high-risk population,
- RR is relative risk,
- PP is the population proportion (the proportion of the population in that risk group),
- *hr* indicates the high-risk group, and
- *lr* indicates the low-risk group.

The adjusted risk in the low-risk group is:

[35] Martin PAJ, Cameron AR and Greiner M, 2007. Demonstrating freedom from disease using multiple complex data sources. 1: A new methodology based on scenario trees. Preventive Veterinary Medicine, 79, 71-97.

$$AR_{ir} = \frac{RR_{ir}}{[(PP_{hr} \times RR_{hr}) + (PP_{lr} \times RR_{ir})]}$$

Where:

- RR_{lr} is the relative risk in the low-risk group, normally equal to 1.

iii. System sensitivity

Calculation of the sensitivity of the surveillance system (probability that at least one affected animal will be detected, given that the population is infected at the design prevalence) first requires calculation of the unit sensitivity, or the average probability that an animal in the system will be detected as positive. Note that the model does not currently deal with specificity or calculate the number of false positive cases detected.

The unit sensitivity is calculated as follows:

$$Se_u = P^* \times Se_c \times [(SP_{hr} \times AR_{hr}) + (SP_{lr} \times AR_{ir})]$$

Where

- Se_u is the unit sensitivity,
- P* is the design prevalence,
- Se_c is the combined sensitivity of all tests,
- SP is the proportion of the animals included in the surveillance (for the subscripted group), and
- AR is the adjusted risk (for the subscripted group).

System sensitivity (assuming independence between animals) is calculated as:

$$Se_s = 1 - (1 - Se_u)^n$$

Where

- Se_s is the system sensitivity, and
- n is the sample size.

iv. Precision

Precision of prevalence estimates is described in terms of half the 95 % confidence interval. For instance, if the estimate and 95 % confidence interval were 20 % +/- 3 %, then the precision would be expressed as 3 %. The precision was calculated using the normal approximation as follows:

$$Precision = z\sqrt{\frac{p(1-p)}{n}}$$

Where

- z is the z value for the confidence level (1.96 for a 95 % confidence interval),
- p is the estimated prevalence, and
- n is the sample size.

ANNEX III. STAGE 3 MODELLING (ALL SPECIES)

a. Overview

Different approaches were used for the three main different purposes of abattoir surveillance:

- *early detection* (scenario-tree modelling),
- *case-finding* (a new approach to the analysis of detection fractions, based on the principles of scenario-tree modelling), and,
- *estimating prevalence*.

> During stage 3, different approaches to scenario-tree modelling were used when considering:
>
> - early detection,
> - case-finding, and,
> - estimating prevalence.

In each case, *multiple different surveillance components (including abattoir surveillance) were modelled (see Section 1.3.2).* The quality of estimates from each surveillance component was assessed independently. Then, overlap between the surveillance systems was analysed, allowing the relative contribution of each component, given the existence of the others, to be calculated. For instance, if surveillance component A has a sensitivity of 80 % and component B has a sensitivity of 90 %, if these two components were completely independent, the combined sensitivity of both together would be 98 %. However, if there is significant overlap between the two systems, it may be that any cases detected by component A would be detected by component B anyway. In this situation, the relative contribution of A given B would be zero. This analysis allows the relative contribution of abattoir surveillance to be assessed before and after any proposed changes to meat inspection procedures are implemented.

b. Surveillance for early detection

Methods for the statistical analysis of surveillance data from well-structured representative surveys have been well described (see, for example, Cameron and Baldock, 1998a, b). Estimation of the sensitivity of these systems is straight forward as risk-based or biased sampling approaches are not used. However, for the analysis of more complex surveillance components, such as abattoir surveillance and passive surveillance, the modelling approach used was based on stochastic scenario tree modelling techniques, as described by Martin et al. (2007a), Martin et al. (2007b) and Martin (2008).

Conceptually, a surveillance system for a particular disease or welfare condition is made up of multiple components, representing different activities or data streams. In this context, two components for each disease or condition studied are abattoir surveillance and the passive farmer reporting system (based on observation of abnormalities by the farmer, and reporting them directly or through a private veterinarian to the veterinary authorities). For some diseases, further components may exist, such as active serological surveillance.

As the purpose of surveillance in this case is early detection, the diseases relevant are those not normally present in the Member State, primarily highly infectious (epidemic) diseases.

Stochastic scenario tree analysis uses two steps. *As a first step*, the sensitivity of each of the surveillance components is estimated separately. A scenario tree is then used to describe the risk-

structure of the population and surveillance system. Different risk factors (factors influencing the probability that a group (farm) or animal will be infected, if infection is present) are identified. Factors influencing the probability that an animal will be detected (i.e. influencing the sensitivity of the test) are also included as this has an impact on sensitivity. Using the tree, these factors are used to divide the animals under surveillance into roughly homogenous risk groups, each with a different probability of being infected or being detected.

