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### SCIENTIFIC OPINION

# Scientific Opinion on the public health hazards to be covered by inspection of meat from farmed game<sup>1</sup>

EFSA Panel on Biological Hazards (BIOHAZ)<sup>2,3</sup>

#### With the contribution of the EFSA Panels on Contaminants in the Food Chain (CONTAM) and Animal Health and Welfare (AHAW)

European Food Safety Authority (EFSA), Parma, Italy

#### ABSTRACT

Salmonella spp. in farmed wild boar and Toxoplasma gondii in farmed deer and farmed wild boar were ranked as a high priority for meat inspection. Trichinella spp. in wild boar was ranked as low priority due to current controls, which should be continued. For chemical hazards, all substances were ranked as medium or lower potential concern. More effective control of biological hazards could be achieved using an integrated farm to chilled carcass approach, including improved food chain information (FCI) and risk-based controls. Further studies are required on Salmonella spp. in farmed wild boar and T. gondii in farmed wild boar and farmed deer. If new information confirms a high risk to public health from meat from these species, setting targets at carcass level should be considered. Palpation and incision should be omitted, as it will not detect biological hazards contamination of the carcasses with Salmonella. Palpation and/or incision may be applied where abnormalities have been detected but away from the slaughter line. However the elimination of routine palpation and incision would be detrimental for detecting tuberculosis. As farmed deer and farmed wild boar can act as tuberculosis reservoirs, any reduction in the detection, due to changes in the post-mortem inspection procedures, will have

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consequences for the overall surveillance of tuberculosis. Monitoring programmes for chemical hazards should be more flexible and based on the risk of occurrence, taking into account FCI, which should be expanded to reflect the specific environmental conditions of the farms where the animals are reared, and the ranking of chemical substances, which should be regularly updated and include new hazards. Control programmes across the food chain, national residue control programmes, feed control and monitoring of environmental contaminants should be better integrated.

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#### **KEY WORDS**

meat inspection, farmed game, ante-mortem, post-mortem, contaminants, residues, surveillance



#### SUMMARY

Following a request from the European Commission, the EFSA Panel on Biological Hazards (BIOHAZ) was asked to deliver a scientific opinion on the public health hazards to be covered by inspection of meat from several animal species, with the contribution of the Panel on Contaminants in the Food Chain (CONTAM) and the Panel on Animal Health and Welfare (AHAW). Briefly, the main risks to public health that should be addressed by meat inspection were identified and ranked; the strengths and weaknesses of the current methods of meat inspection were evaluated; and recommendations were made for inspection methods fit for the purpose of meeting the overall objectives of meat inspection for hazards not covered by the current meat inspection system, and for adaptations of inspection methods and/or frequencies of inspections that provide an equivalent level of protection. In addition, the implications for animal health and animal welfare of any changes proposed to current inspection methods were assessed. This opinion covers the inspection of meat from farmed game, specifically farmed deer, reindeer, ostrich, wild boar and rabbit.

To fulfil this mandate, the first stage in this assessment focused on identifying the biological hazards that occur in farmed game in Europe. The relevance of each biological hazard was evaluated based on two criteria: (1) any evidence that the biological hazard is transmissible to humans through the handling, preparation and/or consumption of farmed game meat; and (2) evidence that the biological hazard is present in the farmed game population in the European Union (EU). Biological hazards that satisfied these two criteria were then ranked using a decision tree which considered such information as incidence of human disease caused by the specific biological hazard, severity of the disease in humans, epidemiological linkage as well as animal and carcass hazard prevalence. A decision tree was also developed for the risk ranking of chemical hazards into categories of potential concern based on the outcomes of the national residue control plans (NRCPs) for the period 2005-2010, and of other testing programmes, as well as on substance-specific parameters such as the toxicological profile and the likelihood of the occurrence of chemical residues and contaminants in farmed game. Farming of deer, reindeer, ostriches and wild boars is markedly different from rabbit farming and the types and likelihood of occurrence of chemical residues and contaminants varies between these animal species. Therefore, in the context of chemical hazards, rabbits were considered separately from other farmed game (deer, reindeer, ostrich, and wild boar).

Based on the assessment, the biological hazards; *Salmonella* spp. in farmed wild boar and *Toxoplasma gondii* in farmed deer and farmed wild boar were ranked as a high priority for meat inspection. *Yersinia enterocolitica* and *Y. pseudotuberculosis* were ranked as low priority in farmed deer. *Y. enterocolitica* and pathogenic verotoxigenic *Escherichia coli* (VTEC) and *Trichinella* spp. were also ranked as low priority in farmed wild boar, the last because of currently applied controls. The following hazards were categorised as 'priority undetermined due to insufficient data': *Campylobacter* spp., *Salmonella* spp., pathogenic VTEC and Hepatitis E virus (HEV) in farmed deer; *Campylobacter* spp and *Salmonella* spp. in ostrich; *Campylobacter* spp. and HEV in farmed wild boar; and *Salmonella* spp., pathogenic VTEC and Hepatitis. For chemical hazards, no substance was classified in the high potential concern category for farmed game or rabbits; all substances were ranked as of medium or lower concern. It should be noted that the identification and ranking of biological and chemical hazards is based on current knowledge and available data and, therefore, should be updated regularly, taking account of new information and data and including 'new hazards'.

Strengths of the current meat inspection were identified. Food chain information (FCI) serves as a two-way communication channel between primary production and meat inspection. It should provide information on the health status of the animals including mortality rates, occurrence of disease, veterinary treatments, specific laboratory testing, etc., allowing the evaluation of the health status of incoming batches and thus preventing sick animals from entering the food chain. In principle, therefore, adequate collection and proper utilisation of FCI can be beneficial to *ante-* and/or *post-mortem* meat inspection. *Ante-mortem* inspection of farmed game animals facilitates the detection of observable abnormalities and animal identification enabling traceability. Visual examination during *ante-mortem* inspection detects extensive faecal and other contamination on hides and feathers, which

increases the risk of microbial cross-contamination during slaughter. This facilitates the implementation of preventative control measures. *Post-mortem* inspection detects visible, primarily faecal, carcass contamination and allows for removal by trimming and may also be used to assess the general health status of the animal.

With regard to chemical hazards, it was noted that chemical testing is based on common standards for method performance and interpretation of results, laboratory accreditation and quality assurance schemes. In the case of most farmed game (i.e. deer, wild boars and ostriches) the production site is known and, therefore, collection of FCI, traceability and follow-up mechanisms are possible. In the case of rabbits reared in integrated systems, a large amount of FCI is provided to the slaughterhouse which, in combination with *ante-/post-mortem* inspection, is supportive, in general, of the collection of appropriate samples for monitoring of chemical residues and contaminants. Also, for rabbits reared in integrated systems, and the regular sampling and testing for chemical residues and contaminants is a disincentive for the development of undesirable practices.

A number of weaknesses of the current meat inspection system were also identified. FCI is probably underutilised owing to the lack of indicators and harmonisation across the EU. In its current form, FCI provides generic data that cannot be used to evaluate the risk of specific hazards of public health concern in a given batch of animals and cannot be used to distinguish between high- and low-risk farms. The main weakness of *ante-mortem* inspection is the inability to detect the zoonotic hazards identified as high priority for farmed game. Manual handling of meat including the use of palpation and incision techniques during *post-mortem* inspection does not contribute to the detection of biological hazards of high priority such as *Salmonella* spp., but may actually increase the spread these hazards by cross-contamination.

In the case of chemical hazards, a major weakness of the current *ante-/post-mortem* meat inspection procedures is that the presence of chemical hazards generally cannot be detected at the slaughterhouse level. For farmed game, including rabbits, there is poor integration between the testing of feed materials for undesirable substances and the NRCPs. For some farmed game species, such as reindeer, FCI may be incomplete (particularly relating to environmental contaminants) due to the fact that the animals are in migratory herds. For rabbits reared in small holdings, FCI may also be incomplete due to the trading practices for these animals prior to slaughter.

Control of high-priority hazards is currently reliant on the implementation of effective prerequisite (good hygiene practice; GHP) and hazard analysis and critical control point (HACCP) programmes in the slaughterhouse. More effective control of these hazards could be achieved using an improved FCI system and risk-based controls along the farm to chilled carcass continuum. This should include clear and measurable EU targets to be reached at the national level for prevalence and/or concentration of *T. gondii* in farmed deer carcasses and *Salmonella* spp. and *T. gondii* on/in farmed wild boar carcasses and, when appropriate, on/in farmed deer/wild boar farms/herds. An important element of an integrated farmed deer/wild boar carcass meat safety assurance system should be risk categorisation of farms/herds based on farm descriptors and historical data as well as herd-specific information, including monitoring of harmonised epidemiological indicators (HEIs). Improvement of slaughter hygiene should be sought in abattoirs with historically unsatisfactory performance, starting with a thorough review of current HACCP and prerequisite systems with follow-up improvement actions including technological and managerial interventions.

The possibility of identifying high- and low-risk herds/batches for *Salmonella* spp. in farmed wild boar before slaughter should be investigated, as should the development of *Salmonella* targets and/or reduction targets at the primary production stage. If *Salmonella* spp. is present in the farmed wild boar slaughtered at the slaughterhouse, improved hygiene is recommended. Decontamination methods should also be considered as a complementary 'multiple hurdle' strategy to control *Salmonella* contamination of farmed wild boar carcasses. As is currently the case for other livestock, process hygiene criteria should be mandatory for all farmed game species.

*T. gondii* in farmed deer and farmed wild boar should be investigated using a baseline study and thereafter controlled using risk management options such as freezing or heat treatment. This would be facilitated by a risk assessment; however, this is reliant on the successful completion of source attribution studies.

'New'chemical hazards identified are largely persistent organic pollutants that have not been comprehensively covered by the sampling plans of the current meat inspection or which have not been included in such sampling plans. Due to the nature of the husbandry systems applied, farmed game are more likely to be exposed to environmental contaminants (including radioactivity in certain geographic regions) than some other farm animals, and therefore, sampling and testing plans should be developed for these chemical hazards.

Palpation/incision used in current *post-mortem* inspection should be omitted in farmed wild boar to reduce the risk of cross-contamination of the carcasses with *Salmonella* spp. from the lymph nodes. Although *Salmonella* spp. was not prioritised for meat inspection in farmed deer and reindeer, omitting palpation and incision should also be considered as these activities do not facilitate the detection of zoonotic agents but increase the risk of carcass contamination. Palpation and incision may be used during *post-mortem* examination if relevant abnormalities have been detected on/in an animal as a result of FCI/*ante-mortem* or other *post-mortem* inspection activities. This should be performed separately from the slaughter-line operation and accompanied by laboratory testing as required. The omission of mandatory *Trichinella* testing would most likely increase exposure of consumers to viable larvae, but to what extent is unclear.

With regard to biological hazards it is recommended that FCI be systematically collected and analysed for the high-priority hazards in farmed game at both the herd and abattoir levels. Research on the optimal ways of collecting and using FCI for risk categorisation and differentiated slaughter of farmed deer and farmed wild boar is required. Categorisation of farmed wild boar farms in terms of *Salmonella* spp. and *T. gondii* should be investigated with a view to implementing additional measures in the slaughterhouse for those hazards categorised as high priority for meat inspection. The efficacy of farmed wild boar carcass treatments to be used for controlling *Salmonella* spp. should be reviewed and further investigations undertaken as required with the specific objective of making recommendations regarding the most effective methods. *Trichinella* testing should continue in farmed wild boar and positive carcasses should continue to be removed from the food chain. The effect of this omission on the risk posed by non-meat-borne zoonoses such as *Echinococcus granulosus*, *Fasciola hepatica*, *Dicrocoelium dendriticum* and *Mycobacterium bovis* should be assessed.

With some few exceptions, veterinary medicinal products are not specifically licensed for farmed game and only a very few are licensed for use in rabbits. However, diseased or injured animals will be treated as required under the 'Cascade Usage' system. European Commission Decision 97/747/EC requires a minimum of 100 samples of farmed game (unspecified as to species) to be taken annually for NRCP testing, rather than the level of testing being proportional to the production of each species in each Member State (MS). Future monitoring programmes should be based on the risk of occurrence of chemical residues and contaminants, taking into account the completeness and quality of the FCI supplied and the ranking of chemical substances into categories of potential concern, which ranking needs to regularly updated. FCI for farmed game and rabbits should provide information on the specific environmental conditions of the farms where the animals are reared, including treatments, and any medication given should be presented in on-farm registries serving as FCI prior to slaughter. Control programmes for chemical residues and contaminants should be less prescriptive, with sufficient flexibility to adapt to results of testing, and should include 'new hazards'. There is a need for an improved integration of sampling, testing and intervention protocols across the food chain, NRCPs, feed control and monitoring of environmental contaminants. A series of further recommendations, dealing with control measures, testing and analytical techniques, are made in relation to chemical hazards.



The implications for surveillance of animal health and welfare of the changes proposed to the current meat inspection system were evaluated quantitatively and qualitatively. The proposed changes included the omission of palpation and incision in farmed game subjected to routine slaughter at *post-mortem* inspection. In the case of farmed deer, reindeer and wild boar, this implies omission of palpation and incision of several organs and lymph nodes. In the case of farmed rabbits and ostriches, the current meat inspection procedure is already visual only; therefore, no impact is expected from this specific recommendation for these species. The recommendations for chemical hazards were related to the ranking of chemical substances of potential concern, to sampling based on the types and likelihood of occurrence of chemical residues and contaminants and on the completeness and quality of the FCI supplied, and to the inclusion of 'new hazards' in control programmes for residues and contaminants.

The assessment on animal health and welfare concluded that the elimination of palpation and incision would be strongly detrimental for the likelihood of detecting tuberculosis through meat inspection. As farmed deer and farmed wild boar can act as tuberculosis reservoirs, any reduction in the detection, due to changes in the *post-mortem* inspection procedures will have some consequences for the overall surveillance of tuberculosis. It is therefore recommended, from the assessment on animal health and welfare, to maintain palpation and incision of lymph nodes and organs, both for farmed deer and for farmed wild boar. Slaughterhouse surveillance was found to be far more effective than clinical surveillance for the detection of tuberculosis in farmed deer. The setting up of proper animal identification schemes throughout the MSs for these two farmed game species, and the inclusion of premises where they are kept in the national tuberculosis monitoring and control programmes, would help to the overall surveillance of tuberculosis. The prevalence and number of diseases affecting reindeer is very low, thus, changes in meat inspection are not expected to significantly affect the surveillance of animal diseases in farmed reindeer. The proposed changes to meat inspection are not expected to affect the detection levels for welfare conditions as they can also be detected during visual only meat inspection.

The assessment on animal health and welfare concluded that recommendations for chemical hazards would not have a negative impact on surveillance of animal health and welfare conditions.



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#### BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Regulation (EC) No 854/2004<sup>4</sup> 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. 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 methods should be recommended as explained in detail under points 2, and 4 of the terms of reference.

<sup>&</sup>lt;sup>4</sup> Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption. Official Journal of the EU L 139, 30.4.2004, p. 206–320.



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* spp., *Campylobacter* spp.) are identified under terms of reference 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. When appropriate, food chain information should be taken into account.



#### 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 are also covered with respect to the possible implications of adaptations/alterations to current inspection methods or the introduction of novel inspection methods proposed by this mandate.

Issues that are not of public health significance but which compromise fitness of the meat for human consumption (Regulation (EC) No 854/2004,<sup>5</sup> Annex I, Section II, Chapter V) are outside the scope of the mandate. Examples include sexual odour ('boar taint'). Transmissible spongiform encephalopathies (TSEs) are also outside the scope of the mandate.

The impact of changes to meat inspection procedures on the occupational health of abattoir workers, inspectors, etc., is outside the scope of the mandate. Additionally, biological hazards representing primarily occupational health risks, the controls related to any biological hazards at any meat chain stage beyond chilling in the 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 854/20045 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 reports.

The European Food Safety Authority (EFSA) has been requested to issue scientific opinions related to inspection of meat from different species. In addition, EFSA has been requested to provide technical assistance 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. 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 the fact that consideration has to be given to zoonotic hazards, animal health and welfare issues, and chemical hazards (e.g. residues of veterinary drugs and chemical contaminants), the involvement of several EFSA units was necessary. More specifically, the mandate for the delivery of the scientific opinion was allocated to the Biological Hazards (BIOHAZ), Animal Health and Welfare (AHAW) and Contaminants in the Food Chain (CONTAM) Panels, and the mandate for the delivery of the technical assistance was allocated to the Biological Monitoring (BIOMO), Scientific Assessment Support (SAS) and Dietary and Chemical Monitoring (DCM) Units of the Risk Assessment and Scientific Assistance Directorate.

This scientific opinion therefore concerns the assessment of meat inspection in farmed game, and it includes the answer to the terms of reference proposed by the European Commission. Owing to the complexity of the mandate, the presentation of the outcome does not follow the usual layout. For ease of reading, the 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 appendices as endorsed by these 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).

<sup>&</sup>lt;sup>5</sup> 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.



#### CONCLUSIONS AND RECOMMENDATIONS ANSWERING THE TERMS OF REFERENCE

#### CONCLUSIONS

Answer to Term of Reference 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 with fattening animals).

#### **Conclusions on biological hazards**

- Biological hazards identified as farmed game meat borne and currently present in the EU farmed game population include; *Campylobacter* spp., *Salmonella* spp., pathogenic VTEC, *Yersinia enterocolitica, Yersinia pseudotuberculosis, Toxoplasma gondii* and Hepatitis E virus (HEV) in farmed deer; *Campylobacter* spp. and *Salmonella* spp. in farmed ostriches; *Campylobacter* spp., *Salmonella* spp., pathogenic VTEC, *Y. enterocolitica, T. gondii, Trichinella* spp. and HEV in farmed wild boar; and *Salmonella* spp., pathogenic VTEC and HEV in farmed rabbits. These were subjected to prioritisation for meat inspection based on a decision tree.
- Based on the limited data available, the identified farmed game meat-borne biological hazards were categorised as follows:
  - *T. gondii* in farmed deer and *Salmonella* spp. and *T. gondii* in farmed wild boar were assessed as of high priority for farmed game meat inspection;
  - *Y. enterocolitica* and *Y. pseudotuberculosis* were ranked as low priority in farmed deer. *Y. enterocolitica*, pathogenic VTEC and *Trichinella* spp. were also ranked as low in farmed wild boar, the last because of current controls;
  - The following hazards were categorised as 'priority undetermined due to insufficient data': *Campylobacter spp.*, *Salmonella* spp., pathogenic VTEC and HEV in farmed deer; *Campylobacter* spp. and *Salmonella* spp. in ostrich; *Campylobacter* spp. and HEV in farmed wild boar and *Salmonella* spp., pathogenic VTEC and HEV in farmed rabbit.

#### **Conclusions on chemical hazards**

- Game farming (deer, reindeer, ostriches and wild boars) is markedly different to rabbit farming, and the types and likelihood of occurrence of chemical residues and contaminants vary between these animal species. Therefore, farmed game and rabbits were considered separately in the identification and ranking of chemical hazards.
- A multi-step approach was used for the identification and ranking of chemical hazards. Evaluation of the 2005–2010 national residue control plans (NRCPs) outcome indicated that 0.91 % of the total number of farmed game samples and 0.67 % of the total number of rabbit samples were non-compliant for one or more substances listed in Council Directive 96/23/EC. Available data, however, do not allow for a reliable assessment of consumer exposure.
- Ranking of chemical residues and contaminants based on predefined criteria, relating to bioaccumulation, toxicological profile and likelihood of occurrence, and taking into account the findings from the NRCPs for the period 2005–2010 was as follows:
  - No substances were classified in the high potential concern category for farmed game or for rabbits.



- Within the category of medium potential concern for farmed game are nitrofurans, nitroimidazoles and cadmium.
- Within the category of medium potential concern for rabbits are chloramphenicol and nitrofurans.
- All other substances listed in Council Directive 96/23/EC are ranked as being of low or negligible potential concern. Potentially higher exposure of consumers to these substances from farmed game or rabbit meat takes place only incidentally, as a result of mistakes or non-compliance with known and regulated procedures.

#### Answer to Term of Reference 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.

#### **Conclusions on biological hazards**

It is unclear as to which *post-mortem* inspection procedure should be used for farmed deer.

Strengths of the current meat inspection methodology for biological hazards are as follows:

- Food chain information (FCI) serves as a two-way communication channel between primary production and meat inspection. It should provide information on the health status of the animals, including mortality rates, occurrence of disease, veterinary treatments, specific laboratory testing, etc., allowing evaluation of the health status of incoming batches and thus preventing sick animals from entering the food chain. In principle, therefore, adequate collection and proper utilisation of FCI can be beneficial to *ante-* and/or *post-mortem* meat inspection.
- Ante-mortem inspection of farmed game animals facilitates the detection of observable abnormalities and animal identification, enabling traceability. Although it does not detect asymptomatic carriers of pathogens of public health concern, such as *Salmonella* spp. and *T. gondii*, it does provide an assessment of animal/herd health, which, if compromised, may lead to a greater public health risk.
- *Ante-mortem* inspection also has the potential to detect new diseases, provided these have clinical symptoms, which may be of direct public health significance.
- Visual examination during *ante-mortem* inspection detects extensive faecal and other contamination on hides and feathers, which increases the risk of microbial cross-contamination during slaughter. This facilitates the implementation of preventative control measures.
- *Post-mortem* inspection detects visible, primarily faecal, carcass contamination and allows for removal by trimming and may also be used to assess the general health status of the animal.
- *Trichinella* testing of wild boar carcasses, and removal of positive carcasses from the food chain, has protected consumers from trichinosis.

Weaknesses of the current meat inspection methodology for biological hazards are as follows:

• In practice, FCI is probably underutilised owing to the lack of indicators and harmonisation across the EU. In its current form, FCI provides generic data that cannot be used to evaluate the risk of specific hazards of public health concern in a given batch of animals and cannot be used to distinguish between high- and low-risk farms. Its application is therefore limited.



- *Ante-* and *post-mortem* inspection is not able to detect the public health hazards identified as the main concerns for food safety.
- Manual handling of meat including the use of palpation and incision techniques during *post-mortem* inspection does not contribute to the detection of high-priority farmed game meatborne hazards such as *Salmonella* spp., but may actually increase and spread these hazards by cross-contamination.

#### **Conclusions on chemical hazards**

Strengths of the current meat inspection methodology for chemical hazards are as follows:

- Residue testing is based on common standards for method performance and interpretation of results, laboratory accreditation and quality assurance schemes.
- For farmed game, such as deer, wild boar and ostrich, the production site is known and, therefore, collection of FCI, traceability and follow-up mechanisms are possible.
- In the case of rabbits reared in integrated systems, a high degree of FCI is provided to the slaughterhouse. Moreover, there are well-developed systems and follow-up mechanisms subsequent to the identification of non-compliant samples.
- In the case of rabbits reared in integrated systems, regular sampling and testing for chemical residues and contaminants is a disincentive for the development of undesirable practices.
- For rabbits reared in integrated systems, the current combination of FCI and *ante- and post-mortem* inspection has been found, in general, to be supportive of the collection of appropriate samples for monitoring of chemical residues and contaminants.

Weaknesses of the current meat inspection methodology for chemical hazards are as follows:

- Chemical hazards generally cannot be detected by current *ante-/post-mortem* meat inspection procedures.
- In the case of both farmed game and rabbits, there is poor integration between the testing of feed materials for undesirable substances and the NRCPs in terms of communication and follow-up testing strategies or interventions.
- For some farmed game, such as reindeer, FCI may be incomplete (particularly relating to environmental contaminants) due to the fact that the animals are migratory herds.
- For rabbits reared in small holdings, FCI may be incomplete because of the trading practices for these animals prior to slaughter.

#### Conclusions on animal health and welfare

- A significant difference in the effectiveness between the current and the visual only meat inspection scenarios was seen for tuberculosis in deer, with a significant reduction in the probability of detection of this disease for the visual only meat inspection. No difference in detection effectiveness was observed for the other diseases and welfare conditions analysed for farmed red deer and farmed wild boar.
- Meat inspection is a useful tool for tuberculosis detection in both farmed deer and farmed wild boar, and the only realistic tool for surveillance in farmed wild boar. Given the relevance of farmed deer and farmed wild boar in tuberculosis epidemiology, and given the fact that many cases of confirmed infection only show small local lesions, eliminating palpation and incision would be strongly detrimental for the likelihood of detecting tuberculosis through meat inspection.



- In contrast with other large animals such as cattle or pigs, farmed deer and farmed wild boar currently lack traceability in many Member States. This lack impedes tracing back any detected tuberculosis cases to the farm of origin.
- Also in contrast with most other farming systems, deer and wild boar farms still lack a proper registry in several Member States, and the definition of a deer farm or wild boar farm is not homogeneous throughout the Member States.
- Farmed deer and farmed wild boar can act as tuberculosis reservoirs, owing to this, any reduction in the detection due to changes in the *post-mortem* inspection procedures, will have consequences for the overall surveillance of tuberculosis.
- The conclusions and recommendations on chemical hazards were reviewed by the AHAW Working Group experts and none of them were considered to have an impact on animal health and welfare surveillance and monitoring.

#### Answer to Term of Reference 3

If new hazards currently not covered by the meat inspection system (e.g. *Salmonella*, *Campylobacter*) are identified under terms of reference 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 on biological hazards**

- It is not possible to detect the hazards ranked as high priority for farmed game meat inspection using traditional meat inspection methods. Control is currently reliant on the implementation of an effective HACCP programme and prerequisite activities (GHP) in the slaughterhouse.
- Information on the biological risks associated with the consumption of meat from farmed game animal species is sometimes scant and unreliable. In order to facilitate decision making, harmonised surveys are required to establish values for the prevalence of the main hazards at live animal and carcass level in individual MSs. Epidemiological and risk assessment studies could also be required to determine the specific risk to public health associated with the consumption of meat from farmed game animal species.
- In the event that these studies confirm a high risk to public health through the consumption of meat from farmed game animal species, consideration should be given to the setting of clear and measurable EU targets at the farm and carcass level. To meet these targets and criteria, a variety of control options for the main hazards are available, at both farm and abattoir level.
- An important element of an integrated farmed deer/wild boar carcass meat safety assurance system should be risk categorisation of farms/herds based on farm descriptors and historical data as well as herd-specific information, including monitoring of harmonized epidemiological indicators (HEI) as described in the EFSA Report (EFSA, 2013).
- Improvement of slaughter hygiene should be sought in abattoirs with historically unsatisfactory performance, starting with a thorough review of current HACCP and prerequisite systems with follow-up improvement actions including technological and managerial interventions.
- The possibility of identifying high- and low-risk herds/batches for *Salmonella* spp. in farmed wild boar before slaughter should be investigated, as should the development of *Salmonella* targets and/or reduction targets at the primary production stage. If *Salmonella* spp. are present in the farmed wild boar slaughtered at the slaughterhouse, increased hygiene is recommended. Decontamination methods should also be considered as a complementary 'multiple hurdle' strategy to control *Salmonella* contamination of farmed wild boar carcasses. As is currently the cases for other livestock, process hygiene criteria (PHC) should be mandatory for all farmed game species.



• *T. gondii* in farmed deer and farmed wild boar should be investigated using a baseline study and thereafter controlled using risk management options such as freezing or heat treatment. This would be facilitated by a risk assessment; however, this is reliant on the successful completion of source attribution studies.

#### **Conclusions on chemical hazards**

- 'New hazards' are defined as compounds that have been identified as anthropogenic chemicals in food-producing animals and derived products and in humans and for which occurrence data in farmed game and in rabbits are scarce and which may not be systematically covered by the NRCPs. Examples are polychlorinated dibenzo-*p*-dioxins, polychlorinated dibenzofurans (together often termed 'dioxins'), dioxin-like polychlorinated biphenyls (DL-PCBs), non dioxin-like polychlorinated biphenyls (NDL-PCBs), brominated flame retardants, such as polybrominated diphenylethers (PBDEs) and hexabromocyclododecanes (HBCDDs), and perfluorinated compounds, such as perfluoroctane sulfonate (PFOS) and perfluoroctanoic acid (PFOA).
- Due to the nature of the husbandry systems applied, farmed game are more likely to be exposed to environmental contaminants (including radioactivity in certain geographic regions) than some other livestock. Therefore, any incident giving rise to contamination of the environment may be observed primarily in farmed game kept outdoors.

#### Answer to Term of Reference 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 on biological hazards**

- Palpation/incision used in current *post-mortem* inspection should be omitted in farmed wild boar to reduce the risk of cross-contamination of the carcasses with *Salmonella* spp. from the lymph nodes. Although *Salmonella* spp. was not prioritised for meat inspection in farmed deer and reindeer, omitting palpation and incision should also be considered as these activities do not facilitate the detection of zoonotic agents but increase the risk of carcass contamination. *Post-mortem* meat inspection in farmed ostrich and rabbit is already visual only so no change is required.
- Palpation and incision may be used during *post-mortem* examination if relevant abnormalities have been detected on/in an animal as a result of FCI/*ante-mortem* or other *post-mortem* inspection activities. Where appropriate, this should be performed separately from the slaughter line operation and accompanied by laboratory testing as required.
- The omission of mandatory *Trichinella* testing would most likely increase exposure of consumers to viable larvae, but to what extent is unclear.

#### **Conclusions on chemical hazards**

- Game farming in the EU is extremely diverse, with substantial differences between species (deer, reindeer, ostrich and wild boar). It cannot be compared to rabbit farming, which in many areas has evolved towards intensive farming practices. Therefore, the types and likelihood of occurrence of chemical residues and contaminants varies between these animal species.
- With some few exceptions, VMPs are not specifically licensed for farmed game and only a very few are licensed for use in rabbits. However, diseased or injured animals will be treated as



required under the 'cascade usage' system, for which a withdrawal period of 28 days is required, unless a national registration provides specific information regarding a species-specific withdrawal period.

• European Commission Decision 97/747/EC requires that a minimum of 100 samples of farmed game (unspecified as to species) are to be taken annually for the NRCP testing, rather than the level of testing being proportional to the production of each species in each MS.

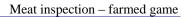
#### RECOMMENDATIONS

#### **Recommendations on biological hazards**

- It was considered that the following combinations may be ranked high priority if more data were available and thus further investigative studies and/or surveillance are recommended: farmed deer and pathogenic VTEC; ostrich and *Campylobacter* spp. and *Salmonella* spp.; wild boar and HEV.
- As the current legislation is not specific, the corresponding post-mortem inspection procedures for each farmed game species should be clarified.
- Systematic collection of FCI and analysis for the main hazards in farmed game at both the herd and abattoir levels is recommended. Research on the optimal ways of collecting and using FCI for risk categorisation and differentiated slaughter of farmed deer and farmed wild boar is required.
- Categorisation of farmed wild boar farms in terms of *Salmonella* spp. and *T. gondii* should be investigated with a view to implementing additional measures in the slaughterhouse for those farms categorised as high risk.
- The efficacy of farmed wild boar carcass treatments in controlling *Salmonella* spp. should be reviewed and further investigations undertaken as required with the specific objective of making clear recommendations regarding the most effective methods.
- *Trichinella* testing should continue in farmed wild boar and positive carcasses should continue to be removed from the food chain.
- The effect of this omission of palpation and incision on the meat safety risk posed by nonmeat-borne zoonoses such as *E. granulosus*, *F. hepatica*, and *M. bovis* should be periodically revisited in the future, particularly in those regions where these hazards are endemic.

#### **Recommendations on chemical hazards**

- Future monitoring programmes should be based on the risk of occurrence of chemical residues and contaminants, taking into account completeness and quality of the FCI supplied and the ranking of chemical compounds into categories of potential concern.
- Both farmed game and rabbits, both the ranking of chemical compounds and sampling plans should be regularly updated, taking into account any new information regarding the toxicological profile of chemical residues and contaminants, usage in the production of these animals and occurrence of individual substances as residues and contaminants.
- Control programmes for residues and contaminants should be less prescriptive, with sufficient flexibility to adapt to results of testing and should include 'new hazards'.
- There is a need for an improved integration of sampling, testing and intervention protocols across the food chain, NRCPs, feed control and monitoring of environmental contaminants.
- FCI for farmed game and rabbits should provide information on the specific environmental conditions of the farms where the animals are reared, including treatments, and any medication given to farmed game should be presented in on-farm registries serving as FCI prior to slaughter.





• The number of samples to be taken for each farmed game species should be proportional to the production in each MS and the application of analytical techniques covering multiple analytes and of new biologically based testing approaches should be encouraged and incorporated into the residue control programmes.

#### **Recommendations on animal health and welfare**

- Acknowledging that meat inspection is a useful tool for tuberculosis detection in farmed deer and farmed wild boar, that both groups of farmed game are relevant as *Mycobacterium bovis* maintenance hosts and that many cases of confirmed infection only show small local lesions, it is recommended to maintain palpation and incision both for deer and for wild boar.
- Given the current lack of individual traceability in farmed deer and wild boar, and considering that this lack likely impedes tracing back any detected tuberculosis cases to the farm of origin, it is recommended to set up proper animal identification schemes throughout the Member States.
- Considering that deer and wild boar farms often lack a proper registry in several Member States and also considering that the definition of a deer farm or wild boar farm is not homogeneous throughout the Member States, it is recommended that all fenced deer or wild boar populations should be defined as game farms. All game farms should be registered in each Member State.
- Given the importance of tuberculosis in farmed game, including deer and wild boar, it is recommended to set up a homogeneous tuberculosis testing scheme. This scheme could be based on live-testing and meat inspection.
- In view of the fact that farmed deer and farmed wild boar act as tuberculosis reservoirs, premises where these two animal species are kept should be included in the national tuberculosis monitoring and control programmes.



#### APPENDICES

#### Appendix A. Assessment on biological hazards

#### SUMMARY

Following a request from the European Commission, the EFSA Panel on Biological Hazards (BIOHAZ) was asked to deliver a scientific opinion on the public health hazards to be covered by inspection of meat from several animal species, with the contribution of the Panel on Contaminants in the Food Chain (CONTAM) and the Panel on Animal Health and Welfare (AHAW). Briefly, the main risks to public health that should be addressed by meat inspection were identified and ranked; the strengths and weaknesses of the current methods of meat inspection were evaluated; and recommendations were made for inspection methods fit for the purpose of meeting the overall objectives of meat inspection for hazards not covered by the current meat inspection system, and for adaptations of inspection methods and/or frequencies of inspections that provide an equivalent level of protection. In addition, the implications for animal health and animal welfare of any changes proposed to current inspection methods were assessed. This opinion covers the inspection of meat from farmed game, specifically farmed deer, reindeer, ostrich, wild boar and rabbit.

To fulfil this mandate, the first stage in this assessment focused on identifying the biological hazards that occur in farmed game in Europe. The relevance of each biological hazard was evaluated based on two criteria: (1) any evidence that the biological hazard is transmissible to humans through the handling, preparation and/or consumption of farmed game meat; and (2) evidence that the biological hazard is present in the farmed game population in the European Union (EU). Biological hazards that satisfy these two criteria were then ranked using a decision tree developed by the BIOHAZ Panel, which considered such information as incidence of human disease caused by the specific biological hazard, severity of the disease in humans, epidemiological linkage as well as animal and carcass hazard prevalence.

Based on the assessment, the biological hazards; *Salmonella* spp. in farmed wild boar and *Toxoplasma* gondii in farmed deer and farmed wild boar were ranked as a high priority for meat inspection. *Yersinia enterocolitica* and *Y. pseudotuberculosis* were ranked as low priority in farmed deer. *Y. enterocolitica* and pathogenic verotoxigenic *Escherichia coli* (VTEC) and *Trichinella* spp. were also ranked low priority in farmed wild boar, the last because of currently applied controls. The following hazards were categorised as 'priority undetermined due to insufficient data': *Campylobacter* spp., *Salmonella* spp., pathogenic VTEC and Hepatitis E virus (HEV) in farmed deer; *Campylobacter* spp. and *Salmonella* spp., pathogenic VTEC and HEV in farmed rabbit.

It should be noted that the identification and ranking of biological hazards is based on current knowledge and available data and, therefore, should be updated regularly, taking account of new data and including 'new hazards'.

Strengths of the current meat inspection were identified. Food chain information (FCI) serves as a two-way communication channel between primary production and meat inspection. It should provide information on the health status of the animals including mortality rates, occurrence of disease, veterinary treatments, specific laboratory testing, etc., allowing the evaluation of the health status of incoming batches and thus preventing sick animals from entering the food chain. In principle, therefore, adequate collection and proper utilisation of FCI can be beneficial to *ante-* and/or *post-mortem* meat inspection. *Ante-mortem* inspection of farmed game animals facilitates the detection of observable abnormalities and animal identification enabling traceability. Visual examination during *ante-mortem* inspection detects extensive faecal and other contamination on hides and feathers, which increases the risk of microbial cross-contamination during slaughter. This facilitates the implementation of preventative control measures. *Post-mortem* inspection detects visible, primarily faecal, carcass contamination and allows for removal by trimming and may also be used to assess the general health status of the animal.

A number of weaknesses of the current meat inspection system were also identified. FCI is probably underutilised owing to the lack of indicators and harmonisation across the EU. In its current form, FCI provides generic data that cannot be used to evaluate the risk of specific hazards of public health concern in a given batch of animals and cannot be used to distinguish between high- and low-risk farms. The main weakness of *ante-mortem* inspection is the inability to detect the zoonotic hazards identified as high priority for farmed game. Manual handling of meat including the use of palpation and incision techniques during *post-mortem* inspection does not contribute to the detection of biological hazards of high priority such as *Salmonella* spp., but may actually increase and spread these hazards by cross-contamination.

Control of high-priority hazards is currently reliant on the implementation of effective prerequisite (good hygiene practice; GHP) and hazard analysis and critical control point (HACCP) programmes in the slaughterhouse. More effective control of these hazards could be achieved using an improved FCI system and risk-based controls along the farm to chilled carcass continuum. This should include clear and measurable EU targets to be reached at the national level for prevalence and/or concentration of *T. gondii* in farmed deer carcasses and *Salmonella* spp. and *T. gondii* on/in farmed wild boar carcasses and, when appropriate, on/in farmed deer/wild boar farms/herds. An important element of an integrated farmed deer/wild boar carcass meat safety assurance system should be risk categorisation of farms/herds based on farm descriptors and historical data as well as herd-specific information, including monitoring of harmonised epidemiological indicators (HEIs). Improvement of slaughter hygiene should be sought in abattoirs with historically unsatisfactory performance, starting with a thorough review of current HACCP and prerequisite systems with follow-up improvement actions including technological and managerial interventions.

The possibility of identifying high- and low-risk herds/batches for *Salmonella* spp. in farmed wild boar before slaughter should be investigated, as should the development of *Salmonella* targets and/or reduction targets at the primary production stage. If *Salmonella* spp. is present in the farmed wild boar slaughtered at the slaughterhouse, improved hygiene is recommended. Decontamination methods should also be considered as a complementary 'multiple hurdle' strategy to control *Salmonella* contamination of farmed wild boar carcasses. As is currently the case for other livestock, process hygiene criteria should be mandatory for all farmed game species.

*T. gondii* in farmed deer and farmed wild boar should be investigated using a baseline study and thereafter controlled using risk management options such as freezing or heat treatment. This would be facilitated by a risk assessment; however, this is reliant on the successful completion of source attribution studies. Palpation/incision used in current *post-mortem* inspection should be omitted in farmed wild boar to reduce the risk of cross-contamination of the carcasses with *Salmonella* spp. from the lymph nodes. Although *Salmonella* spp. was not prioritised for meat inspection in farmed deer and reindeer, omitting palpation and incision should also be considered as these activities do not facilitate the detection of zoonotic agents but increase the risk of carcass contamination. Palpation and incision may be used during *post-mortem* or other *post-mortem* inspection activities. This should be performed separately from the slaughter-line operation and accompanied by laboratory testing as required. The omission of mandatory *Trichinella* testing would most likely increase exposure of consumers to viable larvae, but to what extent is unclear.

With regard to biological hazards it is recommended that FCI be systematically collected and analysed for the high-priority hazards in farmed game at both the herd and abattoir levels. Research on the optimal ways of collecting and using FCI for risk categorisation and differentiated slaughter of farmed deer and farmed wild boar is required. Categorisation of farmed wild boar farms in terms of *Salmonella* spp. and *T. gondii* should be investigated with a view to implementing additional measures in the slaughterhouse for those hazards categorised as high priority for meat inspection. The efficacy of farmed wild boar carcass treatments to be used for controlling *Salmonella* spp. should be reviewed and further investigations undertaken as required with the specific objective of making recommendations regarding the most effective methods. *Trichinella* testing should continue in farmed



wild boar and positive carcasses should continue to be removed from the food chain. The effect of the omission of palpation and incision on the detection and risk posed by non-meat-borne zoonoses such as *Echinococcus granulosus*, *Fasciola hepatica*, *Dicrocoelium dendriticum* and *Mycobacterium bovis* should be assessed.



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#### ASSESSMENT

#### 1. Introduction

#### **1.1.** Definition of meat inspection and scope of opinion

Assessing current meat inspection systems for farmed game with the aim of introducing improvements requires a common understanding of the term 'meat inspection'. However, as discussed previously (EFSA Panel on Biological Hazards (BIOHAZ), 2011, 2012), it seems that there is no precise, universally agreed, definition of *meat inspection*. The term *meat inspection* is not described specifically in current European Union (EU) legislation (Regulation (EC) No 854/2004) or in the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005); rather, there are references to elements of the inspection process for meat such as *ante-* and *post-mortem* inspections and food chain information (FCI). Consequently, the current understanding of the term *meat inspection* is probably based more on its practical application, and is somewhat intuitive, than on a specific, formal definition.

The BIOHAZ Panel defined the main scope of this scientific opinion as identifying and ranking the most relevant public health risks associated with meat from farmed game, assessing the strengths and weaknesses of the current meat inspection system, proposing alternative approaches for addressing current meat safety risks, and outlining a generic framework for inspection, prevention and control (including related methodology) for the prioritised hazards that are not sufficiently covered by the current system. Microbiological hazards representing only occupational health risks and/or whose detection is not required through visual meat inspection are not considered in this document.

In order to evaluate any important differences in meat inspection procedures between countries and/or regions as well as between species, the BIOHAZ Panel was supported by input provided during a technical hearing on meat inspection of farmed game, during which experts from several stakeholder organisations and invited experts presented information that had previously been requested by means of a questionnaire. Following the hearing, an event report was compiled (EFSA, 2012). The conclusions from this report are referred to in this opinion when relevant.

As farmed game often come into contact with wild animals, the risk of acquiring infection and the emergence of new pathogens may be greater than in domestic farm animals. Farmed game animals tend to be more easily stressed by contact with humans than farmed animals domesticated a long time ago, a situation that may be exacerbated by a lack of knowledge of how best to handle these animals. Furthermore, these animals are now living in large groups with very close animal contact, a situation that favours the development and rapid dissemination of new pathogenic organisms. Continuous monitoring for potential new zoonotic agents is therefore important.

Chemical hazards and associated meat safety risks in farmed game are considered by the CONTAM Panel in a separate part of this opinion (Appendix B). Although the highest priority is given to improving biological/chemical meat safety, any implications for animal health and animal welfare of the proposed changes were assessed by the AHAW Panel (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 (BIOMO) Unit in a separate document (EFSA, 2013).

#### **1.2.** Farmed game meat in EU legislation

The legal requirements for farmed game are laid down in Regulation (EC)  $852/2004^6$  and are supplemented by Regulation (EC) No 853/2004,<sup>7</sup> which specifies the hygiene requirements that must

<sup>&</sup>lt;sup>6</sup> Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, OJ L 139, 30.4.2004, p. 1–54.

be implemented by food businesses handling food of animal origin at all stages of the food chain. Regulation (EC) No 854/2004 covers the specific rules for the organisation of official controls on products of animal origin intended for human consumption.

Regulation (EC) No 853/2004 defines farmed game as farmed ratites (e.g. ostrich) and farmed land mammals other than domestic bovine (including *Bubalus* (buffalo) and bison species), porcine, ovine and caprine animals and domestic solipeds (mammals with a single hoof on each foot, e.g. horse); hence, this definition includes farmed lagomorphs (rabbits, hares). However, there are different specific requirements for farmed game (Annex III, Section III: Meat of farmed game) and for lagomorphs (Annex III, Section II: Meat of poultry and lagomorphs).

The same Regulation defines wild game as wild ungulates (hoofed animals) and lagomorphs (e.g. rabbits and hares), as well as other land mammals that are hunted for human consumption and are considered to be wild game under the applicable law in the MS concerned, including mammals living in enclosed territory under conditions of freedom similar to those of wild game and wild birds that are hunted for human consumption. Hunted game, which is dealt with in Regulation 853/2004, Annex III, Section IV, is not included in this opinion.

Regulation (EC) No 854/2004 also makes a distinction between the specific requirements (Annex I, Section IV) for the *ante-* and *post-mortem* inspections for farmed game (chapter VII) and farmed lagomorphs (chapter VI).

#### **1.3.** Selection of farmed game species

Only farmed game species are included in this opinion. These species are subject to *ante-mortem* inspection, in contrast to hunted (wild) game animals, in which only *post-mortem* inspection is possible. Consequently, food-borne hazards originating from wild (i.e. hunted) game were outside the scope of the mandate.

The consumption of game is limited relative to other animal species, and farmed game-associated illness/cases are often difficult to isolate and identify in the public health surveillance data. Thus, although the risk of disease due to consumption of farmed game is negligible at the aggregate population levels, it may be very high for an individual consumer of game meat. The risk to the consumer was therefore assessed in principle, per portion of farmed game meat. By doing so the risk was assessed on a comparable level with the other animal species including solipeds and small ruminants.

The criteria for including a farmed game species in this assessment were:

- amount of game meat produced per year;
- public health concerns;
- regional importance;
- community importance as indicated by, for example, legislation.

The groups of animal species covered by this opinion are farmed deer, farmed reindeer, farmed ostrich, farmed wild boar and farmed rabbit.

In the context of this opinion, farmed deer refers to all species of deer that are farmed. These are mainly red deer (*Cervus elaphus*) and fallow deer (*Dama dama*), but other species, such as roe deer

<sup>&</sup>lt;sup>7</sup> Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin, OJ L 139, 30.4.2004, p. 55–205.

(*Capreolus capreolus*), sika deer (*Cervus nippon*) and wapiti deer (*Cervus canadensis*), may also be included. As no data to the contrary were available, it was assumed that the consumption of meat from all these different species of deer presents the same risk of human illness.

Farmed reindeer was included because of their regional importance in the Nordic countries.

Farmed wild boar represents the same taxonomic species as domestic pigs, *Sus scrofa*. However, there are important differences in animal husbandry including housing, which could influence the risks associated with specific pathogens.

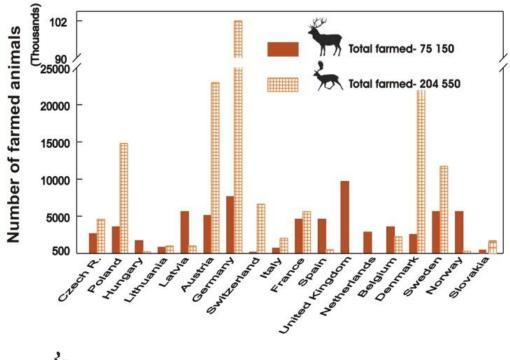
The European Commission requested the inclusion of rabbits as well as hares in the assessment. Farmed rabbits are often produced in intensive systems, different from the extensive systems used for other farmed game such as deer, reindeer, ostrich and wild boar. Hares are usually hunted, not farmed. Nevertheless, the conclusions and recommendations made for farmed rabbits can equally be applied to farmed hares.

#### **1.4.** Farmed game production in Europe

Production and consumption data for farmed game in the EU are scarce. The technical hearing on meat inspection of farmed game organised by EFSA provided useful data (EFSA, 2012). National data from competent authorities were also collected, but only very few scientific publications were available.

#### 1.4.1. Farmed deer

According to information provided during the technical hearing (EFSA, 2012), approximately 280 000 deer, predominantly red deer and fallow deer, are farmed in Europe, but less than half of these are slaughtered annually. Figure 1 shows the distribution of farmed deer production in most EU MSs in 2010.



🐂 Red deer 🦮 Fallow deer

Figure 1: The number and distribution of farmed red and fallow deer (EFSA, 2012).

In Austria, between 2 700 and 5 600 farmed deer were slaughtered annually between 2009 and 2011 (Austrian Ministry for Health, BMG). In Germany 10 000 to 12 400 fallow/sika deer, 2 600 to 3 200 red deer and 500 to 1 200 roe deer were slaughtered annually in the same period (DESTATIS, 2011).

According to a census carried out by the Irish Central Statistics Office, deer were being raised on 183 farms in Ireland in 2010 and the total population of farmed deer was 5 239 (CSO, 2010). There are two slaughterhouses that slaughter deer in Ireland, and the total numbers of animals slaughtered in 2010, 2011 and 2012 were 1 331, 1 115 and 434, respectively (information supplied by the Irish Department of Agriculture, Food and the Marine).

In Finland, there are between 300 and 500 farmed deer on 17 farms (Finnish database). The average number of farmed deer per farm is 20–30. According to meat inspection records, 86 farmed deer were slaughtered in 2009 and two in 2010. In 2011, no deer meat inspection was reported (Finnish Food Safety Authority, Evira).

#### 1.4.2. Farmed reindeer

Reindeer are raised in Sweden and Finland. Reindeer farming is a traditional livelihood in which the animals are pastured extensively in large areas in herds which include animals with different owners. The owner of a given reindeer is indicated by cutting specific marks in the ears. The reindeer herding is organised by Sami villages in Sweden and by local reindeer herding cooperatives in Finland. The total number of reindeer in Finland is about 200 000, in Sweden about 250 000 and in Norway around 240 000.

According to the EU food hygiene legislation, reindeer belong to the category of farmed game. However, they differ from other farmed game as they live in almost the same conditions as wild game.

Before slaughter, reindeer are herded into corrals, where individual animals are selected for slaughter. The selected animals are separated and transported alive to the slaughterhouse, either by specific vehicles or by herding.

In Finland, between 75 000 and 85 000 reindeer were subject to meat inspection annually from 2009 to 2011 (Finnish Food Safety Authority, Evira). The Finnish register of reindeer counts the animals slaughtered from the beginning of June until the end of May the following year (Finnish reindeer slaughter year). According to this register, in 2009/2010 and 2010/2011, around 105 000 reindeer were slaughtered, which includes animals slaughtered in slaughterhouses and presented for official meat inspection but also animals slaughtered at home for own consumption or sold directly to consumers.

The Swedish reindeer slaughter period runs from August to the following April. Between August 2010 and April 2011 (Swedish reindeer slaughter year 2010/2011), 53 000 reindeer were slaughtered in Swedish slaughterhouses and about 4 000 Swedish reindeer were slaughtered in other countries, mostly in Finland.

#### **1.4.3.** Farmed ostriches

Ostriches are produced on a small to medium scale, with about 5 000 animals slaughtered per year in Italy. According to Swedish meat inspection data, approximately 600 ostriches are slaughtered in Sweden each year. According to Finnish meat inspection records, between 11 and 38 ostriches were slaughtered annually from 2009 to 2011 (Finnish Food Safety Authority, Evira). In Austria, data on slaughtered ostriches are recorded under 'other poultry', which also includes ducks and geese, but excludes chicken and turkeys. According to these data, 1 554 'other poultry' were slaughtered in 2009, 4 160 in 2010 and 491 in 2011 (Austrian Ministry for Health, BMG). Based on questionnaires to attendees of the XII World Ostrich Congress, (Carbajo, 2006) it was estimated that ostrich production in 2006 was 12 000 slaughter birds in Hungary and 7 000 in Spain.



Ostriches are slaughtered when about 250 days of age, typically in cattle slaughter plants, but by electrical stunning, as captive-bolt stunning would be very dangerous for the operator. There are exceptions to this; for example in the UK on-farm slaughter is preferred because of animal welfare considerations. In Italy, fewer than 10 cattle slaughter plants are authorised for ostrich slaughter and are required to separate defeathering from other stages. There are probably another five or six slaughter plants that are integrated and located on individual ostrich farms. Ostriches are often skinned rather than defeathered. Ostrich hide and feathers are other valuable products of ostrich slaughter.

#### 1.4.4. Farmed wild boars

Farmed wild boars are produced using extensive systems. The animals are kept as herds in large, outdoor, fenced areas, located in fields or forests. For example, in Finland, there are about 100 wild boar farms according to the national database. The average number of animals per farm is approximately 30, but a few holdings have between 100 and 200 animals.

The EFSA report (EFSA, 2013) revealed that the number of holdings of farmed wild boar in most countries is small, and each holding usually has fewer than 30 animals. Some countries report a few larger holdings of around 150 animals, but there was some confusion in the replies as to whether these were farmed wild boar or boar reared for hunting. Farmed wild boars are reared in external systems or as backyard pigs. Husbandry conditions often attempt to mimic their natural habit, allowing access to woodland and surface water. However, many are reared on pasture land in large paddocks with free-range shelter, similar to the conditions for the production of free-range pigs. Feed, including compound feed, grass, vegetables, silage, hay, fruits and grain, is always provided. Most responding countries reported that drinking water derived from wells or public water sources, and sometimes from natural water sources. Rodent controls were applied at some farms and cats mostly had a free access to the premises.

#### 1.4.5. Farmed rabbits

In southern Europe, rabbits (*Oryctolagus cuniculus*) are produced in intensive systems that are more similar to poultry production systems than to farmed game production. On commercial rabbit farms the number of does varies from several hundred up to thousands (in which case, they are often referred to as 'industrial' farms). The majority of farms are of a closed-cycle type, with breeding and growing units on the same farm. However, farms specialising in breeding or growing rabbits also exist, and are called 'open-cycle' farms. The rabbits are usually housed in closed buildings (breeding stock), but in southern Europe, broiler rabbits are sometimes housed in half-open buildings with open sides, called 'semi-plein-air' systems, or in outside cages, called 'plein-air' systems. Closed buildings have ventilation and heating systems, and many are also equipped with a water-cooling system. The temperature within buildings is normally maintained between 15 °C and 20 °C (EFSA, 2005).

There is an increasing trend to have only reproduction stock in the same reproduction phase or broiler rabbits of the same age within a building in order to facilitate an all-in, all-out system.

For a variety of reasons (reduction in labour costs, delivery of large numbers of broiler rabbits, all-in, all-out systems) and to enable traceability of meat products, batch management is generally used and so females are inseminated in large groups on the same day. As a result, animals are taken to the slaughterhouse on a limited but scheduled number of days in the year (EFSA, 2005).

In northern Europe, rabbits are generally produced using extensive systems and both the farms and slaughterhouses tend to be small.

Avitalia, the Italian union of poultry and rabbit breeders, reported during the technical hearing (EFSA, 2012) that approximately one million tonnes of rabbit meat is produced annually worldwide. The main producing (and consuming) countries in the EU are Italy, Spain and France with 54 % of production.



Some data on rabbit production and consumption based on data from the Avitalia document 'Production and world market: the rabbit in the European Union' and from the Spanish ministry for agriculture is provided in Table 1.

**Table 1:** Available data on annual rabbit production and consumption in the EU (Avitalia<sup>a</sup> and Spanish ministry<sup>b</sup>).

Country	Production (tonnes per annum)	Consumption (kg/person/annum)
Italy	230 000 <sup>a</sup>	4.5 <sup>a</sup>
France	91 000 (in 2010) <sup>b</sup>	$3.0^{a}$
Spain	63 242 (in 2010) <sup>b</sup>	$2.0^{a}$
The Netherlands	30 000 <sup>a</sup>	Data not available
Greece	$6\ 000^{a}$	Data not available
Portugal	$20\ 000^{a}$	$1.0^{\mathrm{a}}$
Other European countries	Negligible	Negligible

a: http://www.rabbitadvocacy.com/pdf\_files/Rabbit%20Industry%20Production%20EU.pdf b: http://www.magrama.gob.es/es/estadistica/temas/estadisticas-agrarias/

#### 2. Hazard identification and risk ranking

#### 2.1. Hazard identification

#### 2.1.1. Methodology of hazard identification

The first step in the hazard identification carried out in this assessment focused on identifying biological hazards that occur in farmed game in Europe and that may be carried by farmed game meat, i.e. potentially transmitted to humans through the handling, preparation and/or consumption of farmed game meat. In the context of this opinion, when referring to *handling and preparation*, this should be interpreted as handling of farmed game meat that occurs immediately prior to consumption, when these activities are carried out by consumers or professional food handlers such as those in catering establishments. The hazards were identified based on evidence found in the peer-reviewed literature, textbooks, official data (e.g. EU zoonoses monitoring data), previous assessments and EFSA opinions, and, when all other evidence was lacking, based on the expert opinion of the BIOHAZ Panel and its working group.

A list of all zoonotic hazards occurring in farmed game was established (long list of zoonotic hazards). Thereafter, the relevance of each hazard in each farmed game species was evaluated in the context of meat inspection, based on the following two criteria:

- Is there any evidence that the hazard is transmissible to humans through handling, preparation and/or consumption of farmed game meat?
- Is there evidence<sup>8</sup> that the hazard is present in the EU farmed game population?

Hazards that met the two criteria mentioned above were included in the shortlist of hazards to be considered for priority ranking.

#### 2.1.2. Results of hazard identification

The long list of zoonotic hazards is shown in Table 2. More details on these hazards can be found in Annexes A and B.

<sup>&</sup>lt;sup>8</sup> Evidence: at least one publication reporting the presence of the organism in farmed deer, reindeer, ostrich, wild boar or rabbit, in the EU.



Table 2:	Longlist of zoonotic hazards.
----------	-------------------------------

Bacteria	Actinobacillus lignieresii	
Dacteria		
	Aeromonas spp. Bacillus anthracis	
	Bacillus cereus	
	Brucella spp.	
	Campylobacter spp.	
	Clostridium botulinum	
	Clostridium difficile	
	Clostridium perfringens	
	Coxiella burnetii	
	Extended-spectrum and/or AmpC β-lactamases (ESBL/AmpC) gene-carrying bacteria	
	Francisella tularensis	
	Leptospira spp.	
	Listeria monocytogenes	
	Mycobacterium bovis, tuberculosis and avium	
	Meticillin-resistant Staphylococcus aureus (MRSA)	
	Pasteurella multocida	
	Salmonella spp.	
	Staphylococcus aureus	
	Streptococcus suis	
	Pathogenic verotoxigenic Escherichia coli (VTEC) <sup>a</sup>	
	Yersinia enterocolitica	
	Yersinia pseudotuberculosis	
Fungi	Dermatophytes	
8-	Encephalitozoon cuniculi	
Parasites	Alaria alata	
	Ascaris suum	
	Cryptosporidium spp.	
	Echinococcus granulosus and multilocularis	
	Giardia duodenalis	
	Taenia solium	
	Toxoplasma gondii	
	Trichinella spp.	
Viruses	Hepatitis E virus (HEV)	
	Parapoxvirus	

a: For the purposes of this opinion, pathogenic VTEC are defined as VTEC capable of causing disease in humans.

Hazards on the long list (Table 2 and described in Annex A) were evaluated in terms of whether the hazard is transmissible to humans through the handling, preparation and/or consumption of farmed game meat and presence in farmed game in Europe. Those hazards that fulfil both screening criteria (as described in Section 2.1.1) are presented in the shortlist of hazards (Table 3).

Hazards such as *Bacillus cereus*, *Clostridium botulinum*, *Clostridium perfringens*, *Listeria monocytogenes* and *Staphylococcus aureus* were considered to be ubiquitous in the environment and therefore likely to be present on animal hides and/or feathers and carcasses. The ubiquitous nature of these organisms means that more often than not confirmed cases of illness cannot be traced to a specific source. As a lack of evidence of transmission to human via farmed game may be due to this limitation, all of these potential hazards were shortlisted for each farmed game species.

*Bacillus anthracis* is also ubiquitous in the environment, where it forms resistant spores that may persist in the soil for extended periods of time. However, unlike the bacterial hazards mentioned above, cases are thoroughly investigated because of the serious nature of anthrax. It is therefore well established that farmed game meat-borne transmission of anthrax in the EU has rarely if ever been reported. Therefore, based on the data available, *B. anthracis* was not shortlisted for priority ranking.



#### **Table 3:**Shortlist of hazards.

Farmed game species	Hazards
Hazards that are ubiquitous in	the environment and therefore likely to be present on farmed game
carcasses	
All farmed game species	Bacillus cereus
	Clostridium botulinum
	Clostridium perfringens
	Listeria monocytogenes
	Staphylococcus aureus
Hazards for which there is eviden	nce of presence in specific farmed game animal species in Europe
Deer	Campylobacter spp.
	Salmonella spp.
	Pathogenic VTEC
	Yersinia enterocolitica
	Yersinia pseudotuberculosis
	Toxoplasma gondii
	Hepatitis E virus
Reindeer	None <sup>a</sup>
Ostrich	Campylobacter spp.
	Salmonella spp.
Wild boar	Campylobacter spp.
	Salmonella spp.
	Pathogenic VTEC
	Yersinia enterocolitica
	Toxoplasma gondii
	Trichinella spp.
	Hepatitis E virus
Rabbit	Salmonella spp.
	Pathogenic VTEC
	Hepatitis E virus

a: No additional hazards were shortlisted for farmed reindeer. Although *Campylobacter* spp. (Kemper et al., 2006) and *T. gondii* (Oksanen et al., 1997) may be present at a low prevalence in reindeer, there is no evidence that these pathogens are transmitted to humans through the handling, preparation and/or consumption of farmed reindeer meat. Hence neither these nor any of the other pathogens in the longlist (Table 2) were shortlisted. If new evidence becomes available in the future this situation should be reviewed.

#### 2.2. Priority ranking

#### 2.2.1. Methodology of priority ranking

In addition to the environmental hazards (*Bacillus cereus*, *Clostridium botulinum*, *Clostridium perfringens*, *Listeria monocytogenes* and *Staphylococcus aureus*), those hazards that met the two criteria set out in Section 2.1.1 (Table 3) were ranked using a decision tree developed by the BIOHAZ Panel (Figure 2) This decision tree was adapted from that presented in the opinion of poultry meat inspection (EFSA Panel on Biological Hazards (BIOHAZ), 2012). However, there are key differences as follows:

Carcass pathogen prevalence and source attribution are not considered as separate questions, or ranking steps, but these two questions are addressed together in a single step, as follows: 'is there evidence for meat from farmed game as an important risk factor'. This modification was considered appropriate as there were insufficient data at EU level for qualifying carcass prevalence and source attribution for the given hazards. Furthermore, farmed game meat consumption is very low, and consumption is unevenly distributed in the EU relative to meat from other animal species such as pigs or poultry. Attribution at the population level, as applied in the previous opinions, may not provide a sufficiently detailed perspective on the relative risk of different hazards in farmed game meat. The risk to consumers of farmed game meat rather than to the population as a whole was therefore assessed.

The term 'priority' has replaced the term 'risk' used in the pork and poultry opinions. Risk ranking requires a significant number of data on both the occurrence of the relevant hazards and the proportion of human disease attributable to the different hazard–meat species combinations. Although there were sufficient data to perform a risk ranking of the hazards associated with pork and poultry, this was not the case for all potential hazards in farmed game, as EU-wide baseline surveys and harmonised monitoring do not always exist and relevant studies published in the scientific and technical literature are often limited. The term 'priority' was therefore considered more appropriate than 'risk' for categorising the hazards associated with farmed game meat.

The modified decision tree therefore includes the following steps:

**Step 1**: Identify and exclude those hazards that are introduced and/or for which the risk for public health requires growth during steps following carcass chilling. The reasons for excluding such hazards from further assessment were as follows:

- The scope and target of meat inspection are focused on hazards present on the final farmed game carcass at the end of slaughter when the carcasses are chilled;
- Hazards introduced and/or for which the risk relates to growth during post-chilling processes or steps are better controlled later in the food production chain through, for instance, various interventions and HACCP-based control programmes.

**Step 2**: Assess the magnitude of the human health impact based on incidence, as measured by the notification rate or reported number of confirmed cases. Human disease data were supplied by The European Surveillance System (TESSy) and covered the years from 2008 to 2011 (Table 4). They were supplied as combined data for all EU reporting MSs, without specifying particular countries. An incidence in humans  $\geq 10/100\ 000$  population was considered to be high.

**Step 3**: Assess the severity of the disease in humans as measured by percentage of cases, for which information is available, resulting in death (see also Table 4). The severity of hazards was judged to high if the fatality rate exceeds 1 per 1 000 in more than one year. The disability-adjusted life years (DALYs), where available, were also considered (Table 5). The DALY metric quantifies the impact of disease on health-related quality of life of acute diseases and sequelae (years lived with disability, YLD), as well as the impact of premature deaths (years of life lost, YLL). Severe disease is considered to have a disease burden > 100 DALYs.

**Step 4**: Evaluate the strength of evidence that meat from farmed game is an important risk factor, based on the following criteria considered in priority order (as presented):

- epidemiological link, based on an association of consumption of farmed game meat as a risk factor for human cases or on outbreak data;
- farm-level prevalence/animal prevalence/carcass prevalence data;
- comparative considerations for meat from related species (e.g. domestic swine and farmed wild boar, wild game and farmed game) and data from outside the EU;
- expert opinion that farmed game meat consumption is a risk factor.

Data or studies from within the EU/EEA were preferred, but in their absence other relevant sources of data were considered. The final outcome of this process was classifying each hazard–farmed game species combination as 'high' priority, 'low' priority or 'priority undetermined due to insufficient data', defined as follows:

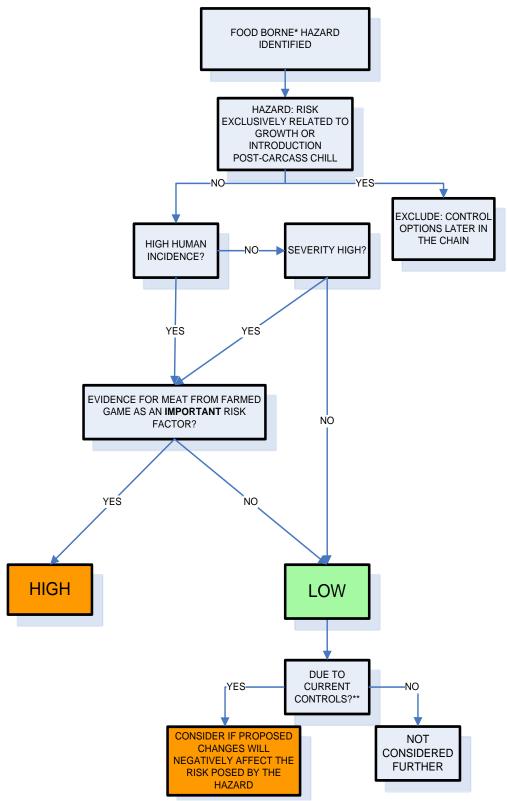
• The priority was characterised as 'high' when a hazard was identified as causing a high incidence and/or severity of illness in humans, and when strong evidence existed for farmed game meat being an important risk factor for human disease. Considering the limitations of the data available for the priority ranking, this risk category could be regarded as combining both



the medium- and high-risk categories of the risk ranking carried out in the poultry meat inspection opinion.

- The priority was characterised as 'low' when a hazard was identified as not associated with a high incidence and a high severity of human disease or if, despite the hazard causing a high incidence and/or severity in humans, there was insufficient evidence that meat from farmed game was an important risk factor for human disease.
- The priority was characterised as undetermined if the data available for the assessment of a given biological hazard were insufficient to conclude on the ranking.
- All hazards placed in the low-priority category were further evaluated to determine if this was a result of currently applied controls (i.e. any hazard-specific control measure implemented at farm and/or slaughter level before chilling of the carcass, including meat inspection procedures). If this was not the case, the hazard was not considered further. However, if this was the case then it was evaluated if any proposed changes to current meat inspection procedures would increase the risk posed by the hazard.





- \* Risk of human infection through handling, preparation and/or consumption of farmed game meat.
- \*\* Current controls: any hazard-specific control measures implemented at farm and/or slaughterhouse level before chilling of the carcasses.

Figure 2: Decision tree for ranking of hazards shortlisted in Table 3.



# 2.2.2. Data employed for priority ranking

Human disease data for Step 2 and Step 3 of the priority ranking were supplied by The European Surveillance System (TESSy) and covered the years 2008 to 2011 (Table 4). The data supplied are officially reported to the European Centre for Disease Prevention and Control (ECDC) by EU MSs; however, some countries do not report on certain diseases, and these are mentioned in Table 4. The data were supplied as aggregates from all reporting MSs. Data show notification rates of confirmed human disease cases as per 100 000 persons, and severity of illness in humans. Cases include all reported confirmed occurrences of the disease, regardless of the origin of the infection. In fact, establishing the food-related origin of infection is often not possible and is seldom reported. The data on severity include the percentage of those who died. This information is usually available in only a small proportion of cases. Finally, it should be borne in mind that the surveillance systems are set up differently in the various EU MSs, with different case definitions, national or restricted coverage, voluntary or compulsory reporting, different focus, target groups, etc. Furthermore, samples are taken and analysed from only a small percentage of patients and more often than not the organisms detected are not typed and/or reported to the relevant national health institutes.



**Table 4:**Incidence and severity estimates based on overall notification rate in humans and deathsas reported by EU MSs from 2008 to 2011.

Selected hazard	Incidence in humans (number of reported confirmed cases per 100 000 EU population <sup>a</sup> [number of confirmed cases])			Severity in humans (percentage of reported deaths [number of confirmed cases with information]) <sup>b</sup>				
	2008	2009	2010	2011	2008	2009	2010	2011
<i>Campylobacter</i> spp. <sup>c</sup>	62.00 [190 577]	64.19 [198 682]	69.37 [215 058 ]	71.53 [215 801]	0.03 [109 671]	0.02 [109 718]	0.03 [117 367]	0.04 [116 292]
VTEC (all serogroups) <sup>d</sup>	0.86 [3 156]	0.97 [3 583]	1.00 [3 656]	2.56 [9 478]	0.15 [1363]	0.35 [1 701]	0.38 [2 108]	0.75 [7 504]
VTEC (0157) <sup>e</sup>	0.35 [1 683]	0.39 [1 888]	0.31 [1510]	0.45 [2 195]	0.00 [241]	0.94 [318]	0.56 [536]	0.36 [1110]
Salmonella spp. <sup>f</sup>	29.46 [132 800]	23.81 [108 977]	21.51 [99 590]	20.37 [94 264]	0.09 [72 837]	0.08 [54273]	0.13 [46 996]	0.12 [46 808]
Yersinia enterocolitica <sup>g</sup>	0.16 [7 484]	0.15 [6 856]	0.13 [6162]	0.14 [6 724]	0.04 [5 314]	0.02 [4 756]	0.00 [4 646]	0.02 [4 792]
Yersinia pseudotubercul osis <sup>h</sup>	< 0.01 [146]	< 0.01 [95]	< 0.01 [118]	< 0.01 [64]	0.00 [7]	0.00 [3]	0.00 [30]	0.00 [23]
<i>Toxoplasma</i> gondii (congenital, i.e. in infants < 1 year) <sup>i</sup>	0.04 [83]	0.10 [306]	0.07 [279]	0.01 [29]	50.00 [2]	9.62 [260]	5.15 [233]	NA
<i>Trichinella</i> spp. <sup>j</sup>	0. 14 [670]	0.15 [750]	0.05 [223]	0.06 [268]	0.00 [36]	0.00 [295]	0.00 [126]	0.37 [205]
HEV	$NA^k$	NA	NA	NA	NA	NA	NA	NA

a EU population data based on individual MS population sizes reported in EUROSTAT (data extracted: September 2012). When the given hazard was not reported by a MS to TESSy, the population size reported by that MS was also taken out of the calculation of the overall EU population size.

b Calculated as the percentage of cases with fatal outcome over all cases of disease with known outcome, for a given hazard.

c Portugal, Greece not reporting.

d Portugal not reporting. For a more detailed review of VTEC (including serotype O157) incidence and severity in the EU see the recently published EFSA opinion on VTEC-seropathotype and scientific criteria regarding pathogenicity assessment (EFSA Panel on Biological Hazards (BIOHAZ), 2013).

e Portugal not reporting.

f S. enterica subsp. enterica serovar Typhi and S. Paratyphi serovars not included; Netherlands not reporting.

g Greece, Netherlands, Portugal not reporting.

h Greece, Netherlands, Portugal not reporting.

i Belgium, Denmark, Greece, Italy, Netherlands, Portugal, Sweden not reporting; Spain reporting inconsistently; France has not yet reported in 2011.

j Denmark not reporting.

k NA, not available.

Additionally, DALY estimates for the Netherlands (Havelaar et al., 2012) were available as an alternative indicator for disease severity. The DALY metric encompasses the impact of mortality as well as morbidity, and is based on estimates of the true incidence of acute disease as well as sequelae. The disease burden per case therefore represents a more comprehensive measure of disease severity than reported hospitalisations and deaths. DALY data are currently available only for the Netherlands and cannot be directly extrapolated to the EU as a whole. However, many parameters that contribute to the disease burden per case are not country specific, supporting the use of the Dutch results in an EU setting. Other parameters may depend on the health care system or other factors that are specific to individual countries.



**Table 5:** Estimated DALYs per 1 000 cases of illness in 2009 in the Netherlands (Havelaar et al., 2012) for selected hazards.

Hazard	DALYs estimates per 1 000 cases of illness		
Campylobacter spp.	41		
STEC 0157 <sup>a</sup>	143		
Salmonella spp.	49		
Yersinia enterocolitica, Yersinia pseudotuberculosis	[40–50] <sup>b</sup>		
Toxoplasma gondii	3 170/6 360 (acquired/congenital)		
Trichinella spp.	NA <sup>c</sup>		
Hepatitis E virus	460		

a: STEC, shiga toxigenic *Escherichia coli*;

b: Assumed to be comparable to *Salmonella* spp.

c: NA, not available.

All other data sources used for the priority ranking are discussed for each hazard and each farmed game species in Section 2.2.3.

## 2.2.3. Results of priority ranking

2.2.3.1. Farmed game meat-associated hazards not included because their risk is related to growth or introduction on carcasses post chill

*B. cereus, C. botulinum* and *C. perfringens* and their spores and *S. aureus* are considered ubiquitous bacteria, and can be found in a variety of foods. Their vegetative forms need temperatures above those used for refrigeration to grow in raw meat to concentration levels of public health relevance and thus the risk of disease seems not to be correlated with occurrence in raw meat but rather to improper storage that allows the production of toxin. Illness caused by *Listeria monocytogenes* is usually associated with ready-to-eat products, contamination of which has occurred during or after processing, followed by growth during storage at refrigeration temperatures.

L. monocytogenes and the toxins of B. cereus, C. botulinum, C. perfringens and S. aureus were therefore excluded after the first step of the risk ranking process.

## 2.2.3.2. Farmed deer

Relevant remaining hazards for priority ranking include *Campylobacter* spp., *Salmonella* spp., pathogenic VTEC, *Y. enterocolitica*, *Y. pseudotuberculosis*, *T. gondii* and HEV, and these hazards therefore moved onto the next step, '*High human incidence*'. According to the data in Table 4, the incidence of both *Campylobacter* spp. and *Salmonella* spp. infection in humans is  $\geq 10/100\ 000$ , and thus these species moved directly to Step 4 ('Evidence for meat from farmed game as an important risk factor'). For all other hazards the human incidence was below this threshold and they moved to Step 3. Pathogenic VTEC and *T. gondii* had fatality rates exceeding 1 per 1 000 (0.1) and moved to Step 4. *Y. enterocolitica* and *Y. pseudotuberculosis* had a 'low' severity and were assigned an overall priority ranking of 'low'. These were later assessed (chapter 4 and/or chapter 5) to determine whether or not this ranking was due to current meat inspection activities. Although there were no fatality rate data for Hepatitis E virus, the DALY was above the threshold required (Table 5) and this pathogen moved to Step 4.

## Epidemiological link

There are very few epidemiological data linking human illness caused by *Campylobacter* spp., *Salmonella* spp., pathogenic VTEC, *T. gondii* or HEV to farmed deer. In a case report, *Salmonella* Birkenhead was isolated from a 65-year-old man who presented with diarrhoea, vomiting and fever in Hawaii. The case was attributed to the consumption of raw venison (Madar et al., 2012). Tei et al. (2003) reported Hepatitis E infection among people who had eaten uncooked deer meat in Japan.



#### Farm/animal/carcass prevalence data

Farm, animal and carcass, prevalence data are also very limited for farmed deer. In Sweden, faecal samples from 56 farmed deer were *Campylobacter*-negative (Wahlstrom et al., 2003). In Ireland, four faecal samples from farmed deer on a mixed farm were similarly negative (Bolton et al., 2012). Paulsen et al. (2003) reported 3 % of German deer carcasses to be contaminated with *Campylobacter* spp. in a study which tested 100 carcasses.

*Salmonella* species have been isolated from farmed deer in Europe and elsewhere. Data reported by EU MSs under the framework of the Zoonoses Directive (2003/99/EC) showed that 2 % of 152 farmed deer sampled for *Salmonella* spp. between 2004 and 2010 were positive. However, other studies have failed to detect *Salmonella* spp. in animal faecal and carcass samples (Deutz et al., 2000; Wahlstrom et al., 2003; Paulsen and Winkelmayer, 2004; Lillehaug et al., 2005; Atanassova et al., 2008; Bolton et al., 2012).

Of the 28 078 farmed deer registered in Great Britain in the June 2010 Agricultural Census, only one case of *Salmonella* spp. was reported in the annual report on *Salmonella* spp. in livestock production for Great Britain for that year (DEFRA-AHVLA, 2010). *S.* Typhimurium DT2 was isolated from a sika deer found dead at an animal park. This was the first reported case of *Salmonella* spp. in deer since 2007, when two cases of *Salmonella* Reading were reported (DEFRA-AHVLA, 2007). No *Salmonella* spp. in deer was reported in 2011.

In New Zealand, *Salmonella* Typhimurium and *Salmonella* Bovismorbificans were isolated from two calves in the same red deer herd (McAllum et al., 1978). The histopathological findings were consistent with an acute septicaemia in both cases. In 2004, Clark et al. (2004) reported the emergence of a new strain of *Salmonella* Brandenburg affecting livestock, including deer, and humans in New Zealand. *Salmonella* Saint Paul was isolated from 16 out of 30 samples from a consignment of farmed venison sampled in one New Zealand game packing house but no *Salmonella* spp. was isolated from a consignment from another packing house (Sumner et al., 1977).

The death of seven deer in a herd of 30 sika deer in a park in Japan was attributed to *S*. Typhimurium (Sato et al., 2000). *Salmonella* Typhimurium infection was also diagnosed as the cause of death of eight captive elk (*Cervus elaphus nelsoni*) in the United States (Foreyt et al., 2001).

The farm prevalence of *E. coli* O157 in farmed deer is reported to be 3.33 % (1/30 farms positive) (French et al., 2010) with animal carriage rates ranging from 0.45 % (Dunn et al., 2004) to 30 % (3/10) (Chapman and Ackroyd, 1997). Several studies in Germany between 1992 and 2007 reported VTEC in 10–62 % of faecal samples (Bartels and Bulte, 2011) while official monitoring data suggest that in the period 2007–2010 an average of 9.8 % of 882 animal samples (EFSA and ECDC, 2012) were VTEC positive in Germany but most isolates were non-O157 and belonged to VTEC serogroups/types rarely if ever associated with human illness.

There is little information on the prevalence of *T. gondii* in farmed deer in Europe. Viable *T. gondii* was isolated from farmed red deer in Scotland (Williamson et al., 1980). In that study, on average 14.1 % of the deer tested in 1972, 1973 and 1975 were positive using the Sabin–Feldman dye test, while a sharp rise to 51.4 % was noted in the animals tested in 1974. In a New Zealand study, 219/417 (52.5 %) of serum samples from farmed deer were positive for *Toxoplasma* antibodies. Seroprevalence increased progressively with age, from 15.4 % in deer less than one year old to 86.6 % in deer aged eight years and older (Reichel et al., 1999).

## Comparative considerations

As farmed deer are reared outdoors in an environment not dissimilar to that encountered by wild deer, data relating to the latter were considered relevant for assessing the hazards in farmed deer. *Campylobacter* spp. carriage rates in wild deer range from 0 % to an estimated 4 %. Wahlstrom et al. (2003) examined faecal samples from 32 wild fallow deer but failed to detect *Campylobacter* spp. In



the same study, pooled samples from 172 wild roe deer gave an estimated prevalence of 4 %. *Campylobacter* spp. was isolated from only one of 324 faecal samples collected from wild red deer, roe deer, moose and reindeer during the 2001, 2002 and 2003 hunting seasons. This study was undertaken as part of the National Health Surveillance Program for Cervids (HOP) in Norway (Lillehaug et al., 2005) and the isolate was *C. jejuni*. A similar German study examined 95 and 67 faecal samples from wild roe and red deer, respectively, and reported three positive for *Campylobacter* spp. (Atanassova et al., 2008).

Several studies have failed to detect *Salmonella* spp. in wild deer. Faecal samples collected from 172 wild roe deer and from 37 wild and farmed fallow and red deer in Sweden were all negative for *Salmonella* spp. (Wahlstrom et al., 2003). Pooled meat samples from 95 wild roe deer and 67 wild red deer were examined for *Salmonella* spp. in Germany and all were negative (Atanassova et al., 2008). In other studies of wild deer, no *Salmonella* spp. was detected in samples of meat and/or faeces in Europe, North America and New Zealand (Smith et al., 1974; Sumner et al., 1977; Riemer and Reuter, 1979; Henderson and Hemmingsen, 1983; Weber and Weidt, 1986; Ring et al., 1988; Deutz et al., 2000; Paulsen et al., 2003; Paulsen and Winkelmayer, 2004; Lillehaug et al., 2005; Bolton et al., 2012).

Among wild deer, the incidence of VTEC may be as high as 50 %, although most isolates are not O157, the serogroup most often associated with serious illness in humans (Dunn et al., 2004; Gill, 2007 French et al., 2010). In wild roe deer in Italy, none of 124 samples taken in the period 2007-2008 tested positive for VTEC (Caprioli et al., 1991; Magnino et al., 2011). Caprioli et al. (1991) also failed to detect VTEC in faecal samples from 46 wild red and 13 wild roe deer. In contrast, a Swiss study in 2011 using molecular (polymerase chain reaction; PCR) methods (more sensitive than culture-based methods) reported that over 50 % of faecal samples from wild red deer (49/84) and wild roe deer (37/64) were vtx gene positive. In approximately two-thirds of these samples, the eae gene (a virulence marker commonly found in VTEC causing human illness) was also detected. Although vtx2 (a toxin gene variant associated with more severe illness in humans) was the predominant verocytotoxin, the combination of vtx2 plus eae was rare (Obwegeser et al., 2012). A similar Belgian study in 2008/2009 reported VTEC in 15/133 wild red and roe deer faecal samples. Of the positive samples, 12 carried the  $vtx_2$  gene; however, none of the VTEC-positive samples tested positive for *eae* (Bardiau et al., 2010). This finding was also reported in Spain, where over 50 % of wild roe deer were VTEC positive, with  $vtx_2$  being common but the combination of  $vtx_2$  and *eae* being rare (Sanchez et al., 2009). In a Norwegian study (Lillehaug et al., 2005) faecal samples from 135 red and 206 roe deer were tested for VTEC by first screening for the five most relevant O antigens, and then performing molecular biology tests for vtx and eae. Two isolates were vtx positive but lacked the eae gene. A Swedish study in 2003 also failed to detect VTEC O157 (Wahlstrom et al., 2003).

*T. gondii* is found in wild deer. In a Norwegian study, 4 339 wild cervids were tested for antibodies to *T. gondii* using a direct agglutination test (Vikoren et al., 2004). Positive titres were found in 33.9 % of 760 roe deer, 12.6 % of 2 142 moose and 7.7 % of 571 red deer. The authors concluded that meat from Norwegian cervids, particularly roe deer, should be regarded as a potential source of infection for humans. In an earlier study, seroprevalences of 63 %, 12 % and 0 % were reported in Norwegian roe deer, red deer and reindeer, respectively (Kapperud, 1978).

In a similar Czech study, sera from 720 wild ruminants were examined for antibodies to *T. gondii* using an indirect fluorescence antibody test (Bartova et al., 2007). *T. gondii* antibodies were found in 50 % (7/14) of sika deer, 45 % (169/377) of red deer, 24 % (19/79) of roe deer and 17 % (24/143) of fallow deer. A previous study in the Czech Republic also reported detection rates of 15 % (46/303) and 14 % (13/95) in wild red and roe deer, respectively. Although antibodies against *T. gondii* were detected, tissue cysts were not isolated (Hejlicek et al., 1997).

Antibodies to *T. gondii* were also detected in 15.6 % of wild red deer, 24 % of wild fallow deer and 21.8 % of wild roe deer in a Spanish study carried out between 1993 and 2005 and involving 441 red deer, 79 fallow deer and 33 roe deer from six regions of Spain (Gauss et al., 2006).



In France, a prevalence of 37 % (228/615) was obtained in samples taken from wild roe deer in the region of Champagne-Ardenne. The same study reported a 4.5 % (2/44) prevalence in wild red deer (AFFSA, 2005).

Viable cysts of *T. gondii* have been demonstrated in the musculature of roe deer (Entzeroth et al., 1981) and red deer (Collins, 1981), and ingestion of infected meat from deer (Sacks et al., 1983; McDonald et al., 1990; Ross et al., 2001) and the evisceration and handling of deer presents a risk of human infection (Dubey, 1994).

Boadella et al. (2010) reported that 10.4 % (93/892) of wild red deer serum samples in Spain were positive by enzyme-linked immunosorbent assay (ELISA) for HEV.

## Conclusion

The data, especially the comparative considerations regarding wild deer suggest that *T. gondii* should be a high priority for farmed deer meat inspection. However, further *T. gondii* studies are required in farmed deer to support this conclusion.

Although the limited data would suggest that the prevalence of *Campylobacter* spp. and *Salmonella* spp. in farmed deer is very low, it was concluded that there is insufficient evidence at this time to rank the risk associated with these hazards. Although the prevalence of pathogenic VTEC may be high, all the available data suggest that the incidence of O157, the serogroup most frequently associated with serious illness in humans, is low. As with *Campylobacter* spp. and *Salmonella* spp., it was concluded that there are insufficient data available to rank this hazard. However, there was a suspicion that pathogenic VTEC may potentially be a serious hazard in farmed deer, and additional studies are now required to determine whether or not this is the case. Finally, there were insufficient data to rank the risks associated with HEV. However, the expert group did not consider this a priority for future studies.

Both *Y. enterocolitica* and *Y. pseudotuberculosis* were ranked low priority. The low ranking is not attributable to current control measures.

## 2.2.3.3. Farmed reindeer

None of the hazards from the longlist (Table 2) met the two criteria specified in Section 2.1.1 for reindeer; thus, no hazards were shortlisted for farmed reindeer (Table 3).

## 2.2.3.4. Farmed ostriches

Having already considered the risks associated with environmentally ubiquitous organisms, the risks associated with *Campylobacter* spp. and *Salmonella* spp. were reviewed in farmed ostriches. After the first step of the risk ranking process, and as the incidence of human illness was above the required threshold, *Campylobacter* spp. and *Salmonella* spp. moved to Step 4 ('Evidence for meat from farmed game as an important risk factor'), as in Section 2.2.3.2.

## Epidemiological link

There are no epidemiological data linking human illness caused by *Campylobacter* spp. and *Salmonella* spp. to farmed ostriches.

## Farm animal/carcass prevalence data

There has been limited research on the prevalence of *Campylobacter* spp. and *Salmonella* spp. in ostriches or in ostrich meat. However, *C. jejuni* has been reported in farmed ostriches in Israel (Perelman et al., 1992), South Africa (Allwright et al., 1993) and Australia (Stephens et al., 1998). One study from Italy (Cuomo et al., 2007) found *Campylobacter* spp. in 40 % (60/150) of examined farmed ostriches. In the USA, Ley et al. (2001) reported *Campylobacter* spp. in 3 % (6/201) of ostrich

large intestine samples and on 10 % (19/191) of carcasses. Furthermore, other studies have identified similar *Campylobacter* genotypes in ostriches and humans (Siemer et al., 2005).

Data reported by EU MSs under the Zoonoses Directive (2003/99/EC) from 2004 to 2011 suggest a *Salmonella* spp. carriage rate in farmed ostriches of 1.8 %. Although other European data are lacking, an Iranian study reported 4.6 % prevalence in ostrich meat (Rahimi et al., 2010). This is considerably lower than the 51 % (61/120) carriage rate reported in farmed ostriches in Zimbabwe (Gopo and Banda, 1997). The same study found that 33.3 % of carcasses were contaminated with this organism.

## Comparative considerations

As ostriches are poultry, a comparison with other poultry, specifically broilers, was considered relevant. *Campylobacter* spp. and *Salmonella* spp. were considered to be 'high' risk hazards in broilers (EFSA Panel on Biological Hazards (BIOHAZ), 2012).

# **Conclusion**

It was concluded that there is insufficient evidence at present to rank the risks associated with *Campylobacter* spp. or *Salmonella* spp. in ostriches. However, it was also considered that ostrich meat may be a potential vehicle for the transmission of these pathogens to humans, and further studies are required including the effects of carcass chilling on the survival of *Campylobacter*.

## 2.2.3.5. Farmed wild boar

Campylobacter spp., Salmonella spp., pathogenic VTEC, Y. enterocolitica, T. gondii, Trichinella spp. and Hepatitis E virus were considered relevant for priority ranking in farmed wild boar. As before, Campylobacter spp. and Salmonella spp. have a human incidence of  $\geq 10/100\ 000$  and therefore moved directly to Step 4 ('Evidence for meat from farmed game as an important risk factor'). The incidence in humans of all the other hazards was below this threshold; thus, these hazards moved to Step 3. Pathogenic VTEC and T. gondii had fatality rates exceeding 1 per 1 000 (0.1) and were deemed to have 'high' severity and also moved to Step 4. Although there were no 'fatality rate' data for Hepatitis E virus, the DALYs were above the threshold required to move to Step 4. Y. enterocolitica and Trichinella had a 'low' severity and were assigned an overall priority ranking of 'low'.