The impact of each risk factor is quantified using three parameters:

- The relative risk (measuring the 'importance' of the risk factor),
- The degree of targeting of the surveillance, as measured by the difference between:
  - The proportion of the population with the risk factor, and,
  - The proportion of the surveillance sample with the risk factor.

The impact of factors influencing sensitivity is quantified using estimates of the sensitivity in different sub-populations and the proportional representation of those sub-populations in the surveillance sample.

Surveillance sensitivity is the probability that, if the population were infected, the surveillance would detect at least one positive animal. If disease were present at a high level, it would be easy to find and the sensitivity of the surveillance would be high, but low levels of disease are difficult to detect. To provide a standard for the evaluation of the sensitivity of surveillance, it is therefore necessary to define a standard hypothetical level of disease (the design prevalence or P*) against which sensitivity is calculated.

In the simplest case where all animals have the same risk of being infected or detected, the sensitivity of surveillance (SSe) can be calculated as:

SSe=1-(1-P^*×Se)^n

Where:

- P* is the design prevalence,
- Se is the sensitivity of the individual animal test used, and,
- n is the number of animals processed by the surveillance system component.

Scenario tree modelling is a tool to modify this simple formula by recognising that not all animals have the same probability of being infected (hence different modifiers for the term P* are included for different sub-populations), and different animals have different probabilities of being detected (hence different modifiers for the term Se are included).

It is common to find that many model parameters, including relative risk, test sensitivity and population proportion values are not readily available and must be estimated, often using expert opinion. These values may also have some variability inherent in them. To capture these two effects, stochastic modelling is used, allowing distributions to be used as model inputs instead of point estimates, resulting in an output distribution for the surveillance sensitivity.

Models are further complicated by the need to take into account the clustered nature of the population, resulting in a lack of independence between animals in the same herd. This is achieved by adding a grouping layer in the scenario tree and another level of design prevalence. The herd-level design prevalence indicates the assumed proportion of herds in the population that would be infected if the disease were present, while the animal-level design prevalence indicates the proportion of animals that would be infected in an infected herd.

The second step of the analysis is to estimate the degree of overlap between different components of the surveillance system. Conceptually this is achieved by considering the probability of infection at

the herd level. For the first component analysed, the assumed probability of infection for each herd is given by the herd-level design prevalence (modified by any risk factors operating at the herd level). However, after considering the number of animals that have been tested from that herd (all with negative results), it is possible to calculate a posterior herd-specific probability of infection.

When surveillance components are considered to be independent, the assumed probability of infection for the analysis of the second component is again equal to the herd-level design prevalence. However, when multiple components are considered together, data from the first component can be used to inform our understanding of the herd status for analysis of the second component. The posterior estimate of probability of infection, based on the analysis of the first component, is used as the prior probability of infection when analysing the second component, instead of the herd-level design prevalence. The result is that negative testing in the first component decreases the likelihood that the herd is infected, resulting in a lower sensitivity for the second component (which, in effect, takes into account the overlap between the two components).

This process is continued in a step-wise fashion across all components to be analysed, and the result is the extra sensitivity provided by each component after accounting for overlap. By varying the order in which components are analysed, it is possible to estimate the relative extra sensitivity contributed by each component, assuming the existence of one or more previous components.

> Stage 3 modelling of surveillance for early detection, using scenario-tree modelling, was conducted to estimate *surveillance sensitivity* (the probability that, if the population were infected, the surveillance would detect at least one positive animal).

c. Surveillance for case-finding

The previous section dealt with surveillance for early detection, mainly for exotic diseases. Abattoir surveillance is also potentially valuable for surveillance for diseases present in a MS that are the subject of a control programme. In this case, the question is not early detection and trying to estimate the probability of detecting at least one infected animal if the disease is present. *Instead, the aim of surveillance is to find all infected animals in a population, so they can be treated or removed*. This approach applies to diseases of importance to public health (e.g. BSE or trichinellosis), as well as diseases and conditions with greater relevance to animal health and welfare, such as brucellosis, tuberculosis, or significant welfare problems.

The measurement of quality for surveillance for case-finding is the detection fraction – that is, *the proportion of infected animals in the population that are successfully detected by the surveillance component*. As with early detection, risk-based surveillance may be used to increase the efficiency of case-finding, by targeting high-risk populations.