## Epidemiological link

There are insufficient epidemiological data linking human illness caused by any of these hazards to farmed wild boar.

## Farm/animal/carcass prevalence data

Zoonoses data for farmed wild boar are extremely limited. Data reported by EU MSs under the Zoonoses Directive (2003/99/EC) from 2004 to 2011 suggest that 14.6 % of farmed wild boar faecal samples are *Salmonella*-positive. Furthermore, Jokelainen et al. (2012) reported that *T. gondii*-specific IgG antibodies were detected in 65/197 (33.0 %) samples, taken from 14/25 (56.0 %) Finnish wild boar farms. However, there is currently no information in the official or industry reports or in the peer-reviewed literature on the incidence of *Campylobacter* spp., pathogenic VTEC or Hepatitis E virus in farmed wild boar or the prevalence on derived meat carcasses.

## Comparative considerations

In the absence of data on farmed wild boar, information about free living wild boar was considered. In the context of this priority ranking exercise, farmed wild boar and domestic swine, which belong to same species (*Sus scrofa*) were also considered comparable.

Campylobacter spp. was not detected in faecal and tonsillar samples in hunted wild boar in Switzerland (n = 153) (Wacheck et al., 2010). Only 3 of 127 carcasses (2.1%) tested positive for



*Campylobacter* spp. in hunted wild boar (Atanassova et al., 2008); similarly, Ziegenfuß (2003) reported *Campylobacter* spp. in 2.9 % (2/70) of hunted wild boar. *Campylobacter* spp. was assessed to be a low risk in the BIOHAZ opinion on meat inspection in swine (EFSA Panel on Biological Hazards (BIOHAZ), 2011) based on the impact of drying during chilling. However, farmed wild boars are more often skinned than scalded which could result in greater cross-contamination. Furthermore, many abattoirs slaughtering these animals may not have a blast chilling facility and thus drying may not be as effective during chilling facilitating the survival of *Campylobacter* spp. Despite these differences, there is currently no data suggesting *Campylobacter* spp. is a greater risk in farmed wild boar as compared to domestic swine.

*Salmonella* spp. may be common in free-living wild boars. Wacheck et al. (2010) reported a *Salmonella* spp. detection rate of 12 %, while a Portuguese study of 77 animals found *S*. Typhimurium and *S*. Rissen carriage rates of 64.7 % and 35.3 %, respectively. In Switzerland, a study of 73 hunted wild boars reported that 5 % of tonsillar and 1 % of faecal samples were *Salmonella*-positive. VTEC was also prevalent (9 %) in tonsillar samples from wild boars (Wacheck et al., 2010). However, in the BIOHAZ opinion on meat inspection in swine (EFSA Panel on Biological Hazard (BIOHAZ), 2011) *Salmonella* spp. were considered of high relevance in pigs in the EU whereas VTEC was not.

*T. gondii* is common in hunted wild boars in EU, where the seroprevalence has been reported to vary between 8 % and 38 % (Lutz, 1997; Gauss et al., 2005; Antolova et al., 2007). A Spanish study of 150 wild boars which used serology and PCR to detect HEV reported 42.7 % of animals to be seropositive, with 19.6% PCR positive for HEV-RNA, suggesting carriage of the viable virus (de Deus et al., 2008).

## **Conclusion**

It was concluded that *Salmonella* spp. and *T. gondii* should be ranked as high priority and pathogenic VTEC should be ranked as low priority for meat inspection.

*Y. enterocolitica* and *Trichinella* spp. were ranked low priority because of their low incidence and severity in reported human cases.

Current control measures applied were not considered to be responsible for the low-priority ranking of pathogenic VTEC and *Y. enterocolitica*, but the *Trichinella* spp. control applied can be considered the main reason for the low number of human cases.

For *Campylobacter* spp. and HEV, the priority was characterised as undetermined due to insufficient data.

Further studies should investigate the prevalence of HEV in farmed wild boar.

## 2.2.3.6. Farmed rabbits

*Salmonella* spp., pathogenic VTEC, and HEV were considered relevant for risk ranking in farmed rabbits. As in Section 2.2.3.2, pathogenic VTEC and *Salmonella* spp. moved to Step 4 ('Evidence for meat from farmed game as an important risk factor'). Although there were no 'fatality rate' data for HEV, DALYs were above the threshold required to move to Step 4.

## Epidemiological link

There are no epidemiological data linking human illness caused by any of these hazards to farmed rabbits.

## Farm/animal/carcass prevalence data

As with most of the farmed game animal species, zoonoses data for farmed rabbits are very limited. Borrelli et al. (2011) tested 1 000 rectal swabs from rabbits on 25 different farms and detected Salmonella spp. on only one farm. A small study of 50 farmed rabbits in Switzerland failed to detect this pathogen (Rodriguez-Calleja et al., 2006). The prevalence of VTEC/*E. coli* O157 would also seem to be low. *E. coli* O157 was not detected in a small sample (n = 50) of rabbit carcasses and meat products tested in Spain (Rodriguez-Calleja et al., 2006). Martinez et al. (2011) reported a VTEC prevalence of less than 2 % among free-ranging wild lagomorphs (rabbit and Iberian hare) in southwest Spain.

There are four recognised and two putative genotypes of mammalian HEV. Genotypes 1 and 2 are restricted to humans, while genotypes 3 and 4 are zoonotic. The recently identified rabbit HEV is a distant member of genotype 3 and can infect pigs (Meng, 2011; Cossaboom et al., 2012). Rabbit HEVs with considerable genetic diversity are prevalent (15 % seroprevalence) in farmed rabbits in China (Geng et al., 2011). Experimental infections showed that rabbits rapidly became infected with rabbit HEV, while only two of nine rabbits infected with HEV genotype 4, and none infected with genotype 1, developed hepatitis, although six of nine rabbits inoculated with the genotype 1 HEV and all rabbits inoculated with the genotype 4 HEV seroconverted to be positive for anti-HEV IgG antibody by 14 weeks post inoculation (Ma et al., 2010). A recent cross-sectional survey in France detected HEV-RNA in 7 % (14/200) of bile samples from farmed rabbits (in 2009) and in 23 % (47/205) of liver samples from wild rabbits (in 2007-2010). Full-length genomic sequences indicated that all rabbit strains belonged to the same clade (nucleotide sequences 72.2-78.2 % identical to HEV genotypes 1-4). Comparison of human strains suggested they are closely related to rabbit HEV. This would suggest that zoonotic transmission of HEV from rabbits to humans is possible (Izopet et al., 2012), but the potential zoonotic risk of rabbit HEV needs to be investigated and evaluated further (Geng et al., 2011; Meng, 2011).

# Comparative considerations

Wild rabbits were also considered to be relevant. A study in northern Portugal detected *Salmonella* spp. in 48 % (38/80) of wild rabbit faecal samples (Vieira-Pinto et al., 2011). Five serovars were identified: Rissen (29 %), Enteritidis (26 %), Havana (24 %), Typhimurium (16 %) and Derby (5%). Almeria et al. (2004) reported that 23 % of wild rabbits in Spain carry HEV.

# Conclusion

It was concluded that there is insufficient evidence to rank the risk associated with pathogenic VTEC, *Salmonella* spp., or HEV in farmed rabbits.

# 2.2.3.7. Conclusions on the priority ranking

*Salmonella* spp. in farmed wild boar and *T. gondii* in farmed deer and farmed wild boar were identified as being high-priority biological hazards for farmed game meat inspection.

However, owing to a lack of data, it was not possible to rank the risk associated with farmed deer and *Campylobacter* spp., *Salmonella* spp., pathogenic VTEC and HEV; farmed ostriches and *Campylobacter* spp. and *Salmonella* spp.; farmed wild boar and HEV; and farmed rabbits and *Salmonella* spp., pathogenic VTEC and HEV.

A low-priority ranking was identified for *Y. enterocolitica* and *Y. pseudotuberculosis* in farmed deer, and for *Y. enterocolitica*, *Trichinella* spp. and pathogenic VTEC in farmed wild boar.

The expert working group considered that some biological hazards may be given a high-priority ranking if more data were available and so recommended that investigative studies be carried out in farmed deer for pathogenic VTEC, in ostriches for *Campylobacter* spp. and *Salmonella* spp. and in farmed wild boar for HEV.

The results of the priority ranking exercise are shown in Table 6.

Farmed game species	Priority ranking				
	High	Low	Undetermined due to insufficient data		
Deer	T. gondii	Y. enterocolitica Y. pseudotuberculosis	<i>Campylobacter</i> spp. <i>Salmonella</i> spp. Pathogenic VTEC <sup>a</sup> Hepatitis E virus		
Reindeer	_	_	_		
Ostrich			<i>Campylobacter</i> spp. <sup>a</sup> Salmonella spp. <sup>a</sup>		
Wild boar	Salmonella spp. T. gondii	Pathogenic VTEC Y. enterocolitica Trichinella	<i>Campylobacter</i> spp. Hepatitis E virus <sup>a</sup>		
Rabbit	_	_	<i>Salmonella</i> spp. Pathogenic VTEC Hepatitis E virus		

## **Table 6:**Conclusions on the priority ranking exercise.

a: May be a 'high' priority if more data were available, so further studies are required.

## 3. Assessment of strengths and weaknesses of current meat inspection

## **3.1.** Background information

Protection of public health is the main priority for meat inspection. The origin of Western European meat inspection dates to the end of the nineteenth century, when it became obvious that meat could play a role in the transmission of disease, particularly tuberculosis, and that the animal trade, meat and meat products should be subject to safety measures and quality assurance (Theves, 2002). Meat inspection procedures were risk based at that time.

Ever since, *ante-mortem* and *post-mortem* inspection have been carried out at individual animal level in cattle and have been extended to other species. The *ante-mortem* inspection is a clinical examination which aims to identify sick or abnormal animals, as well as assessing the welfare and level of cleanliness of the animals entering the slaughter process. The *post-mortem* inspection is a pathological–anatomical examination aiming at detecting and eliminating macroscopic abnormalities that could affect the fitness of meat for human consumption. It is based on visual inspection, palpation, incision and, when required, laboratory examination.

The slaughter process for deer, reindeer, ostrich, wild boar and rabbit is similar to that for conventional livestock, such as cattle, sheep, pigs and poultry, but there can be significant differences. These arise principally when the animals are slaughtered, i.e. stunned, killed and bled, on-farm, and whether the slaughter procedure is dry or wet.

In the case of deer, reindeer and wild boar, stunning is performed by either free bullet or captive bolt. In the case of ostriches, captive bolt and electrical stunning are permitted.

The meat, feathers and hide of ostriches are valuable. Therefore, the slaughter process includes separate stages for removal of feathers and skin and cutting of meat. The slaughter process is dry, in contrast to poultry slaughter (FAO, 2006).

The grey and other literature (farmers' homepages, reports such as Adams and Revell (1998)) note that that slaughter of ostriches may be difficult, as they are easily stressed by changes in environment and during transport. This also applies to other farmed game species. Therefore, some farmers prefer to slaughter on-farm instead of sending the animals to the slaughterhouse. However, this varies within the EU. The slaughtered and bled animals are then transported to a slaughterhouse. Evisceration may

take place on-farm under the supervision of a veterinarian or in the slaughterhouse. Generally, if slaughtering is carried out on-farm, the number of animals slaughtered per day is very low.

The slaughter process for farmed rabbits is similar to that of poultry. Slaughter takes place at approved slaughterhouses. Live animals are transported to the slaughterhouse, kept in cages for less than 24 hours (usually less than eight hours), killed and dressed in a similar way to poultry, with the difference that rabbits are skinned. Carcasses may be handled and processed with the lungs, heart, kidneys and liver, or separately. Both *ante-* and *post-mortem* inspection take the form of visual inspection with no routine handling of the rabbits.

Under EU Regulation 853/2004 (Annex III, Section III), slaughter and bleeding on-farm must be supervised by a veterinarian. The slaughtered animals must be accompanied to the slaughterhouse by a declaration by the food business operator (FBO) who reared the animals and by a certificate issued and signed by the official or approved veterinarian. There is a derogation in EU Regulation 150/2011 which allows the verification and certification of the slaughter and bleeding procedures, done according to legislation, to be included in the declaration by the FBO provided that the holding is not under health restrictions and the food business operator has demonstrated the appropriate level of competence. Council Regulation (EC) No 1099/2009 provides that business operators are to ensure that certain slaughter operations, including the slaughter of farmed game on-farm, are carried out only by persons holding a certificate of competence for such operations, demonstrating their ability to carry them out in accordance with the rules laid down by that Regulation.

At approved slaughterhouses, live farmed game animals are killed and dressed in the same way as other farm livestock and subject to similar veterinary inspection. Approved slaughterhouses vary considerably in size, suitability and procedures. At one end of the scale, there are large slaughterhouses that are purpose-built and dedicated to the processing of farmed game. Generally, these premises will have all of the equipment and facilities required, including a stun pen, bleeding area, inspection rack, overhead dressing rail that extends to a carcass cooling off area and a chiller room. In these premises, the slaughterhouse workers are familiar with the behaviour of the farmed game and are competent in the handling of the animals. At the other end of the scale are small local slaughterhouses. These may not be dedicated to the processing of certain farmed game. Equipment must be washed down between species. Some small slaughterhouses are owned by the farmer and located on the farm. Slaughter in these small on-farm slaughterhouses is often preferable for animal welfare reasons, avoiding the transport that causes stress to farmed game animals.

In many MSs, the number of slaughterhouses processing farmed game is small, and farmers often have to transport the animals long distances. Long journey times mean increased time between slaughter of farm-slaughtered animals and evisceration, and this can have implications for meat quality and safety. EU Regulation 853/2004 requires that carcasses are to be refrigerated if transport will take more than two hours.

Individual identification of farmed game is not obligatory in the EU and is, in general, not practised. Irrespective of the meat inspection procedures in place, it is recognised that farmed game presented for slaughter can be carriers of zoonotic microorganisms or residues of veterinary drugs, which cannot be detected during *ante-* and *post-mortem* inspection. In the following, an assessment of the strength and weaknesses of the current practices for protection of public health will be undertaken.

# **3.2.** Food chain information

# 3.2.1. Description

The principle of food chain information (FCI) includes a flow of information from the farm to the slaughterhouse and *vice versa* in order to contribute to the classification of each batch according to its expected food safety risk, so that slaughter procedures and/or decisions on fitness for consumption can be adapted to the health status and food safety risk presented by the batch of farmed game. In theory, FCI may be used to adapt *ante-* and/or *post-mortem* inspections, e.g. plan the number of inspectors

needed on the slaughter line. FCI is recorded at the batch level and its minimum content is described in Annex II of Regulation (EC) No 853/2004. FCI related to primary production is currently based on a farmer's declaration. FCI must be checked by the slaughterhouse operator for completeness and content. Slaughterhouse operators must be provided with the FCI at least 24 hours before the arrival of animals at the slaughterhouse. However, the FCI may accompany the animals to which it relates if those animals have undergone *ante-mortem* inspection at the holding of provenance and if the animals are accompanied by a certificate signed by a veterinarian stating that he or she examined the animals at the holding and found them to be healthy. Some MSs have implemented a standardised FCI declaration form for farmers of cattle and other species. However, it is not clear how common this is, or indeed to what extent FCI is implemented in MSs.

In the case of reindeer in Finland, the FCI is provided by the local reindeer herding cooperative, rather than the owner, who will be a member in the cooperative. In Sweden, the operator is the Sami village of which the reindeer owner is a member. The FCI is given for the batch of reindeer sent to slaughter. The batch may include animals from different owners. The reindeer herding cooperative/Sami village organises transportation of reindeer to slaughterhouses and slaughtering. The FCI will accompany the reindeer to which it relates to the slaughterhouse. There is no organised reindeer health care/monitoring system in Finland or Sweden. However, in Sweden, animal health care is a cooperative process between the Swedish Animal Health Service, Sami villages and practising veterinarians.

# 3.2.2. Strengths

FCI serves as a channel of communication between primary production and meat inspection. This, theoretically, facilitates the process of evaluating the health of incoming batches and preventing sick or abnormal animals entering the slaughterhouse, by providing early data on probable disease conditions that may be present in the flock or herd. This is based on information related to the on-farm health status of the animals (e.g. mortality rate, occurrence of disease, veterinary treatments, specific laboratory testing, etc.). In practice, there may be information on potential treatment with drugs or infections, e.g. *Trichinella* spp., detected in previously slaughtered batches. FCI may also be used to plan the number of inspectors needed on the slaughter line or to reduce the speed of the slaughter line to allow for a more detailed *post-mortem* inspection or to fix the order of slaughter, i.e. logistic slaughter.

# 3.2.3. Weaknesses

In practice, *ante-* or *post-mortem* inspections of farmed game are rarely adapted to take account of FCI. FCI is probably insufficiently utilised because of the lack of adequate and harmonised indicators, such as those currently available for *Salmonella* spp. in broiler and turkey flocks, that could help in classifying the animals according to the risk to public health they may pose. The use of FCI may not be consistent between MSs or even between producers and slaughterhouses in the same MS. In addition, the food safety relevance of FCI is often limited because it is usually very general and does not address specific hazards of public health importance. Furthermore, farmers might not be in a position to properly assess the presence of relevant hazards.

# 3.3. *Ante-mortem* inspection

# 3.3.1. Description

An *ante-mortem* clinical examination is carried out by an official veterinarian to evaluate the health and welfare of the animals, and to prevent sick or abnormal animals entering the slaughterhouse. This is a visual inspection, consisting of the identification of clinical signs of a disease.

In the case of farmed game slaughtered at a slaughterhouse, *ante-mortem* inspection may be carried out at the holding of provenance or at the slaughterhouse. *Ante-mortem* inspection at the holding must include checks on the records including FCI. When *ante-mortem* inspection takes place no more than three days before the arrival of the animals at the slaughterhouse, and animals are delivered to the

slaughterhouse live, a less stringent inspection is carried out at the slaughterhouse, which includes a confirmation of the animals identity and screening of their health and welfare status. If more than three days has elapsed between *ante-mortem* inspection at the holding and arrival at the slaughterhouse, a full *ante-mortem* inspection is carried out on arrival of the animals, as for other species.

Free-ranging reindeer are herded into corrals for *ante-mortem* inspection by an official veterinarian. Selected animals are then separated, marked with metallic, numbered ear tags and transported to the slaughterhouse. Alternatively, *ante-mortem* inspection is carried out at the slaughterhouse.

Rabbits and ostriches are not individually identified but are treated as a flock, with the *ante-mortem* inspection being based on flock inspection. *Ante-mortem* inspection is carried out on-farm within 72 hours before slaughter, similar to the procedure described above.

# 3.3.2. Strengths

The public health-related strengths of *ante-mortem* inspection include inspection of individual animals for signs of disease and the evaluation of animal cleanliness. In addition, *ante-mortem* inspection may have a preventative effect, in that the primary producer is unlikely to send a sick animal for slaughter knowing that it will have to undergo an *ante-mortem* examination. However, as farmed game carrying zoonotic agents may not show clinical signs of infection, the strengths of *ante-mortem* inspection are mainly related to animal welfare and animal health. In the case of farmed game, it is useful for the official veterinarian to have the ability to observe the herd as a whole. Untypical behaviour of an individual compared with others can be a sign of illness. *Ante-mortem* inspection is also the point in the food chain at which dirty and contaminated animals can be removed from the slaughter process, which promotes good hygiene and reduces cross-contamination of carcasses during slaughter and subsequent processing.

# 3.3.3. Weaknesses

From a public health perspective, *ante-mortem* examination is of limited value for farmed game since animals infected with or carrying the 'high'-priority hazards previously identified (*T. gondii* in farmed deer and *Salmonella* spp. and *T. gondii* in farmed wild boar) may not show clinical signs as in both cases infection is asymptomatic. Hence, zoonotic infections such as those caused by *Salmonella* spp. and *T. gondii* cannot be detected by *ante-mortem* inspection.

Given the excitable nature of most farmed game (in essence, their behaviour is similar to that of wild game), it is not always advisable, from an animal welfare perspective, to hold these animals in a bright open space, as is required to observe individual animals in their entirety. It is preferable that farmed game is moved from a darkened vehicle into a darkened collection area/crush. Consequently, the poor quality of light can have a negative impact on the quality of *ante-mortem* inspection at the slaughterhouse.

Farmed rabbits constitute an exception as *ante-mortem* inspection at the slaughterhouse is easy to perform and allows animals that have died during transport and clinically sick individuals (e.g. those with clear signs of emaciation or diarrhoea) to be detected.

# 3.4. *Post-mortem* inspection

# 3.4.1. Description

*Post-mortem* inspection of carcasses is designed to detect and withdraw from the food chain any carcass that has identifiable abnormalities that could affect its meat safety or wholesomeness. The meat inspector examines external and internal surfaces of the carcasses and internal organs, after evisceration, for disease conditions and contamination that could make all or part of the carcass unfit for human consumption.

Generally, inspection procedures include mainly visual examination of the carcass and offal. The *post-mortem* procedures for farmed game are described in Annex I, Section IV, Chapter VII, of Regulation (EC) No 854/2004. This states that *post-mortem* inspection procedures described for bovine and ovine animals, domestic swine and poultry are to be applied to the corresponding species of farmed game. The requirements for poultry apply to farmed lagomorphs.

# 3.4.1.1. *Post-mortem* meat inspection procedure for deer and reindeer

For reindeer the *post-mortem* meat inspection procedure for ovine animals is applied. It is unclear as to which *post-mortem* meat inspection procedure should be used for deer. Both the procedures for bovine and ovine carcasses could be applied. These are summarised in Tables 7 and 8, respectively. Neither would detect the high-priority meat-borne hazards identified in farmed deer.

**Table 7:** Summary of current (Regulation (EC) 854/2004) post-mortem inspection procedures for cattle by age, level of requirement (mandatory or optional) and actual inspection action required (V=visual; P=palpation; I=incision).

Organ/ system	Part of organ/system	Domestic bovine animals				
		< 6 w	veeks	> 6weeks		
system		Mandatory	Optional	Mandatory	Optiona	
	Surface	V		V		
	Pleura	V		V		
Carcass	Peritoneum	V	т	V		
	Umbilical region Joints	V+P V+P	I I			
	Head, mouth, pharynx, etc	V	1	V		
	Retropharingeal Lnn <sup>b</sup>	I		I		
	Submaxillar Lnn	1		I		
Head	Parotid Lnn			I		
	Masseters			I		
	Tongue	Р		V + P		
	Parenhim	$V + P + I^a$		$V + P + I^a$		
	Trachea	$V + I^a$		$\mathbf{V} + \mathbf{I}^{\mathrm{a}}$		
Lungs	Larger bronchi	$I^a$		$I^a$		
	Mediastinal Lnn	Ι		Ι		
	Bronchial Lnn	Ι		Ι		
Oesophagus		V		V		
	Heart	V + I		V + I		
Heart	Pericardium	V		V		
Diaphragm		V		V		
	Parenhim	V + P	Ι	V + P + I		
Liver	Hepatic Lnn	V + P	Ι	V+P		
	Pancreatic Lnn	V		V+P		
	Stomachs, intestines	V		V		
Gastrointe-	Mesenterium	V		V		
stinal tract	Gastric Lnn	V + P	Ι	V + P	Ι	
	Mesenteric Lnn	V + P	Ι	V + P	I	
Spleen		V	Р	V	Р	



		Domestic bovine animals				
Organ/	Part of organ/system	< 6 w	> 6weeks			
system		Mandatory	Optional	Mandatory	Optional	
V: da ana	Parenhim	V	Ι	V	Ι	
Kidneys	Renal Lnn		Ι		Ι	
~	Uterus			V		
Genitals and udder	Udder			V	(P+I) <sup>a</sup>	
uuuuu	Supramamary Lnn			V	(P+I) <sup>a</sup>	

a: Not required if not intended for human consumption;

b: Lnn – lymph nodes

**Table 8:** Summary of current (Regulation (EC) 854/2004) *post-mortem* inspection procedures for sheep and goats, level of requirement (mandatory or in the event of doubt) and actual inspection action required (V, visual; P, palpation; I, incision).

Organ/system	Part of organ/system	Mandatory	In the event of doubt
Carcass	Pleura	V	
	Peritoneum	V	
	Umbilical region	$V^a + P^a$	$I^{a}$
	Joints	$V^a + P^a$	$I^{a}$
Head	Head	V <sup>b</sup>	
	Throat		$V^{b}$
	Mouth		$\mathbf{V}^{b}$
	Tongue		$\mathbf{V}^{b}$
	Retropharyngeal lymph node		$\mathbf{V}^{\mathbf{b}}$
	Parotid lymph node		$V^{b}$
Lungs	Lungs	V + P	Ι
0	Trachea	V	Ι
	Bronchial lymph nodes	Р	Ι
	Mediastinal lymph nodes	Р	Ι
Heart	Heart	V	Ι
	Pericardium	V	Ι
Diaphragm	Diaphragm	V	
Liver	Liver	V + P + I	
	Hepatic lymph nodes	V + P	
	Pancreatic lymph nodes	V + P	
Gastrointestinal tract	Oesophagus	V	Ι
	Gastrointestinal tract	V	
	Mesentery	V	
	Gastric lymph nodes	V	
	Mesenteric lymph nodes	V	
Spleen	Spleen	V	Р
Kidneys	Kidneys	V	Ι
•	Renal lymph nodes		Ι
Genital and udder	Genital	V	
	Udder	V	
	Udder lymph nodes	V	

a Applies to young animals only.

b Not necessary if the head, including the tongue and the brains, will be excluded from human consumption.

There are few or no data available on *post-mortem* findings in deer. According to the Federation of Veterinarians in Europe (FVE), the main findings in deer are organoleptic anomalies and parasites (hypodermia, gastrointestinal parasites) (EFSA, 2012).

The most common findings at *post-mortem* inspection of reindeer are parasitic lesions (warble flies (*Hypoderma tarandi*) and booth flies), including the inflammatory traces of parasitic infection. For example, in a study carried out in Sweden, around 20 % (8 280/42 362) of the reindeer inspected at slaughter were found to be infected by warble fly (Mossing, 2007). In late winter, cachexia with serious atrophy may manifest as subcutaneous bleedings and other trauma. However, the number of carcasses condemned is very small. In Sweden, approximately 100–200 reindeer, of approximately 50 000 slaughtered (0.2–0.4 %), are condemned each year. In Finland, out of 75 053 reindeer subject to meat inspection in 2011, 77 (0.1 %) carcasses were condemned as unfit for human consumption and parts of 8 241 (11 %) other carcasses were also condemned.

# 3.4.1.2. *Post-mortem* meat inspection procedure for wild boar

The *post-mortem* inspection procedure for domestic swine as prescribed in Regulation (EC) 854/2004 is also used for wild boar. These are summarised in Table 9.

**Table 9:** Summary of current (Regulation (EC) 854/2004) *post-mortem* inspection procedures for domestic swine, level of requirement (mandatory or in the event of doubt) and actual inspection action required (V, visual; P, palpation; I, incision).

Domestic swine Organ/system	Part of organ/system	Mandatory	In the event of doubt
Carcass	Pleura	V	In the event of doubt
Calcass	Peritoneum	v V	
		$\mathbf{v}^{a}$	I <sup>a</sup>
	Umbilical region Joints	$\mathbf{v}^{\mathrm{a}}$	I I <sup>a</sup>
TT 1			1
Head	Head	V	
	Throat	V	
	Mouth	V	
	Fauces	V	
	Tongue	V	
	Submaxillary lymph node	I	
Lungs	Lungs	$V + P + I^b$	
	Trachea	$V + I^b$	
	Bronchi	$\mathbf{I}^{\mathrm{b}}$	
	Bronchial lymph nodes	Р	
	Mediastinal lymph nodes	Р	
Heart	Heart	V + I	
	Pericardium	V	
Diaphragm	Diaphragm	V	
Liver	Liver	V + P	
	Hepatic lymph nodes	V + P	
	Pancreatic lymph nodes	V + P	
Gastro-intestinal tract	Oesophagus	V	
	Gastrointestinal tract	V	
	Mesentery	V	
	Gastric lymph nodes	V	Ι
	Mesenteric lymph nodes	V	Ī
Spleen	Spleen	V	P
Kidneys	Kidneys	V	I
1101030	Renal lymph nodes		I
Genital and udder	Genital	V	*
	Udder	v	
	Udder lymph nodes	V V	I <sup>c</sup>
· Applies to young anim		Ŷ	T

a: Applies to young animals only.

b: Incisions are not necessary where the lungs are excluded from human consumption (palpation is mandatory).

c: In sows.

In Germany, very few carcasses (not more than six per year) are condemned annually and these are removed from the food chain. Most are condemned because of the presence of parasites (other than *Cysticercus* and *Trichinella*) (DESTATIS, 2011). In 2011, in Germany, 4 012 farmed wild boars were slaughtered. Four carcasses were condemned (0.1 %) because of cachexia/emaciation (1), faecal contamination (1), other obvious or extensive alterations such as decay (1) or "meat that in the judgment of the official veterinarian poses a risk to the health of humans and animals or is unfit for other reasons" (1) (DESTATIS, 2011). In 55 cases, organs or parts of the carcasses were condemned (DESTATIS, 2011).

# 3.4.1.3. *Post-mortem* meat inspection procedure for ostrich and rabbit

The *post-mortem* inspection procedure for poultry as prescribed in Regulation (EC) 854/2004 is used for rabbits. It is unclear as to which *post mortem* inspection procedure should be used for ostriches, although the procedures for poultry are often used. Furthermore, a separate *post-mortem* inspection procedure has been designed by the Food and Agriculture Organisation of the United Nations (FAO, 2000).

For poultry the requirements are that all birds are to undergo *post-mortem* inspection in accordance with Sections I and III of Regulation (EC) 854/2004. In addition, the official veterinarian is personally to carry out the following checks:

- daily inspection of the viscera and body cavities of a representative sample of birds;
- a detailed inspection of a random sample, from each batch of birds having the same origin, of parts of birds or entire birds declared unfit for human consumption following post-mortem inspection; and
- any further investigations necessary when there is reason to suspect that the meat from the birds concerned could be unfit for human consumption.

The main difference as compared to poultry is that rabbits and ostriches undergo skinning and dry slaughter. The *post-mortem* inspection is designed to detect and withdraw from the food chain any carcass that has grossly identifiable abnormalities that could affect the meat safety or wholesomeness. Those carcasses rejected as unfit for human consumption are detected on the basis of visual macroscopic criteria. The meat inspector visually inspects the internal and external surface of the carcasses and internal organs for disease conditions and contamination that could make all or part of the carcass unfit for human consumption.

# 3.4.2. Strengths

*Post-mortem* inspection detects lesions related to animal health and welfare, which are dealt with in Appendix C of this document. In the case of food safety concerns, *post-mortem* examination can detect visibly contaminated carcasses and offal which might present an increased food safety risk and is an indication of a hygienically inefficient slaughter process. *Post-mortem* inspection also allows for an assessment of the general health status of the animal but the procedures used could increase the likelihood of important meat-borne hazards cross-contaminating the carcass.

Except in the case of rabbits, the speed of slaughter of farmed game slaughter lines is low so the inspector has sufficient time to examine the carcasses and offal.

In contrast to other species, palpation and incision of organs is not required for rabbit and ostrich carcasses. This may reduce the extent of cross-contamination during meat inspection.

Bovine tuberculosis (bTB), a disease that has been targeted for control since the beginning of the twentieth century, is still not eradicated in the EU. Furthermore, farmed game, especially farmed deer, but also farmed wild boar, represents a 'new' reservoir for bTB. *Post-mortem* examination, together with tuberculin testing, constitutes the major surveillance activities for bTB. However, although tuberculin testing is routinely performed in cattle in MSs not declared free of this disease, it is more



difficult to carry out in farmed game as these animals are not used to human contact. TB detection in farmed game is therefore completely reliant on meat inspection.

*Taenia solium* is a zoonotic, meat-borne parasite that has been controlled by *post-mortem* inspection. *T. solium* cysticerci present in farmed wild boar can be detected by traditional *post-mortem* inspection. However, the sensitivity of detection of cysticerci in cattle by *post-mortem* inspection has been shown to be low (EFSA, 2005). It is likely that this also applies to the detection of *T. solium* cysticerci in pigs.

*Post-mortem* inspection can also detect other non meat-borne hazards of public health significance that can be present in carcasses or offal from farmed game. Examples of these hazards are *E. granulosus* and trematode parasites such as *F. hepatica* and *D. dendriticum*. Human infection occurs when the eggs or cysts (*E. granulosus*) or just the cysts (*F. hepatica* and *D. dendriticum*) are ingested on contaminated vegetables or in water (Fried and Abruzzi, 2010). From the public health standpoint, only *E. granulosus* is still of importance in some MSs (EFSA and ECDC, 2012). Meat inspection plays an important role in the monitoring of these parasites as they are detected during *post-mortem* examination of farmed game, particularly deer, reindeer and wild boar. This also allows for appropriate disposal of infected organs, thus breaking the life cycle of the parasites. The extent to which meat inspection contributes to reducing the risk to human health posed by *F. hepatica* and *D. dendriticum*, compared with other control measures (e.g. anti-parasitic treatments of the final hosts) is not known, so it is difficult to assess the relative importance or effectiveness of this activity in protecting public health. However, for *E. granulosus*, as for bTB in deer, surveillance is completely reliant on meat inspection. The importance of meat inspection as a monitoring tool has also been stressed previously (EFSA external report, 2010<sup>9</sup>).

*Trichinella* testing has protected consumers from trichinosis and to date there have been no reported human cases associated with tested farmed game meat. *Alaria alata* infection has sometimes been detected as an additional finding during *Trichinella* testing.

# 3.4.3. Weaknesses

Visible meat quality-related abnormalities are detectable at *post-mortem* inspection, but these are not as important for human health as serious zoonoses. Sometimes, septicaemia and conditions associated with foci of infection in tissue, such as arthritis, bronchopneumonia, mastitis, pleuritis or abscesses, can be detectable at *post-mortem* inspection. Some of these are caused by pathogens that might have zoonotic implications (e.g. *Erysipelothrix rhusiopathiae*, *Staphylococcus aureus*), but the risk to public health arising from these hazards is mostly related to occupational exposure or the way in which the meat is handled after it leaves the slaughterhouse.

Potential threats to public health associated with the consumption of farmed game meat include agents such as *Salmonella* spp. and *T. gondii*. These are carried by animals without clinical signs or lesions. Current meat inspection is not designed to detect or eliminate these agents. Cysts of *T. gondii* can be macroscopically visible but it is impossible to distinguish them from *Sarcosystis* cysts, except cysts of *S. ovifelis*. The major food-borne hazards of public health relevance are therefore generally not detected during *post-mortem* inspection.

The potential for cross-contamination of carcasses exists whenever palpation and/or incision methods are used in the inspection process. Palpation and/or incision of heart, lungs, liver, the umbilical region, joints and lymph nodes during the *post-mortem* examination could contribute to the spread of the bacterial hazards of public health importance through cross-contamination. The importance of cross-contamination in farmed game is not clear, although it has been considered important in other species (Walker et al., 2000). Current legislation foresees more detailed palpation and incision if abnormalities

<sup>&</sup>lt;sup>9</sup> External scientific report submitted to EFSA on the Contribution of meat inspection to animal health surveillance in poultry. Available online: http://www.efsa.europa.eu/en/supporting/doc/287e.pdf



are detected during visual inspection. This could also facilitate the cross-contamination of normal carcasses with microbiological hazards of public health importance.

The 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 food-borne risk distinction between different sub-categories i.e. between non-zoonotic conditions making meat unfit for consumption 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. foot and mouth disease), zoonotic conditions making meat unfit due to transmissibility to humans via food-borne route (e.g. toxoplasmosis) and zoonotic conditions making meat unfit due to transmissibility via routes other than meat-borne (e.g. *Echinococcus*).

The high speed of the rabbit slaughter lines reduces the sensitivity of post-mortem visual inspection for the detection of both lesions and faecal contamination of carcasses. Thus, proper control cannot be achieved on all carcasses and, at best, only a sample of the carcasses can be thoroughly examined.

## **3.5.** Conclusions and recommendations

FCI serves as a channel of two-way communication between primary production and meat inspection at the slaughterhouse, but *ante-* or *post-mortem* inspections of farmed game are rarely adapted to take account of FCI. FCI could serve as a valuable tool for risk management if adequate and harmonised indicators for relevant hazards were developed.

The public health-related strengths of *ante-mortem* inspection include inspection of individual animals for signs of disease and the evaluation of animal cleanliness. However, as farmed game carrying zoonotic agents may not show clinical signs (asymptomatic carriage), the strengths of *ante-mortem* inspection are mainly related to animal welfare and animal health.

*Post-mortem* examination can detect visibly contaminated carcasses and offal, which might present an increased food safety risk and is an indication of a hygienically inefficient slaughter process. *Post-mortem* inspection also allows for an assessment of the general health status of the animal to be carried out, which could influence the likelihood of important meat-borne hazards being present on the carcass.

*Ante-* and *post-mortem* inspection is not able to detect many of the public health hazards identified as the main concerns for food safety. It would therefore be expected that more efficient additional procedures could be implemented to monitor the occurrence of microscopic biological hazards.

With the present disease situation, meat inspection will provide a control method to ensure food safety and animal welfare. Meat inspection is also a general surveillance tool to detect new or emerging diseases if they present either clinical or *post-mortem* signs. However, meat inspection will not ensure that a new or emerging subclinical disease will be detected. Other surveillance methods have to be in place to detect changes in these diseases. Given that the current procedures involve palpation and incision of some organs, there is a potential for cross-contamination of carcasses.

# 4. Recommend new inspection methods for the main public health hazards related to farmed game meat that are not currently addressed by meat inspection

# 4.1. Introduction

As identified by risk ranking earlier in this opinion, the principal biological hazard associated with farmed deer is *T. gondii*. In farmed wild boar, *Salmonella* spp. and *T. gondii* were also ranked as a high priority for meat inspection. Other hazards were ranked as low risk. However, there were insufficient data to rank many of the risks associated with farmed game. Future baseline and other relevant studies will provide data which may change the current ranking or facilitate the ranking of hazards for which there are currently insufficient data.



None of the high-risk hazards identified in this opinion can be detected by current meat inspection, which is focused on the identification of visible abnormalities and issues relating to the health and welfare of the animals on the farm, in transit and at the slaughterhouse before slaughter. Detection and quantification of those hazards in/on farmed game and farmed game carcasses is possible only through laboratory testing. Therefore, from a food safety perspective, a change to farmed game meat safety assurance is needed to replace or supplement some of the current meat inspection practices.

The occurrence and numbers of these hazards on farmed deer and farmed wild boar carcasses depends on (a) their occurrence in farmed deer and wild boar before slaughter and the application and the effectiveness of related pre-slaughter control strategies; (b) the extent of direct and/or indirect faecal cross-contamination during slaughter line operations (*Salmonella* spp. only); and (c) the application and the effectiveness of possible interventions to eliminate/reduce these organisms in/on carcasses. Therefore, as far as the presence of these pathogens in/on carcass meat is concerned, the risk reduction strategies and related controls should be focused on these three aspects.

Changes are therefore necessary to identify and control these microbiological hazards, and this may be achieved by improved use of FCI and interventions based on risk. Control measures for *Salmonella* spp. in farmed wild boar are also likely to be effective against other enteric pathogens, as they would all be controlled by addressing faecal contamination of carcasses.

# 4.2. Proposal for an integrated food safety assurance system for the main public health hazards related to meat from farmed game

A comprehensive food safety assurance system for farmed game meat that combines preventative measures applied both on the farm and at the slaughterhouse in a longitudinally integrated way is the best approach to control the main hazards in the context of meat inspection of farmed game. The main responsibility for a food safety assurance system should be allocated to FBOs, at both pre-harvest and harvest, whereby compliance is to be audited by the competent authority.

The setting up of a comprehensive food safety assurance system for farmed game at EU level is dependent on the information about the biological risks associated with the consumption of meat from farmed game. As indicated in the risk ranking section of this opinion, information on the biological risks associated with the consumption of farmed game is limited and often unreliable. Consequently, better information on the risks associated with the consumption of farmed game meat is needed for those hazards that were categorised "priority undetermined due to insufficient information" as these may be a 'high' priority if more data were available; thus, further studies are required (Section 2.2.3) before specific recommendations for changes of the meat inspection can be made. The recommended changes for the hazards that were ranked 'high', i.e. *Salmonella* spp. in farmed wild boar and *T. gondii* in farmed wild boar and farmed deer, are discussed below. In order to facilitate decision-making for these hazards, harmonised surveys are required to establish values for the prevalence of these hazards at herd, live animal and carcass level in individual MSs. Epidemiological studies are also required to determine the risk to public health associated with the consumption of meat from farmed deer and farmed wild boar.

In the event that these surveys confirm a high risk to public health from particular pathogens through the consumption of meat from farmed wild boar and deer, consideration should be given to the setting of clear and measurable targets at the carcass level. EU targets to be reached at the national level are already in place for *Salmonella* spp. in breeding flocks of *Gallus gallus* and turkeys, and production flocks of broilers, turkeys and laying hens. Similar targets in primary production could also be considered for the main hazards of other species, including wild game. The use of specific hazard-based targets (i.e. *T. gondii* for deer and *Salmonella* spp. and *T. gondii* for wild boar) for chilled carcasses provides:

• a measurable and transparent focus for the abattoir meat safety assurance system;



- information (as a 'benchmark') on what has to be achieved at earlier steps in the food production chain;
- information for the purpose of consumer exposure assessment for each hazard; and
- a measurable aim for the meat industry in the context of global pathogen reduction programmes.

Additional information on the development of targets can be found in the EFSA opinions on meat inspection of swine and poultry (EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM), EFSA Panel on Animal Health and Welfare (AHAW), 2011, 2012).

Further information on harmonised epidemiological indicators (HEIs) and related methodologies therefore, the main hazards that could be used in studies to establish the prevalence of the main pathogens and to establish targets for carcasses and performance criteria for slaughterhouses, as well as targets for incoming farmed game animals, is provided in the EFSA report (EFSA, 2013). Therefore, this opinion and the report should be used in combination.

# 4.3. Specific inspection methods for *Salmonella* spp. in farmed wild boar in an integrated system

## **4.3.1.** Farm element (options for control)

At farm level, the primary goal is to reduce the risk of *Salmonella* spp., which may be achieved through preventive and control measures.

It is possible to control *Salmonella* spp. in pig production pre-harvest, both in the more industrialised production as well as in outdoor pig production in low-prevalence countries (Viske and Vågsholm, 2007). The main elements of this control are to ensure that:

- only pigs from *Salmonella* spp.-free farms enter the herd;
- the breeding pyramid is free from *Salmonella* spp.;
- direct or indirect contact with infected animals is avoided;
- feed is *Salmonella*-free;
- action is taken to eliminate infection/contamination at any finding of *Salmonella* spp.

Thus, more knowledge is needed on *Salmonella* control in farmed wild boar in low-prevalence countries. It can be assumed that *Salmonella* control in farmed wild boar may be more challenging than in conventional domestic pig-raising systems. For example, it may be more difficult to prevent contact with the *Salmonella* serotypes in wild animals and birds and to eliminate the infection from the herd. On the other hand, the exposure of farmed wild boar to *Salmonella* spp. should be lower, as animal stocking densities are lower and the feed of the wild boar should be free from *Salmonella* contamination. Comparison of wild boar and domestics pigs should highlight the importance of intensive farming for *Salmonella* spp. occurrence.

In high-prevalence countries, where *Salmonella* spp. is common in food-producing animals, contamination of the environment, as well as the occurrence of *Salmonella* spp. in wildlife and other animals, is expected to be much higher. In this case, it may be very difficult to prevent infection from these sources, and in such areas it can also be expected to be difficult to obtain breeding animals from *Salmonella*-free farms. However, depending on several factors, such as population density, the occurrence of crowding at feeding places, environmental exposure, management and level of hygiene, the prevalence of *Salmonella* spp. in wild boar herds in high-prevalence countries.

An important element of an integrated food safety assurance system is risk categorisation of herds based on the use of HEI. Further information on HEIs is provided in the EFSA report (EFSA, 2013). Therefore, this opinion and that report should be used in combination. Detailed information on risk categorisation of domestic swine herds for *Salmonella* spp. and other pathogens is provided in the opinion of the BIOHAZ Panel on meat inspection in swine (EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM), EFSA Panel on Animal Health and Welfare (AHAW), 2011). In general, the same principles would apply to farmed wild boar herds.

# **4.3.2.** Slaughterhouse element (options for control)

*Salmonella* spp. are carried in the gastrointestinal tract and/or on the skin of wild boar presented for slaughter, and carcass meat becomes contaminated as a result of direct or indirect contamination. As mentioned in Section 3.1, farmed wild boar may be slaughtered, bled and eviscerated on-farm. In that circumstance, the level of contamination of the carcass is highly dependent on the hygiene on the farm, during transport and at the abattoir.