Where multiple surveillance components for case-finding exist, each component may detect a certain proportion of cases. However, once again the overlap between components must be considered. If all the cases that would be detected by component A would also be detected by component B, then there may be no extra benefit in using component A in addition to component B.

Figure 4 illustrates the principles of the analysis of multiple case-finding surveillance components. The rectangular areas represent the overall population, divided into sub-populations according to two different risk factors. The first risk factor divides the population into high-risk (red) and low-risk (green) sub-populations. The second risk factor further subdivides each of these groups into high-risk (dark) and low-risk (light) sub-populations. Within the model, this is undertaken using a modified version of a scenario-tree, including factors influencing risk of infection and probability of detection. In contrast to traditional scenario tree modelling, which deals with diseases that are absent, it should often be relatively straight-forward to estimate the relative risk between different risk groups, as the number of cases of disease in each group can be measured (because the disease is present).

Once the population is described, the coverage of each surveillance component is described. This is quantified in terms of the proportion of each risk sub-population that is captured by each of the different components. The proportion of the risk sub-populations that falls into both surveillance components (the overlap) is also estimated. In the figure below, the coverage and overlap of the surveillance components are represented by the circles of the Venn diagram.

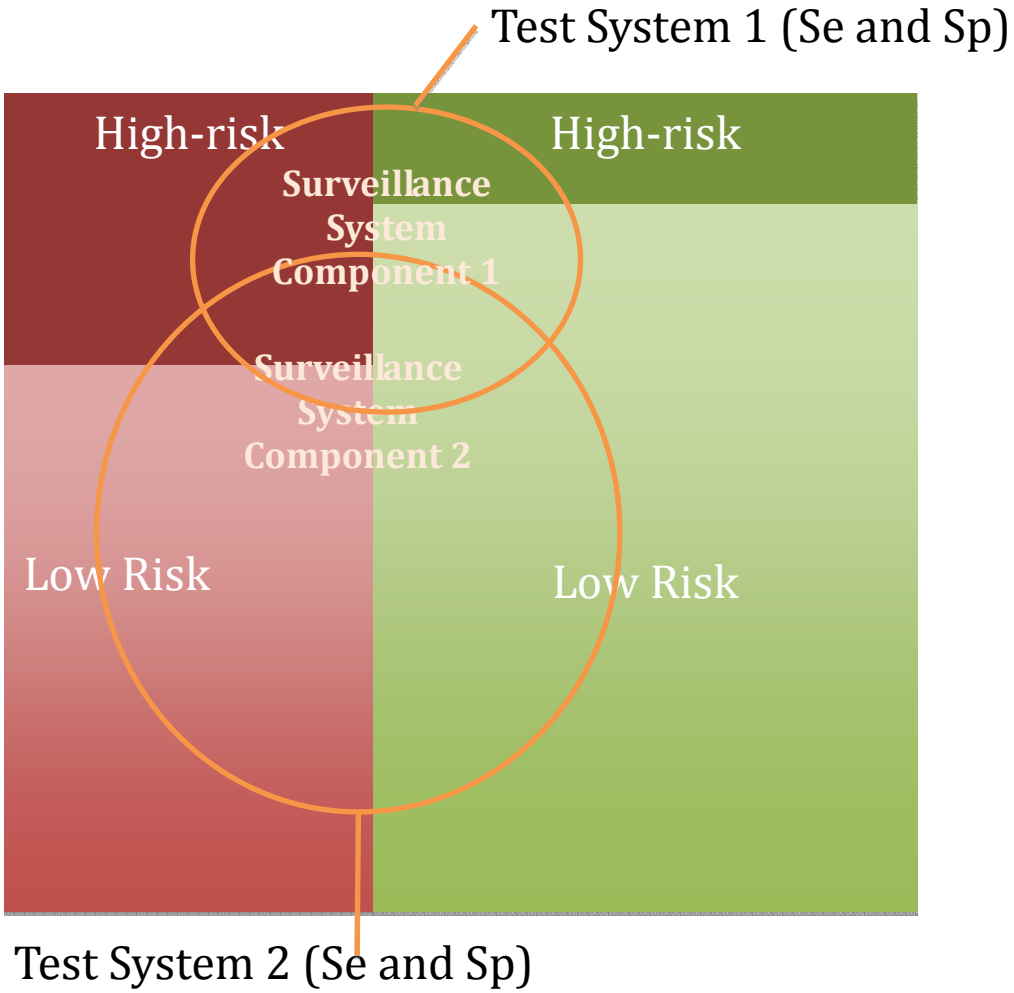


Figure 4: Schematic representation of analysis of multiple components of surveillance for case-finding

Once risk groups, coverage and overlap are described, it is possible to calculate the detection fraction for each of the areas in the Venn diagram. This allows the estimation of the proportion of cases in the population that would be detected by component 1, the proportion that would be detected by component 2, the proportion that would be detected by both (the overlap) and the incremental benefit of one component over the other.