In the case of animals slaughtered at the abattoir, the level of contamination is mainly dependent on abattoir hygiene. While technical aspects of individual steps of pig slaughter line operations 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*. Farmed wild boar are usually skinned (instead of dehairing) which may result in greater cross-contamination of the carcasses. Each of the slaughter steps will also contribute differently to the final microbial load on the carcass. In general, slaughter and evisceration of *Salmonella*-infected pigs increases *Salmonella* spp. contamination as perforation of the gut results in faecal spillage and cross-contamination to other carcasses.

Increased hygiene, including anal bunging, has also been shown to decrease *Salmonella* contamination of carcasses in pig production (EFSA BIOHAZ Panel, 2010). Decontamination of the carcasses can also reduce *Salmonella* contamination. Physical decontamination, e.g. using hot water, steam or irradiation, may effectively reduce the bacterial load. Chemical decontamination can also reduce the bacterial load on carcasses (Loretz et al., 2010). Some combinations of treatments can further enhance these reductions (Loretz et al., 2010). However, some of these methods are inhibited by cost, environmental impact, practicability, regulatory requirements or acceptability to consumers (EFSA Panel on Biological Hazards (BIOHAZ), 2010). A detailed discussion of the possible modification of pig abattoir operations that can be used to improve the microbial status of carcasses can be found in the EFSA opinion on meat inspection of swine (EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM), EFSA Panel on Animal Health and Welfare (AHAW), 2011).

The slaughter of *Salmonella*-positive animals may result in the contamination not only of carcasses, but also of the slaughter line (Corry et al., 2002; Olsen et al., 2003). Several studies in pig slaughterhouses have shown that slaughter equipment may remain contaminated for extended periods, resulting in cross-contamination of many carcasses (Swanenburg et al., 2001; Warriner et al., 2002; Hald et al., 2003; Smid et al., 2012). A recent study performed in three Belgian broiler slaughterhouses indicated that contamination of equipment with resident *Salmonella* strains may also play an important role in the contamination of broiler carcasses with *Salmonella* spp. (Rasschaert et al., 2007). It is therefore recommended that the effect of post-slaughter cleaning and disinfection on *Salmonella* reduction is monitored and that corrective actions are taken if cleaning and disinfection is ineffective.

Each slaughterhouse can be viewed as unique, owing to differences in the species slaughtered, logistics, processing practices, plant layout, equipment design and performance, standardised and documented procedures, personnel motivation, management and other factors. These variations,

individually and in combination, result in differences in risk reduction capacities and, consequently, in the microbiological status of the final carcass. Although information is lacking in relation to slaughterhouses dealing with wild boar, a few studies have reported variability in pig slaughterhouses, in respect of the microbiological status of carcasses. A comprehensive study (Delhalle et al., 2008) demonstrated relatively high variability among the 10 largest pig slaughterhouses in Belgium in respect of the microbial outcomes of their operations, as measured by microbiological testing of carcasses. *Salmonella* prevalence in microbiologically 'the best' and 'the worst' abattoirs differed by approximately 13-fold (i.e. from 2.6 to 34.3 %), median *E. coli* count (ECC) by 35-fold and aerobic bacterial colony counts (ACCs) by 19-fold. Consequently, this suggests a risk categorisation of farmed game slaughterhouses may be possible, based on the assessment of individual hygiene process performance. For such a scheme, a standardised methodology and criteria for the assessment of process hygiene are a prerequisite.

It can be argued that slaughter of farmed wild boar on farms or in slaughterhouses which do not specialise in these species will result in untrained workers performing multiple tasks without proper cleaning and disinfection of hands and utensils, thus resulting in higher bacterial numbers (including hygiene indicators) on the finished carcass. Evidence for this has been presented for small ruminants (Loncaric et al., 2009).

## Process hygiene criteria

The hygienic status or performance during slaughter and processing is monitored using indicator organisms. Microbiological standards for carcasses before chill are set out for most farmed animal species in Regulation EC No 2073/2005, but not for farmed game. The regulation states that the FBO must use ACC and total *Enterobacteriaceae* counts (TECs) as process hygiene criteria (PHC), to evaluate hygiene and faecal contamination in the slaughter of cattle, sheep, goats, horses and pigs. The results are an indicator of the acceptable (or otherwise) functioning of prerequisite (GHP) programmes in the slaughterhouse processes. They are an indicator of the microbiological status of the carcass immediately before chilling, but not of products (retail cuts, etc.) subsequently placed on the market.

Bacteriological analysis of carcasses, as outlined in this regulation, is carried out by the FBO. Four sites are sampled on five randomly selected carcasses weekly. Depending on the results, the frequency of sampling may be reduced to fortnightly. Samples are pooled and ACCs and TECs are measured in the laboratory. The PHC also include testing for *Salmonella* spp., but the number of samples is limited and the chance of detecting the organism, even if present, is very low. It is generally agreed that indicator microorganisms are better suited for monitoring process hygiene than specific pathogenic microorganisms (Bolton et al., 2000; Koutsoumanis and Sofos, 2004; Blagojevic et al., 2011) as the latter generally occur sporadically, in low numbers, and may be unevenly distributed on carcasses, all of which factors inhibit detection. The disadvantage of ACC and/or TEC testing is that the data do not give a reliable indication of the prevalence or levels of a specific pathogen such as *Salmonella* spp. and therefore may not be used in risk assessment.

Failure to achieve the targets set out in Regulation EC No 2073/2005 requires a review of the implementation of the prerequisite programme and corrective action. In addition to microbiological testing, compliance with both the prerequisite and HACCP programmes must be routinely verified by audit. The competent authority carries out this role on behalf of the MS as defined by Regulation (EC) No 854/2004.

As compliance with the PHC verifies the effective functioning of the prerequisite (GHP) programme rather than the safety of the product, it does not require validation by independent sampling on behalf of the competent authority. Microbiological testing alone may convey a false sense of food safety owing to the statistical limitation of sampling plans, particularly in the cases where the hazard presents an unacceptable risk at low concentrations and/or low and variable prevalences. In addition, for pathogens other than enteric organisms (e.g. *T. gondii*), PHC do not provide any information about risk. Sampling and testing, as required by Regulation (EC) No 2073/2005, is only part of the



verification process of systems in place. These criteria should not be considered in isolation from other aspects of EU food legislation, including audit-based compliance (EFSA, 2007b).

Salmonella spp. was ranked as a high priority for meat inspection in farmed wild boar and, despite the limitations mentioned above, Salmonella spp. testing could be an important activity in an improved integrated farmed game meat safety system. Issues related to the sporadic incidence, uneven distribution and low prevalence on carcasses could be overcome by using half-carcass sponge swabbing and PCR in addition to enrichment (presence or absence) and direct counting culture techniques. Once a baseline is established, contamination events could be related to a breakdown in the prerequisite programme and possibly the HACCP system if this included an intervention specifically targeting Salmonella control. If the ACCs and TECs suggest that the prerequisite programme was effective and therefore carcass cross-contamination was under control, the data generated for a specific batch of animals could be related to the farm of origin and could be used, with animal testing data, to categorise farms, thereby facilitating other control activities such as logistic slaughter of animals from high-risk farms.

# 4.4. Inspection methods for *T. gondii* in farmed deer and farmed wild boar in an integrated system

# **4.4.1.** Farm element (options for control)

Surveillance and monitoring of T. gondii in animals is essential in the control of this parasite, which currently is not addressed effectively within the EU (EFSA, 2007a). Such monitoring programmes could help in the risk assessment and categorisation of farmed deer and farmed wild boar with regard to T. gondii at the slaughterhouse as part of the FCI provided. Only a very limited number of studies that have been carried out on the prevalence of T. gondii in wild boar and in deer in the EU, and most of those in deer have been carried out in wild deer. These studies have indicated regional differences in seroprevalence, which may be accounted for by differences in environmental contamination or by factors that influence the level of exposure of farmed deer or farmed wild boar, such as the presence of cats and farm management practices. Studies are required to establish the prevalence of T. gondii in farmed deer and farmed wild boar in EU MSs. The most feasible surveillance method is likely to be the use of indirect serological tests (e.g. ELISA or microagglutination) for the detection of T. gondii antibodies at the time of slaughter, as seropositivity has been correlated with the presence of cysts in tissues (Dubey, 2009; Opsteegh et al., 2010). However, in evaluating data based on serological tests, it should be borne in mind that little is known concerning the specificity and sensitivity of serological diagnosis of T. gondii infection in farmed deer and wild boar. For more details on the different options for indicators of the presence of T. gondii, we refer the reader to technical specifications on HEIs for biological hazards to be covered by meat inspection of farmed game (EFSA, 2013).

Measures should also be taken to control *T. gondii* in farmed deer and farmed wild boar. Herbivorous animals are most likely to contract *T. gondii* infection via pasture, hay, forage, feed or surface water contaminated with oocysts shed by infected cats (Skjerve et al., 1998; Tenter et al., 2000). Omnivorous wild boars often become infected by ingesting infested cadavers or rodents. A continuous input of sporulated oocysts, originating from young infected cats, must be present to sustain the oocyst reservoir in the environment (Kijlstra and Jongert, 2008). The risk of environmental oocyst contamination can be addressed by using heat-treated feed and clean bedding, and not allowing animals outdoor access. However, such husbandry practices are not viable for farmed deer and farmed wild boar. Removing cats from the farm surroundings, or vaccinating cats, could theoretically lead to a reduction in the oocyst load on the farm but, generally, this is not a realistic option.

Vaccination also provides a possible control measure, although it must be borne in mind that this may not be practical in many situations because of the difficulty of handling farmed deer and farmed wild boar. Vaccines against *T. gondii* could be targeted using a number of different strategies: (i) immunisation of domestic cats to disrupt the zoonotic cycle and prevent contamination of the environment by oocysts; (ii) prevention of infection in animals raised for human consumption, thereby preventing transmission; and/or (iii) prevention of infection or at least of clinical disease in humans (EFSA, 2007a). Currently, the only vaccine commercially available is a live toxoplasma vaccine for sheep, based on the attenuated S48 strain of the parasite (Toxovax<sup>®</sup>, Intervet Schering-Plough). This vaccine is usually administered to young sheep as a preventative measure to reduce the risk of abortion in adult ewes. Vaccination does reduce foetal damage but it does not eliminate vertical transmission of the parasite when infection occurs during pregnancy (Dubey, 1996; Kijlstra and Jongert 2008). Moreover, the vaccine may revert to a pathogenic strain and is, therefore, not suitable for human use (Hiszczyńska-Sawicka et al., 2011). An oral vaccine composed of live bradyzoites from an oocystnegative mutant strain (T-263) has been shown in experimental trials to be effective in preventing oocyst shedding by cats, but a vaccine for cats is not yet commercially available (Innes et al., 2009). Although the S48 strain vaccine remains the only one commercially available, there has been significant progress over the last 15 years in the development of vaccines against toxoplasmosis as a result of technological advances in molecular biology (Kur et al., 2009). A cocktail DNA vaccine has been shown to prime the immune system of animals against toxoplasmosis, with increased immune responses being observed after experimental challenge (Hoseinian Khosroshahi et al., 2011). In principle, an effective recombinant vaccine against both sexual and asexual stages of the parasite should be able to address all three targets listed above, but this is hampered by stage-specific expression of T. gondii proteins (Jongert et al., 2009).

Overall, the measures currently available to control T. gondii at farm level are very limited.

# 4.4.2. Slaughterhouse element (options for control)

T. gondii does not cause clinical signs in farmed deer and farmed wild boar or macroscopic lesions on the carcass or in the organs. Consequently, the parasite cannot be detected during current meat inspection of farmed deer or farmed wild boar at either ante- or post-mortem inspection. The hazard can be detected only through laboratory testing. The testing methods are based on direct detection of T. gondii in tissues by bioassay, histological or molecular methods, or indirect detection of specific antibodies in serum. Bioassay, using mice or cats that are injected or orally fed, respectively, with extracts or portions of meat/organs, is ethically unacceptable for routine purposes. Currently used molecular or histological methods are not sufficiently sensitive to detect T. gondii in meat because the density of these parasites in meat is low (one tissue cyst per 25 g or more; Dubey, 2009). However, recently a more sensitive method to detect T. gondii in meat was described, based on pre-enrichment of parasite DNA by magnetic capture followed by PCR (Opsteegh et al., 2010). Nevertheless, there may be practical difficulties with the routine use of the method to test individual carcasses in slaughterhouses, including issues related to storing the carcasses and organs whilst awaiting the result, availability of appropriate laboratory facilities and high cost; 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.

Studies have indicated that *T. gondii* cysts in meat are susceptible to various physical procedures that can take place at the abattoir or beyond. These include heat treatment, freezing, irradiation, high pressure and curing (addition of salt combined with drying) (Table 10). Heat treatment is the most secure method of inactivating the parasite; however, freezing is the risk management option to control *Toxoplasma* that will probably be the most practical for the meat industry to implement (Kijlstra and Jongert, 2008).



Post-processing intervention	Species to which the reference applies	Conditions	Reference	
Cooking	Swine	> 56 °C for at least 10 minutes	Dubey et al., 1990	
Freezing	Swine	< -10 °C for at least three days	El-Nawawi et al., 2008	
	Sheep	-20 °C for at least 54 hours	Lundén and Uggla, 1992	
Curing or applying salt	Swine	> 2 % salt for at least seven days at 20 °C	Hill et al., 2004, Dubey, 1997	
solutions	Sheep	Salt and sugar <sup>a</sup> for at least 64 h at 4 °C	Kijlstra and Jongert, 2008; Lundén and Uggla, 1992	
High pressure	Swine	300 MPa/at least 90 seconds	Aymerich et al., 2008; Lindsay et al., 2006	
Gamma irradiation	Swine	75–100 krad	El-Nawawi et al., 2008	

#### **Table 10:** Interventions available to inactivate *Toxoplasma gondii* tissue cysts.

a: "Curing was done according to a common household recipe [...] with 30–50 g sodium chloride and 25–40 g sucrose to 200–360 g meat, and kept at +4 °C for 64 h".

Microwave cooking is unreliable for killing *T. gondii*. Salting, curing, smoking and the addition of products to meat to enhance colour and taste (enhancing solutions) can have a deleterious effect on the viability of *T. gondii* in meat, but the variability in standards for these procedures is too great to make a safety recommendation (Dubey, 2009).

As there is no issue of animal/carcass cross-contamination with *T. gondii* at slaughter, it is not necessary to handle deer or wild boar from negative and positive herds separately during the transport–lairage–slaughter line period. However, incoming batches of farmed deer or wild boar could be categorised into those from *T. gondii*-free herds and those from infected herds based on historical testing results, as described above. Both categories could undergo usual slaughter, dressing and chilling operations, but after chilling carcasses 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 could be heat treated or deep frozen after de-boning.

## 4.5. Conclusions and recommendations

The possibility of identifying, before slaughter, herds/batches of farmed wild boar at high and low risk of *Salmonella* contamination should be investigated, as should the development of *Salmonella* targets and/or reduction targets at the primary production stage. If *Salmonella* spp. are present in farmed wild boar slaughtered at the slaughterhouse, increased hygiene is recommended. Decontamination methods should also be considered as a complementary 'multiple hurdle' strategy to control *Salmonella* contamination of farmed wild boar carcasses. As is currently the cases for other livestock, PHC should be mandatory for all farmed game species.

*T. gondii* in farmed deer and farmed wild boar should be investigated using a baseline study and thereafter controlled using risk management options such as freezing or heat treatment. It might be appropriate to wait until a source attribution of *T. gondii* risk for humans is available before making a final assessment of the *T. gondii* risk.

# 5. Recommend adaptations of inspection methods and/or frequencies of inspections that provide an equivalent level of protection

*Trichinella* spp. were categorised as of low priority in the assessment. However, this was considered to be the result of the current hazard-specific control measures applied (i.e. testing of all farmed wild

boar carcasses). Therefore, the possible adaptation of methods that provide an equivalent public health protection for *Trichinella* spp. are discussed in this chapter.

In addition, recommendations for adaptation of other aspects of current meat inspection practices are also formulated.

# 5.1. Inspection methods for *Trichinella* spp. in farmed wild boar in an integrated system

In Europe, *Trichinella* spp. occur in wildlife; however, the prevalence and species of *Trichinella* vary according to the area, and *T. spiralis*, *T. britovi*, *T. nativa and T. pseudospiralis* have been found. In 2010, the prevalence in farmed wild boar was 0.07 % (26/36 871), which is approximately 780 times higher than the prevalence reported for domestic pigs. In Finland, four wild boars were reported positive for *T. pseudospiralis*, whereas in Austria two wild boars and in Greece 20 wild boars tested positive for *Trichinella* spp. (species not reported)(EFSA and ECDC, 2012). The seroprevalence of *Trichinella* spp. in farmed wild boar has been reported to be 2 % in Finland (n = 197) (Jokelainen et al., 2012).

Meat from farmed wild boar, which is placed on the market in the EU has to pass an examination for larvae of *Trichinella* spp. (Regulation (EC) No. 2075/2005). From each carcass, a sample of 5 g lean muscle tissue from the foreleg, tongue or diaphragm is tested by artificial digestion (magnetic stirrer) or an equivalent method listed in Annex I of the regulation. If *Trichinella* spp. are detected in a pooled sample (e.g. up to 20 carcasses), 50 g of muscle tissue per carcass is tested separately. Carcasses which test positive for this parasite are declared unfit for human consumption.

# **5.1.1.** Farm element (options for control)

Theoretically, separation of farmed wild boar during the pre-slaughter phase (i.e. on-farm) into lower or higher risk categories with respect to *Trichinella* spp. could be based on certain criteria, including (a) the biosecurity system, i.e. whether they are, or are not, kept in high-containment level conditions preventing exposure to the parasite; and/or (b) the results of serological testing of live farmed wild boar for the parasite; and/or (c) geographical origin, i.e. whether or not they originate from countries/regions where *Trichinella* is present in the domestic and/or sylvatic cycles.

With respect to breeding system criterion, farmed wild boars are not reared under high containment level conditions. Hence, when comparing the *Trichinella* risk categorisation of domestic pigs and farmed wild boar (Table 11), it is considered that the concept of negligible risk (high containment level) used for pigs cannot be applied to farmed wild boar.

Breeding condition	Pig	Systematic control for <i>Trichinella</i>	Farmed wild boar	Systematic control for <i>Trichinella</i>
High containment level	Yes	No	No <sup>a</sup>	NA <sup>c</sup>
Indoor without outdoor Access	Yes	Yes	No <sup>b</sup>	NA
Indoor with outdoor access	Yes	Yes	Yes	Yes
Backyard	Yes	Yes	Yes	Yes
Free-ranging	Yes	Yes	Yes	Yes

**Table 11:** Comparison of pig and farmed wild boar breeding practices which can prevent or facilitate *Trichinella* transmission.

a: Farmed wild boar are not reared in high containment levels.

b: Farmed wild boar always have an outdoor access.

c: NA, not applicable.

Wild boar can be tested serologically for *Trichinella* antibodies. The sampling can be performed only at slaughter. ELISA is more sensitive than the traditional digestion method of muscle samples; however, false-negative reactions may occur. Farmed wild boar originating from different farms have been tested with results showing differences in antibody levels in animals according to farm (Sukura et al., 2001; Jokelainen et al., 2012). In theory, testing of animals at slaughter could be used to categorise



wild boar farms, assuming that the infection status of the herd would not change and that the antibody levels would remain constant. The results from the carcass testing required under EU Regulation 2075/2005 could potentially be used for this purpose. However, when animal production is a small-scale activity and animals are generally slaughtered in small numbers per year, the categorisation of farms is difficult. In addition, the epidemiology of the parasite makes it challenging, because, for instance, *T. pseudospiralis* has an ability to spread via infected birds and wild boars are omnivorous animals which also eat small birds and mammals.

# 5.1.2. Slaughterhouse element (options for control)

Alternative approaches to meat safety assurance with respect to muscle larvae of *Trichinella* have been considered for pigs (EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM), EFSA Panel on Animal Health and Welfare (AHAW), 2011). They are primarily based on meat treatments which aim to inactivate the larvae. The most reliable larvae inactivation treatments (Gamble et al., 2000, 2007) recommended in the context of abattoir pork carcass safety assurance (EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM), EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM), EFSA Panel on Animal Health and Welfare (AHAW), 2011) are based on the application of (a) an adequate meat heating regime, e.g. 71 °C for at least one minute; and/or (b) an adequate meat freezing regime, e.g. at least -15 °C for three weeks (if meat is cut in pieces up to 15 cm in thickness) or -15 °C for four weeks (if meat pieces are up to 50 cm thick). While it has been reported that *T. spiralis*, *T. britovi* and *T. pseudospiralis* have high freeze tolerance in horse meat (-18 °C for 4 weeks), related studies suggest that all *Trichinella* species were inactivated in pig and wild boar meat after storage at -18 °C for one week (Kapel et al., 2004). In the absence of further studies, freezing is therefore a potential control treatment in farmed wild boar.

It can be argued that application of measures to control the presence or infectivity of the parasites by heat treatment as described above would allow omission of mandatory *Trichinella* testing, provided that such treatment is an integrated part of the food business's HACCP plan.

As there is no issue of cross-contamination with *Trichinella* spp. at slaughter, it is not necessary to handle farmed wild boar from negative and positive herds separately during the transport–lairage–slaughter line period. However, as with *T. gondii*, incoming batches of farmed wild boar could be categorised into low-risk and higher risk categorises (sows are particularly at risk) based on historical testing results.

There is a possibility that the competent authority can ascertain, by risk assessment, the risk of *Trichinella* infection of farmed wild boar as negligible. However, the conditions for such ascertainment have not been defined.

# 5.1.3. Conclusions and recommendation

It was concluded that:

- The omission of mandatory *Trichinella* testing would most likely increase exposure of consumers to viable larvae, but to what extent is unclear.
- Risk categorisation of wild boar farms appears to be unreliable considering current husbandry and the low numbers of wild boar slaughtered.
- Conditions for assessing the risk as negligible should be defined clearly or omitted.

Therefore, Trichinella testing as currently practised for wild boar should be continued.



## 5.2. Recommendations for additional adaptations of farmed game meat inspection

#### 5.2.1. Food Chain Information

The main rationale behind the concept of FCI is that animals for slaughter can be categorised into different risk groups based on relevant information from the flock/herd of origin. This enables appropriate measures to be put in place during slaughter to deal with the level of risk identified. Currently, the available FCI in relation to the main biological hazards in meat of farmed game is very limited and it is very rare for adaptations of slaughter plant procedures to be made based on this information. Although EC No 853/2004 mentions the basic requirements for FCI, these are very general, and as a consequence the reported FCI is not adequate, as described above (Section 3.2). It is therefore necessary to define specific indicators to be monitored and reported in a standardised way, for example by providing the relevant data on the high-risk hazards based on specific epidemiological indicators. More specific information could then be used for assessing the risks associated with batches of animals arriving at the slaughterhouse, resulting in a classification according to these risks, as explained in chapter 4.

The main benefit of the FCI is that it may create awareness among primary producers of the need for high standards of animal health and welfare, proper identification of animals and appropriate use of medicines. By contributing to the overall health of the animals sent to slaughter, such a system should have a positive impact on public health by ensuring that the animals are less likely to carry hazards of public health importance.

Membership of quality assurance schemes and certification systems can have a similar benefit. Schemes relating to animal identification, animal health and welfare help to ensure that animals entering the slaughterhouse are healthy. Farmers should be encouraged to participate in these schemes, and information on whether or not a primary producer is a member should be included in the FCI. However, because game farming and slaughtering are, in many cases, very small-scale activities, there may not be any quality assurance schemes or systems for certification of farms available.

In case of hazards for which the ultimate risk reduction on carcasses also depends on the process hygiene performance of slaughterhouses (e.g. *Salmonella* spp. in farmed wild boar), it is necessary that related historical data are also considered within the FCI. In other words, information about each slaughterhouse should become an additional, slaughterhouse-related element of FCI, to be used by the risk manager in combination with the incoming farm-related element of FCI. EU Regulations 854/2004 and 2074/2005 already require that information gathered during meat inspection is fed back to the primary producer. The main value of such feedback relates to animal health and welfare and production-related diseases, such as liver fluke, pleuritis and pneumonia. However, use of this information to produce healthier animals would have indirect benefits for public health. From discussions with the stakeholders, it is clear that feedback to the producers is very limited in most MSs and that there is considerable room for improvement in this area.

## 5.2.2. Ante-mortem inspection

Ante-mortem inspection does not directly contribute to the detection of the hazards identified as high priority for meat inspection in this document (*Salmonella* and *T. gondii*), but it can help to assess the general health status of the animals. Meat for human consumption should be derived from the slaughter of healthy animals. Inspection of animals on arrival at the slaughterhouse will help to enforce acceptable standards of transport and handling. This might indirectly contribute to the maintenance of operating standards that minimise the general risk associated with unhygienic and stressful management of food-producing animals. Stress has been shown to be an important factor in the excretion of enteric pathogens such as pathogenic VTEC, *Salmonella* spp. and *Campylobacter* spp., so inspection procedures that prevent stress are likely to be beneficial (EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM), EFSA Panel on Animal Health and Welfare (AHAW), 2011).



The *ante-mortem* procedure will detect animals heavily contaminated with faeces and other material. Measures to exclude excessively dirty animals from entering the slaughter line will prevent contamination of the carcasses and may reduce the level of cross-contamination with enteric pathogens.

Taking these factors into consideration, and given that current methods do not increase the microbiological risk to public health and have considerable benefits in relation to the monitoring of animal health and welfare, no adaptations for the existing visual *ante-mortem* inspection are required.

## 5.2.3. *Post-mortem* inspection

In the inspection procedure for farmed game as set out in EU Regulation 854/2004, depending on the farmed game species, palpation and/or incision may be mandatory for certain organs. The hazards identified as high priority in this document (*Salmonella* spp. and *T. gondii*), cannot be detected by routine *post-mortem* examination. Consequently, palpation of organs such as the liver and lungs and of the umbilical region and incision of organs such as the gastric surface of the liver do not contribute to preventing the risk to public health arising from these hazards.

Incision and palpation could contribute to the spread of bacterial hazards through cross-contamination. Although the importance of cross-contamination in farmed game is not clear, it has been considered important in other species (Walker et al., 2000). In cattle, cross-contamination of the carcasses and offals as a result of *post-mortem* inspection has been demonstrated (Jankuloski et al., 2009). A more recent study by Brichta-Harhay et al. (2012) reported that incisions made during lymph node inspection resulted in the cross-contamination of surrounding tissue with *Salmonella*. In pigs, Hamilton et al. (2002) demonstrated a 2.5 fold reduction in combined *Salmonella* and *Y. enterocolitica* contamination of carcasses when visual only inspection was used. This is supported by risk assessment studies that suggest incision during *post-mortem* inspection of pigs represents a cross-contamination risk for enteric pathogens (Pointon et al., 2000; Nesbakken et al., 2003).

For these reasons, the Panel recommends that palpation and incision as described above should be omitted in those farmed game species in which they are currently practised, i.e. deer, reindeer and wild boar.

Visual examination contributes by detecting visible faecal contamination and/or spilled intestinal contents, although it is unclear how sensitive the current system is or what contribution this detection makes towards preventing public health risk.

Current legislation foresees palpation and incision if abnormalities are detected during visual inspection. It is recommended that these procedures, if necessary, are carried out separately from the routine inspection of carcasses, to prevent cross-contamination.

Elimination of abnormalities on aesthetic/meat quality grounds could be assured through a meat quality assurance system instead of through the official food safety assurance system including meat inspection, as at present. Any handling of carcass or organs should be performed on a separate line and accompanied by laboratory testing as required.

In summary, the following changes are proposed:

- For farmed deer and reindeer: omission of palpation and incision as required by the *post-mortem* inspection procedure for bovine and/or ovine animals.
- For farmed wild boar: omission of palpation and incision as required by the *post-mortem* inspection procedure for pigs.
- For farmed ostrich and rabbit: no change is suggested as the *post-mortem* inspection procedure for poultry is applied, which does not require palpation and incision.



# 5.2.4. The effects of proposed changes on hazards/conditions addressed by current meat inspection

The proposed FCI-related changes in farmed game meat inspection will not have any negative effect on hazards/conditions addressed by current meat inspection. On the contrary, it is expected that proposed wider, more systematic and better focused use of the FCI will have positive impact on control of those hazards/conditions as well as on control of emerging hazards.

As indicated previously, no change to *ante-mortem* inspection is proposed, so there will be no effect of the proposed new farmed game meat inspection system on hazards/conditions addressed by current *ante-mortem* inspection.

Cessation of incision and palpation during *post-mortem* inspection as proposed above would not increase the public health risk associated with farmed game carcasses as none of the conditions that can be detected in a reliable way is relevant for public health.

# 5.2.5. Impact of these changes on meat-borne zoonotic hazards

Y. enterocolitica and Y. pseudotuberculosis are found in farmed deer. Y. enterocolitica and Trichinella are also present in farmed wild boar. All of these hazards were ranked as a low priority for meat inspection using the decision tree in chapter 2, based on low human incidence and low severity of disease. Trichinella was discussed in Section 5.1. Trichinella testing of sensitive host species such as farmed wild boar is a mandatory part of post-mortem inspection. Testing of every carcass has protected consumers from trichinosis, and to date there have been no reported human cases associated with tested meat. However, cases are still reported when meat is not tested, for example in home-slaughtered pigs and hunted game.

The presence of *Y. enterocolitica* and/or *Y. pseudotuberculosis* cannot be detected using current *ante*and *post-mortem* meat inspection practices. Thus, the low risk of *Y. enterocolitica* and *Y. pseudotuberculosis* is not low because of current meat inspection practices. The proposed changes to meat inspection would therefore not increase the risk of *Y. enterocolitica* or *Y. pseudotuberculosis* contamination on farmed deer or wild boar carcasses. Indeed, the opposite may be true as making incisions in lymph nodes will spread these organisms, if present, over the carcass, and possibly between carcasses (Pointon et al., 2000; Nesbakken et al., 2003). Similarly, the requirement for simultaneous presentation of the head, organs and carcasses for inspection during farmed wild boar slaughter facilitates the cross-contamination of *Y. enterocolitica* and *Y. pseudotuberculosis* from the highly contaminated heads (up to one-third of wild boar tonsillar samples have been reported to carry these two organisms; Wacheck et al., 2010) to the carcass.

# 5.2.6. Impact of these changes on non-meat-borne zoonotic hazards

Palpation and incision will assist in the identification of zoonootic pathogens that are not meat borne, such as *E. granulosus*, *F. hepatica*, *D. dendriticum* (although *E.* cysts are usually visible before incisions are made) and *M. bovis*. The removal of palpation and incision as a requirement in the post-mortem procedure in farmed deer and reindeer could have some effect on the detection of *Echinococcus*. The *post-mortem* examination will also identify a wide variety of pathogens and abnormalities of relevance for animal health and welfare, and the impact of these changes is discussed elsewhere in the opinion (Appendix C).



## **CONCLUSIONS AND RECOMMENDATIONS**

## CONCLUSIONS

Answer to Term of Reference 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).

- Biological hazards identified as farmed game meat borne and currently present in the EU farmed game population include; *Campylobacter* spp., *Salmonella* spp., pathogenic VTEC, *Yersinia enterocolitica, Yersinia pseudotuberculosis, Toxoplasma gondii* and Hepatitis E virus (HEV) in farmed deer; *Campylobacter* spp. and *Salmonella* spp. in farmed ostriches; *Campylobacter* spp., *Salmonella* spp., *Y. enterocolitica*, pathogenic VTEC, *T. gondii, Trichinella* spp. and HEV in farmed wild boar; and *Salmonella* spp., pathogenic VTEC and HEV in farmed rabbits. These were subjected to prioritisation for meat inspection based on a decision tree.
- Based on the limited data available, the identified farmed game meat-borne biological hazards were categorised as follows:
  - *T. gondii* in farmed deer and *Salmonella* spp. and *T. gondii* in farmed wild boar were assessed as of high priority for farmed game meat inspection;
  - *Y. enterocolitica* and *Y. pseudotuberculosis* were ranked as low priority in farmed deer. *Y. enterocolitica*, pathogenic VTEC and *Trichinella* spp. were also ranked as low in farmed wild boar, the last because of current controls;
  - The following hazards were categorised as 'priority undetermined due to insufficient data': *Campylobacter spp.*, *Salmonella* spp., pathogenic VTEC and HEV in farmed deer; *Salmonella* spp. and *Campylobacter* spp. in ostrich; *Campylobacter* spp. and HEV in farmed wild boar and *Salmonella* spp., pathogenic VTEC and HEV in farmed rabbit.

## Answer to Term of Reference 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.

It is unclear as to which *post-mortem* inspection procedure should be used for farmed deer.

Strengths of the current meat inspection methodology for biological hazards are as follows:

• Food chain information (FCI) serves as a two-way communication channel between primary production and meat inspection. It should provide information on the health status of the animals, including mortality rates, occurrence of disease, veterinary treatments, specific laboratory testing, etc., allowing evaluation of the health status of incoming batches and thus preventing sick animals from entering the food chain. In principle, therefore, adequate collection and proper utilisation of FCI can be beneficial to *ante-* and/or *post-mortem* meat inspection.



- *Ante-mortem* inspection of farmed game animals facilitates the detection of observable abnormalities and animal identification, enabling traceability. Although it does not detect asymptomatic carriers of pathogens of public health concern, such as *Salmonella* spp. and *T. gondii*, it does provide an assessment of animal/herd health, which, if compromised, may lead to a greater public health risk.
- *Ante-mortem* inspection also has the potential to detect new diseases, provided these have clinical symptoms, which may be of direct public health significance.
- Visual examination during *ante-mortem* inspection detects extensive faecal and other contamination on hides and feathers, which increases the risk of microbial cross-contamination during slaughter. This facilitates the implementation of preventative control measures.
- *Post-mortem* inspection detects visible, primarily faecal, carcass contamination and allows for removal by trimming and may also be used to assess the general health status of the animal.
- *Trichinella* testing of wild boar carcasses and removal of positive carcasses from the food chain has protected consumers from trichinosis.

Weaknesses of the current meat inspection methodology for biological hazards are as follows:

- In practice, FCI is probably underutilised owing to the lack of indicators and harmonisation across the EU. In its current form, FCI provides generic data that cannot be used to evaluate the risk of specific hazards of public health concern in a given batch of animals and cannot be used to distinguish between high- and low-risk farms. Its application is therefore limited.
- *Ante-* and *post-mortem* inspection is not able to detect the public health hazards identified as the main concerns for food safety.
- Manual handling of meat including the use of palpation and incision techniques during *post-mortem* inspection does not contribute to the detection of high-priority farmed game meatborne hazards such as *Salmonella* spp., but may actually increase and spread these hazards by cross-contamination.

## Answer to Term of Reference 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, FCI should be taken into account.

- It is not possible to detect the hazards ranked as high priority for farmed game meat inspection using traditional meat inspection methods. Control is currently reliant on the implementation of an effective HACCP programme and prerequisite activities (GHP) in the slaughterhouse.
- Information on the biological risks associated with the consumption of meat from farmed game animal species is sometimes scant and unreliable. In order to facilitate decision making, harmonised surveys are required to establish values for the prevalence of the main hazards at live animal and carcass level in individual MSs. Epidemiological and risk assessment studies could also be required to determine the specific risk to public health associated with the consumption of meat from farmed game animal species.
- In the event that these studies confirm a high risk to public health through the consumption of meat from farmed game animal species, consideration should be given to the setting of clear and measurable EU targets at the carcass level. To meet these targets and criteria, a variety of control options for the main hazards are available, at both farm and abattoir level.
- An important element of an integrated farmed deer/wild boar carcass meat safety assurance system should be risk categorisation of farms/herds based on farm descriptors and historical



data as well as herd-specific information, including monitoring of harmonized epidemiological indicators (HEI) as described in the EFSA Report (EFSA, 2013).

- Improvement of slaughter hygiene should be sought in abattoirs with historically unsatisfactory performance, starting with a thorough review of current HACCP and prerequisite systems with follow-up improvement actions including technological and managerial interventions.
- The possibility of identifying high- and low-risk herds/batches for *Salmonella* spp. in farmed wild boar before slaughter should be investigated, as should the development of *Salmonella* targets and/or reduction targets at the primary production stage. If *Salmonella* spp. are present in the farmed wild boar slaughtered at the slaughterhouse, increased hygiene is recommended. Decontamination methods should also be considered as a complementary 'multiple hurdle' strategy to control *Salmonella* contamination of farmed wild boar carcasses. As is currently the cases for other livestock, process hygiene criteria (PHC) should be mandatory for all farmed game species.
- *T. gondii* in farmed deer and farmed wild boar should be investigated using a baseline study and thereafter controlled using risk management options such as freezing or heat treatment. This would be facilitated by a risk assessment; however, this is reliant on the successful completion of source attribution studies.

## Answer to Term of Reference 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.

- Palpation/incision used in current *post-mortem* inspection should be omitted in farmed wild boar to reduce the risk of cross-contamination of the carcasses with *Salmonella* spp. from the lymph nodes. Although *Salmonella* spp. was not prioritised for meat inspection in farmed deer and reindeer, omitting palpation and incision should also be considered as these activities do not facilitate the detection of zoonotic agents but increase the risk of carcass contamination. *Post-mortem* meat inspection in farmed ostrich and rabbit is already visual only so no change is required.
- Palpation and incision may be used during *post-mortem* examination if relevant abnormalities have been detected on/in an animal as a result of FCI/*ante-mortem* or other *post-mortem* inspection activities. Where appropriate, this should be performed separately from the slaughter line operation and accompanied by laboratory testing as required.
- The omission of mandatory *Trichinella* testing would most likely increase exposure of consumers to viable larvae, but to what extent is unclear.

## RECOMMENDATIONS

- It was considered that the following combinations may be ranked high priority if more data were available and thus further investigative studies and/or surveillance are recommended: farmed deer and pathogenic VTEC; ostrich and *Campylobacter* spp. and *Salmonella* spp.; wild boar and HEV.
- As the current legislation is not specific, the corresponding post-mortem inspection procedures for each farmed game species should be clarified.
- Systematic collection of FCI and analysis for the main hazards in farmed game at both the herd and abattoir levels is recommended. Research on the optimal ways of collecting and using FCI



for risk categorisation and differentiated slaughter of farmed deer and farmed wild boar is required.

- Categorisation of farmed wild boar farms in terms of *Salmonella* spp. and *T. gondii* should be investigated with a view to implementing additional measures in the slaughterhouse for those farms categorised as high risk.
- The efficacy of farmed wild boar carcass treatments in controlling *Salmonella* spp. should be reviewed and further investigations undertaken as required with the specific objective of making clear recommendations regarding the most effective methods.
- *Trichinella* testing should continue in farmed wild boar and positive carcasses should continue to be removed from the food chain.
- The effect of this omission of palpation and incision on the meat safety risk posed by nonmeat-borne zoonoses such as *E. granulosus*, *F. hepatica*, and *M. bovis* should be periodically revisited in the future, particularly in those regions where those hazards are endemic.



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# ANNEXES

Annex A: A short summary description of the microorganisms potentially transmitted from farmed game to humans

#### 1. Bacteria

#### 1.1. Actinobacillus lignieresii

Actinobacillus lignieresii causes actinobacillosis, a tumorous abscess of the tongue (i.e. 'wooden tongue') and other forms of granulomatous disease of the head, neck, limbs, and occasionally the lungs, pleura, udder and subcutaneous tissue, primarily in cattle and sheep, but also in horses and pigs. A few human soft-tissue *A. lignieresii* infections originating from contact with, or bites from, cattle or sheep have been reported. *A. lignieresii* is rarely reported in farmed deer and is not found in other farmed game and was excluded from the assessment.

#### **1.2.** Aeromonas spp.

*Aeromonas* spp. are ubiquitous bacteria in terrestrial and aquatic milieus. They are enteric pathogens of serious public health concern as they have acquired a number of virulence determinants that are linked with human diseases, such as gastroenteritis, soft-tissue and muscle infections, septicaemia and skin diseases (Igbinosa et al., 2012). Aeromonads have recurrently been isolated from meat and the edible organs of sheep and poultry, fish and seafood, raw milk, red meats as well as pork and beef (Ceylan et al., 2009). Rodriguez-Calleja et al. (2006) found motile *Aeromonas* spp. in rabbit meat (average count 1.77  $\pm$  0.62 log colony-forming units (CFU)/g). However, only a few food-borne outbreaks have been documented (Isonhood and Drake, 2002) and they were not related to meat from farmed game. Hence, they were not included in the ranking.

#### **1.3.** *Bacillus anthracis*

Humans are usually infected with this pathogen via aerosols or as a result of direct contact with infected animals. Although oropharyngeal and gastrointestinal anthrax in humans may result from ingesting contaminated meat from infected animals that has not been sufficiently cooked, cases are extremely rare. *B. anthracis* infection has been reported in white-tailed deer in North America but not in Europe. Anthrax cases are thoroughly investigated because of the serious nature of the disease associated with infection with this organism (in the EU the percentage of reported deaths among confirmed human cases in was 50 % in 2009 and 37.9 % in 2010). Between 2006 and 2009 the number of cases reported to ECDC ranged from three confirmed (2008) to 14 (2006). Human cases of pulmonary anthrax have been linked to the enclosed factory environments where contaminated material such as hides and wool are processed. Humans may also acquire the cutaneous form of anthrax from handling contaminated animal products, such as hides, wool and hair. The consumption of raw or undercooked meat has also been associated with ingestion cases (CFSPH, 2007). Farmed game meat-borne transmission of anthrax in the EU has rarely, if ever, been reported. Therefore, based on the data available, *B. anthracis* was not shortlisted for priority ranking.

## **1.4.** *Bacillus cereus*

*Bacillus cereus* is a ubiquitous organism that may be isolated from soil, plants and animal faeces as well as raw meat and milk. *B. cereus* causes two types of food-borne disease: (a) an emetic syndrome, due to consumption of food (usually starch-based foods such as rice) containing the toxin; and (b) a diarrhoeal syndrome, in which the toxin is produced in the intestines. For both types of disease, growth of the pathogen is a prerequisite, as the emetic syndrome is associated with ingestion of  $10^{5}$ – $10^{8}$  cells/g of food and the diarrhoeal syndrome with consumption of  $10^{5}$ – $10^{7}$  cells (Gibbs, 2002). As *B. cereus* are prevalent in the environment, it is a potential contaminant on farmed game meat and has been shortlisted for risk ranking using the decision tree.



# 1.5. Brucella spp.

*Brucella abortus* and *Brucella melitensis* may infect cattle, sheep, goats, deer and wild boar. *Brucella suis* occurs in red deer (Böhm et al., 2007), reindeer (Zheludkov and Tsirelson, 2010) and wild boar (Galindo et al., 2010; Abril et al., 2011). However, there have been no reported cases of brucellosis in European deer. The main route of infection in humans is direct contact with infected animals and/or contaminated food, particularly milk and products thereof. These bacteria remain viable for only a short period in the muscles after slaughter, and human infection arising from the consumption of farmed game meat has not been reported. *Brucella* spp. were excluded from ranking.

## **1.6.** *Campylobacter* spp.

Campylobacteriosis is the most frequently reported zoonosis in Europe, with 212 064 confirmed cases in 2010 (EFSA and ECDC, 2012). Poultry and related products are the primary source of human infection, and these organisms have been reported in ostriches (Cuomo et al., 2007). *Campylobacter* spp. have also been found in rabbits (Kohler et al., 2008) but the prevalence in the live animals and on associated meat was very low (Rodriguez-Calleja et al., 2006). However, as this organism is potentially associated with farmed game meat and campylobacteriosis is an important zoonotic disease in the EU, *Campylobacter* spp. was shortlisted for risk ranking using the decision tree.

## 1.7. *Clostridium* spp.

*C. botulinum* and *C. perfringens* are ubiquitous bacteria and can be found in a variety of food as well as in the environment. They can produce a range of neurotoxins, causing severe food-borne illness. However, germination, multiplication and neurotoxin production is required before the food is consumed, with the exception of honey, which is associated with infant botulism. The risk of disease seems be related not to the occurrence in raw meat but rather to improper hygiene and storage. Although there is no documented evidence that *C. botulinum* or *C. perfringens* is associated with farmed game meat, they were considered for further ranking because of their wide distribution in the environment.

*C. difficile* is traditionally considered to be a hospital-acquired infection but has been isolated from many domestic and wild animals. Evidence of food-borne transmission is limited and there are no data supporting the hypothesis that *C. difficile* is a hazard associated with farmed game with the exception of ostriches, although this organism has been reported to have caused illness in a small number of ostrich chicks in the USA (Frazier et al., 1993; Shivaprasad, 2003). As there is no documented evidence that *C. difficile* is a risk associated with the consumption, preparation or handling of farmed game meat in Europe, this bacterium was excluded from further consideration.

## **1.8.** *Coxiella burnetii*

*Coxiella burnetii* (*Rickettsia burnetii*), which causes Q fever in humans, is found in almost all species of domestic animals and many wild animals. The most important sources of human infection are cattle, sheep and goats, primarily via aerosols or contact with foetuses, placentas, uteruses, hide, wool and mechanical vectors. It was therefore excluded from ranking.

## 1.9. ESBL/AmpC gene-carrying bacteria

ESBL/AmpC gene-carrying bacteria have been isolated from many farm species of food-producing animals. However, evidence of direct transmission of ESBL- and/or AmpC-producing *E. coli* or *Salmonella* isolates from food-producing animals or food to humans is limited. Few studies support the theory that transfer of ESBL- and/or AmpC-producing organisms from food animal production to humans is likely to be taking place (Lavilla et al., 2008; Smet et al., 2009). One study described the occurrence of ESBL-carrying bacteria in a wild bird (black-headed gull) (Bonnedahl et al., 2010).

Very few studies report ESBL-carrying *E. coli* in wild boar and rabbit. As there is no evidence that farmed game meat is a transmission route for ESBL/AmpC carrying bacteria to humans, they were excluded from ranking.



# 1.10. Francisella tularensis

*Francisella tularensis* is a hardy, non-spore forming organism capable of surviving for weeks at low temperatures in water, moist soil, hay, straw or animal carcasses. Natural reservoirs include crayfish, voles, wild rabbits, hares and muskrats as well as some domestic animals. Tularaemia is a relatively uncommon disease in the EU. Human infection occurs through a variety of mechanisms such as bites from infected ticks or mosquitoes; direct contact or ingestion of water, food or soil contaminated by reservoirs; handling of animal tissues or fluids or undercooked contaminated meat; and inhalation of infective aerosols.

An outbreak of tularaemia occurred in Castilla y León, in north-western Spain, between June and December 2007, with a total of 507 laboratory-confirmed cases. The transmission routes responsible for the outbreak were mainly inhalation of the bacteria and direct contact (Allue et al., 2008). *F. tularensis* was excluded from ranking.

## 1.11. Leptospira spp.

*Leptospira* spp. are commonly found in domestic animals, mainly dogs, cattle, swine and horses. Rodents are the most common carriers. Exposure is through contact of mucous membranes or skin with urine-contaminated water or feed. Another source is milk from acutely infected cows. *Leptospira* spp. cause leptospirosis but have not been identified as a farmed game meat-related hazard and are not considered meat borne. *Leptospira* spp. were excluded from ranking.

#### 1.12. Listeria monocytogenes

*L. monocytogenes* is usually associated with ready-to-eat products (including products made of farmed game meat), in which contamination has occurred before or during processing, followed by growth during prolonged storage at refrigeration temperatures. In food-producing animals, including farmed game (EFSA, 2008), *L. monocytogenes* is found at prevalences from 1 to 10 %. Membre et al. (2011), for example, estimated the numbers of *Listeria monocytogenes* to be close to or under the detection limits of 1 per cm<sup>2</sup> for wild deer and wild boar in several EU MSs, while Paulsen and Winkelmayer (2004) found no *L. monocytogenes* on carcasses in Austria from wild deer post chill. Rodriquez-Calleja et al. (2006) found the organisms in 2/51 rabbit carcass samples. There are currently no data in the official or peer-reviewed literature on *L. monocytogenes* on ostriches or reindeer carcasses, but it has been isolated from ostrich meat patties (Mastromatteo et al., 2010). *L. monocytogenes* was included in the risk ranking.

#### 1.13. Mycobacterium spp.

The official monitoring data collected under the Zoonoses Directive (2003/99/EC) for the period 2004–2010 reported 6 % of deer positive for *Mycobacterium* spp. However, no speciation was reported. Furthermore, as reporting is not harmonised, this figure does not reflect the true prevalence of *Mycobacterium* spp. in farmed deer in the EU. *Mycobacterium bovis* can probably infect reindeer (*Rangifer tarandus*), but this is a very rare occurrence. As there is no documented evidence that farmed game meat is associated with human infection with *Mycobacterium* spp., these pathogens were not shortlisted for further consideration.

## 1.14. Pasteurella spp.

*Pasteurella multocida* and *Pasteurella haemolytica* cause a range of diseases in humans and animals, including in red and fallow deer. However, there is no evidence to link human infection with the consumption of deer meat or other farmed game and these bacteria were therefore excluded from further consideration.

#### 1.15. Staphylococcus aureus

S. aureus is commonly found on the skin and mucous membrane of animals including humans. It causes subcutaneous abscesses, mastitis, exudative dermatitis and pododermatitis in does and young



rabbits and has been detected on approximately one-third of rabbit carcasses (Kohler et al., 2008). Contamination by animal strains of *S. aureus* which are thought to have a low enterotoxin-forming potential is probably of less consequence than contamination from human sources. *S. aureus* was included in the risk ranking.

# 1.16. Meticillin-resistant S. aureus (MRSA)

Meat-derived products may also serve as a potential source of MRSA, with CC398 being the MRSA lineage most commonly associated with intensively reared food-producing animals, especially pigs. MRSA has been isolated from a variety of foods, including raw meat (pork, beef, lamb, chicken, turkey and rabbit) and dairy products (milk and cheese). Various studies have reported a prevalence of *S. aureus* in rabbits of up to 52.9 %, but strains are rarely meticillin resistant (Vancraeynest et al., 2004; Rodriguez-Calleja et al., 2006; Ortega et al., 2009). Based on these findings, MRSA was eliminated as there is no documented evidence linking this pathogen with farmed game.

## 1.17. Salmonella enterica (non-typhoid)

*Salmonella* has long been recognised as an important zoonotic pathogen of economic significance in animals and humans. Human salmonellosis is usually characterised by the acute onset of fever, abdominal pain, nausea and sometimes vomiting. Symptoms are often mild and most infections are self-limiting, lasting a few days. The common reservoir of *Salmonella* is the intestinal tract of a wide range of domestic and wild animals, which may result in a variety of foodstuffs of both animal and plant origin becoming contaminated with faecal organisms either directly or indirectly.

The incidence of *Salmonella* spp. in rabbits and associated carcasses is low (Rodriguez-Calleja et al., 2006; Kohler et al., 2008). However, Wacheck et al. (2010) reported a *Salmonella* spp. detection rate of 12 % in wild boar. Furthermore, according to data reported by EU MSs in the framework of the Zoonoses Directive (2003/99/EC) in 2004–2011, 1.1 % of deer, 11.1 % of reindeer, 18.3 % of wild boar, 1.8 % of ostrich and 2 % of rabbit faecal samples were positive for this organism. *Salmonella* was therefore shortlisted for risk ranking.

## **1.18.** *Streptococcus suis*

*Streptococcus suis* is a zoonotic bacterial pathogen that has been reported in tonsillar samples from farmed wild boar (Bonmarchand et al., 1985). In a few sporadic cases of human disease, handling/butchering of wild boar carcasses has been implicated as a causative factor (Bonmarchand et al., 1985). The mode of infection is generally agreed to be direct contact, and bacteria may infect humans via skin wounds/abrasions or via mucosal membranes. There is no documented evidence that consumption of contaminated pork would cause infection in humans (ECDC, 2012<sup>10</sup>) and this pathogen was therefore not considered further.

## 1.19. Pathogenic verotoxigenic *E. coli* (VTEC)

*E. coli* pathotypes include enteroinvasive (EIEC), enterotoxigenic (ETEC), verocytotoxigenic (VTEC), enteropathogenic (EPEC), enteroaggregative (EAEC) and diffuse adherent (DAEC) *E. coli*. Surveillance data on the association between meat and these *E. coli* pathogenic groups are limited, except in the case of VTEC, which causes significant outbreaks of food and/or water-borne infections, in humans resulting in a range of serious, chronic and potentially fatal diseases, including haemorrhagic colitis, with a range of potentially fatal systemic sequelae in adults and acute renal failure in children (Karmali, 1989).

VTEC is characterised by the production of verocytoxins (so called because of their activity on Vero cells) and may also be referred to as shiga toxins because of their similarity with the toxin produced by

<sup>&</sup>lt;sup>10</sup> ECDC (2012): Streptococcus suis—Factsheet for health professionals http://www.ecdc.europa.eu/en/healthtopics/streptococcus\_suis/basic\_facts



*Shigella dysenteriae*. Not all VTEC strains have been associated with human disease and there is no single or combination of marker(s) that defines a 'pathogenic' strain of VTEC (EFSA Panel on Biological Hazards (BIOHAZ), 2013). Although *vtx*2- and *eae*-positive strains are associated with a high risk of more serious illness, other virulence gene combinations and/or serotypes may also be associated with serious disease in humans, including haemolytic–uraemic syndrome (HUS). Patient-associated factors, such as age, immune status and antibiotic therapy, also influence the likelihood and severity of disease. For the purposes of this opinion, human-pathogenic *E. coli* is defined as VTEC capable of causing disease in humans.

In Europe, approximately half of all confirmed cases are associated with serogroup O157. In the non-O157 cases, O26, O103, O145, O111 and O91 are routinely isolated from patients. In 2011, VTEC O104:H4 caused a major outbreak of 4 321 confirmed cases, 3 469 cases of VTEC infection and 852 of HUS, with a total of 54 deaths reported in 14 EU countries, the USA and Canada by the time the epidemic was declared over at the end of July 2011 (Buchholz et al., 2011; Karch et al., 2012).

It is generally accepted that many cases are not recorded by the notification or surveillance system because health care advice is not always sought. This is referred to as 'under-ascertainment'. Under-reporting (which arises when health care advice is sought but the infection status is misdiagnosed, misclassified, miscounted or the information is not reported in detail) is also an issue. Thus, the incidence of VTEC cannot be calculated on the basis of historical data alone but requires a 'disease multiplier' (a hazard-specific value that takes account of the degree of under-reporting and under-ascertainment). In Europe, the disease multipliers for O157 and non-O157 VTEC are estimated to be 51.2 and 209.6, respectively (EFSA Panel on Biological Hazards (BIOHAZ), 2013). Using these, the average number of confirmed cases of O157 and non-O157 in the EU per annum between 2007 and 2010 is estimated to have been 85,222 and 149,445, respectively (EFSA Panel on Biological Hazards (BIOHAZ), 2013).

Kohler et al. (2008) tested rabbit faecal samples for *vtx* and *eaeA* and found that 1.2 % were positive for *vtx* and 1.8 % were positive for both. It was previously reported that wild rabbits are a potential reservoir of VTEC (Garcia and Fox, 2003). However, this may have been the result of cross-contamination from infected cattle. French et al. (2010) recovered *E. coli* O157 from 3.3 % of farmed deer faecal samples while VTEC was also common (9%) in tonsillar samples from wild boar (Wacheck et al., 2010). VTEC is therefore considered to be a potential hazard in farmed game and was included in the risk ranking.

## **1.20.** *Yersinia enterocolitica* and *Y. pseudotuberculosis*

In recent years, Y. enterocolitica has been the third most common cause of bacterial food-borne disease in many European countries, with 6 776 confirmed cases in the EU in 2010 (EFSA and ECDC, 2012). The most common manifestation of Y. enterocolitica infection is gastroenteritis, which is usually self-limiting, resulting in diarrhoea, mild fever and abdominal pain. Y. enterocolitica was isolated from 35 % of tonsillar samples and 5 % of faecal samples from feral wild boar (Wacheck et al., 2010). It was also present in 30 % of faecal samples from farmed deer in the USA (French et al., 2010). Y. pseudotuberculosis is a Gram-negative bacillus widely distributed in Europe. This organism infects a wide range of species, including ruminants, pigs, dogs and cats, but rodents are the main reservoir and human infection is usually related to the consumption of contaminated water or vegetables. Y. pseudotuberculosis has been reported in 35 % of wild boar tonsillar samples (Wacheck et al., 2010) and deer may be highly susceptible to this pathogen. The serotypes identified in both Yersinia species are associated with human disease (Fredriksson-Ahomaa et al., 2009, Wacheck et al., 2010). Furthermore, according to data reported by EU MSs in the framework of the Zoonoses Directive (2003/99/EC) in 2004-2011, 5.1 % of wild boars were infected with Y. enterocolitica and 0.4 % with Y. pseudotuberculosis. These pathogens were therefore considered to be a relevant farmed game meat-borne hazard and were included in the risk ranking exercise.



#### 2. Parasites

#### 2.1. Alaria alata

*Alaria alata* is a trematode parasite that infects carnivores. Transmission of this parasite occurs when humans eat tainted, undercooked game or frog meat infected with the mesocercarial stage of this parasite. The epidemiology of *Alaria* infection is not well understood (Moehl et al., 2009a; Portier et al., 2011). The reported cases of human larval alariosis are most likely due to mesocercariae from *Alaria* species other than *A. americana*, but primates can be infested by *A. americana* (Odening, 1961; Moehl et al., 2009b).

A study in Germany found a high prevalence of *A. alata* in wild boar. Over a two-year period, 286 retained samples of fresh meat from wild boars originating from different hunting areas in Brandenburg and Saxony-Anhalt, which tested negative for *A. alata* during the official *Trichinella* inspection in the competent veterinary inspection offices, were re-examined with the *A. alata* mesocercariae migration technique (AMT). In 33 out of 286 retained meat samples (11.5 %) with a preliminary negative report, the trematode was demonstrated during the follow-up examination using AMT (Riehn et al., 2012). Recent studies conducted in the eastern parts of Austria indicated an overall prevalence of *Alaria alata* mesocercariae in hunted wild boar of 2 % (10/490), when lean muscle (*M. masseter*) tissue was tested (Sailer et al., 2012) or 6.7 % (30/451), when a muscle – fat tissue mixed sample was tested (Paulsen et al., 2012). Data for farmed wild boar specifically were not reported (Odening, 1961; Paulsen et al., 2012).

Jakšić et al. (2002) and Grosse and Wüste (2006) pointed out that the parasite represents a potential source of infection for both humans and animals and that consumption of wild boar meat can be an important factor in the epidemiology of this zoonosis (Moehl et al., 2009b); however, to date there has been no report on human alariosis cases due to consumption of wild boar meat and thus *Aaria alata* was excluded from the ranking.

#### 2.2. Ascaris suum

*Ascaris suum* has very occasionally been associated with visceral larva migrans, and some parasite infection has even been detected in the human intestine. In addition, some serological studies link asthma in children to contact with this parasite. However, there is no evidence of an association between asthma and farmed game meat consumption; therefore, this infection does not meet the basic requisites to be considered for further ranking.

# 2.3. *Cryptosporidium* spp.

The protozoan parasite *Cryptosporidium* is widespread among vertebrates, causing mainly gastrointestinal disease in mammals and reptiles, and enteric, renal and respiratory disease in birds. In human cryptosporidiosis, symptoms can last for up to three weeks but are usually self-limiting (Chalmers and Giles, 2010). Transmission is faecal–oral, either through direct contact with infected hosts or through multiple vehicles including recreational and drinking water, food or fomites (Casemore, 1990). Major hosts are alpaca, cattle, red deer, goats and sheep. *Cryptosporidium* oocyst shedding by wild animals is extensive. Wildlife appears to harbour a wide variety of *Cryptosporidium* species and genotypes, many of which are not found in humans (Xiao et al., 2004; Appelbee et al., 2005). However, the rabbit genotype has emerged as a human pathogen (Chalmers et al., 2009).

Cattle are thought to be a major reservoir of zoonotic *C. parvum* because of their large faecal output, high herd prevalence and year-round calving patterns (Fayer et al., 1998; Castro-Hermida et al., 2002). Although it has been reported in ruminants, two recent Scandinavian studies failed to detect this organism in approximately 2 400 reindeer samples. *C. cuniculus* was found in 2.4 % of rabbit faecal samples in a Chinese study (Zhang et al., 2012).

Although *Cryptosporidium* has been reported in farmed game, it is transmitted mainly through water and not through meat. It was therefore excluded from further consideration.



## 2.4. Echinococcus granulosus

The adult stage of the tapeworm *Echinococcus granulosus* lives in the small intestines of dogs and, rarely, of other canids, e.g. wolves and jackals, which are the definitive hosts. The adult parasite releases eggs that are passed in the faeces. Sheep, goats, cattle and reindeer are the intermediate hosts in which ingested eggs hatch and release the larval stage (oncosphere) of the parasite. The larvae may enter the bloodstream and migrate into various organs, especially the liver and lungs, where they develop into hydatid cysts. The definitive hosts become infected by ingestion of the cyst-containing organs of the infected intermediate hosts (EFSA and ECDC, 2012). Humans are a dead-end host and may become infected through accidental ingestion of the eggs, shed in the faeces of infected dogs or other canids. *E. granulosus* occurs in reindeer at a low prevalence (< 0.013 %, 1992–2005; Hirvela-Koski et al., 2003); human infection is not associated with meat consumption. This parasite was therefore excluded from the shortlist.

#### 2.5. Encephalitozoon cuniculi

*Encephalitozoon cuniculi* is a microsporidian. It has been shown to naturally infect several host species, including humans. It is a frequent cause of disease in pet rabbits and an opportunistic pathogen able to cause generalised disease in immunocompromised individuals (Kuenzel and Joachim, 2010). The main methods of detection use serology, and studies in Taiwan (Tee et al., 2012), Egypt (Ashmawy et al., 2011) and Italy (Santaniello et al., 2009) have found contact with this microsporidian in a high percentage of farmed rabbits. However, there is no epidemiological or other evidence suggesting rabbit meat contamination is a hazard for humans. As there is no documented evidence that this hazard can be transmitted to humans via the consumption of farmed game meat, it was excluded from further consideration.

#### 2.6. *Giardia duodenalis*

*Giardia* sp. is one of the most common intestinal parasites of humans. It causes a generally selflimiting clinical illness (i.e. giardiasis) characterised by diarrhoea, abdominal cramps, bloating, weight loss and malabsorption. The life cycle of *Giardia* is direct, and the infective stage of the parasite, the cyst, is encysted when released into the faeces and is immediately infectious (Feng and Xiao, 2011). Cysts remain infectious for months in cool, damp areas and rapidly accumulate in the environment. Transmission is most commonly water-borne or by the faecal–oral route. Person-to-person transmission is common (Feng and Xiao, 2011).

*Giardia duodenalis* has been detected in wild reindeer (*Rangifer tarandua*) (Hamnes et al., 2006) but has not been found in farmed reindeer. Subtyping of the wild deer isolates suggested they belonged to assemblage A, which is pathogenic to humans. As there is no documented evidence that this parasite occurs in farmed deer or other farmed game, it was excluded from further consideration.

## 2.7. Taenia solium

As described by Davies (2011), *T. solium* is a cestode tapeworm that lives only in the intestines of humans (García et al., 2003; Phiri et al., 2003). Pigs are intermediate hosts for this parasite, and develop cysts in the muscles and other tissues after ingesting tapeworm eggs shed in human faeces. In turn, people acquire intestinal tapeworm infections by eating undercooked pork that contains the cysts (Phiri et al., 2003). However, people can also acquire the cystic form of the disease (cysticercosis) if exposed directly or indirectly to infested human faeces. The cysts can form throughout the human body, but most importantly in the brain and eyes. Besides seizures, cysticercosis causes headaches, raised intracranial pressure, psychiatric manifestations, ocular symptoms, and focal neurologic deficits (Rajshekhar et al., 2006). Methods of modern confinement swine production virtually eliminate any risks of pork-borne transmission of *T. solium* in developed countries.

## 2.8. Toxoplasma gondii

*T. gondii* infection is common in animals and humans. *T. gondii* is an obligate intracellular protozoan parasite. Nearly all warm-blooded animals can act as intermediate hosts, and seemingly all animals



may be carriers of tissue cysts of this parasite. However, the parasite matures only in domestic and wild cats, which are the definitive hosts (EFSA ad ECDC, 2012).

Toxoplasmosis is usually contracted by the oral ingestion of oocysts present in cat faeces or the environment, or of tissue cysts present in the meat of infected animals (Tenter et al., 2000). It is common in wild boar in the EU, where the seroprevalence has been reported to range between 8 % and 38 %. The seroprevalence in farmed wild boar has been reported to be 33 % (n = 197) (EFSA, 2007a; Kijlstra and Jongert, 2008; Jokelainen et al., 2012). In pregnant women, the parasite can cause congenital infections (resulting in abortion, stillbirth, mortality and hydrocephalus in newborns or retinochoroidal lesions leading to chronic ocular disease) and complications (lymphadenopathy, retinitis or encephalitis). The parasite can also cause severe disease in immunocompromised individuals such as organ graft recipients and individuals with AIDS or cancer (EFSA, 2007a). In immune-competent individuals, 80–90 % of cases of *T. gondii* infection are asymptomatic and the majority of the remainder result in only mild, self-limiting symptoms. Given the high incidence in farmed wild boar this organism was shortlisted for further consideration.

## 2.9. *Trichinella* spp.

Trichinellosis is a zoonotic disease caused by parasitic nematodes of the genus *Trichinella*. The parasite has a wide range of host species, mostly mammals. Humans typically acquire the infection by eating raw or inadequately cooked meat contaminated with infectious larvae. In 2010, 223 human confirmed cases were reported in the EU. The most common sources of human infection are pig meat (backyard slaughter), wild boar meat and other game meat. Horse, dog and many other animal meats have also transmitted the infection (EFSA and ECDC, 2012).

In Europe, the parasites occur in wildlife; however, the prevalence and species of *Trichinella* vary according to area. In Europe, *T. spiralis*, *T. britovi*, *T. nativa* and *T. pseudospiralis* have been detected. In 2010, the prevalence in farmed wild boar was 0.07 % (26/36 871), which is  $1000 \times$  higher than the prevalence reported for domestic pigs (EFSA and ECDC, 2012). In Finland, four wild boar were reported positive for *Trichinella pseudospiralis*, while in Austria two wild boar and in Greece, 20 wild boar tested positive for *Trichinella spp*. (species not reported). *Trichinella pseudospiralis* has been detected in wild boar in several MSs, e.g. France, Finland, Sweden, Germany and the Netherlands (Oivanen et al., 2002; Nockler et al., 2006). Seroprevalence of *Trichinella* sp. in farmed wild boar has been reported to be 2 % in Finland (n = 197). Reindeer have been successfully infected experimentally by *Trichinella* but no natural infections have been reported (Oksanen et al., 2000; Jokelainen et al., 2012).

## 3. Viruses

## 3.1. Hepatitis E virus (HEV)

HEV is a small RNA virus causing acute hepatitis in human beings. HEV is a common water-borne health hazard in developing countries. In industrialised countries, human cases are increasingly reported from individuals who did not travel outside their country. These cases have repeatedly been linked to consumption of raw meat or raw meat products (Meng, 2011). HEV is moderately heat resistant (Barnaud et al., 2012).

Current zoonoses reports do not constitute a reliable basis for assessing the origin of overall Hepatitis E virus infection incidence. However, HEV infection has been linked to meat and meat product consumption in Europe, including consumption of farmed rabbits (Adams and Revell, 1998), farmed wild boar (de Deus et al., 2008) and farmed and wild red deer (Boadella et al., 2010). Moreover, antibody seroprevalence among European adults ranges from 5 to 40 % (Mastromatteo et al., 2010). Because of the high human contact rate with HEV, the high prevalence in several farmed game species and the existence of reported acute human cases linked to game meat, this organism was shortlisted for further consideration.



## 3.2. Parapoxvirus

*Poxviridae* are a family of oval or brick-shaped, double-stranded DNA viruses that can infect both humans and animals. Parapoxvirus species are enzootic to hoofed animals (ungulates) throughout the world. Three similar parapoxviruses (orf virus, pseudocowpox virus and bovine papular stomatitis virus) commonly cause infection in humans; transmission is through direct or indirect contact with infected animals. Other parapoxviruses have been recognised in New Zealand red deer and Finnish reindeer. A novel parapoxvirus from white-tailed deer in the USA has caused cases of human infection.

Parapoxvirus occurs in reindeer and is zoonotic. However, transmission is by direct or indirect contact with infected animals (Palatsi et al., 1993; Büttner et al., 1995) and is not associated with the consumption of meat. It was therefore excluded from further consideration.

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Annex B: Evaluation of hazards of the longlist based on the farmed game meat-borne transmission and presence in farmed game in the EU criteria

Table 12:Farmed deer.

		Farmed de	eer		
		Evidence supporting the hypothesis	Evidence that	Transferred to	References (for those included in
		that this hazard may be farmed	the hazard is	shortlist?	shortlist)
		game meat borne and potentially	currently		
		transmissible to humans through the	present in the		
		handling, preparation and/or	EU farmed deer		
		consumption of farmed deer meat	population		
Bacteria	Actinobacillus lignieresii	No	No	No	
	Aeromonas spp.	No	No	No	
	Brucella spp.	No	Yes	No	
	Campylobacter spp.	Yes	Yes	Yes	Paulsen et al., 2003; Wahlstrom et al., 2003; Lillehaug et al., 2005;
	Coxiella burnetii	No	Yes	No	
	Extended spectrum and/or AmpC β-lactamases (ESBL/AmpC)	Yes	No	No	
	Francisella tularensis	Yes	No	No	
	Leptospira spp.	No	Yes	No	
	Mycobacterium bovis,	No	Yes	No	
	tuberculosis and avium				
	Meticillin-resistant Staphylococcus aureus (MRSA)	No	No	No	
	Pasteurella multocida	No	Yes	No	
	Salmonella spp.	Yes	Yes	Yes	Sumner et al., 1977; DEFRA-AHVLA 2007, 2010
	Streptococcus suis	No	Yes	No	
	Pathogenic VTEC	Yes	Yes	Yes	Keene et al., 1997; Rabatsky-Ehr et al., 2002; Miko et al., 2009; Bardiau et al., 2010; French et al., 2010; Martin and Beutin, 2011; Rounds et al., 2012
	Yersinia enterocolitica	Yes	Yes	Yes	Pagano et al., 1985; Paulsen et al., 2003; Aschfalk et al., 2008; Bucher et al., 2008;



		Farme	l deer		
	Yersinia pseudotuberculosis	Yes	Yes	Yes	Fukushima and Gomyoda, 1991; Böhm et al., 2007
Fungi	Dermatophytes	No	Yes	No	
-	Encephalitozoon cuniculi	No	No	No	
Parasites	Alaria alata	No	No	No	
	Ascaris suum	No	No	No	
	Cryptosporidium spp.	No	Yes	No	
	Echinococcus granulosus	No	Yes	No	
	Echinococcus multilocularis	No	No	No	
	Giardia duodenalis	No	Yes	No	
	Taenia solium	Yes	No	No	
	Toxoplasma gondii	Yes	Yes	Yes	Entzeroth et al., 1981; Sacks et al., 1983; Dubey, 1994; Ross et al., 2001; Vikoren et al., 2004Gauss et al., 2006; Bartova et al., 2007;
	<i>Trichinella</i> spp.	Yes	No	No	. ,
Viruses	Hepatitis E virus	Yes	Yes	Yes	Tei et al., 2003; Boadella et al., 2010
	Parapoxvirus	No	Yes	No	



# **Table 13:**Farmed reindeer.

		Farmed rein			
		Evidence supporting the hypothesis	Evidence that the	Transferred to	References (for those included in
		that this hazard may be farmed	hazard is	shortlist?	shortlist)
		game meat borne and potentially	currently present		
		transmissible to humans through the	in the EU farmed		
		handling, preparation and/or	reindeer		
		consumption of farmed deer meat	population		
Bacteria	Actinobacillus lignieresii	No	No	No	
	Aeromonas spp.	No	No	No	
	Brucella spp.	No	No	No	
	Campylobacter spp.	Yes	No	No	
	Coxiella burnetii	No	No	No	
	Extended spectrum and/or AmpC	No	No	No	
	$\beta$ -lactamases (ESBL/AmpC)				
	Francisella tularensis	No	No	No	
	Leptospira spp.	No	No	No	
	Mycobacterium bovis,	No	No	No	
	tuberculosis and avium				
	Meticillin-resistant	No	No	No	
	Staphylococcus aureus (MRSA)				
	Pasteurella multocida	No	No	No	
	Salmonella spp.	Yes	No	No	
	Streptococcus suis	No	No	No	
	Pathogenic VTEC	No	No	No	
	Yersinia enterocolitica	No	No	No	
	Yersinia pseudotuberculosis	No	No	No	
Fungi	Dermatophytes	No	No	No	
C	Encephalitozoon cuniculi	No	No	No	
Parasites	Alaria alata	No	No	No	
	Ascaris suum	No	No	No	
	Cryptosporidium spp.	No	No	No	
	Echinococcus granulosus	Yes	No	No	
	Echinococcus multilocularis	No	No	No	
	Giardia duodenalis	No	No	No	
	Taenia solium	Yes	No	No	
	Toxoplasma gondii	Yes	No	No	



Farmed reindeer					
	Trichinella spp.	No	No	No	
Viruses	Hepatitis E virus	No	No	No	
	Parapoxvirus	No	Yes	No	



# **Table 14:**Farmed ostrich.

		Farmed ost	rich		
		Evidence supporting the hypothesis	Evidence that the	Transferred to	References (for those included in
		that this hazard may be farmed	hazard is	shortlist?	shortlist)
		game meat borne and potentially	currently present		
		transmissible to humans through the	in the EU farmed		
		handling, preparation and/or	ostrich population		
		consumption of farmed deer meat			
Bacteria	Actinobacillus lignieresii	No	No	No	
	Aeromonas spp.	No	No	No	
	Brucella spp.	No	No	No	
	Campylobacter spp.	Yes	Yes	Yes	Siemer et al., 2005; Cuomo et al., 2007
	Coxiella burnetii	No	No	No	
	Extended spectrum and/or AmpC	No	No	No	
	$\beta$ -lactamases (ESBL/AmpC)				
	Francisella tularensis	No	No	No	
	Leptospira spp.	No	No	No	
	Mycobacterium bovis,	No	No	No	
	tuberculosis and avium				
	Meticillin-resistant	No	No	No	
	Staphylococcus aureus (MRSA)				
	Pasteurella multocida	No	No	No	
	Salmonella spp.	Yes	Yes	Yes	Higgins et al., 1997; Ley et al., 2001; de Freitas Neto et al., 2009
	Streptococcus suis	No	No	No	
	Pathogenic VTEC	Yes	No	No	
	Yersinia enterocolitica	No	No	No	
	Yersinia pseudotuberculosis	No	No	No	
Fungi	Dermatophytes	No	No	No	
-	Encephalitozoon cuniculi	No	No	No	
Parasites	Alaria alata	No	No	No	
	Ascaris suum	No	No	No	
	Cryptosporidium spp.	No	No	No	
	Echinococcus granulosus	No	No	No	
	Echinococcus multilocularis	No	No	No	
	Giardia duodenalis	No	No	No	
	Toxoplasma gondii	Yes	No	No	



Farmed ostrich						
	Taenia solium	Yes	No	No		
	Trichinella spp.	Yes	No	No		
Viruses	Hepatitis E virus	No	No	No		
	Parapoxvirus	No	No	No		



# **Table 15:**Farmed wild boar.

		Farmed wild	boar		
		Evidence supporting the hypothesis that this hazard may be farmed	Evidence that the hazard is	Transferred to shortlist?	References (for those included in shortlist)
		game meat borne and potentially	currently		
		transmissible to humans through the	present in the		
		handling, preparation and/or	EU farmed wild		
		consumption of farmed deer meat	boar population		
Bacteria	Actinobacillus lignieresii	No	No	No	
	Aeromonas spp.	No	No	No	
	<i>Brucella</i> spp.	No	Yes	No	
	Campylobacter spp.	Yes	Yes	Yes	Ziegenfuß, 2003; Gill, 2007; Atanassova et al., 2008
	Coxiella burnetii	No	No	No	,
	Extended spectrum and/or AmpC β-lactamases (ESBL/AmpC)	No	No	No	
	Francisella tularensis	No	Yes	No	
	Leptospira spp.	No	Yes	No	
	Mycobacterium bovis, tuberculosis and avium	No	Yes	No	
	Methicillin-resistant Staphylococcus aureus (MRSA)	No	Yes	No	
	Pasteurella multocida	No	No	No	
	Salmonella spp.	Yes	Yes	Yes	Gill, 2007; Wacheck et al., 2010; Closa-Sebastia et al., 2011
	Streptococcus suis	No	Yes	No	
	Pathogenic VTEC	Yes	Yes	Yes	Wacheck et al., 2010; Martin and Beutin, 2011
	Yersinia enterocolitica	Yes	Yes	Yes	Al Dahouk et al., 2005; Fredriksson Ahomaa et al., 2006, 2009; Laukkanen et al., 2010
	Yersinia pseudotuberculosis	No	Yes	No	
Fungi	Dermatophytes	No	No	No	
C	Encephalitozoon cuniculi	No	No	No	
Parasites	Alaria alata	No	Yes	No	
	Ascaris suum	No	Yes	No	
	Cryptosporidium spp.	No	No	No	



		Farmed w	vild boar		
	Echinococcus granulosus	No	No	No	
	Echinococcus multilocularis	No	No	No	
	Giardia duodenalis	No	No	No	
	Taenia solium	Yes	No	No	
	Toxoplasma gondii	Yes	Yes	Yes	Edelhofer and Prossinger, 2010; Closa-Sebastia et al., 2011; Jokelainen et al., 2012
	Trichinella spp.	Yes	Yes	Yes	Schynts et al., 2006; Gill, 2007; Rodriguez et al., 2008; Richomme et al., 2010; Jokelainen et al., 2012
Viruses	Hepatitis E virus	Yes	Yes	Yes	Li et al., 2005; Shimizu et al., 2006; de Deus et al., 2008; Meng et al., 2009
	Parapoxvirus	No	No	No	No



# **Table 16:** Farmed rabbit.

		Farmed rat	obit		
		Evidence supporting the hypothesis	Evidence that the	Transferred to	References (for those included in
		that this hazard may be farmed	hazard is	shortlist?	shortlist)
		game meat-borne and potentially	currently present		
		transmissible to humans through the	in the EU farmed		
		handling, preparation and/or	rabbit population		
		consumption of farmed deer meat			
Bacteria	Actinobacillus lignieresii	No	No	No	
	Aeromonas spp.	No	No	No	
	Brucella spp.	No	No	No	
	Campylobacter spp.	No	No	No	
	Coxiella burnetii	No	No	No	
	Extended spectrum and/or AmpC	Yes	No	No	
	$\beta$ -lactamases (ESBL/AmpC)				
	Francisella tularensis	No	No	No	
	Leptospira spp.	No	No	No	
	Mycobacterium bovis,	No	No	No	
	tuberculosis and avium				
	Meticillin-resistant	No	Yes	No	
	Staphylococcus aureus (MRSA)				
	Pasteurella multocida	No	Yes	No	
	Salmonella spp.	Yes	Yes	Yes	Badr, 2004; Borrelli et al., 2011;
	Streptococcus suis	No	No	No	
	Pathogenic VTEC	Yes	Yes	Yes	Garcia and Fox, 2003; Scaife et al. 2006; Martinez et al., 2011
	Yersinia enterocolitica	No	No	No	
	Yersinia pseudotuberculosis	No	No	No	
Tungi	Dermatophytes	No	Yes	No	
U	Encephalitozoon cuniculi	No	Yes	No	
Parasites	Alaria alata	No	No	No	
	Ascaris suum	No	No	No	
	Cryptosporidium spp.	No	Yes	No	
	Echinococcus granulosus	No	No	No	
	Echinococcus multilocularis	No	No	No	
	Giardia duodenalis	No	No	No	
	Taenia solium	Yes	No	No	



Farmed rabbit							
	Toxoplasma gondii	Yes	No	No			
	Trichinella spp.	No	No	No			
Viruses	Hepatitis E virus	Yes	Yes	Yes	Izopet et al., 2012		
	Parapoxvirus	No	No	No			



#### Appendix B. Assessment on chemical hazards

#### SUMMARY

Meat inspection in the European Union (EU) is specified in Regulation (EC) No 854/2004. 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, also includes the control of chemical residues and contaminants that could be potentially harmful for consumers. This aspect is not fully addressed by the current procedures.

The EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) was asked to identify and rank undesirable or harmful chemical residues and contaminants in farmed game, covering deer, reindeer, ostriches, wild boar and rabbits. Such substances may occur as residues in edible tissues as a result of the exposure of the animals to contaminants in feed materials as well as following the possible application of non-authorised substances and the application of authorised veterinary medicinal products (VMPs) and feed additives. It should be noted that game farming (deer, reindeer, ostriches and wild boar) is markedly different to rabbit farming, and the types and likelihood of occurrence of chemical residues and contaminants vary between these animal species. Therefore, farmed game and rabbits were considered separately in the context of this annex. A multi-step approach was used to rank these substances into categories of potential concern. As a first step, the CONTAM Panel considered substances listed in Council Directive 96/23/EC and evaluated the outcome of the national residue control plans (NRCPs) for the period 2005-2010. The CONTAM Panel noted that 0.91 % of the total number of farmed game samples and 0.67 % of the total number of rabbit samples were non-compliant for one or more substances listed in Council Directive 96/23/EC. The available aggregated data indicate the number of samples that were non-compliant with current EU/national 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 for a reliable assessment of consumer exposure. Independently from the occurrence data reported in the NRCPs, other criteria used for the identification and ranking of chemical substances of potential concern included the identification of substances that are found in other testing programmes, and that bio-accumulate in the food chain, substances with a toxicological profile of concern and the likelihood that a substance under consideration will occur in farmed game or in rabbit carcasses. Taking into account these criteria, the individual compounds were ranked into four categories denoted as of high, medium, low and negligible potential concern.

No substances were classified in the high potential concern category for farmed game or for rabbits.

For farmed game, nitrofurans, nitroimidazoles and cadmium, and for rabbits chloramphenicol and nitrofurans, were ranked as of medium potential concern because they have proven toxicity for humans, are effective as antibacterial treatments for farmed game and/or for rabbits and residues have been found in the NRCPs.

All other substances listed in Council Directive 96/23/EC were ranked as being of low or negligible potential concern. Potentially higher exposure of consumers to these substances from farmed game or rabbit meat takes place only incidentally, as a result of mistakes or non-compliance with known and regulated procedures.

The CONTAM Panel emphasises that this ranking into specific categories of potential concern is based on current knowledge regarding the toxicological profiles, usage in the production of these animals and occurrence as chemical residues and contaminants. Where changes in any of these factors occur, the ranking might need amendment.



The CONTAM Panel was also asked to assess the main strengths and weaknesses of current meat inspection protocols within the context of chemical hazards. It was noted that residue testing is based on common standards for method performance and interpretation of results, laboratory accreditation and quality assurance schemes. In the case of most farmed game (i.e. deer, wild boar and ostriches), the production site is known and, therefore, collection of food chain information (FCI), traceability and follow-up mechanisms are possible. For rabbits reared in integrated systems, a large amount of FCI that is provided to the slaughterhouse is, in combination with the ante-/post-mortem inspection, supportive, in general, of the collection of appropriate samples for monitoring of chemical residues and contaminants. In addition, in the case of rabbits reared in integrated systems, there are welldeveloped systems and follow-up mechanisms subsequent to the identification of non-compliant samples, and the regular sampling and testing for chemical residues and contaminants is a disincentive to the development of undesirable practices. Nevertheless, a major weakness is that presence of chemical hazards generally cannot be detected by current ante-/post-mortem meat inspection procedures at the slaughterhouse level. For both farmed game and rabbits, there is poor integration between the testing of feed materials for undesirable substances and the NRCPs. For some farmed game, such as reindeer, FCI may be incomplete (particularly relating to environmental contaminants) because the animals are in migratory herds. For rabbits reared in small holdings, FCI may also be incomplete owing to the trading practices for these animals prior to slaughter.

The CONTAM Panel was also asked to identify and recommend inspection methods for new hazards. Such new hazards are organic contaminants that may accumulate in food-producing animals, for which occurrence data in farmed game and in rabbits are scarce and which may not be systematically covered by the NRCPs. Examples are dioxins and dioxin-like polychlorinated biphenyls (DL-PCBs), non dioxin-like polychlorinated biphenyls (NDL-PCBs), brominated flame retardants, such as polybrominated diphenylethers (PBDEs) and hexabromocyclododecanes (HBCDDs), and perfluorinated compounds, such as perfluoroctane sulfonate (PFOS) and perfluoroctanoic acid (PFOA). Owing to the nature of the husbandry systems applied, farmed game is more likely to be exposed to environmental contaminants (including radioactivity in certain geographic regions) than some other livestock.

The CONTAM Panel concludes that game farming in the EU is extremely diverse, with substantial differences between species (deer, reindeer, ostriches and wild boar). It cannot be compared to rabbit farming, which in many areas has evolved towards intensive farming practices. Therefore, the types and likelihood of occurrence of chemical residues and contaminants vary between these animal species. The Panel noted that, with a few exceptions, VMPs are not specifically licensed for farmed game and only a very few are licensed for use in rabbits. However, diseased or injured animals will be treated as required under the 'cascade usage' system. Moreover, European Commission Decision 97/747/EC requires that a minimum of 100 samples of farmed game (unspecified as to species) are to be taken annually for NRCP testing, rather than the level of testing being proportional to the production of each species in each MS. The CONTAM Panel recommends that future monitoring programmes should be based on the risk of occurrence of chemical residues and contaminants, taking into account completeness and quality of the FCI supplied and the ranking of chemical compounds into categories of potential concern, which ranking needs to be regularly updated. Control programmes for residues and contaminants should be less prescriptive, with sufficient flexibility to adapt to results of testing and should include 'new hazards'. There is a need for an improved integration of sampling, testing and intervention protocols across the food chain, NRCPs, feed control and monitoring of environmental contaminants. The Panel also recommends that FCI for farmed game and rabbits should include information on the specific environmental conditions of the farms where the animals are reared, including treatments, and that any medication given to farmed game should be presented in onfarm registries, serving as FCI prior to slaughter. In addition, the number of samples to be taken for each farmed game species should be proportional to the production in each MS and, as for other livestock species, the application of analytical techniques covering multiple analytes and of new biologically based testing approaches should be encouraged and incorporated into the residue control programmes.



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#### ASSESSMENT OF CURRENT MEAT INSPECTION PROTOCOLS FOR THE IDENTIFICATION OF CHEMICAL SUBSTANCES OF POTENTIAL CONCERN THAT MAY OCCUR AS RESIDUES OR CONTAMINANTS IN FARMED GAME

#### 1. Introduction

Meat inspection in the European Union (EU) is specified in Regulation (EC) No 854/2004.<sup>1</sup> The main objective of meat inspection is to ensure that meat<sup>2</sup> 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, also includes the control of chemical residues and contaminants in meat that could be potentially harmful to consumers. This aspect is not fully addressed by the current procedures. For the purposes of this document, 'chemical residues' are chemical compounds which result from the intentional administration of legal or illegal pharmacologically active substances whereas 'contaminants' are chemical compounds originating from the environment.

This document aims to identify undesirable or harmful chemical residues and contaminants that may occur in farmed game animals taking into account the current legislation and the results from the national residue control plans (NRCPs) implemented in line with Council Directive 96/23/EC.<sup>3</sup> These findings, together with the characteristics of the individual substances and the likelihood that a substance will occur in meat from farmed game, 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 current meat inspection protocols were assessed within the context of chemical hazards. The ultimate aim is an overall evaluation of the current strategies for sampling and analytical testing, resulting in recommendations for possible amendments to the current meat inspection protocols.

As identified in the Appendix A, the farmed animal species to be included in this opinion are deer, reindeer, ostriches, wild boar and rabbits. Rabbits are included in this opinion because they were included in the mandate provided by the European Commission. It should be noted, however, that, in contrast to the other species addressed in this opinion, which for the most part are reared extensively, 'rabbits' refers not to game animals (hares and wild rabbits), as they are not farmed, but to farmed rabbits which for the most part are reared intensively. Therefore, throughout Appendix B on assessment of chemical hazards, the term 'farmed game' covers farmed deer, farmed reindeer, farmed ostriches and farmed wild boar, and the term 'rabbits' covers farmed rabbits.

NOTE: In this opinion, where reference is made to European legislation (regulations, directives, decisions), the reference should be understood as relating to the most current amendment, unless otherwise stated.

#### **1.1.** Farmed game and rabbits in Europe

In this section, a short introduction into the husbandry of farmed game and rabbits is presented. Information is from public sources and obtained also during the European Food Safety Authority (EFSA) technical hearing meeting with stakeholders. The four farmed game species are described first, followed by a description of rabbit farming in Europe. This sequence is chosen to differentiate between extensively reared farmed game animals (deer, reindeer, ostriches and wild boar) and (semi-)intensively reared domestic rabbits. Game farming in the EU is extremely diverse, with substantial

<sup>&</sup>lt;sup>1</sup> 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.

<sup>&</sup>lt;sup>2</sup> The term 'meat' in this opinion is understood to refer to meat and edible tissues (including offal), unless otherwise stated.

<sup>&</sup>lt;sup>3</sup> 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 Directive 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC. OJ L 125, 23.5.96, p. 10–32.



differences between species (deer, reindeer, ostriches, and wild boar). It cannot be compared to rabbit farming, which in many areas has evolved towards intensive farming practices. Therefore, the types and likelihood of occurrence of chemical residues and contaminants vary between these animal species.

It needs to be also considered that, because consumption of meat from these species by EU consumers is relatively low compared with consumption of the main meat species, it is expected to contribute to only a minor extent to overall human exposure to chemical residues and contaminants.