Again, where there is uncertainty or variability in parameter estimates, this analysis can be implemented using stochastic modelling, resulting in distributions as outputs instead of point values.

Stage 3 modelling of surveillance for case-finding, using modified scenario-tree modelling, was conducted to estimate *the detection fraction* (the proportion of infected animals in the population that are successfully detected).

d. Surveillance for estimating prevalence

In contrast to the previous two purposes of surveillance, current analytical techniques for unbiased estimates of prevalence are heavily dependent on the use of a representative sample, such as that obtained using formal random sampling, systematic sampling, or by taking a census of the entire population.

As previously noted, the population of interest depends on the disease or welfare condition under study. In many cases, the population of interest may be the entire farmed population, however for welfare conditions related to transport and lairage, the population of interest may be the slaughter population. Census or representative sampling of the abattoir population will provide an unbiased estimate of the prevalence of the condition in the abattoir population, but not in the broader farmed population.

When there are multiple components of a surveillance system, each of which may contribute to estimates of prevalence, the relative contribution of each component must be assessed separately in terms of bias and precision.

If any single component is representative, and therefore produces unbiased estimates of prevalence, this is clearly superior to any component that provides biased estimates. However, an unbiased estimate with very poor precision may be of less value than a biased estimate with high precision, if the bias can be understood and corrected. The selection of the most valuable surveillance component for estimation of prevalence is therefore based on judgement of the relative importance of precision and bias.

When assessing multiple components of a surveillance system, three other approaches are possible:

- *Pooling results*. This involves combining the results of multiple components to provide a single estimate of prevalence. If bias is present in any of the components, then the pooled result will most likely be biased (however, the bias may be diluted, counter-balanced or exacerbated depending on the situation). Naive analysis of pooled results will result in a more precise estimate, but valid analysis taking into account different sampling designs may be very complex.
- *Capture-recapture methods*. These use two or more surveillance components with (preferably) independent identification of cases in the population. By matching cases and assessing the overlap, the total number of undetected cases can be estimated, allowing estimation of the true population prevalence and biases present in the surveillance components.
- *Modelling methods based on the use of scenarios* to understand the risk structure of the population and biases inherent in one or more surveillance components. These techniques are still under development but may lead to improved tools for the analysis of biased surveillance.

Stage 3 modelling of surveillance for estimating prevalence, using modified scenario-tree modelling, was conducted to estimate precision and bias.

GLOSSARY

Census	No sampling is applied and the entire surveillance population is examined
Detectable cases	These are all cases that are detectable by routine meat inspection procedures. They will consist of a range of combinations of clinical and pathological signs. A proportion of detectable cases will fit the definition of the typical case
DFD	Dark firm dry meat
Early cases	This relates to the sequence of the development of clinical and pathological signs during the development of a disease or condition. Early cases will have more subtle signs and may be detectable, but more likely will not be detectable.
Endemic disease	A disease, clinically expressed or not, constantly present in a population in a given region (Toma et al., 1999)
Epidemic disease	A disease affecting a number of individuals in clear excess of what would be expected for a specific region and period of time (modified from Toma et al., 1999)
Monitoring	The intermittent performance and analysis of routine measurements and observations, aimed at detecting changes in the environment or health status of a population (OIE, 2011)
Non-detectable cases	These are all cases that are not detectable by routine meat inspection procedures. They may be sub-clinical or mild and will often be early cases at a stage where distinct clinical signs have not yet developed
Population	A group of units sharing a common defined characteristic (OIE, 2011)
Representative sample	A sample drawn from a population in such a way as to ensure that the prevalence of the character of interest in the sample is the same as that in the surveillance population (i.e. there is no sampling bias)
Risk-based sample	A sample drawn from the population with the intention that the prevalence or risk of a disease or welfare condition in the sample is greater than in the surveillance population
Sample	The animals that are actually examined as part of the surveillance system, drawn from the surveillance population
Stereotypy	A repeated, relatively invariant sequence of movements with no apparent function
Surveillance	The systematic ongoing collection, collation, and analysis of information related to animal health and the timely dissemination of information to those who need to know so that action can be taken (OIE, 2011)
Surveillance population	The population from which the animals included in surveillance are drawn

Typical cases	Cases fitting the case definition provided by the experts. It was aimed for at least 60 % of detectable cases to fall in this category
Welfare	The state of an individual as regards its attempts to cope with its environment