# 1.1.1. Farmed game

## 1.1.1.1. Farmed deer

Deer farming, in the context of this opinion, refers to all deer species that are farmed, such as red deer (*Cervus elaphus*) and fallow deer (*Dama dama*). Deer farming occurs in a large number of European countries, with relatively high levels of production in some countries, e.g. Austria, Germany, Spain, Switzerland, Denmark and Sweden. Figures for deer production in Europe, provided by the Federation of Deer Farmers Associations (FEDFA), show that, in the 18 countries that are members of this organisation, there are over 10 000 deer farmers and a total population of nearly 300 000 farmed deer. Typical stocking density is 15 animals per hectare. Treatment with veterinary medicines is confined, generally, to some prophylactic treatment with anthelmintics, based on clinical features and faeces analyses. Because of the nature of deer production with low stocking density and a natural environment, bacterial diseases do not occur frequently and the use of antimicrobial agents is very limited. However, animals may be exposed to contaminants present in their environment.

Usually, deer are slaughtered before 18 months of age. Slaughtering of farmed deer is undertaken mainly on-farm, in the fenced pastures and using a rifle, although there are some abattoirs in Belgium, Denmark, Poland, France, the United Kingdom and Italy that offer this service.

#### 1.1.1.2. Farmed reindeer

Reindeer (*Rangifer tarandus*) production is by semi-domesticated herding, occurring over about 50 % of the area of Sweden and about 40 % of the area of Norway and Finland. Reindeer are reared in herds, with animals with different owners reared together, and they are farmed extensively as migratory herds in conditions similar to those of wild game. Various parasites may occur in reindeer, such as nematodes and warble fly. Reindeer farming is very traditional.

All animals are identified individually by ear tags or other individual marks. In Sweden, there are about 900 reindeer enterprises, with approximately 4 700 producers. The number of animals in Sweden is about 260 000, and every year some 60 000 animals are slaughtered. In Finland, around 80 000 reindeer are subjected to meat inspection each year (Finnish Food Safety Authority, Evira). Most of the animals presented for slaughter are calves (75 % of the kill in Sweden and 90 % of the kill in Finland).

## 1.1.1.3. Farmed ostriches

Although farming of ostriches (*Struthio camelus*) is widespread in some countries, such as South Africa, Brazil and Australia, ostrich farming in Europe is of minor scale; most farms are involved in local trade so data for European production are limited. Ostrich meat is not widely consumed as a traditional food (Cooper, 2007) but ostrich farming for the hides is also important. Both the hides and meat may be marketed directly from the farms.

Ostriches digest roughage (e.g. alfalfa) very well and are highly efficient meat producers. Generally, they are reared semi-intensively, being kept mostly outside, but they may be housed in winter to protect them from adverse weather conditions (EFSA, 2013). They are reared in herds and identified as a group, rather than individually. There are no specific parasites for ostriches in Europe. Of some

concern (Busch, 2003) are injuries, and even deaths, to ostriches caused by ingestion of foreign bodies, strangulation on fencing wire and bone breakages.

Ostriches are slaughtered at between 250 and 400 days of age. At slaughter, ostriches weigh in the order of 90 kg and the carcass yield amounts to approximately 50 % of the total body weight (b.w.). Frequently, slaughter would be integrated on individual ostrich farms.

# 1.1.1.4. Farmed wild boar

Wild boars (*Sus scrofa*) are bred in farms worldwide for their meat. In Europe, there is a limited number of farms and, typically, these are of small size (EFSA, 2013). The natural habitat of wild boar is woodland and they are kept outside in fenced areas. The nominal stocking rate is six sows per hectare. Mature wild boars are large (up to 1.8 m in length, weighing around 200 kg). Female wild boars live in groups of 6–10 sows (sometimes known as 'sounders'). Wild boars are generally robust but may be susceptible to the same diseases that affect domestic pigs, particularly parasite infestations. They may be slaughtered at 9–12 months of age at a size of 80–90 kg live weight, and a carcass weight of 50-55 kg.

# 1.1.2. Rabbit farming

Rabbits (*Oryctolagus cuniculus*, and others), generally, are produced in intensive systems more similar to poultry production rather than to farmed game production. Among the common breeds for meat production are New Zealand Whites, Californians, Large Belgians and Rex Rabbits (China). Rabbit farming in many European countries is on a large scale, but rabbits also may be produced on smaller, private holdings. Many rabbit farms in the EU are specialised and involved in intensive production. There is also production on a very large number of smaller farms; these farms typically have low technology, are family businesses, and supply local markets.

The total world-wide production of rabbit meat in 2007 was estimated to be 1.8 million tonnes, with European production at 0.5 million tonnes and Asian production at 0.8 million tonnes. China is the biggest producer country, and there is a high level of importation of rabbit meat from China into the EU (Rodriguez-Calleja et al., 2006). In 2003, rabbit meat accounted for 1.2 % of the total meat produced in the EU from all species (EFSA, 2005a). EU MSs producing large quantities of rabbit meat include Italy, France and Spain.

Rabbits are kept in cages or on litter. Groups should not exceed 20–30 animals (Hoy et al., 2006). Ringworm, fungal infections caused by various dematophytes such as Trichophyton mentagrophytes and *Microsporum* species, is the main zoonosis occurring rabbits. Coccidiosis may also be a problem in rabbits and if identified in the liver at *post-mortem* inspection the liver is discarded. Anticoccidial treatment of rabbits may be routine, with anticoccidials added to feed for breeding animals, but is not necessary in young animals (70-80 days) raised in cages. The scientific opinion on farmed rabbits (EFSA, 2005a) indicated that farmed rabbits suffer a wide range of enteric conditions, perhaps partly as a result of their housing conditions and coprophagic habits. This leads to a common requirement for the use of anticoccidial drugs during their life. Coprophagy, which typically occurs twice a day, should be considered in an evaluation of food safety, because any drug/metabolites eliminated or produced in the digestive tract will be partially recycled and possibly reabsorbed in the small intestine. For example, a plasma concentration rebound was observed for chloramphenicol 24 hours after an intravenous (i.v.) administration (Guillot et al., 1988). Rabbits may be particularly susceptible to mycotoxins, such as aflatoxins (EFSA, 2005a). Antimicrobials used in rabbits are similar to those used in other farmed species, but specific withdrawal periods have not been established for rabbits; a generic withdrawal period of seven days is applied. As for poultry farming, in most cases, treatments are given via water or feed.

Generally, rabbits are slaughtered at 8-16 weeks of age, depending on the targeted market weight (1.8–3.5 kg). Slaughtering facilities in the EU comprise a mix of small and larger premises, with the larger processing more than 1 million rabbits per year. The trend is towards a smaller number of larger

slaughterhouses (EFSA, 2012a). Since a similar trend in farm size can be seen, there is better integration along the food chain, with specifications and quality certification.

## **1.2.** Procedures in the current meat inspection of farmed game and rabbits

In accordance with Annex I of Regulation (EC) No 854/2004 all animals should be inspected prior to slaughter (*ante-mortem* inspection) as well as after slaughter and evisceration (*post-mortem* inspection).

### **1.2.1.** Food chain information and *ante-mortem* inspection

Food Chain Information (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 (FBO) at the slaughterhouse should receive information related to the VMPs 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 test results for samples 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.

Visual *ante-mortem* inspection for farmed game and rabbits is carried out at the herd level, as described for each species in Section 1.1, above.

## 1.2.1.1. Farmed game

Farmed game may be presented for slaughter in small numbers or even as individuals. The production systems used for some of these animals, such as wild boar, reindeer and deer, including extensive periods on pasture or as nomadic herds may preclude detailed lifetime FCI. In the case of ostriches, more detailed lifetime FCI may be available.

*Ante-mortem* inspection of farmed game may be carried out at the holding. Based on Annex III, Section III, of Regulation (EC) No 853/2004, the herd should undergo regular veterinary inspection and the herd can be inspected using appropriate procedures. The procedures for *ante-mortem* inspection are not specified but Annex I, Section I, Chapter II, of Regulation (EC) No 853/2004 indicates that the aim of such inspection is "to determine whether there are any signs of compromise of animal welfare or any condition with a potentially adverse effect on human or animal health".

#### 1.2.1.2. Rabbits

Rabbits may be presented for slaughter either from intensive farms, where detailed lifetime FCI is generally available, or from small ('backyard') units, in which case complete FCI may be lacking. Small producers may deliver only small numbers of animals of differing ages and possibly of variable health status, whereas animals of more uniform quality may be expected from integrated rabbit farms.

Rabbits reared for food production should undergo *ante-mortem* inspection following the rules for poultry, according to Chapter VI, Section IV (Specific requirements), Annex I (Fresh Meat), of Regulation (EC) No 854/2004. Visual *ante-mortem* inspection of rabbits is carried out at the group level, as described in Section A.1 of the above regulation. *Ante-mortem* inspection may be carried out at the farm or after shipment of the animals to the slaughterhouse. In either case, it includes checking that animals are clean and healthy, with satisfactory welfare, properly identified and from a holding that is not restricted or prohibited. Where small numbers of animals are involved, the slaughterhouse should be regarded as the appropriate place for inspection and sampling, rather than the holding. When the *ante-mortem* inspection is done at farm level, the official veterinarian visits the farm to check, among other things, VMP usage and the drug register, withdrawal times, etc.

#### **1.2.2.** *Post-mortem* inspection

Based on Regulation (EC) No 854/2004, *post-mortem* inspection was, and still is, directed primarily at the detection of lesions due to infections, based on observation, palpation and incision.

Visual inspection of the carcass (and offal) of both farmed game and rabbits may allow, in some cases, for the identification of gross alterations in carcass morphology, and organ-specific lesions in kidneys, liver or other organs that are indicative of recent use of VMPs or acute or chronic exposure to toxic substances. In most cases, exposure to chemical compounds, including substances that accumulate in the body (toxic elements, certain organic pollutants), does 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 inspection of farmed game and rabbit carcasses. Therefore, meat inspection based on the 'detect and immediately eliminate' approach, as used for biotic (microbiological) hazards in slaughterhouses, is generally not applicable to abiotic hazards.

Although monitoring programmes (Council Directive 96/23/EC, which is fully described in Section 1.3) may provide a gross indication of the prevalence of undesirable chemical residues and contaminants in farmed game and rabbit 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.

# 1.2.2.1. Farmed game

Regulation (EC) No 854/2004 does not describe special procedures for inspection of farmed game (Annex I, Section IV, Chapter VII, of Regulation (EC) 854/2004). However, post-mortem inspection procedures described for domestic bovine and ovine animals and domestic swine are to be applied to the corresponding species of farmed game. Therefore, for the species of farmed game included in this opinion, the procedures outlined in Table 1 apply.

Table 1:	Post-mortem inspection procedures to be applied to farmed game, according to Regulation
(EC) No 85	54/2004.

Species of farmed game	Procedures used for corresponding domestic species
Farmed deer, reindeer	Domestic bovine/ovine
Wild boar	Domestic swine
Ostriches	(no corresponding domestic species)

As there is no domestic species corresponding to ostriches, specific *post-mortem* inspection procedures are not available. Therefore, general rules for *post-mortem* inspection (Annex I, Section I, Chapter II, D of Regulation (EC) No 854/2004) apply, which are, as follows:

- *post-mortem* inspection to be carried out without delay;
- all external surfaces to be examined (the extent of which depends on the processing procedures);
- whenever necessary, incision of those parts which have undergone any change and additional examination (palpation, incision, laboratory testing) are to take place;
- minimal handling of carcass and offal to occur, or special technical facilities may be required.

# 1.2.2.2. Rabbits

Regulation (EC) 854/2004 (Annex I, Section IV, Chapter VI) specifies that rabbits are to be inspected according to the procedures for poultry. Similar to poultry, rabbit carcasses are not split and the head remains in natural connection with the carcass. The same is true of the organs. *Post-mortem* inspection, generally, is focused on the surfaces, without any special procedures.

# **1.3.** Current legislation

Council Directive 96/23/EC prescribes the measures to monitor certain substances and residues thereof in live animals and animal products. It requires that MSs adopt and implement a national residue

monitoring plan, also referred to as the National Residue Control Plan (NRCP), for defined groups of substances.<sup>4</sup> MSs 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 VMPs according to the Commission Regulation (EU) No 37/2010<sup>5</sup>, with the maximum residue levels (MRLs) for pesticides as set out in Regulation (EC) No 396/2005<sup>6</sup>, or with the maximum levels (MLs) for contaminants as laid down in Commission Regulation (EC) No 1881/2006<sup>7</sup>. This means that in the NRCPs the MS target the groups of animals/gender/age combinations where in, 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.

Council Directive 96/23/EC does not specify the number of samples of farmed game or rabbits to be tested annually under NRCPs. However, European Commission Decision  $97/747/EC^8$  sets specific requirements for sampling and for the compounds to be analysed.

# 1.3.1. Farmed game

Sampling requirements for farmed game are as follows:

- The sample size will depend on the analytical method used.
- The samples must be taken at the processing unit level. It must be possible to trace the animals or their meat back to the farm of origin.
- Without prejudice to the provisions of Directive 96/23/EC, some additional samples of drinking water and feedingstuffs may be taken at farm level, for the control of illegal substances.

Sampling level and frequency for farmed game are as follows:

- The number of samples to be taken each year must at least be equal to 100 samples and the following breakdown must be respected:
  - Group A: 20 % of the total number of samples

The majority of the samples must be analysed for compounds of Group A 5 and Group A 6.

- Group B: 70 % of the total number of samples with the following breakdown:
  - 30 % must be checked for Group B 1 substances
  - 30 % must be checked for Group B 2 (a) and (b) substances
  - 10 % must be checked for Group B 2 (c) and (e) substances

<sup>&</sup>lt;sup>4</sup> Commission Staff Working Document on the Implementation of National Residue Monitoring Plans in the Member States in 2009 (Council Directive 96/23/EC).

<sup>&</sup>lt;sup>5</sup> 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.

<sup>&</sup>lt;sup>6</sup> 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.

<sup>&</sup>lt;sup>7</sup> 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.

<sup>&</sup>lt;sup>8</sup> Commission Decision 97/747/EC of 27 October 1997 fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products. OJ L 303, 6.11.1997, p. 12–15.



- 30 % must be checked for Group B 3 substances
- The balance (10 %) will be allocated according to the experience of the MS.

MSs shall provide to the Commission the figures corresponding to their national production of farmed game meat destined for human consumption. In the light of this information, the above figures will be reviewed within one year after the adoption of this decision.

## 1.3.2. Rabbit meat

Sampling requirements for rabbit meat are as follows:

- One sample consists of one or more animals from the same producer, according to the requirements of the analytical methods.
- Each official sample must be taken by official competent authorities in such way that it is always possible to trace it back to the farm of origin of the rabbits. The samples, according to the structure of the rabbit production in each MS, can be taken (i) either at farm level, or (ii) at the level of the registered slaughterhouse (within the meaning of Council Directive 91/495/EEC<sup>9</sup>);
- Without prejudice to the provisions of Directive 96/23/EC, some additional samples of drinking water and feedingstuffs may be taken at farm level, for the control of illegal substances.

Sampling level and frequency for rabbit meat are as follows:

- The number of samples to be taken each year must be equal to 10 per 300 tonnes of the annual production (dead weight) for the first 3 000 tonnes of production, and one sample for each additional 300 tonnes.
- The following breakdown must be respected (in accordance with Annex I of Directive 96/23/EC):
  - Group A: 30 % of the total number of samples
    - 70 % must be checked for Group A 6 substances
    - 30 % must be checked for substances of other subgroups of Group A.
  - Group B: 70 % of the total number of samples
    - 30 % must be checked for Group B 1 substances
    - 30 % must be checked for Group B 2 substances
    - 10 % must be checked for Group B 3 substances
  - The balance must be allocated according to the situation of the MS.

An overview of the sampling frequency carried out in the EU is presented in Table 2 for farmed game, excluding rabbits, and in Table 3 for rabbits. Data have been gathered from the NRCPs for the period 2005–2010.

<sup>&</sup>lt;sup>9</sup> Council Directive 91/495/EEC of 27 November 1990 concerning public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat. OJ L 268, 24.9.1991, p. 41–55.

Year	Farmed game production (tonnes)	Number of targeted samples taken <sup>a</sup>
2005	42 290	1 894
2006	51 944	2 236
2007	40 895	2 286
2008	18 485	1 959
2009	84 482	1 975
2010	25 449	2 157

**Table 2:** Overview of farmed game (excluding rabbit) sampling intensity in the EU as reported in the NRCPs for the period 2005–2010.

a: Based on the production for the previous year.

**Table 3:** Overview of rabbit sampling intensity in the EU as reported in the NRCPs for the period 2005–2010.

Year	Rabbit production (tonnes)	Number of targeted samples taken <sup>(a)</sup>
2005	234 931	4 502
2006	181 603	4 061
2007	189 932	4 480
2008	187 389	3 625
2009	199 655	3 691
2010	172 353	3 885

a: Based on the production for the previous year.

General provisions for imports of animals and animal products set in Council Directive 96/23/EC also apply to farmed game and rabbits. In the case of imports from Third Countries, Chapter VI of Directive 96/23/EC describes the system to be followed to ensure an equivalent level of control on such imports. In particular, it specifies (a) that each Third Country must provide a plan setting out the guarantees which it offers as regards the monitoring of the groups of residues and substances referred to in Annex I of the Directive; (b) that such guarantees must have an effect at least equivalent to those provided for in Directive 96/23/EC; (c) that compliance with the requirements of and adherence to the guarantees offered by the plans submitted by Third Countries shall be verified by means of the checks referred to in Article 5 of Directive 72/462/EEC<sup>10</sup> and the checks provided for in Directives 90/675/EEC<sup>11</sup> and 91/496/EEC;<sup>12</sup> and (d) that MSs are required to inform the Commission each year of the results of residue checks carried out on animals and animal products imported from Third Countries, in accordance with Directives 90/675/EEC and 91/496/EEC.

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

In accordance with Article 8 of Directive 96/23/EC, MSs 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 MSs to obtain an overview of these actions, for example when residues of non-authorised substances are detected or when the MRLs/MLs established in EU legislation are exceeded. The actions taken by the MS may include:

• suspect sampling;

<sup>&</sup>lt;sup>10</sup> Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries. OJ L 302, 31.12.1972, p. 28–54.

<sup>&</sup>lt;sup>11</sup> Council Directive 90/675/EEC of 10 December 1990 laying down the principles governing the organization of veterinary checks on products entering the Community from third countries. OJ L 373, 31.12.1990, p. 1–14.

<sup>&</sup>lt;sup>12</sup> Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC. OJ L 268, 24.9.1991, p. 56–68.



- modifications of the NRCPs;
- 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);
- 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);
- samples taken where the veterinarian suspects, or has evidence of, illegal treatment or noncompliance with the withdrawal period for an authorised veterinary medicinal product (Article 24 of Directive 96/23/EC).

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.

## **1.4.2.** Modification of the NRCPs

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

It should be noted that targeted sampling as defined by Directive 96/23/EC aims at monitoring certain substances and residues thereof in live animals and animal products across EU MSs. 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 of.



#### **1.4.4.** Self-monitoring residue testing

In addition to the minimum testing requirements which form part of the NRCPs, Council Directive 96/23/EC also establishes the requirements for self-monitoring and co-responsibility on the part of operators.

In accordance with Article 9, Chapter III, of Directive 96/23/EC, MSs shall ensure that the owners or persons in charge of the establishment of initial processing of primary products of animal origin (slaughterhouses) take all necessary measures, in particular by carrying out their own checks, to:

- accept only those animals for which the producer is able to guarantee that withdrawal times have been observed;
- satisfy themselves that the farm animals or products brought into the slaughterhouse do not contain residue levels which exceed maximum permitted limits and that they do not contain any trace of prohibited substances or products.

The farmers and the food processing operators (slaughterhouses) must place on the market only:

- animals to which no unauthorised substances or products have been administered or which have not undergone illegal treatment;
- animals for which where authorized products or substances have been administered, the withdrawal periods prescribed for these products or substances have been observed.

#### 2. TOR 1: Identification, classification and ranking of substances of potential concern

#### 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. Identification and ranking of potential concerns within this document includes all chemical compounds listed in this Council Directive. Annex I of Council Directive 96/23/EC groups substances that may be found in animal tissues into two categories:

Group A—Substances having anabolic effects and unauthorised substances

- A.1. Stilbenes, stilbene derivatives, and their salts and esters
- A.2. Antithyroid agents
- A.3. Steroids
- A.4. Resorcylic acid lactones, including zeranol
- A.5. Beta-agonists
- A 6. Compounds included in Annex IV of Council Regulation (EEC) No 2377/90 of 26 June 1990<sup>13</sup> (repealed by Commission Regulation (EU) No 37/2010).

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

B.1. Antibacterial substances, including sulphonamides, quinolones

<sup>&</sup>lt;sup>13</sup> Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin. OJ L 224, 18.8.90, p. 1–8.



- B.2. Other veterinary drugs
  - a) Anthelmintics
  - 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 polychlorinated biphenyls (PCBs)
  - b) Organophosphorus compounds
  - c) Chemical elements
  - d) Mycotoxins
  - e) Dyes
  - f) Others

According to Council Directive 96/23/EC, for farmed game and rabbits, analysis for chemical residues and contaminants for all the listed substances is required with the exception of B2d—Sedatives, B2f— Other pharmacologically active substances, B3b—Organophosphorus compounds, B3d—Mycotoxins, B3e—Dyes and B3f—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 farmed game and rabbits, but have not been specifically addressed in Council Directive 96/23/EC, a more general grouping of chemical substances was chosen, resulting in the following three major groups:

- substances that have an anabolic effect and unauthorised<sup>14</sup> for use in food-producing animals, corresponding to Group A substances in Council Directive 96/23/EC;
- veterinary medicinal products (VMPs) and medicated feed additives, corresponding to Groups B1 and B2 substances in Council Directive 96/23/EC; and
- contaminants, corresponding to Group B3 substances in Council Directive 96/23/EC.

The **first group** of chemicals that may occur in edible tissues as residues are those substances prohibited for use in food-producing animals; these substances correspond largely with Group A substances in Council Directive 96/23/EC. There were different rationales for banning these substances for application to animals and Group A substances comprise compounds that are of toxicological concern (including VMPs for which an acceptable daily intake (ADI) could not be established) as well as substances having anabolic effects and pharmacologically active compounds 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 are VMPs (including antibiotics, antiparasitic agents and other pharmacologically active substances) and substances authorised as feed additives. In the health care of domestic animals these substances correspond largely with Group B1 and B2 substances in Council Directive 96/23/EC. 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

<sup>&</sup>lt;sup>14</sup> Unauthorised substances are also referred to as prohibited substances.



Regulation (EU) No  $470/2009^{15}$  or are licensed as feed additives following a review of the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel) according to Regulation (EC) No.  $1831/2003^{16}$ . For all VMPs and feed additives licensed for use in food-producing animals, an ADI is established on the basis of the pharmacological and toxicological profile of the candidate drug/additive. On the basis of the established ADI, MRLs are derived for the parent drug or its metabolites/derivatives (marker residues) in target tissues and these MRLs (µg/kg tissue) are used to establish compliance. The list of allowed substances is presented as Table 1 of Commission Regulation (EU) No 37/2010 and in the Community Register of feed additives. With regard to antimicrobial agents, it is important to state that the ranking of substances of concern in this part of the document considers only toxicological concerns related to the presence of residues. Other aspects, such as the emergence of antimicrobial resistance is considered by the EFSA Panel on Biological Hazards (BIOHAZ Panel) in a separate part of this opinion (Appendix A of the BIOHAZ Panel).

For farmed game, only very few substances (mainly antiparasitic agents) have been licensed in the EU. This applies also to rabbits, for which a number of coccidiostatic agents are licensed as feed additives, but only very few other medicinal products, including frequently used antibiotics. This implies that some of the use of VMPs in farmed game and in rabbits needs to follow the procedures set for drugs that are applied by a veterinarian to an animal for which it is not licensed or for an indication for use not registered, mainly to deal with exceptional circumstances and/or to avoid animal suffering . This is commonly referred to as 'cascade usage'. In accordance with Article 10 of Directive 2001/82/EC, treatment can be applied under the 'cascade usage' system (i.e. with products licensed for other animals and humans, but not specifically for farmed game or for rabbits), subject to a minimum withdrawal period of 28 days being observed

A **third group** of chemical substances that may occur in farmed game and rabbits are contaminants that may enter the animal's body mainly via feed, ingested soil and more exceptionally by drinking water, inhalation or direct (skin) contact. These substances include the Group B3 substances in Council Directive 96/23/EC. Feed materials can contain a broad variety of undesirable substances comprising persistent environmental pollutants, toxic metals and other elements as well as natural toxins, including toxic secondary plant metabolites and fungal toxins (mycotoxins). Feed producers have to act in compliance with Commission Directive 2002/32/EC, listing the undesirable substances in feed and feed materials and presenting maximum contents in feed materials or complete feedingstuffs. In a recent re-assessment of these undesirable substances in animal feeds, the Panel on Contaminants in the Food Chain (CONTAM Panel) re-evaluated the risk related to exposure to these substances for animals. Special attention was given to toxic compounds that accumulate or persist in edible tissues, including meat, or are directly excreted into milk and eggs.

# 2.2.1. Statutory limits

In order to protect public health, Article 2 of Council Regulation (EEC) No. 315/93 of 8 February 1993 laying down Community procedures for contaminants in food stipulates that, where necessary, maximum tolerances for specific contaminants shall be established.

Although a number of MLs for various contaminants in different foodstuffs were laid down in the Annex of Commission Regulation (EC) No 1881/2006 of 19 December 2006 (setting MLs for certain contaminants in foodstuffs), no MLs were set for farmed game, except for pigs. The term 'pigs' does not make any distinction between domestic, wild or farmed pigs and does not provide any exclusion. Regarding the definition of foodstuffs listed in this category, Footnote 6 of this regulation refers to

<sup>&</sup>lt;sup>15</sup> Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 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.

<sup>&</sup>lt;sup>16</sup> Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29–43.

Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin. According to Annex I of Regulation (EC) No 853/2004, 'meat' means "edible parts of domestic bovine (including *Bubalus* and *Bison* species), porcine, ovine and caprine animals, and domestic solipeds". Following this definition, farmed wild boar are generally covered by the foodstuff 'pigs'. However, it depends on the conditions under which these wild boar are farmed. Annex I of Regulation (EC) No 853/2004 defines 'wild game' as "wild ungulates and lagomorphs, as well as other land mammals that are hunted for human consumption and are considered to be wild game under the applicable law in the MS concerned, including mammals living in enclosed territory under conditions of freedom similar to those of wild game". From this it follows that only to those wild boar that are farmed under much more restrictive conditions than 'wild' wild boar would the MLs apply.

Contaminant	MLs	Health-based guidance values/MOE approach	Assessments: Reference
Dioxins and dioxin-	Dioxins	TWI: 14 pg WHO-	SCF, 2001
like PCBs	Meat, fat and meat products:	TEQ/kg b.w.	
	1.0 pg WHO-TEQ/g fat		
	Liver and derived products:		
	4.5 pg WHO-TEQ/g fat		
	Dioxins + DL-PCBs		
	Meat, fat and meat products:		
	1.25 pg WHO-TEQ/g fat		
	Liver and derived products:		
	10.0 pg WHO TEQ/g fat		
Non dioxin-like	Meat, fat and meat products:	MOE approach	EFSA, 2005b
PCBs (sum of PCB-	40 ng/g fat		
28, -52, -101, -138, -			
153 and -180)	Liver and derived products:		
	40 ng/g fat		
Cadmium	Meat: 0.050 mg/kg wet weight	TWI: 2.5 μg/kg b.w.	EFSA, 2009a;
	Liver: 0.50 mg/kg wet weight		EFSA CONTAM
	Kidney: 1.0 mg/kg wet weight		Panel, 2011a
Lead	Meat: 0.10 mg/kg wet weight	MOE approach	EFSA CONTAM
	Offal: 0.50 mg/kg wet weight		Panel, 2010

**Table 4:**Contaminants currently regulated in Regulation (EC) No. 1881/2006<sup>17</sup> in pigs.

b.w., body weight; ML, maximum level; MOE, margin of exposure; TEQ, toxic equivalent; TWI, tolerable weekly intake; DL-PCB, dioxin-like polychlorinated biphenyls.

Recently, the MLs for dioxins and the sum of dioxins and dioxin-like polychlorinated biphenyls (DL-PCBs) in food were reviewed taking into account new data, and amended accordingly. The revised MLs above apply from 1 January 2012. In contrast to the former values, the revised MLs are expressed as toxic equivalents (TEQs) using the WHO-TEF<sub>2005</sub> s for human risk assessment based on the conclusions of the World Health Organization (WHO) International Programme on Chemical Safety (IPCS) expert meeting, which was held in Geneva in June 2005 (Van den Berg et al., 2006).

In addition to dioxins and the sum of dioxins and DL-PCBs, Regulation EC (No) 1881/2006, amended by Regulation EC (No) 1259/2011,<sup>18</sup> also sets MLs for the sum of the six indicator PCBs identified by the CONTAM Panel (PCB-28, -52, -101, -138, -153 and -180) (EFSA, 2005b) for various kinds of foodstuffs following the same food categorisation as for dioxins and the sum of dioxins and DL-PCBs.

<sup>&</sup>lt;sup>17</sup> 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.

<sup>&</sup>lt;sup>18</sup> Commission Regulation No 1259/2011 of 2 December 2011 amending Regulation (EC) No 1881/2006 as regards maximum levels for dioxins, dioxin-like PCBs and non dioxin-like PCBs in foodstuffs. OJ L 320, 3.12.2011, p. 18–23.

As an early warning tool, the European Commission has set action levels for dioxins and DL-PCBs in food through Commission Recommendation 2011/516/EC<sup>19</sup>. Due to the fact that their sources are generally different, separate action levels for dioxins and DL-PCBs were established. The action levels for dioxins and DL-PCBs in meat and meat products (excluding edible offal) of pigs are 0.75 pg WHO-TEQ/g fat and 0.50 pg WHO-TEQ/g fat, respectively. In cases where levels of dioxins and/or DL-PCBs in excess of the action levels are found, it is recommended that MS, in cooperation with FBOs, initiate investigations to identify the source of contamination, take measures to reduce or eliminate the source of contamination and check for the presence of non dioxin-like polychlorinated biphenyls (NDL-PCBs).

MRLs for certain elements in rabbits and ostriches are laid down in Regulation (EC) No 396/2005 of the European Parliament and of the Council on Maximum Residue Levels of pesticides in or on food and feed of plant and animal origin (originally specified for the use of copper-containing and mercury-containing compounds as pesticides). For copper, the maximum residue levels are each 5 mg/kg for meat and fat and 30 mg/kg each for liver, kidney and edible offal. For mercury compounds (sum of mercury compounds expressed as mercury), the maximum residue levels are 0.01 mg/kg each for meat, fat, liver, kidney and edible offal.

# 2.3. Ranking of the substances of potential concern

A multi-step approach was used for ranking the potential concern of the three groups of substances that are presented in Sections 2.1 and 2.2. The steps are:

- evaluation of the outcomes of the NRCPs indicating the number of results that are noncompliant with the current legislation;
- evaluation of the likelihood that specific residues or contaminants, including 'new hazards (see Section 2.3.5.6), may be present in carcasses of farmed game and rabbits;
- consideration of the toxicological profile for chemical substances.

# 2.3.1. Outcome of the NRCPs within the EU

Data from the NRCPs are published annually and these data were considered as the first step for hazard ranking. Aggregated data for the outcome of the NRCPs for targeted sampling of farmed game and rabbits from 2005 to 2010 are presented in Tables 4–9. The grouping follows Council Directive 96/23/EC. Data reported in 2005 were from the 25 EU MSs, whereas for the subsequent years (2006–2010) data have been gathered from 27 EU MSs, following 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 chemical residues and contaminants. As stated above, suspect sampling arises (i) as 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 VMPs (Articles 5, 11 and 24 of Directive 96/23/EC, respectively).

A non-compliant result refers to an analytical result exceeding the permitted limits or, in the case of prohibited substances, any measured level with sufficient statistical certainty that it can be used for legal purposes.<sup>20</sup> As mentioned above, for VMPs, MRLs are laid down in Commission Regulation (EU) No 37/2010. For pesticides, maximum residue levels are laid down in Regulation (EC) No

<sup>&</sup>lt;sup>19</sup> Commission Recommendation of 23 August 2011 on the reduction of the presence of dioxins, furans and PCBs in feed and food (2011/516/EC). OJ L 218, 24.8.2011, p. 23–25.

<sup>&</sup>lt;sup>20</sup> 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.



396/2005. MLs for contaminants are laid down in Commission Regulation (EC) No 1881/2006. National tolerance levels are sometimes applied by individual MSs for contaminants for which no EU maximum levels have been established. For some of the non-allowed VMPs, for which no permitted limit can be set, minimum required performance limits (MRPLs) have been established (Commission Decision 2002/657/EC<sup>21</sup>) to make results of residue monitoring comparable between laboratories and MSs. For residues of some of these substances that are not licensed within the EU for use in farmed game or rabbits, such as chloramphenicol, nitrofurans and their metabolites, and medroxyprogesterone acetate, MRPLs have been established (Commission Decision 2003/181/CE<sup>22</sup>) and are used in the reporting system.

It should be noted that information on the number of total analyses performed for an individual substance is transmitted only by those MSs that were reporting at least one non-compliant sample for that substance within the NRCPs. Therefore, it is not possible to extract from the data supplied complete information on the individual substances from each subgroup tested or on the number of samples tested for an individual substance where no non-compliant result is reported.

In addition, in some cases, the same samples were analysed for different substance groups/subgroups and therefore the number of substance groups/subgroups tested is higher than the total number of samples collected. It is to be noted that there is a lack of harmonisation regarding details provided on non-compliant results for the NRCPs from MSs. This hampers the interpretation and the evaluation of these data. Moreover, no information is readily available on the nature of the positive samples (i.e. from which species samples were taken and whether they refer to muscle, liver, kidney or skin/fat samples) and these results often give no indication of the actual measured concentrations of residues or contaminants. In addition, some of the non-compliant results listed in the tables under the category of 'farmed game' are for animal species different to the species of farmed game covered in this document, including, for example, quail, partridge and pigeon. As a result, in the absence of speciesspecific and substance-specific information and the actual concentration of a residue or contaminant measured, these data do not allow for an assessment of consumer exposure.

<sup>&</sup>lt;sup>21</sup> Commission Decision 2002/657/EC of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results. OJ L 221, 17.8.2002, p. 8–36.

<sup>&</sup>lt;sup>22</sup> Commission Decision 2003/181/EC of 13 March 2003 amending Decision 2002/657/EC as regards the setting of minimum required performance limits (MRPLs) for certain residues in food of animal origin. OJ L 71, 15.3.2003, p. 17–18.

**Table 5:** Non-compliant (NC) results<sup>a</sup> for prohibited substances (Group A) in farmed game (excluding rabbits) reported from national residue monitoring plans, 2005–2010 (targeted sampling). Information extracted from the reports published by the European Commission.<sup>b</sup> In brackets: number of MS providing NC data.

Substance	2010	(EU-27)	2009	(EU-27)	2008	( <sup>EU-27)</sup>	2007	(EU-27)	2006	( EU-27)	2005	(EU-25)
Subgroup	NC	Total	NC	Total	NC	Total	NC	Total	NC	Total	NC	Total
A1 Stilbenes	0	52	0	63	0	60	0	58	0	90	0	71
A2 Thyreostats	0	35	0	42	0	27	0	33	0	26	0	23
A3 Steroids	0	47	0	72	0	79	0	64	0	62	0	63
A4 Resorcylic acid lactones	0	52	0	59	0	59	0	56	0	65	0	72
(RALs)												
A5 Beta-agonists	0	137	0	133	0	102	1	103	0	119	0	116
Salbutamol	0		0		0		1 (1)		0		0	
A6 Annex IV compounds	1	282	1	203	4	221	3	317	0	283	2	253
AMOZ	0		1 (1)		2 (1)		0		0		0	
AOZ	0		0		0		0		0		2 (2)	
Metronidazole	0		0		1 (1)		0		0		0	
Chloramphenicol	0		0		1(1)		0		0		0	
Ronidazole	1 (1)		0		0		3 (1)		0		0	

AMOZ: 3-amino-5-morpholinomethyl-1,3-oxazolidine-2-one; AOZ: 3-amino-2-oxazolidinone

(a): One sample can be non-compliant for more than one substance.

(b): Published at http://ec.europa.eu/food/food/chemicalsafety/residues/control\_en.htm, .

**Table 6:** Non-compliant (NC) results<sup>a</sup> for Veterinary Medicinal Products (Antibacterial substances and other veterinary drugs, Groups B1 and B2) in farmed game (excluding rabbits) reported from national residue monitoring plans, 2005–2010 (targeted sampling). Information extracted from the reports published by the European Commission<sup>(b)</sup>. In brackets: number of Member States (MS) providing NC data.

Substance	2010	(EU-27)	2009	(EU-27)	2008	(EU-27)	2007	(EU-27)	2006	(EU-27)	2005	5 (EU-25)
Sub-group	NC	Total	NC	Total	NC	Total	NC	Total	NC	Total	NC	Total
<b>B1</b> Antibacterials	0	482	1	472	0	382	1	585	1	512	3	560
Benzylpenicillin	0		0		0		0		1 (1)		0	
Chlortetracycline	0		0		0		0		0		1(1)	
Doxycycline	0		1(1)		0		0		0		0	
Enrofloxacin	0		0		0		1 (1)		0		0	
Oxytetracycline	0		0		0		0		0		1(1)	
Sulfadiazine	0		0		0		0		0		1 (1)	
B2a Anthelmintics	1	243	0	250	0	215	0	254	0	267	0	245
Moxidectin	1 (1)		0		0		0		0		0	
B2b Anticoccidials	1	172	1	185	0	128	2	171	0	165	0	120
Monensin	1 (1)		0		0		1 (1)		0		0	
Lasalocid	0		1(1)		0		0		0		0	
Salinomycin	0		0		0		1 (1)		0		0	
B2c Carbamates and												
pyrethroids	0	104	0	93	0	108	0	113	0	115	0	93
B2d Sedatives	0	7	0	6	0	0	0	3	0	4	0	
B2e NSAIDs	0	62	0	59	0	49	0	43	1	59	0	44
Methamizole	0		0		0		0		1 (1)		0	
B2f Other	0	11	0	4	0	4	0	3	0	0	0	4

NSAID: non-steroidal anti-inflammatory drug.

(a): One sample can be non-compliant for more than one substance.

(b): Published at http://ec.europa.eu/food/food/chemicalsafety/residues/control\_en.htm.

**Table 7:** Non-compliant (NC) results<sup>a,b</sup> for other substances and environmental contaminants (Group B3) in farmed game (excluding rabbits) reported from national residue monitoring plans, 2005–2010 (targeted sampling). Information extracted from the reports published by the European Commission.<sup>(c)</sup>. In brackets: number of Member States (MS) providing NC data.

Substance	2010	(EU-27)	2009	(EU-27)	2008	(EU-27)	2007	(EU-27)	2006	(EU-27)	2005 (	EU-25)
Sub-group	NC	Total	NC	Total	NC	Total	NC	Total	NC	Total	NC	Total
B3a Organochlorine compounds	0	230	0	164	0	237	0	181	1	249	2	205
Dioxins	0		0		0		0		1(1)		0	
PCDD	0		0		0		0		0		1 (1)	
PCDF	0		0		0		0		0		1(1)	
B3b Organophosphorus	0	26	0	29	0	28	0	16	0	57	0	31
compounds												
B3c Chemical elements	15	281	15	262	13	252	22	342	10	296	15	213
Cadmium	13(1)		12(1)		10 (2)		17(1)		10 (3)		15 (2)	
Lead	1(1)		1(1)		3 (2)		5 (3)		0		0	
Mercury	1(1)		2 (1)		0		0		0		0	
B3d Mycotoxins	0	32	0	37	0	14	0	48	0	33	0	16
B3e Dyes	0	0	0	0	0	0	0	0	0	0	0	0
B3f Other	0	59	0	48	0	33	0	32	0	43	0	18

PCDD: polychlorinated dibenzo-p-dioxin; PCDF, polychlorinated dibenzofuran.

(a): One sample can be non-compliant for more than one substance.

(b): National tolerance levels are applied by individual MS for contaminants where no EU maximum levels have been established.

(c): Published at http://ec.europa.eu/food/food/chemicalsafety/residues/control\_en.htm.



Substance	2010	(EU-27)	2009	(EU-27)	2008	(EU-27)	2007	(EU-27)	2006	(EU-27)	2005	(EU-25)
Sub-group	NC	Total	NC	Total	NC	Total	NC	Total	NC	Total	NC	Total
A1 Stilbenes	0	88	0	104	0	78	0	113	0	69	0	99
A2 Thyreostats	0	36	0	45	0	32	0	42	0	46	0	70
A3 Steroids	0	80	0	128	0	97	0	105	0	94	0	96
A4 Resorcylic acid lactones												
(RALs)	0	69	0	98	0	71	0	97	0	75	0	91
A5 Beta-agonists	0	148	0	140	0	130	0	176	0	173	0	284
A6 Annex IV compounds	2	817	0	747	1	703	0	857	1	795	5	870
AHD	0		0		0		0		0		1 (1)	
AMOZ	0		0		1(1)		0		0		0	
SEM	0		0		0		0		0		1(1)	
Chloramphenicol	2 (2)		0		0		0		1 (1)		3 (2)	

**Table 8:** Non-compliant (NC) results<sup>(a)</sup> for prohibited substances (Group A) in rabbits reported from national residue monitoring plans, 2005–2010 (targeted sampling). Information extracted from the reports published by the European Commission.<sup>(b)</sup> In brackets: number of MS providing NC data.

AHD, 1-Amino-hydantoin; AMOZ, 3-amino-5-morpholinomethyl-1,3-oxazolidin-2-one; AOZ, 3-amino-2-oxazolidinone; SEM, semicarbazide.

(a): One sample can be non-compliant for more than one substance.

(b): Published at http://ec.europa.eu/food/food/chemicalsafety/residues/control\_en.htm



Substance	201	0 <sup>(EU-27)</sup>		(EU-27)	<b>2008</b> <sup>()</sup>	EU-27)	2007	(EU-27)	2006	EU-27)	2005 <sup>(EU</sup>	J <b>-25</b> )
Substance Sub-group	NC	Total	NC	Total	NC	Total	NC	Total	NC	Total	NC	Total
B1 Antibacterials	11	1 615	10	1 4 3 0	25	1 547	21	1 803	29	1 713	24	2 0 2 6
Antibacterials (unspecified)	0		0		0		0		1(1)		0	
Benzosulfonamide	0		1(1)		0		0		0		0	
Ciprofloxacin	0		0		0		0		0		1(1)	
Doxycycline	0		0		0		2(1)		0		0	
Enrofloxacin	0		0		0		4(1)		3 (1)		4 (2)	
Oxytetracycline	0		2(1)		0		4 (2)		11(1)		6(1)	
Sulfadiazine	0		0		0		0		1(1)		2(1)	
Sulfadimidine	0		0		1(1)		0		1(1)		0	
Sulfadimethoxine	11 (2)		7 (2)		3 (1)		10 (2)		10(2)		10(2)	
Sulfonamides	0		0		5(1)		1(1)		0		0	
Sulfanilamide	0		0		1(1)		0		0		0	
Sulfaquinoxaline	0		0		0		0		2(1)		0	
Tetracyline	0		0		14 (2)		1(1)		0		0	
Trimethoprim	0		0		1(1)		0		0		0	
B2a Anthelmintics	0	179	0	167	1	194	0	244	0	227	0	257
B2b Anticoccidials	4	315	12	270	5	214	5	376	1	297	2	254
Diclazuril	0		7 (1)		2 (1)		0		0		0	
Maduramicin	3 (1)		3 (1)		0		0		0		0	
Nicarbazin	0		0		0		0		0		1(1)	
Salinomycin	0		2 (2)		2 (1)		0		0		0	
Robenidine	1 (1)		0		1 (1)		5 (2)		1 (1)		1 (1)	
B2c Carbamates and								11				
pyrethroids	0	98	0	84	0	97	0	5	0	129	0	153
B2d Sedatives	0	3	0	3	0	3	0	6	0	3	0	5
B2e NSAIDs	1	73	1	72	0	78	0	68	0	78	1	80
Antipyrin-4-methylamino	1 (1)		0		0		0		0		0	
Ketoprofen	0		1(1)		0		0		0		0	
Sodiumsalicylate	0		0		0		0		0		1 (1)	
B2f Other	0	34	0	47	0	44	0	61	2	108	0	33
Olaquindox	0		0		0		0		2 (2)		0	

**Table 9:** Non-compliant (NC) results<sup>a</sup> for Veterinary Medicinal Products (Antibacterial substances and other veterinary drugs, Groups B1 and B2) in rabbits reported from national residue monitoring plans, 2005–2010 (targeted sampling). Information extracted from the reports published by the European Commission<sup>(b)</sup>. In brackets: number of Member States (MS) providing NC data.

NSAID, non-steroidal anti-inflammatory drug.

(a): One sample can be non-compliant for more than one substance.

 $(b): \ Published \ at \ http://ec.europa.eu/food/chemicalsafety/residues/control\_en.htm.$ 



**Table 10:** Non-compliant (NC) results<sup>(a),(b)</sup> for other substances and environmental contaminants (Group B3) in rabbits reported from national residue monitoring plans, 2005–2010 (targeted sampling). Information extracted from the reports published by the European Commission.<sup>c</sup> In brackets: number of Member States (MS) providing NC data.

2010	(EU-27)	2009	(EU-27)	2008	(EU-27)	2007	(EU27)	2006	(EU-27)	2005	(EU-25)
NC	Total	NC	Total	NC	Total	NC	Total	NC	Total	NC	Total
3	190	0	208	1	207	1	243	5	255	0	275
3 (1)		0		0		1(1)		5 (1)		0	
0		0		1(1)		0		0		0	
0	16	0	22	0	33	0	46	0	63	0	47
1	197	1	208	0	190	1	265	2	228	0	269
1(1)		1(1)		0		1(1)		1(1)		0	
0		0		0		0		1(1)		1(1)	
0	45	0	43	0	43	0	63	0	53	0	41
0	0	0	0	0	0	0	0	0	0	0	0
0	14	0	15	0	6	0	20	0	19	0	5
	NC 3 3 (1) 0 0 1	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	NC         Total         NC           3         190         0           3 (1)         0         0           0         0         0           0         16         0           1         197         1           1 (1)         0         0           0         45         0           0         0         0	NC         Total         NC         Total           3         190         0         208           3 (1)         0         0         208           0         0         0         0           0         16         0         22           1         197         1         208           1 (1)         0         0         0           0         45         0         43           0         0         0         0	$\begin{array}{c c c c c c c c c c c c c c c c c c c $	$\begin{array}{c c c c c c c c c c c c c c c c c c c $	$\begin{array}{c c c c c c c c c c c c c c c c c c c $	$\begin{array}{c c c c c c c c c c c c c c c c c c c $	$\begin{array}{c c c c c c c c c c c c c c c c c c c $	$\begin{array}{c c c c c c c c c c c c c c c c c c c $	$\begin{array}{c c c c c c c c c c c c c c c c c c c $

HCH, hexachlorocyclohexane.

(a): One sample can be non-compliant for more than one substance.

(b): National tolerance levels are applied by individual MS for contaminants where no EU maximum levels have been established.

(c): Published at http://ec.europa.eu/food/chemicalsafety/residues/control\_en.htm.

A summary of the data presented in the previous tables (Tables 5, 6 and 7) shows that 117 of the 12 909 farmed game samples (0.91 %) analysed in the EU NRCPs during the period 2005–2010 were non-compliant for one or more substance groups listed in Annex I of Directive 96/23/EC. For rabbits, Tables 8, 9 and 10 show that 162 of the 24 345 samples (0.67 %) analysed in the EU NRCPs during the period 2005–2010 were non-compliant for one or more substance groups listed in Annex I of Directive 96/23/EC. Further details are presented in Tables 11 and 12. As mentioned above, one sample can be non-compliant for multiple substances, so that the number of non-compliant results is higher than the number of non-compliant samples.

**Table 11:** Analysis of non-compliant (NC) farmed game (excluding rabbits) samples<sup>a</sup> as reported in the NRCPs<sup>b</sup> for the period 2005–2010 in the EU.

Period 2005–2010	Group A	Groups B1 and B2	Group B3	Total
Total samples analysed <sup>c</sup>	3 443	6 363	3 103	12 909
Farm level	530	656	450	1 636
Slaughterhouse level	2 913	5 707	2 653	11 273
Total NC samples	12	12	93	117
Farm level	1	3	1	5
Slaughterhouse level	11	9	92	112

a: One sample can be non-compliant for more than one substance.

b: Published at http://ec.europa.eu/food/food/chemicalsafety/residues/control\_en.htm.

c: Some of the samples were analysed for several substances in different subgroups (e.g. same sample analysed for B3a, B3b and B3c); this total represents the total number of samples analysed for at least one substance in the group.

**Table 12:** Analysis of non-compliant (NC) rabbit samples<sup>a</sup> as reported in the NRCPs<sup>b</sup> for the period 2005–2010 in the EU. Note: The sampling point for rabbits is not specified in the NRCP results.

Period 2005–2010	Group A	Groups B1 and B2	Group B3	Total
Total samples analysed <sup>c</sup>	7 257	14 451	3 056	24 345
Total NC samples	7	141	14	162

a: One sample can be non-compliant for more than one substance.

b: Published at http://ec.europa.eu/food/food/chemicalsafety/residues/control\_en.htm.

c: Some of the samples were analysed for several substances in different subgroups (e.g. same sample analysed for B3a, B3b and B3c); this total represents the total number of samples analysed for at least one substance in the group.

It should be noted that the data in Tables 5–10 are the results of sampling and testing carried out by MSs under the terms of Directive 96/23/EC within the NRCPs. However, there may be other chemical substances of relevance for control in farmed game and rabbits, particularly in the case of contaminants which are not included in the NRCPs at all or which are not covered systematically in the NRCPs. Some of these substances are addressed further under TOR 3 of this opinion ('New hazards').

#### 2.3.2. Analysis of the data

#### 2.3.2.1. Farmed game (excluding rabbits)

The results of the NRCP testing show that 0.91 % of the total samples were non-compliant for one or more substances, with 0.35 %, 0.19 % and 3.0 % being non-compliant for Group A, Group B1/B2 and Group B3 substances, respectively. Of the total number of farmed game (excluding rabbits) samples taken for analysis during the period 2005–2010, 12.7 % were taken at farm level while the remaining 87.3 % were taken at slaughterhouse level. It should be noted that sample details are not always available, particularly in respect of the numbers of samples taken for each species of farmed game. Moreover, some of the non-compliant results reported for farmed game refer to 'other poultry' species such as pigeon, quail, and partridge, which overestimates to some extent the number of non-compliant results found for farmed game. This makes it difficult to draw other than very general conclusions regarding the occurrence of non-compliant results for the various chemical substances in particular species of farmed game. Compared with opinions on meat inspection for other species, the low

numbers of samples taken at farm level and the low number of non-compliant samples (5) found at farm level precludes an assessment of farm versus slaughterhouse sampling.

The highest overall proportion of non-compliant samples (3.0%) was for Group B3 substances, contaminants, representing largely exceedances of the MLs/MRLs specified for these substances. For Group A, prohibited substances (0.35%), and for Group B1/B2 substances, VMPs (0.19%), the proportions of non-compliant samples were much lower, representing largely illicit use of prohibited substances and exceedances of the MRLs specified for VMPs, respectively.

For prohibited substances (Group A), the majority (11 of 12) of samples found to be non- compliant relate to substances such as chloramphenicol, nitrofurans and nitroimidazoles with only one sample being non-compliant for the beta-agonist salbutamol. While only one non-compliant result was reported from the limited farm level sampling undertaken for farmed game, such sampling is an integral component of the system for controlling illicit use of prohibited substances in food-producing animals, particularly in the case of substances having anabolic effects.

In the case of VMPs (Group B1/B2), most (10 of 12) of the non-compliant results relate to antimicrobials and anticoccidials. Slaughterhouse-level sampling is more appropriate for identifying non-compliant samples for VMPs, based on compliance with or exceedance of the specified MRLs in edible tissues.

In the case of contaminants (Group B3), the majority (97 %) of samples found to be non-compliant relate to chemical elements, particularly cadmium. Sampling for Group B3 substances is more appropriate, generally, at slaughterhouse level where identification of non-compliant results, based on compliance with or exceedance of specified MRLs/MLs in edible tissues, can be made.

# 2.3.2.2. Rabbits

Of the total number of rabbit samples taken for analysis during the period 2005–2010, 0.67 % were non-compliant for one or more substances, with 0.10 %, 0.98 % and 0.46 % being non-compliant for Group A, Group B1/B2 and Group B3 substances, respectively. The highest overall proportions of non-compliant samples were for Group B1/B2 substances, VMPs (0.98 %) and for Group B3 substances, contaminants (0.46 %), representing largely exceedances of the MRLs specified for VMPs and the MLs/MRLs specified for contaminants, respectively. For Group A, prohibited substances (0.10 %), the proportion of non-compliant samples was much lower, representing largely illicit use of such substances. All of the samples found to be non-compliant for Group A substances relate to chloramphenicol and nitrofurans. The majority (96 %) of samples found to be non-compliant samples relate to organochlorine compounds and chemical elements, particularly cadmium and lead.

Because the sampling point (farm level or slaughterhouse level) is not specified for rabbits in the NRCP results, no further analysis of the data is possible.

It should also be noted that a direct comparison of data from the NRCPs over the years is not entirely appropriate as the test methods used and the number of samples tested for an individual substance varied between MSs. In addition, there are ongoing improvements in analytical methods, in terms of sensitivity, accuracy and scope (i.e. number of substances covered by the method), which affect interyear and inter-country comparisons. Therefore, the cumulative data from the NRCPs provide only a broad indication of the prevalence and nature of the non-compliant samples.

In conclusion, this compilation of data indicates that, with the exception of the contaminant cadmium in farmed game (for which non-compliant samples represent 4.7 % of farmed game samples tested for chemical elements, B3e), there is a low prevalence of abiotic hazards in edible tissues of farmed game and rabbits. Therefore, it can be concluded that potentially higher exposure of consumers to these substances from edible tissues of farmed game and rabbits takes place only incidentally, as a result of mistakes and/or non-compliance with known and regulated procedures.



# **2.3.3.** Criteria for the evaluation of the likelihood of the occurrence of residues or contaminants in farmed game and rabbits

Independent from the occurrence data as reported from the NRCPs, substances or groups of chemical substances that may enter the food chain were also evaluated for the likelihood that potentially toxic or undesirable substances might occur in farmed game and rabbits, including consideration of the various species of farmed game and rabbits used for meat production.

For prohibited substances and VMPs/feed additives, the following criteria were used:

- the likelihood of the substance(s) being used in an illicit or non-compliant way in farmed game or rabbits (suitability for animal production; commercial advantages);
- the potential availability of the substance(s) for illicit or non-compliant usage in farmed game or rabbit production (allowed usage in Third Countries; availability in suitable form for use in animals; 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 farmed game or rabbits based on the kinetic data (pharmacokinetic and withdrawal period data; persistence characteristics; special residue issues);
- toxicological profile and nature of hazard and the relative contribution of residues in farmed game and rabbits and in meat products to dietary human exposure.

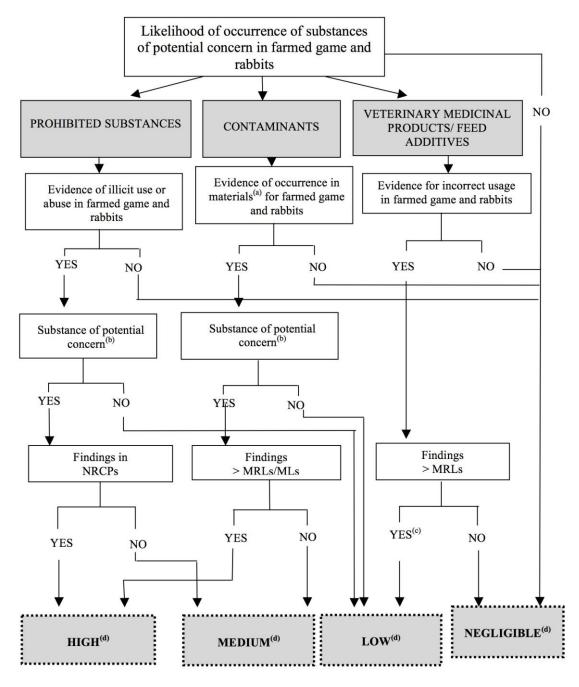
For contaminants, the following criteria were considered:

- the prevalence (where available) of occurrence of the substances in animal feeds/forages and pastures, and in the specific environmental conditions of the farms;
- the level and duration of exposure, tissue distribution and deposition including accumulation in edible tissues of farmed game and rabbits;
- toxicological profile and nature of hazard, and the relative contribution of residues in farmed game and rabbits to dietary human exposure.

#### 2.3.4. General flow chart

Considering the above-mentioned criteria, a flow chart approach was used for ranking of the chemical residues and contaminants of potential concern. The outcome of the NRCPs (indicating the number of non-compliant results), the evaluation of the likelihood that residues of substances of potential concern can occur in farmed game and rabbits and the toxicological profile of the substances were considered in the development of the general flow chart, as presented in Figure 1.





ML, maximum level: MRL, maximum residue limit; NRCP, national residue control plan.

- a: Contaminants from the soil and the environment, associated with feed material, are considered to be part of the total feed intake for the purposes of this opinion.
- b: Potential concern was based on the toxicological profile and nature of hazard for the substances.
- c: The CONTAM Panel notes that the ranking of VMPs/feed additives was carried out in the general context of authorised usage of these substances in terms of doses, route of treatment, animal species and withdrawal periods. Therefore, this ranking is made within the framework of the current regulations and control and within the context of a low rate of exceedances in the NRCPs.
- d: See definitions as provided in Section 2.3.5.

**Figure 1:** General flow chart used for the ranking of residues and contaminants of potential concern that can be detected in farmed game and rabbits.

# 2.3.5. Outcome of the ranking of residues and contaminants of potential concern that can occur in farmed game and rabbits

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

## Category 1—Negligible potential concern:

Substance irrelevant in farmed game or rabbit production (no known use at any stage of production); no evidence for illicit use or abuse in farmed game or rabbits; not or very seldom associated with exceedances in MRLs in control plans; no evidence of occurrence as a contaminant in feeds for farmed game or rabbits.

## Category 2—Low potential concern:

VMPs/feed additives which have an application in farmed game or rabbit production, residues above MRLs are found in control plans, 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 or are not found above MLs in farmed game or rabbits.

# Category 3—Medium potential concern:

Contaminants and prohibited substances to which farmed game or rabbits are known to be exposed and/or with a 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 farmed game or rabbits; contaminants generally not found in concentrations above the MRLs/MLs in edible tissues of farmed game or rabbits.

#### Category 4—High potential concern:

Contaminants and prohibited substances to which farmed game or rabbits are known to be exposed and with a history of misuse, with a distinct toxicological profile comprising a potential concern to consumers; evidence for ongoing occurrence of residues of prohibited substances in farmed game or rabbits; evidence for ongoing occurrence and exposure of farmed game or rabbits to feed contaminants.

### 2.3.5.1. Substances classified in the high potential concern category

No substances were classified in the high potential concern category for farmed game or rabbits.

# 2.3.5.2. Substances classified in the medium potential concern category

2.3.5.2.1. Prohibited substances: chloramphenicol, nitrofurans, nitroimidazoles

# (a) Chloramphenicol

Chloramphenicol is included in Table 2 of Commission Regulation (EU) No. 37/2010 (previously Annex IV of Council Regulation (EEC) No. 2377/90), due to its toxicological profile that includes the possible induction of a fatal aplastic anaemia in humans. There is no clear correlation between dose and the development of aplastic anaemia and 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 for the induction of this idiosyncratic aplastic anaemia could be defined (EMEA, 2009). In addition, several studies suggest that chloramphenicol and some of its metabolites are genotoxic (FAO/WHO, 1988, 2004; EMEA, 2009). Considering the available evidence from *in vitro* experiments and from animal studies as well as from

a case–control study conducted in China, in which there was evidence for the induction of leukaemia in patients receiving long-term treatment with chloramphenicol, the International Agency for Research in Cancer (IARC) classified chloramphenicol as a group 2A (probably carcinogenic to humans) substance (IARC, 1990). Although prohibited for use in food-producing animals in many countries, chloramphenicol is likely to be available on the black market for illicit use in farmed game and rabbit production, despite the fact that alternative compounds, such as thiamphenicol and florfenicol (with no toxicological concern) have been licensed for different farm animal species and might be used under the regulations set for the 'cascade usage' treatment of animals. Non-compliant results for chloramphenicol in rabbits have been reported in most year's results from the European NRCPs for 2005–2010, indicating that abuse of chloramphenicol in rabbit production in Europe is a continuing occurrence.

Considering that chloramphenicol has proven toxicity for humans, may be effective as an antibacterial treatment for rabbits and that non-compliant results are found in a number of years of the NRCPs, chloramphenicol is ranked as of medium potential concern for rabbits. However, as only one non-compliant result for chloramphenicol in farmed game is found in the NRCP testing 2005-2010, chloramphenicol is ranked as of low potential concern for farmed game.

#### (b) Nitrofurans

Nitrofurans, including furazolidone, furaltadone, nitrofurantoin and nitrofurazone, are very effective antimicrobial agents. Nitrofurans are effective in treatment of bacterial and protozoal infections, including coccidiosis. Although prohibited for use in food-producing animals in many countries, as tissue-bound metabolites of nitrofurans have been shown to be mutagenic and potentially carcinogenic, they are likely to be available in Third Countries for illicit use in animal production. Non-compliant results for nitrofurans in farmed game and rabbits have been reported in the results from the European NRCPs 2005–2010, indicating that abuse of nitrofurans in farmed game and rabbit production in Europe may be a continuing occurrence.

Considering that nitrofurans have proven toxicity for humans, may be effective as antibacterial treatments for farmed game and rabbits and that non-compliant results are found in the NRCPs, these substances are ranked as of medium potential concern for both farmed game and rabbits.

#### (c) Nitroimidazoles

The 5-nitroimidazoles, dimetridazole, metronidazole and ronidazole, are a group of drugs having antibacterial, antiprotozoal and anticoccidial properties. Due to their potential carcinogenicity, mutagenicity, genotoxicity and the occurrence of covalently bound metabolites with an intact imidazole structure, their use in food-producing animals is prohibited in the EU and other countries.

Although prohibited for use in food-producing animals, nitroimidazoles are likely to be available for illicit use in animal production, particularly since some drugs, such as metronidazole, are readily available as human medicines and in veterinary medicine for non-food-producing (companion) animals. Non-compliant results for nitroimidazoles in farmed game have been reported in a number of years in the results from the European NRCPs 2005–2010, indicating that abuse of nitroimidazoles may occur in farmed game production in Europe.

Considering that nitroimidazoles have proven toxicity for humans, that they may be effective as antibacterial/antiprotozoal treatments for farmed game, and that non-compliant results are found in a number of years in the NRCPs, these substances are ranked as of medium potential concern for farmed game. However, as no non-compliant results for nitroimidazoles in rabbits are found in the NRCP testing 2005–2010, nitroimidazoles are ranked as of low potential concern for rabbits.

## (d) Chemical elements (cadmium)

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 in accordance with 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.

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. Older animals are expected to have higher concentrations of cadmium accumulated in the kidneys; however, the proportion of non-compliant results in the NRCPs (Table 7) that derive from kidney samples is not readily available. The results from the NRCPs for the 2005–2010 period show that, of the 1 646 farmed game samples tested for chemical elements, 77 were non-compliant results for cadmium. In rabbits, out of the 1 357 samples tested for chemical elements, only four were non-compliant for cadmium.

Considering the high number of non-compliant results for farmed game samples in all years of the NRCPs, its substantial contribution to the overall exposure for high consumers of farmed game and its toxicological and kinetic profile, cadmium is ranked as being of medium potential concern for farmed game. However, as only a small number of non-compliant results for rabbit samples are found in the NRCP testing 2005–2010, cadmium is ranked as of low potential concern for rabbits.

- 2.3.5.3. Substances classified in the low potential concern category
- 2.3.5.3.1. Prohibited substances: stilbenes, thyreostats, steroids, resorcylic acid lactones,  $\beta$ -agonists

Prohibited substances that might be used for growth promotion purposes in other species, such as stilbenes, thyreostats, steroids, resorcylic acid lactones and  $\beta$ -agonists, but for which there is no history of widespread abuse in farmed game or in rabbits and/or which are unsuitable for such use in these species, have been allocated to the category of substances of low potential concern. In farmed game, only one non-compliant result reported during the period 2005–2010 for Group A was a non-compliant result for salbutamol. No non-compliant results for these substances in rabbits were reported from the NRCPs.

2.3.5.3.2. Contaminants: organochlorine pesticides, chemical elements (lead and mercury) and natural toxins

(a) Organochlorine compounds

Organochlorine pesticides, such as hexachlorocyclohexanes (HCHs), may occur in housing for rabbits. The results from the NRCPs for the 2005–2010 period show that, of the 1 338 rabbit samples tested for organochlorine pesticides, 10 were non-compliant results for  $\gamma$ -HCH or  $\beta$ -HCH; no non-compliant results for farmed game samples were reported. Organochlorine pesticides have been allocated to the category of contaminants of low potential concern for rabbits and as of negligible potential concern for farmed game.

(b) Chemical elements (lead and mercury)

Lead (EFSA CONTAM Panel, 2010) 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 and cereal-based products, potatoes, leafy vegetables and tap water. The contribution of lead in meat



from farmed game and rabbits to human exposure is limited. The results from the NRCPs for the 2005–2010 period show that, of the 2 653 farmed game samples tested for chemical elements, 10 were non-compliant results for lead. In rabbits, two non-compliant results were recorded out of a total of 1 357 samples analysed.

Mercury (EFSA, 2008a) 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 depend on its chemical form. Elemental mercury is volatile and mainly absorbed through the respiratory tract, whereas its absorption through the gastrointestinal tract is negligible. Gastrointestinal absorption of inorganic mercury is in the range of 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 well as in humans, methylmercury and its salts are readily absorbed in the gastrointestinal tract (> 80 %) and rapidly distributed to all tissues including the central nervous system. Still the highest concentrations of free mercury are found in the kidneys. Human exposure is predominantly associated with fish consumption; farmed game meat and offal are assumed to contribute only to a minor extent to human exposure (FAO/WHO, 2011). The results from the NRCPs for the 2005–2010 period show that, of the 2 653 farmed game and rabbit samples tested for chemical elements, only three farmed game samples were non-compliant results for mercury.

Considering the toxicological profile of these chemical elements but the relatively low number of noncompliant results from the NRCPs, lead and mercury have been allocated to the group of substances of low potential concern for farmed game and rabbits.

- (c) Natural toxins: mycotoxins and toxic plant secondary metabolites
- c.1. 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. However, residues in tissues of farm animals, rabbits and farmed game are likely to contribute only to a very limited extent to human exposure and the main sources of human exposure are related to the consumption of cereal products, nuts and spices. Due to the generally limited transfer into edible tissues, mycotoxins have been allocated to the category of low potential concern for farmed game and rabbits.

c.2. Toxic plant secondary metabolites (toxic PSMs)

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 plant metabolites such as glucosinolates (EFSA, 2008b), saponins (EFSA, 2009b) pyrrolizidine alkaloids (EFSA, 2007a; EFSA CONTAM Panel, 2011b), tropane alkaloids (EFSA, 2008c) and cyanogenic compounds (EFSA, 2007b) as well as a number of individual substances, such as theobromine (EFSA, 2008d), gossypol (EFSA, 2008e) and ricin (EFSA, 2008f). 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 risk for consumers. Such substances, therefore, have been allocated to the category of low potential concern for farmed game and rabbits.

## 2.3.5.3.3. Veterinary medicinal products (VMPs) and feed additives above MRLs

In general, VMPs and feed additives, except the substances allocated to Table 2 of Regulation (EU) 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 NRCPs (antimicrobials: six non-compliant results out of 2 993 farmed game samples tested and 120 non-compliant results out of 10 134 rabbit samples tested; anthelmintics: one non-compliant result out of 1 474 farmed game samples tested and one non-compliant result out of 1 268 rabbit samples tested; NSAIDs: one non-compliant result out of 316 farmed game samples tested and three non-compliant results out of 449 rabbit samples tested; anticoccidials: four non-compliant results out of 941 farmed game samples tested and 29 non-compliant results out of 1 726 rabbit samples tested), these are typically of an occasional nature that do not constitute a concern to public health.

## 2.3.5.4. Substances classified in the negligible potential concern category

This category comprises substances irrelevant in farmed game or rabbit production (no known use at any stage of production) with no evidence of illicit use or abuse in farmed game or rabbits, which are not or very seldom associated with exceedances in MRL levels in NRCPs, and for which there is no evidence of occurrence as a contaminant in farmed game or rabbit feeds.

2.3.5.4.1. Prohibited substances

In the negligible potential concern category are the prohibited substances chlorpromazine, chloroform, colchicine, dapsone and plant remedies containing *Aristolochia* species, as these are not relevant to farmed game or rabbit production and there is no evidence of illicit use or abuse of these substances in farmed game or rabbit production.

2.3.5.4.2. Veterinary medicinal products (VMPs) below MRLs: carbamates and pyrethroids, sedatives

VMPs used in farmed game animal production but with no evidence for residues above MRLs being found in monitoring programmes as well as those VMPs irrelevant for farmed game production are ranked as of negligible potential concern.

#### (a) Carbamates and pyrethroids

Carbamates and pyrethroids are used in animal houses and occasionally in animals including farmed game for control of environmental infections, such as lice eggs in buildings. There are no recent incidents of non-compliance reported in the NRCPs for farmed game or rabbits during the period 2005–2010, resulting in the allocation of these substances to the category of negligible potential concern.

### (b) Sedatives

A range of sedative substances, including barbiturates, promazines, xylazine and ketamine, are licensed for use in farmed game and other animal species for sedation and analgesia during surgical procedures or for euthanasia. They are rarely used in farmed game or rabbits. Owing to their rapid excretion, these substances generally do not have detectable residues in muscle and so do not have MRLs registered in the EU. Animals euthanised with these substances are not allowed to enter the food chain.



2.3.5.4.3. Contaminants: dyes, organophosphorus compounds

(a) Dyes

There are no indications for use of dyes such as (leuco-)malachite green in farmed game or rabbits. Testing of farmed game or rabbits for this group of substances is not required under Council Directive 96/23/EC.

(b) Organophosphorus compounds

Organophosphorus compounds are unlikely to be used as VMPs on farmed game and rabbits. In addition, considering their generally short half-life, these compounds are allocated to the category of negligible potential concern.

A summary of the outcome of the ranking is presented in Table 13.

**Table 13:** Ranking of chemical residues and contaminants in farmed game (excluding rabbits) based on pre-defined criteria and taking into account the findings from the national residue control plans (NRCPs) for the period 2005–2010.

Group Potential concern category	Prohibited substances	VMPs and licensed feed additives	Contaminants		
Category 1 <b>Negligible potential</b> concern	<ul> <li>Aristolochia spp.</li> <li>Chloroform</li> <li>Colchicine</li> <li>Dapsone</li> <li>Chlorpromazine</li> </ul>	• Substances with residues below limits <sup>(a)</sup>	<ul> <li>Organophosphorus compounds</li> <li>Organochlorine pesticides</li> <li>Dyes</li> </ul>		
Category 2 Low potential concern	<ul> <li>Stilbenes</li> <li>Thyreostats</li> <li>Steroids</li> <li>Resorcylic acid lactones</li> <li>Chloramphenicol</li> <li>Beta-agonists</li> </ul>	• Substances with residues exceeding limits <sup>a</sup>	<ul> <li>Chemical elements (lead and mercury)</li> <li>Natural toxins (mycotoxins and PSMs)</li> </ul>		
Category 3 Medium potential concern	<ul><li>Nitrofurans</li><li>Nitroimidazoles</li></ul>		• Chemical elements (cadmium)		
Category 4 High potential concern	No substances ranked in this category				

PSM, plant secondary metabolite.

a: It should be noted that where no specific MRLs at EU level have been established for a farmed game species, provisions set in national regulations and/or for the 'cascade usage' system are applied.



**Table 14:** Ranking of chemical residues and contaminants in rabbits based on pre-defined criteria and taking into account the findings from the national residue control plans (NRCPs) for the period 2005–2010.

Group Potential concern category	Prohibited substances	VMPs and licensed feed additives	Contaminants	
Category Negligible potential concern	<ul> <li>Aristolochia spp.</li> <li>Chloroform</li> <li>Colchicine</li> <li>Dapsone</li> <li>Chlorpromazine</li> </ul>	• Substances with residues below limits <sup>a</sup>	<ul><li>Organophosphorus compounds</li><li>Dyes</li></ul>	
Category 2 Low potential concern	<ul> <li>Stilbenes</li> <li>Thyreostats</li> <li>Steroids</li> <li>Resorcylic acid lactones</li> <li>Beta-agonists</li> <li>Nitroimidazoles</li> </ul>	• Substances with residues exceeding limits <sup>a</sup>	<ul> <li>Organochlorine pesticides</li> <li>Chemical elements (cadmium, lead and mercury)</li> <li>Natural toxins (mycotoxins and PSMs)</li> </ul>	
Category 3 Medium potential concern Category 4	<ul><li>Chloramphenicol</li><li>Nitrofurans</li></ul>			
High potential concern	No substances ranked in this category			

MRL, maximum residue limit; NRCP, national residue control plan; PSM, plant secondary metabolite; VMP, veterinary medicinal product.

a: It should be noted that where no specific MRLs at EU level have been established for rabbits, provisions set in national regulations and/or for the 'cascade usage' system are applied.

#### 2.3.5.5. Future aspects

The ranking into specific categories of potential concern of prohibited substances, VMPs and contaminants presented in this section is based on current knowledge regarding the toxicological profiles, usage in the production of farmed game and rabbits and occurrence as residues or contaminants, as demonstrated by the data from the NRCPs for the 2005–2010 period. Where changes in any of these factors occur, the ranking might need amendment.

#### 2.3.5.5.1. New hazards

Another element of future aspects is the issue of 'new hazards'. In this context, new hazards are defined as compounds which have been identified as anthropogenic chemicals in food-producing animals and derived products and in humans and for which occurrence data in farmed game and rabbits are scarce and which may not be systematically covered by the NRCPs. Examples are polychlorinated dibenzo-*p*-dioxins, polychlorinated dibenzofurans (together often termed 'dioxins', dioxin-like PCBs (DL-PCBs), non dioxin-like PCBs (NDL-PCBs), brominated flame retardants, such as polybrominated diphenylethers (PBDEs) and hexabromocyclododecanes (HBCDDs), or perfluorinated compounds, such as perfluoroctane sulfonate (PFOS) and perfluoroctanoic acid (PFOA). Radioactive caesium is another 'new hazard' to be considered for farmed reindeer.

(a) Dioxins<sup>33</sup>

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, 2010). A number of incidents in the past 15 years were caused by contamination of feed with dioxins. Examples are feeding of contaminated citrus pulp pellets or incorrectly dried bakery by-products, kaolinitic clay containing potato peels or mixing of compound feed with contaminated fats or fatty acids intended for industrial purposes.

All these incidents were caused by grossly negligent or criminal actions and led to widespread contamination of feed and subsequently to elevated dioxin levels in the animals and the foodstuffs produced from them. Besides these incidents, the extensive rearing of farmed game may lead to elevated dioxin levels, especially in areas with substantial environmental contamination.

Dioxin concentrations in meat, fat and liver from various game animals and rabbits were reported by several MSs to EFSA following a call for data (EFSA, 2012b). The following results are all given as upper-bound concentrations:

- Levels in 23 meat samples from **reindeer** (not specified whether farmed or wild) ranged from 0.01 to 12.63 (mean 1.58, median 0.88) pg WHO-TEQ<sub>2005</sub>/g fat. Dioxin levels in nine fat samples ranged from 0.32 to 0.73 (mean 0.53, median 0.55) pg WHO-TEQ2005/g fat.
- Levels in 29 meat samples from **venison** (not specified whether farmed or wild) ranged from 0.15 to 33.4 (mean 2.74, median 0.87) pg WHO-TEQ2005/g fat. Dioxin levels in three liver samples ranged from 8.57 to 27.9 (mean 17.84, median 17.06) pg WHO-TEQ2005/g fat. For two fat samples, dioxin concentrations of 1.01 and 1.22 pg WHO-TEQ2005/g fat were reported.
- Levels in 50 meat samples from **wild boar** (not specified whether farmed or wild) ranged from < 0.01 to 4.14 (mean 0.84, median 0.65) pg WHO-TEQ2005/g fat. Dioxin levels in 42 fat samples ranged from 0.13 to 7.61 (mean 1.22, median 0.52) pg WHO-TEQ<sub>2005</sub>/g fat. For one liver sample, a dioxin concentration of 5.53 pg WHO-TEQ<sub>2005</sub>/g fat was reported.
- For two samples from farmed **ostriches**, dioxin concentrations of 0.44 and 0.49 pg WHO-TEQ<sub>2005</sub>/g fat were reported.
- Levels in six meat samples from **rabbits** (not specified whether farmed or wild) ranged from 0.09 to 0.54 (mean 0.29, median 0.29) pg WHO-TEQ<sub>2005</sub>/g fat. Dioxin levels in 11 fat samples ranged from 0.04 to 0.20 (mean 0.13, median 0.16) pg WHO-TEQ<sub>2005</sub>/g fat.

Dioxins have a long half-life and are accumulated in various tissues. The findings of elevated levels in food are of public health concern due to potential for effects on liver, thyroid, immune function, reproduction and neuro-development (EFSA, 2005b, 2010). 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 dioxins (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.

<sup>&</sup>lt;sup>33</sup> The term 'dioxins' used in this opinion refers to the sum of polychlorinated dibenzo-*p*-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs).



Based on the high toxicity, widespread occurrence in the environment and limited data on occurrence in farmed game and rabbits, dioxins deserve attention and should be considered for inclusion in the NRCPs.

(b) 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<sup>34</sup>, MS were required to take the necessary measures to ensure that used PCBs are disposed of 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. Also, PCBs were used in paints and sealants, therefore they may be present at farms.

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 aryl hydrocarbon (Ah)-receptor, thus showing toxicological properties similar to dioxins (effects on liver, thyroid, immune function, reproduction and neuro-development). Therefore, this group of PCBs is 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).

As for dioxins, the keeping of several farmed game species outdoors may lead to elevated levels of DL-PCBs.

DL-PCB concentrations in meat, fat and liver from various game animals and rabbits were reported by several MSs to EFSA following a call for data (EFSA, 2012b). The following results are all given as upper-bound concentrations:

- Levels in 23 meat samples from **reindeer** (not specified whether farmed or wild) ranged from 0.03 to 17.2 (mean 2.61, median 1.61) pg WHO-TEQ<sub>2005</sub>/g fat. DL-PCB levels in nine fat samples ranged from 0.73 to 1.60 (mean 1.30, median:1.39) pg WHO-TEQ<sub>2005</sub>/g fat.
- Levels in 29 meat samples from **venison** (not specified whether farmed or wild) ranged from 0.47 to 23.06 (mean 3.20, median 1.89) pg WHO-TEQ2005/g fat. DL-PCB levels in three liver samples ranged from 31.75 to 56.53 (mean 45.71, median 48.84) pg WHO-TEQ2005/g fat. For two fat samples, DL-PCB concentrations of 1.82 and 3.83 pg WHO-TEQ2005/g fat were reported.
- Levels in 50 meat samples from **wild boar** (not specified whether farmed or wild) ranged from < 0.01 to 13.64 (mean 1.25, median 0.72) pg WHO-TEQ<sub>2005</sub>/g fat. DL-PCB levels in 42 fat samples ranged from 0.13 to 22.2 (mean 1.72, median 0.51) pg WHO-TEQ<sub>2005</sub>/g fat. For one liver sample, a DL-PCB concentration of 2.09 pg WHO-TEQ<sub>2005</sub>/g fat was reported.
- For two samples from farmed **ostriches**, DL-PCB concentrations of 0.16 and 0.25 pg WHO-TEQ<sub>2005</sub>/g fat were reported.

<sup>&</sup>lt;sup>34</sup> 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.



• Levels in six meat samples from **rabbits** (not specified whether farmed or wild) ranged from 0.07 to 1.05 (mean 0.39, median 0.22) pg WHO-TEQ<sub>2005</sub>/g fat. DL-PCB levels in 11 fat samples ranged from 0.01 to 0.92 (mean 0.14, median 0.02) pg WHO-TEQ<sub>2005</sub>/g fat.

As DL-PCBs in general, show a comparable lipophilicity, bioaccumulation, toxicity and mode of action as dioxins (EFSA, 2005b), 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 occurrence in the environment and limited data on occurrence in farmed game and rabbits, DL-PCBs deserve attention and should be considered for inclusion in the NRCPs.

(c) Non dioxin-like PCBs (NDL-PCBs)

The non dioxin-like PCBs (NDL-PCBs) show a different toxicological profile to the DL-PCBs. In 2005, the CONTAM Panel undertook a risk assessment on NDL-PCBs in food (EFSA, 2005b). 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 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, 2005b).

Concentrations for the sum of these six NDL-PCBs in meat, fat and liver from various game animals and rabbits were reported by several MSs to EFSA following a call for data (EFSA, 2012b). The following results are all given as upper-bound concentrations:

- Levels in 22 meat samples from **reindeer** (not specified whether farmed or wild) ranged from 0.26 to 48.6 (mean 10.4, median 5.04) µg/kg fat. NDL-PCB levels in nine fat samples ranged from 2.62 to 4.97 (mean 3.38, median 3.17) µg/kg fat.
- For two meat samples from farmed venison, NDL-PCB concentrations of 24.0 and 27.5 μg/kg fat were reported. NDL-PCB levels in 20 fat samples from farmed venison ranged from 4.80 to 14.2 (mean 7.05, median 6.15) μg/kg fat.
- Levels in 87 meat samples from **wild boar** (not specified whether farmed and wild) ranged from 0.24 to 227.0 (mean 3.9, median 15.0) μg/kg fat. NDL-PCB levels in 22 fat samples ranged from 3.72 to 104.3 (mean 36.7, median 27.5) μg/kg fat.
- For four samples from farmed **ostriches**, NDL-PCB concentrations ranging from 0.52 to  $68.0 \ \mu g/kg$  fat were reported.
- Levels in 21 meat samples from **rabbits** (not specified whether farmed or wild) ranged from 0.58 to 33.3 (mean 7.32, median 3.78) µg/kg fat. NDL-PCB levels in eight fat samples ranged from 4.56 to 16.0 (mean 11.6, median 12.0) µg/kg fat.

As NDL-PCBs bioaccumulate in the food chain and, considering the potential for improper disposal practices of technical PCB products, they deserve attention and should be considered for broader inclusion in the NRCPs.



(d) Polybrominated diphenyl ethers (PBDEs)

In 2011, EFSA undertook a risk assessment on polybrominated diphenyl ethers (PBDEs) in food (EFSA CONTAM Panel, 2011c). 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 limits for a benchmark response of 10 %, the BMDL<sub>10</sub>s, for a number of PBDE congeners: BDE-47, 309 µg/kg b.w.; BDE-99, 12 µg/kg b.w.; BDE-153, 83 µg/kg b.w.; BDE-209, 1700  $\mu$ g/kg b.w. Due to the limitations and uncertainties in the current database, the Panel concluded that it was inappropriate to use these benchmark dose lower confidence limits (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 meat from farmed game and rabbits to the total human exposure is currently not known.

As these compounds bioaccumulate in the food chain and as knowledge about the occurrence and the levels of PBDEs in edible tissues of farmed game and rabbits is currently lacking, inclusion in the NRCPs should be considered.

(e) Hexabromocyclododecanes (HBCDDs)

In 2011, EFSA delivered a risk assessment on hexabromocyclododecanes (HBCDDs) in food (EFSA CONTAM Panel, 2011d). HBCDDs are additive flame retardants primarily used in expanded and extruded polystyrene applied as construction and packing materials, and in textiles. Technical HBCDD predominantly consists of three stereoisomers ( $\alpha$ -,  $\beta$ - and  $\gamma$ -HBCDD). Also  $\delta$ - and  $\epsilon$ -HBCDD may be present but at very low concentrations. HBCDDs are present in the environment and likewise in biota and in food and feed. Data from the analysis of HBCDDs in 1 914 food samples were provided to EFSA by seven European countries, covering the period from 2000 to 2010. The CONTAM Panel selected  $\alpha_{\gamma}$ ,  $\beta_{\gamma}$  and  $\gamma$ -HBCDD to be of primary interest. Since all toxicity studies were carried out with technical HBCDD, a risk assessment of individual stereoisomers was not possible. Main targets were the liver, thyroid hormone homeostasis and the reproductive, nervous and immune systems. HBCDDs are not genotoxic. The CONTAM Panel identified neurodevelopmental effects on behaviour as the critical endpoint, and derived a benchmark dose lower confidence limit for a benchmark response of 10 % (BMDL<sub>10</sub>) of 0.79 mg/kg b. w. Due to the limitations and uncertainties in the current data base, the CONTAM Panel concluded that it was inappropriate to use this BMDL to establish a health-based guidance value, and instead used an MOE approach for the health risk assessment of HBCDDs. Since elimination characteristics of HBCDDs in animals and humans differ, the Panel used the body burden as starting point for the MOE approach. The CONTAM Panel concluded that based on the available data current dietary exposure to HBCDDs in the European Union does not raise a health concern.

As knowledge about the occurrence and the levels of HBCDDs in edible tissues of farmed game and rabbits is currently lacking, inclusion in the NRCPs should be considered.

# (f) Perfluorinated compounds (PFCs)

Perfluorinated compounds (PFCs), such as PFOS, PFOA and others, have been widely used in industrial and consumer applications including stain- and water-resistant coatings for fabrics and

carpets, oil-resistant coatings for paper products approved for food contact, fire-fighting foams, mining and oil well surfactants, floor polishes, and insecticide formulations. A number of different perfluorinated organic compounds have been found widely in the environment. In 2008, EFSA delivered a risk assessment on PFOS and PFOA in food (EFSA, 2008g). The CONTAM Panel established a tolerable daily intake (TDI) for PFOS of 150 ng/kg b.w. per day and a TDI for PFOA of 1.5  $\mu$ g/kg b.w. per day. Some few data indicated the occurrence of PFOS and PFOA in meat samples. However, due to the low number of data, it has not been possible to perform an assessment of the relative contribution from different foodstuffs to human exposure to PFOS and PFOA.

In 2011, EFSA published a scientific report on 'Results of the monitoring of perfluoroalkylated substances in food in the period 2000-2009 (EFSA, 2011). For this report, a total of 4 881 samples from 7 MS were considered for a detailed data analysis. The highest contamination frequency and levels were found in the food category 'Edible offal, game animals'. Some 96 % of the analyses carried out in this food category were on wild boar liver. Of the eleven perfluorinated compounds for which analyses were carried out within this food category, PFOS and PFOA were the compounds mostly analysed. PFOS, PFOA, perfluornonanoic acid (PFNA), perfluordecanoic acid (PFDA) and perfluordodecanoic acid (PFDoDA) were found in over 90 % of the samples. The highest concentrations in liver were reported for PFOS with mean concentrations of 216  $\mu$ g/kg (both lowerbound and upperbound) based on 874 samples analysed, of which 849 were positive. Compared to PFOS, the frequency of positive results for PFOA was roughly 2.5-times lower; the mean lowerbound and upperbound values were 50-30 times lower. Although the number of samples analysed for PFNA, PFDA and PFDoDA was relatively limited, the frequency of positive samples was higher than 90 %. These findings were substantiated by more recent data from EFSA in 2012 (EFSA, 2012c).

The EFSA report (EFSA, 2011) states that an overestimation may occur in products of animal origin, notably in liver, due to interference of PFOS with bile acids, such as taurodeoxycholic acid. Thus, it could not be ruled out whether all methods applied for obtaining the data included in the report were selective enough to completely discriminate between perfluorinated compounds and the interfering substances.

Although it was not stated how many liver samples originated from farmed wild boar, the high frequency of positive samples is an indicator that perfluorinated compounds are frequent contaminants in edible offal of game animals and particularly in wild boar liver.

As perfluorinated compounds have found widespread use and ubiquitous distribution in the environment, but data on their occurrence in meat from farmed game and rabbits are lacking, inclusion of these compounds in the NRCPs should be considered.

# (g) Radioactive caesium

Council Regulation (EC) No 733/2008<sup>35</sup> of 15 July 2008 on the conditions governing imports of agricultural products originating in Third Countries following the accident at the Chernobyl nuclear power station sets accumulated maximum radioactive level in terms of caesium-134 and caesium-137 of 370 Bq/kg for various milk and milk products and for foodstuffs intended for the special feeding of infants during the first four to six months of life, and 600 Bq/kg for all other products concerned. While these provisions apply to imports from Third Countries, Commission Recommendation 2003/274/EURATOM<sup>36</sup> refers to Council Regulation (EC) No 733/2008 and recommends, for the purpose of protecting the health of the consumer, that MS should take appropriate steps to ensure that the above maximum permitted levels in terms of caesium-134 and caesium-137 are respected in the

<sup>&</sup>lt;sup>35</sup> Council Regulation (EC) No 733/2008 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station. OJ L 201, 30.7.2008, p. 1–7.

<sup>&</sup>lt;sup>36</sup> Commission Recommendation of 14 April 2003 on the protection and information of the public with regard to exposure resulting from the continued radioactive caesium contamination of certain wild food products as a consequence of the accident at the Chernobyl nuclear power station. OJ L 99, 17.4.2003, p. 55.

Community for the placing on the market of wild game, wild berries, wild mushrooms and carnivorous lake fish<sup>37</sup>.

According to recital 10 of this Recommendation, certain wild berries, edible wild mushrooms, wild game meat from roe deer and red deer and carnivorous freshwater fish from lakes in certain regions of the EU continue to show levels of radioactive caesium exceeding 600 Bq/kg.

# 3. TOR 2: Strengths and weaknesses of the current meat inspection methodology

In the light of the existing regulations and the daily practice of the control of residues/chemical substances in farmed game and rabbits, the strengths and weaknesses of the current meat inspection methodology can be summarised as follows.

# **3.1.** Strengths of the current meat inspection methodology for chemical hazards

The strengths of the current meat inspection methodology for chemical hazards are as follows:

- Residue testing is based on common standards for method performance and interpretation of results (Commission Decision 2002/657/EC), laboratory accreditation (ISO/IEC 17025) and quality assurance schemes (QAS). The NRCPs are supported by a network of EU and National Reference Laboratories and by research in the science of residue analysis that serves to provide state-of-the-art testing systems for control of residues and contaminants (see Annex A).
- For farmed game, such as deer, wild boar and ostriches, the production site is known and, therefore, collection of FCI, traceability and follow-up mechanisms are possible.
- In the case of rabbits reared in integrated systems, a high degree of FCI is provided to the slaughterhouse. Moreover, there are well-developed systems and follow-up mechanisms subsequent to the identification of non-compliant samples.
- In the case of rabbits reared in integrated systems, regular sampling and testing for chemical residues and contaminants is a disincentive for the development of undesirable practices.
- For rabbits reared in integrated systems, the current combination of FCI and ante- and postmortem inspection has been found, in general, to be supportive of the collection of appropriate samples for monitoring of chemical residues and contaminants.

# **3.2.** Weaknesses of the current meat inspection methodology for chemical hazards

The weaknesses of the current meat inspection methodology for chemical hazards are as follows:

- Chemical hazards generally cannot be detected by current *ante-/post-mortem* meat inspection procedures.
- In the case of both farmed game and rabbits, there is poor integration between the testing of feed materials for undesirable substances and the NRCPs in terms of communication and follow-up testing strategies or interventions.
- For some farmed game, such as reindeer, FCI may be incomplete (particularly relating to environmental contaminants) due to the fact that the animals are migratory herds.
- For rabbits reared in small holdings, FCI may be incomplete because of the trading practices for these animals prior to slaughter.

<sup>&</sup>lt;sup>37</sup> It is reported (technical hearing reference) that, for the control of radioactivity (caesium-137) in reindeer, the following controls are applied in one MS: a sampling programme for caesium-137 for each year is applied and revised based on the findings for the previous year; animals may be diverted to 'clean' areas for feeding or slaughtered early to reduce exposure. External direct monitoring of carcasses occurs at slaughterhouses. If greater than a particular level is detected, a muscle sample is taken for further confirmatory testing, which may result in carcass condemnation.



#### 4. TOR 3: New hazards

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

Considering the recent information available from the re-assessment of undesirable substances in the food chain, covered by more recent EFSA opinions of the CONTAM Panel, additional compounds have been identified that require attention. Prominent examples of such substances are dioxins and DL-PCBs, as they bioaccumulate in the food chain and have a toxicological profile that points towards public health concerns even at low concentrations. In addition, it has been shown that these substances are found in edible tissues of farmed game and rabbits (see Section 2.3.5.5.1). Other halogenated substances such as brominated flame retardants, including PBDEs as well as HBCDDs, and PFCs, such as PFOS and PFOA, have a different toxicological profile. They bioaccumulate in the food chain and deserve attention, as currently the knowledge about the prevalence and level of residues of these compounds in edible tissues from farmed game and rabbits is limited. Inclusion of these various substances in the NRCPs should be considered to support forthcoming decisions on whether or not these substances require continued monitoring in slaughter animals. (Note: further detailed information on each of these compounds is presented in Section 2.3.5.5.1.)

Due to the nature of the husbandry systems applied, farmed game are more likely to be exposed to environmental contaminants (including radioactivity in certain geographic regions) than some other livestock. Therefore, any incident giving rise to contamination of the environment may be observed primarily in farmed game kept outdoors.

#### 5. TOR 4: Adaptation of inspection methods

Game farming in the EU is extremely diverse, with substantial differences between species (deer, reindeer, ostriches and wild boar). It cannot be compared with rabbit farming which in many areas has evolved towards intensive farming practices. Therefore, the types and likelihood of occurrence of chemical residues and contaminants varies between these animal species.

For farmed game and rabbits, the FCI should provide information on the specific environmental conditions of the farms where the animals are reared, including treatments. It is recommended that sampling of farmed game and rabbits should be based on the risk of occurrence of chemical residues and contaminants and on the completeness and quality of the FCI supplied.

With some few exceptions, for example some antiparasitic agents, VMPs are not specifically licensed for farmed game. However, diseased or injured animals will be treated as required. In this case, veterinarians may follow the rules applying to the so-called 'cascade usage', mainly established for minor species and minor indications for use. Applying the 'cascade usage', a minimum withdrawal period of 28 days is required for meat from avian species and mammals. For farmed wild boar, medication used for pigs are preferential and established withdrawal periods provide a good indication about the risk of undesirable residues in animal tissues. Any medication given to farmed game should be presented in on-farm registries serving as FCI prior to slaughter.

For rabbits, kept on integrated farms, full FCI including documentation on all treatments is mandatory. As for this minor species only a very few VMPs are licensed, all other compounds are used under the 'cascade usage' system for which a withdrawal period of 28 days is required, unless a national registration provides specific information regarding a species-specific withdrawal period.

In contrast to the current specification, under European Commission Decision 97/747/EC, that a minimum of 100 samples of farmed game (unspecified as to species) are to be taken annually for

NRCP testing, the number of samples to be taken for each species of farmed game should be proportional to the production in each MS.

Better integration of results from official feed control with residue monitoring seems essential to indicate whether monitoring of residues in slaughter animals needs to be directed to particular substances. Therefore, there is a need for an improved integration of sampling, testing and intervention protocols across the food chain, NRCPs, feed control and monitoring of environmental contaminants.

As for other livestock species, the application of analytical techniques covering multiple analytes and of new biologically based testing approaches should be encouraged and incorporated into the residue control programmes.

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.

#### **CONCLUSIONS AND RECOMMENDATIONS**

This section contains conclusions derived from the information discussed in the document, together with recommendations for improvements to meat inspection with regard to chemical hazards within the EU.

TOR 1. To identify and rank the main risks for public health that should be addressed by meat inspection at European Union (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

- Game farming (deer, reindeer, ostriches and wild boar) is markedly different to rabbit farming and the types and likelihood of occurrence of chemical residues and contaminants varies between these animal species. Therefore, farmed game and rabbits were considered separately in the identification and ranking of risks for public health.
- As a first step in the identification and ranking of chemical substances of potential concern, the EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) considered the substances listed in Council Directive 96/23/EC and evaluated the outcome of the national residue control plans (NRCPs) for the period 2005–2010. The CONTAM Panel noted that 0.91 % of the total number of farmed game samples and 0.67 % of the total number of rabbit samples were non-compliant for one or more substances listed in Council Directive 96/23/EC. The available aggregated data indicate the number of samples that were non-compliant with current EU/national 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 for a reliable assessment of consumer exposure.
- Other criteria used for the identification and ranking of chemical substances of potential concern include the identification of substances that are found in other testing programmes and which bio-accumulate in the food chain, and substances with a toxicological profile of concern, and the likelihood that a substance under consideration will occur in farmed game or in rabbit carcasses. Taking into account these criteria, the individual compounds were ranked into four categories denoted as of high, medium, low and negligible potential concern.
- In the case of farmed game, the highest overall proportion of non-compliant samples (3.0 %) was for Group B3 substances, contaminants (particularly cadmium) representing largely exceedances of the Maximum Levels/Maximum Residue Limits (MLs/MRLs) specified for these substances. For Group A, prohibited substances (0.35 %), and for Group B1/B2 substances, Veterinary Medicinal Products (VMPs) (0.19 %), the proportions of non-compliant



samples were much lower, representing largely illicit use of prohibited substances and exceedances of the MRLs specified for VMPs, respectively.

- For rabbits, the highest overall proportions of non-compliant samples were for Group B1/B2 substances, VMPs (0.98 %) and for Group B3 substances, contaminants (0.46 %), representing largely exceedances of the MRLs specified for VMPs and the MLs/MRLs specified for contaminants, respectively.
- No substances were classified in the high potential concern category for farmed game or for rabbits.
- Within the category of medium potential concern for farmed game are nitrofurans, nitroimidazoles and cadmium.
- Within the category of medium potential concern for rabbits are chloramphenicol and nitrofurans.
- All other compounds listed in Council Directive 96/23/EC are ranked as being of low or negligible potential concern due to the toxicological profile of these substances at residue levels in edible tissues, or to the very low or non occurrence of non-compliant results in the NRCPs for 2005–2010. Potentially higher exposure of consumers to these substances from farmed game or rabbit meat takes place only incidentally, as a result of mistakes or non-compliance with known and regulated procedures
- The CONTAM Panel emphasises that this ranking into specific categories of potential concern of prohibited substances, veterinary medicinal products and contaminants mainly applies to farmed game and rabbits and is based on current knowledge regarding the toxicological profiles, usage in the production of these animals, and occurrence as residues or contaminants, as demonstrated by the data from the NRCPs for the 2005–2010 period.

#### RECOMMENDATIONS

- Future monitoring programmes should be risk based, taking into account the ranking of chemical compounds into categories of potential concern.
- Both for farmed game and for rabbits, regular updating of the ranking of chemical compounds as well as of the sampling plans should occur, taking into account any new information regarding the toxicological profile of chemical residues and contaminants, usage in the production of these animals, and occurrence of individual substances as residues and contaminants.

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

The strengths of the current meat inspection methodology for chemical hazards are as follows:

- Residue testing is based on common standards for method performance and interpretation of results, laboratory accreditation and quality assurance schemes.
- For farmed game, such as deer, wild boar and ostriches, the production site is known and, therefore, collection of FCI, traceability and follow-up mechanisms are possible.



- In the case of rabbits reared in integrated systems, a high degree of FCI is provided to the slaughterhouse. Moreover, there are well-developed systems and follow-up mechanisms subsequent to the identification of non-compliant samples.
- In the case of rabbits reared in integrated systems, regular sampling and testing for chemical residues and contaminants is a disincentive for the development of undesirable practices.
- For rabbits reared in integrated systems, the current combination of FCI and *ante- and post-mortem* inspection has been found, in general, to be supportive of the collection of appropriate samples for monitoring of chemical residues and contaminants.

The weaknesses of the current meat inspection methodology for chemical hazards are as follows:

- Chemical hazards generally cannot be detected by current *ante-/post-mortem* meat inspection procedures.
- In the case of both farmed game and rabbits, there is poor integration between the testing of feed materials for undesirable substances and the NRCPs in terms of communication and follow-up testing strategies or interventions.
- For some farmed game, such as reindeer, FCI may be incomplete (particularly relating to environmental contaminants) due to the fact that the animals are migratory herds.
- For rabbits reared in small holdings, FCI may be incomplete because of the trading practices for these animals prior to slaughter.

#### RECOMMENDATION

• Meat inspection systems for chemical residues and contaminants should be less prescriptive and should be more risk and information based, with sufficient flexibility to adapt the residue monitoring programmes to results of testing.

# 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

- New hazards are defined as compounds that have been identified as anthropogenic chemicals in food-producing animals and derived products and in humans and for which occurrence data in farmed game and in rabbits are scarce and which may not be systematically covered by the NRCPs. Examples are polychlorinated dibenzo-*p*-dioxins, polychlorinated dibenzofurans (together often termed 'dioxins'), dioxin-like polychlorinated biphenyls (DL-PCBs), non dioxin-like polychlorinated biphenyls (NDL-PCBs), brominated flame retardants, such as polybrominated diphenylethers (PBDEs) and hexabromocyclododecanes (HBCDDs), and perfluorinated compounds, such as perfluoroctane sulfonate (PFOS) and perfluoroctanoic acid (PFOA).
- Due to the nature of the husbandry systems applied, farmed game are more likely to be exposed to environmental contaminants (including radioactivity in certain geographic regions) than some other livestock. Therefore, any incident giving rise to contamination of the environment may be observed primarily in farmed game kept outdoors.

#### RECOMMENDATION

• Control programmes under the NRCPs should include 'new hazards' and take into account information from environmental monitoring programmes which identify chemical hazards to which animals may be exposed.



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

- Game farming in the EU is extremely diverse, with substantial differences between species (deer, reindeer, ostriches and wild boar). It cannot be compared to rabbit farming, which in many areas has evolved towards intensive farming practices. Therefore, the types and likelihood of occurrence of chemical residues and contaminants varies between these animal species.
- With some few exceptions, VMPs are not specifically licensed for farmed game and only a very few are licensed for use in rabbits. However, diseased or injured animals will be treated as required under the 'cascade usage' system, for which a withdrawal period of 28 days is required, unless a national registration provides specific information regarding a species-specific withdrawal period.
- European Commission Decision 97/747/EC requires that a minimum of 100 samples of farmed game (unspecified as to species) are to be taken annually for the NRCP testing, rather than the level of testing being proportional to the production of each species in each MS.

#### RECOMMENDATIONS

- For farmed game and rabbits, the FCI should provide information on the specific environmental conditions of the farms where the animals are reared, including treatments. It is recommended that sampling of farmed game and rabbits should be based on the types and likelihood of occurrence of chemical residues and contaminants and on the completeness and quality of the FCI supplied.
- Any medication given to farmed game should be presented in on-farm registries serving as FCI prior to slaughter.
- The number of samples to be taken for each farmed game species should be proportional to the production in each MS.
- There is a need for an improved integration of sampling, testing and intervention protocols across the food chain, NRCPs, feed control and monitoring of environmental contaminants.
- As for other livestock species, the application of analytical techniques covering multiple analytes and of new biologically based testing approaches should be encouraged and incorporated into the residue control programmes.



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#### ANNEXES

#### Annex A: Analytical methods: performance characteristics and validation

#### **1. Method performance**

Commission Decision 2002/657/EC specifies the performance characteristics and interpretation of results for analytical methods used to implement the residue monitoring required by Council Directive 96/23/EC. According to this decision, suitable screening methods are those for which it can be demonstrated in a documented traceable manner that they are validated and have a false compliant rate of <5 % at the level of interest. In the case of confirmatory methods, distinction is made between those methods suitable for confirming the presence of prohibited (Group A) substances and those that may be used for confirming the presence of licensed VMPs and contaminants (Group B substances). For Group A substances, LC (liquid chromatography) or GC (gas chromatography) separation with MS (mass spectrometry) or IR (infrared) spectrometric detection is required and, in the case of MS techniques where mass fragments are produced, the relationship between different classes of mass fragment and identification points are specified, with a minimum of four identification points being required for confirmation. Apart from LC or GC chromatographic separation with MS or IR spectrometric detection, suitable confirmatory techniques for Group B substances may include LC with diode-array or fluorescence detection for appropriate molecules, two-dimensional thin layer chromatography (2-D TLC) with full-scan UV/VIS detection, and gas chromatography with electron capture detector (GC-ECD), LC-immunogram or LC-UV/VIS where at least two different chromatographic separations are used.

Commission Decision 2002/657/EC specifies the performance criteria for methods, including recovery and accuracy, trueness and precision. The Decision specifies, also, the validation required to demonstrate that each analytical method is fit for purpose. In the case of screening methods, validation requires determination of the performance characteristics of detection limit (CC $\beta$ ), precision, selectivity/specificity and applicability/ruggedness/stability. For confirmatory methods, in addition to determination of those performance characteristics, validation requires, also, determination of decision limit (CC $\alpha$ ) and trueness/recovery.

The analytical requirements for the determination of dioxins, dioxin-like and non dioxin-like PCBs are laid down in Commission Regulation (EC) No 252/2012<sup>38</sup>. Following a criteria approach analyses can be performed with whatever method, provided the analytical performance criteria are fulfilled. While methods, such as GC-MS, cell-and kit-based bioassays are allowed for screening purposes, the application of GC/high resolution MS is mandatory for confirmation of positive results.

#### 2. Screening methods

Screening methods include a broad range of methods, such as ELISAs, biosensor methods, receptor assays, bioassays and biomarkers for the presence of residues of concern. These screening methods generally use specific binding of the molecular structure of the residue(s) by antibodies or other receptors to isolate and measure the presence of the residues in biological fluids (urine, plasma) or sample extracts. More recently, biomarkers for the use of prohibited substances such as hormonal growth promoters have been identified as potential screening methods for these substances. Physicochemical methods, such as LC or GC with various detectors, may be used, also, as screening methods.

In the particular case of antimicrobials, microbiological or inhibitory substance tests are widely used for screening. In such tests, using multiple plates/organisms or kit formats, the sample or sample extract is tested for inhibition of bacterial growth. If, after a specific period of incubation, the sample

<sup>&</sup>lt;sup>38</sup> Commission Regulation (EU) No 252/2012 of 21 March 2012 laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EC) No 1883/2006. OJ L 84, 23.3.2012, p. 1–22.



inhibits the growth of the bacteria, it is considered that an antibacterial substance is present in the sample, but the specific substance is not identified. Given that this is a qualitative analytical method, a misinterpretation of the results cannot be ruled out, and some false positives can occur. Microbiological methods are screening methods which allow a high sample throughput but limited information is obtained about the substance identification and its concentration in the sample. When residues are found in a screening test, a confirmatory test may be carried out, which normally involves a more sophisticated testing method providing full or complementary information enabling the substance to be identified precisely and confirming that the MRL has been exceeded.

#### **3.** Confirmatory methods

With the significant developments in liquid chromatography and in mass spectrometry over the last decade, confirmatory methods are largely MS-based, using triple quadrupole, ion trap, and other MS techniques. Indeed, with current methodology in a modern residue laboratory with good MS capability, much of the two-step approach of screening followed by confirmatory testing has been replaced by single confirmatory testing. This has been made possible by the greatly-enhanced separation capability of ultra high performance liquid chromatography (UPLC), coupled with sophisticated MS detection systems. The parallel growth in more efficient sample extraction/clean-up methods is an integral part of these advances in confirmatory methods and such chemistries produce rapid, sometimes (semi)-automated procedures providing multi-residue capability. Techniques based on highly-efficient sorbent chemistries for solid-phase extraction and techniques such as QuEChERS (quick easy cheap effective rugged safe) are examples of these advances. Such combination of UPLC-MS/MS methods with appropriate sample extraction/cleanup technologies allows for unequivocal, quantitative determination of a broad spectrum of substances in a single analytical method.

Particularly in the area of prohibited substances, the power of MS techniques is being applied to identify hitherto unknown compounds and to identify exogenous from endogenous substances. For example, time-of-flight MS provides accurate mass capability and may allow for retrospective analysis capability from the MS data. The technique of GC–combustion–isotope ratio MS has been utilized to study the <sup>13</sup>C/<sup>12</sup>C ratio of substances in urine samples, where, for example, such <sup>13</sup>C/<sup>12</sup>C ratio differs significantly between endogenous (or natural) testosterone and exogenous (or synthetic) testosterone.



#### **ABBREVIATIONS**

ADI	acceptable daily intake
AHD	1- amino-hydantoin
AMOZ	3-amino-5-morpholinomethyl-1,3-oxazolidin-2-one
AOZ	3-amino-2-oxazolidinone
<b>BIOHAZ</b> Panel	EFSA Panel on Biological Hazards
BMD	benchmark dose
BMDL	benchmark dose lower confidence limit
$BMDL_{10}$	lower 95 % confidence limits for a benchmark response of 10 %
b.w.	body weight
ССα	decision limit
ССβ	detection limit
CONTAM Panel	EFSA Panel on Contaminants in the Food Chain
DL-PCB	dioxin-like polychlorinated biphenyls
2-D TLC	two-dimensional thin-layer chromatography
ECDC	European Centre for Disease Prevention and Control
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EU	European Union
FCI	food chain information
FEEDAP Panel	EFSA Panel on Additives and Products or Substances used in Animal Feed
FEDFA	Federation of Deer Farmers Associations
GC	gas chromatography
GC-ECD	gas chromatography with electron capture detector
HBCDD	hexabromocyclododecanes
НСН	hexachlorocyclohexanes
IARC	International Agency for Research in Cancer
IPCS	International Programme on Chemical Safety
IR	Infrared
i.v.	intravenous
LC	liquid chromatography
ML	maximum level
MOE	margin of exposure
MRL	maximum residue limit
MRPL	minimum required performance limit
MS	Member State/mass spectrometry
NC	non-compliant



NDL-PCB	non-dioxin-like polychlorinated biphenyl
NRCP	national residue control plan
NSAID	non-steroidal anti-inflammatory drug
OIE	World Organization for Animal Health
PBDE	polybrominated diphenylethers
PCB	polychlorinated biphenyls
PCDD	Polychlorinated dibenzo-p-dioxin
PCDF	polychlorinated dibenzofuran
PFC	perfluorinated compounds
PFDA	perfluordecanoic acid
PFDoDA	perfluordodecanoic acid
PFNA	perfluornonanoic acid
PFOA	perfluorooctanoic acid
PFC	perfluorinated compound
PFOS	perfluorooctane sulfonate
PSM	plant secondary metabolite
QAS	quality assurance schemes
QuEChERS	quick easy cheap effective rugged safe
RAL	resorcylic acid lactone
SEM	semicarbazide
TDI	tolerable daily intake
TEQ	toxic equivalent
TOR	term of reference
TWI	tolerable weekly intake
UPLC	ultra-high-performance liquid chromatography
VMP	veterinary medicinal product
WHO	World Health Organization



#### Appendix C. Assessment on animal health and welfare

#### SUMMARY

This opinion focuses on the implications for animal diseases and welfare conditions of changes to the current meat inspection system, as proposed by Biological Hazards (BIOHAZ) and Contaminants in the Food Chain (CONTAM) Panels. 'Implications for animal diseases and welfare' relates specifically to their monitoring and surveillance during meat inspection (that is, inspection at the slaughterhouse before and after slaughter, in this document referred to as *ante-mortem* and *post-mortem* inspection, respectively). Therefore, the objective of this work was to identify possible effects and to assess the possible consequences on surveillance and monitoring of animal diseases and welfare conditions if the proposed changes on meat inspection system were applied.

The Biological Hazards (BIOHAZ) Panel proposed the omission of palpation and incision in farmed game subjected to routine slaughter at *post-mortem* inspection. For farmed deer (inspected as domestic bovines), reindeer (inspected as domestic small ruminants) and wild boar (inspected as domestic swine), this implies omission of palpation and incision of several organs and lymph nodes.

For farmed lagomorphs and ostriches, the current meat inspection procedure (e.g. poultry procedure) is already visual only; therefore, as there are no changes in the general procedure, no impact has to be expected from this specific recommendation.

To assess the impact of changes to the current meat inspection on the overall sensitivity for surveillance and control of animal disease and welfare conditions in the above-mentioned farmed game species, a quantitative assessment was performed based on expert opinion and modelling. An external consortium (COMISURV), under the provision of EFSA procurement, performed this work. The detailed methodology, as well as results and conclusions, together with assumptions and limitations of the modelling, have been published elsewhere. Diseases and conditions considered were those having a high likelihood of detection at meat inspection where the surveillance component provided by meat inspection was significant for the whole surveillance of the condition. In addition, only conditions relevant to animal health and welfare and present in the EU were considered. A total of 11 diseases and welfare conditions of farmed deer and farmed wild boar were included in the assessment.

A stochastic model to quantify the monitoring and surveillance effectiveness of meat inspection in farmed game was developed. Definitions of typical and mild cases of each of the diseases and welfare conditions assessed were provided by experts, and the proportion of presentation of each of them was estimated. The most likely detection probability, as well as 5th and 95th percentiles (the probability intervals), were derived for each of the conditions both under the current meat inspection system and when a visual only system was applied.

The probability of detection was calculated for both detectable cases (mild and typical) and for all cases (Stage 2). Further modelling (Stage 3) was implemented to quantify the effectiveness of monitoring and surveillance in the overall monitoring and surveillance system, both prior to and following suggested changes to the meat inspection system. For endemic diseases and welfare conditions, the performance of surveillance for case-finding was measured as the detection fraction (the proportion of cases in the population that are detected by the meat inspection surveillance). For exotic diseases, the focus was placed on component sensitivity (probability that a surveillance system will detect at least one case, given that the disease is present in the population at a specific prevalence).

It should be noted that the word 'surveillance' as used in this opinion does not imply that any action is taken to capture, or act upon, the information. It merely points to the potential of these systems to be used for such purposes.

A significant reduction (non-overlapping 90 % probability intervals) in the overall effectiveness of the meat inspection procedure in the visual only scenario was seen only for tuberculosis in farmed deer, probably because of the omission of palpation and incision of lungs and respiratory tract lymph nodes in the visual only procedure. The same reduction in effectiveness from the current meat inspection system to the visual only was not observed in the case of tuberculosis in farmed wild boar, because the case definition of tuberculosis in farmed wild boar included poor body condition, which would be easily detectable already through *ante-mortem* inspection and, therefore, the omission of the other meat inspection tasks does not affect the detection probability. However, tuberculosis in farmed wild boar was further analysed, as the case definition of tuberculosis used by COMISURV was in contradiction to field data. No difference in detection effectiveness could be observed for the other farmed deer and wild boar diseases and welfare conditions examined when comparing the current and the visual only meat inspection systems.

When slaughterhouse and clinical surveillance components were compared, slaughterhouse surveillance was found to be far more effective than clinical surveillance for the detection of tuberculosis in farmed red deer. In the absence of other surveillance methods, the contribution of meat inspection to the overall surveillance should be regarded as important.

Overall, clinical surveillance in farmed wild boar had a greater sensitivity for detecting African swine fever and classical swine fever than slaughterhouse surveillance, but the sensitivity of meat inspection was found to increase when the number of slaughtered farmed wild boar is high.

The consequences of a reduction in the detection effectiveness of tuberculosis in farmed deer and farmed wild boar were analysed by experts. It was concluded that elimination of palpation and incision would be strongly detrimental for the likelihood of detecting tuberculosis through meat inspection. As farmed deer and farmed wild boar can act as tuberculosis reservoirs, any reduction in the detection due to changes in the *post-mortem* inspection procedures will have some consequences for the overall surveillance of tuberculosis. From the analysis it was also evident that, in contrast with domestic animals such as cattle or pigs, farmed deer and farmed wild boar currently lack traceability and farming registry in several Member States, and this is likely to impede the tracing back of any detected tuberculosis cases to the farm of origin. In addition, the definition of a deer farm or wild boar farm is not homogeneous throughout the Member States. While acknowledging that meat inspection is a useful tool for tuberculosis detection in farmed deer and farmed wild boar, that both groups of farmed game are relevant as Mycobacterium bovis maintenance hosts and that many cases of confirmed infection only show small local lesions, it is recommended to maintain palpation and incision of lymph nodes and organs relevant for the diagnosis of tuberculosis, both for farmed deer and for farmed wild boar. The setting up of proper animal identification schemes throughout the Member States for these two farmed species, and the inclusion of premises where they are kept in the national tuberculosis monitoring and control programmes, would help to the overall surveillance of tuberculosis.

Reindeer is mainly farmed in northern regions of Norway, Sweden and Finland. Since reindeer are kept at low stocking densities and in sub-Arctic environmental conditions, the number of diseases affecting them and their prevalence is very low. Changes in meat inspection are not expected to significantly affect the surveillance of animal diseases in farmed reindeer.

The proposed changes to meat inspection are not expected to affect the detection levels of welfare conditions as winter death syndrome in farmed deer and trauma and injury in farmed deer and farmed reindeer, farmed wild boar can also be detected during visual only meat inspection.

Recommendations of the Contaminants in the Food Chain (CONTAM) Panel would not have a negative impact of surveillance of animal health and welfare conditions.



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#### 1. Introduction

In this mandate, the AHAW Panel and the *ad hoc* working group (WG) focus on the implications for animal health and welfare of any changes to the current meat inspection (MI) system, as proposed by Biological Hazards (BIOHAZ) and Contaminants in the Food Chain (CONTAM) Panels. 'Implications for animal health and welfare' relates specifically to monitoring and surveillance of animal health and welfare during MI (that is, inspection at the slaughterhouse before and after slaughter, in this document referred to as *ante-mortem* (AMI) and *post-mortem* (PMI) inspection, respectively). Therefore, the objective of this work is to identify possible effects and to assess the possible consequences on surveillance and monitoring of animal diseases and welfare conditions if the proposed changes on MI system were applied.

Apart from its contribution to assuring public health, current MI also contributes to surveillance and monitoring of animal diseases and welfare conditions, (EFSA, 2003) and may be an important component of the overall monitoring and surveillance system, or even be the unique place allowing for monitoring some diseases and welfare conditions at certain stages of a control and eradication programme. Therefore, any change in MI system that could lead to a loss of sensitivity (reduced probability of detection) may compromise the surveillance efficacy.

In the case of animal welfare, AMI and PMI play also a role in surveillance and monitoring welfare of farmed animals, and moreover, it is the only place to assess poor welfare during transport of animals to the slaughterhouse.

Although a significant growth in the production and consumption of farmed game animals, such as red deer, wild boar, rabbit and ostrich, has been observed in Europe, there is limited scientific literature concerning the welfare of these animals (with the possible exception of red deer) and their specific welfare needs during production stages, transport and slaughter.

Farmed red deer, reindeer, wild boars and ostriches have traditionally been slaughtered on farms but are nowadays transported to slaughterhouses for legislative (e.g. meat hygiene) or logistical (e.g. centralised slaughter) reasons, which inevitably leads to long transport distance and duration for some animals.

Since farmed game are not accustomed to being handled, they are prone to trauma and injury during stressful procedures such as herding on the farm, loading, transport, unloading, lairage and pre-slaughter handling in slaughterhouses. Slaughterhouse surveillance system (AMI and PMI) is the only place where poor welfare during handling and transport of farmed game animals can be detected.

### 2. Implications for surveillance and monitoring for farmed game health and welfare of changes to meat inspection as proposed by the BIOHAZ Panel

#### 2.1. The proposed BIOHAZ Panel changes

The proposed modifications for the MI system which may have implications for animal health and welfare, see BIOHAZ Appendix A for full details) are summarised below:

• Omission of palpation and incision, for farmed deer, reindeer and farmed wild boar subjected to routine slaughter at PMI (see BIOHAZ Appendix A, Section 5.2.3).

For rabbit and ostrich, as visual only MI is performed (i.e. no palpation and incision), then no changes are being proposed by the BIOHAZ Panel. Consequently, rabbits and ostriches will not be discussed any further in Appendix C of the opinion.



## 2.2. Quantitative assessment of the impact of changes on meat inspection on the effectiveness of the detection of animal diseases and welfare conditions (COMISURV report)

To assess the impact of proposed changes to the current MI on the overall sensitivity for surveillance and control of animal diseases and welfare conditions, a quantitative assessment was performed based on expert opinion and modelling. An external consortium (COMISURV), under the provision of an EFSA procurement, performed this work. As specified in Section 1 of this appendix, MI procedures are different for the species included under farmed game. Therefore, scenarios compared by the COMISURV consortium were also different for each species. For red deer and wild boar, the current systems (e.g. bovine MI and swine MI respectively) were compared to a visual only scenario. Reindeer was not included in the COMISURV assessment. For lagomorphs and ostriches, the current MI procedure (e.g. poultry procedure) is already visual only; therefore, as there are no changes in the general procedure, no impact is to be expected from this specific recommendation. Consequently, data related to domestic rabbits and ostriches in the COMISURV report will not be further analysed in this opinion.

#### 2.2.1. Materials and methods

The detailed methodology, as well as results and conclusions, together with assumptions and limitations of the modelling, can be found in the COMISURV report for farmed game MI (Dadios et al., 2012). These limitations include:

- The parameters for the probability of detection were based on expert opinion and therefore there is uncertainty as to the true range of these values.
- Scarcity of peer reviewed scientific literature on the role of meat inspection on surveillance of farmed game diseases and welfare conditions.
- Limited number of experts to cover the different subjects needed for the assessment.
- Variations in the epidemiological situation of the disease and welfare conditions between countries.

A brief description of the methodology that was applied in the COMISURV report is given below.

2.2.1.1. Identification of diseases and conditions which could be affected by changes in meat inspection

An initial long list of farmed game diseases and welfare conditions relevant to the EU was established, based on general textbooks, references and expert opinion. WG experts filtered this list using a decision tree, following previous methodology and criteria developed for previous opinions (EFSA BIOHAZ, CONTAM and AHAW Panels, 2011, 2012). A disease or condition was retained on the list by the WG experts using the following criteria:

- A high likelihood of detection of a disease or welfare condition at MI, at the age that animals are presented at the slaughterhouse (if likelihood was medium, low, or the condition was undetectable, it was excluded from the list).
- The disease or welfare condition is considered relevant to the EU (conditions not occurring in EU Member States (MS) were omitted).
- The condition is relevant to animal health and welfare (conditions mainly relevant to public health were not retained, as they should be dealt with by the BIOHAZ Panel).



• The slaughterhouse surveillance component (AMI + PMI) provided by MI is significant for the overall surveillance of the disease or welfare condition (if there are other surveillance or detection systems much more effective and highly preferable to MI, the conditions were removed from the list).

The final list of conditions established by the WG experts to be assessed by the COMISURV consortium is shown in Table 1. For deer, a total of seven conditions (five diseases and two welfare conditions) and for wild boar four conditions (three diseases and one welfare condition) were included in this list.

2.2.1.2. Development of a stochastic model to quantify the effectiveness of meat inspection

A stochastic model to quantify the monitoring and surveillance effectiveness of MI in farmed game was developed. A definition of a typical and a mild case of each of the conditions listed in Table 1 was provided by experts.

Typical cases were by definition detectable cases and express more developed clinical signs than mild cases. Typical cases were defined as those in which clinical signs and/or lesions were expected to be observed in more than 60 % of affected or infected animals arriving at slaughter.

A mild case of a disease or welfare condition is the form that can be seen at the early stages of the disease or at some point between the subclinical (and without pathological lesions that are observable through the meat inspection process) and the fully developed form (i.e. "typical" form). A mild case is neither typical nor non-detectable. The animal will probably present more subtle signs than in the typical case. As an example, a typical case of tuberculosis at PMI was one showing abscesses or granulomas in the lymph nodes of the head, and especially in the retropharyngeal lymph nodes, and a mild case was defined as having enlarged retropharyngeal and/or mesenteric lymph nodes.

The proportion of presentation of each of these forms, as well as the non-detectable fraction was estimated (see COMISURV report for details).

The most likely detection probability, as well as the 5th and 95th percentiles (the probability intervals) of the output distribution of AMI, PMI, and both combined, were derived for each of the conditions in Table 1, by expert elicitation, both prior to and following suggested changes to the MI system as proposed by BIOHAZ. The inspection protocols in the current and visual only systems are compared in Table 2 (farmed red deer, inspected using the bovine MI protocol) and Table 3 (farmed wild boar, inspected using the domestic swine MI protocol).

The probability of detection was calculated for both detectable cases (mild and typical) and for all cases (referred to as Stage 2 in the COMISURV report).

For the assessment of the relative importance of the MI system as part of the whole disease surveillance system (referred to as Stage 3 in the COMISURV report), a comparison was made with surveillance using clinical signs, looking at the proportion of infected or affected animals among the population that are successfully detected in either system (for endemic diseases and welfare conditions) as well as the sensitivity of the different surveillance components in detecting one or more infected animals within a period of a month (for exotic conditions). One disease or welfare condition per species, considered to be more adversely affected in terms of detection probability following the proposed changes to the MI system, was included in this extended analysis.

Note that the word "surveillance" as used in the COMISURV report does not imply that any action is taken to capture, or act upon, the information. It merely points to the potential of these systems to be used for such purposes.



Species	Nature of condition	Disease or welfare condition	Stage 2 <sup>1</sup>	Stage 3 <sup>1</sup>
Deer <sup>3</sup>	Epidemic	Foot and mouth disease (FMD)	Х	
	Endemic	Necrobacillosis	Х	
		Pasteurellosis	Х	
		Tuberculosis (M. bovis) (TB)	Х	Х
		Yersiniosis	Х	
	Welfare	Trauma. Injuries	Х	
		Winter death syndrome (WDS)	Х	
Boar	Epidemic	Classical swine fever (CSF)/African swine fever (ASF)	Х	Х
	-	FMD	Х	
	Endemic	Tuberculosis ( <i>M. bovis</i> ) (TB)	Х	
	Welfare	Trauma. Injuries	Х	

**Table 1:** Diseases and welfare conditions in farmed game identified by the AHAW WG for consideration in the assessment conducted by COMISURV.

<sup>1</sup> Stage 2 - all diseases and welfare conditions listed were evaluated with regards to their probability of being detected at MI.

<sup>2</sup> Stage 3 - for selected diseases and welfare conditions, surveillance by MI was to be compared with clinical surveillance.

<sup>3</sup> Red deer (*Cervus elaphus*).

**Table 2:** List of *ante-mortem* and *post-mortem* inspection procedures for bovines under and over six weeks old (applicable to farmed red deer) according to Regulation (EC) 854/2004 (the current procedure) and according to the proposed changes in procedures based on visual inspection (visual-only), where V represents visual inspection; I represents incision; P represents palpation. Grey boxes indicate inspection points where the visual only scenario implies a change to current procedures for bovine under and/or over six weeks old.

	Inspectio	on step			procedure			
	-	-	Current Visual only					
			Bovine <6 weeks	Bovine >6 weeks	Bovine <6 weeks	Bovine >6 weeks		
AMI	Food chain information	Diseases, morbidity and mortality on farm	V	V	V	V		
	Live animal	General health	V	V	V	V		
	Whole carcass	External surface	V	V	V	V		
	Head	Head and throat	V	V	V	V		
		Retropharyngeal lymph nodes	Ι	Ι	V	V		
		Submaxillary and parotid lymph nodes	_	Ι	_	V		
		External and internal masseter	_	V+I	_	V		
		Mouth and fauces	V	V	V	V		
		Tongue	Р	Р	V	V		
	Lungs	Parenchyma	$V + P + I^1$	$V + P + I^1$	V	V		
		Trachea	$V + I^1$	$V + I^1$	V	V		
		Major bronchi	$I^1$	$I^1$	V	V		
		Mediastinal lymph nodes	Ι	Ι	V	V		
		Bronchial lymph nodes	Ι	Ι	V	V		
	Oesophagus		V	V	V	V		
	Heart	Heart	V + I	V+I	V	V		
		Pericardium	V	V	V	V		
	Diaphragm		V	V	V	V		
	Liver	Parenchyma	$V + P + I^2$	V +P+ I	V	V		
IMA		Hepatic lymph nodes (=portal)	$V + P + I^2$	V + P	V	V		
		Pancreatic lymph nodes	$V + I^2$	V + P	V	V		
	GI tract	Stomach and intestines	V	V	V	V		
		Mesentery	V	V	V	V		
		Gastric lymph nodes	$V + P + I^2$	$V + P + I^2$	V	V		
		Mesenteric lymph nodes	$V + P + I^2$	$V + P + I^2$	V	V		
	Spleen		$V + P^3$	$V + P^3$	V	V		
	Kidneys	Parenchyma	$V + I^2$	$V + I^2$	V	V		
		Renal lymph nodes	$V + I^2$	$V + I^2$	V	V		
	Uterus and mammary	Uterus	-	V	-	V		
	glands	Udder	-	$V + P^3 + I^1$	-	V		
		Supramammary lymph nodes	-	$V + P^3 + I^2$	-	V		
	Pleura		V	V	V	V		
	Peritoneum		V	V	V	V		
	Umbilical area		$V + P + I^4$	-	V	-		
	Joints		$V + P + I^4$	-	V	_		
	Synovial fluid		V	_	V	_		



1 Not required if not intended for human consumption.

2 Incision if necessary

3 Palpation if necessary

4 Incision if in doubt.

**Table 3:** List of *ante-mortem* and *post-mortem* inspection tasks in swine (applicable to farmed wild boar) 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 s	Inspection procedure			
	•		Conventional	Visual only	
AMI	Food chain information	Diseases, morbidity and mortality on farm	V	V	
	Live animal	General health	V	V	
	Whole carcass	External surface	V	V	
	Head	Head, mouth, throat, etc.	V	V	
		Submaxillary lymph nodes	Ι	_1	
		Tongue	V	V	
	Lungs	Parenchyma	$V + P + I^2$	V	
		Trachea	$V + I^{2}, V^{3}$	V	
		Major bronchi	$I^2$	_1	
		Mediastinal lymph nodes	Р	_1	
		Bronchial lymph nodes	Р	_1	
	Oesophagus		V	V	
	Heart	Heart	V+I	V	
		Pericardium	V	V	
	Diaphragm		V	V	
	Liver	Parenchyma	V + P	V	
IMI		Hepatic lymph nodes (=portal)	V + P	V	
4		Pancreatic lymph nodes	V	V	
	GI tract	Stomach and intestines	V	V	
		Mesentery	V	V	
		Gastric lymph nodes	V + P	V	
		Mesenteric lymph nodes	V + P	V	
	Spleen		V	V	
	Kidneys	Parenchyma	V	V	
	Uterus and mammary	Uterus	V	V	
	glands	Udder	V	V	
		Supramammary lymph nodes	$V + I^3$	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.



#### 2.2.2. Results and discussion

The detection probability of the different diseases and welfare conditions for detectable cases are shown in Table 4 (Stage 2 of the COMISURV assessment). The values indicate the effectiveness of MI as a means of detecting the disease or condition in question. Any statements regarding significant differences between the current and the alternative scenarios are based on non-overlapping 90 % probability intervals.

No difference could be observed in detection effectiveness for most farmed red deer and farmed wild boar diseases and welfare conditions (see Table 4), when comparing the current MI system and the visual only one. The only significant difference in the effectiveness between the current and the visual only meat inspection scenarios was seen for tuberculosis (TB) in deer, with a significant reduction in the probability of detection of this disease for the visual only meat inspection. The most likely detection probability was 0.76 (0.70-0.82 probability intervals) for the current MI system and 0.38 (0.34-0.45 probability intervals) for the visual only MI.

It has to be noted that the same decrease in effectiveness resulting from changing from the current MI system to the visual only was not observed in the case of TB in farmed wild boar. This finding was attributed to the fact that the definition of TB in farmed wild boar included poor body condition, which would easily be detectable through visual inspection and, therefore, the omission of the other MI tasks do not affect the detection probability. However, this case definition of TB is not supported by field data (Christian Gortázar, University of Castilla-La Mancha, Spain, personal communication, 2013) (see Section 2.3.3 for a detailed discussion). It is also worth noting that, in contrast to farmed wild boar, poor body condition was not included in the case definition of TB in deer in the COMISURV report.

**Table 4:** The probability of detection of eleven farmed deer and farmed boar diseases and welfare conditions at AMI and PMI for detectable cases and for all MI scenarios (detection effectiveness). Note that PMI estimates are conditional on cases not being detected at AMI. Detection probabilities were derived for two different PMI scenarios. Most likely values (mode) as well as 5th and 95th percentiles are given.

	1 51 10							F	MI				Com	oined A	MI an	d PMI	
Animal species		e or welfare	AMI		Current		Visual only			Current			Visual only		ıly		
species	condition -		5 %	Mode	95 %	5 %	Mode	95 %	5 %	Mode	95 %	5 %	Mode	95 %	5 %	Mode	95 %
Deer <sup>1</sup>	Epidemic	FMD	0.02	0.06	0.08	0.31	0.46	0.51	0.31	0.46	0.51	0.36	0.50	0.57	0.36	0.49	0.56
	Endemic	Necrobacillosis	0.07	0.12	0.18	0.67	0.74	0.80	0.67	0.75	0.80	0.80	0.88	0.90	0.80	0.87	0.90
		Pasteurellosis	0.77	0.85	0.90	0.08	0.13	0.19	0.08	0.13	0.18	0.95	0.98	0.99	0.94	0.97	0.99
		TB (M. bovis)	0.00	0.00	0.00	0.70	0.75	0.82	0.34	0.38	0.45	0.70	0.76	0.82	0.34	0.38	0.45
		Yersiniosis	0.70	0.72	0.73	0.27	0.28	0.30	0.26	0.28	0.29	1.00	1.00	1.00	0.99	1.00	1.00
	Welfare	Trauma, injuries	0.44	0.69	0.76	0.17	0.25	0.32	0.16	0.24	0.32	0.62	0.97	0.97	0.62	0.96	0.97
		WDS	0.51	0.59	0.69	0.27	0.36	0.43	0.27	0.34	0.43	0.92	0.96	0.98	0.92	0.96	0.98
Boar	Epidemic	CSF or ASF	0.59	0.64	0.72	0.14	0.19	0.23	0.13	0.17	0.23	0.78	0.85	0.89	0.78	0.84	0.88
		FMD	0.57	0.62	0.69	0.14	0.19	0.23	0.14	0.19	0.23	0.76	0.82	0.86	0.76	0.82	0.86
	Endemic	TB (M. bovis)	0.27	0.40	0.51	0.30	0.37	0.52	0.29	0.38	0.49	0.72	0.79	0.86	0.70	0.75	0.84
	Welfare	Trauma, injuries	0.69	0.74	0.83	0.15	0.22	0.28	0.15	0.23	0.28	0.95	0.98	0.99	0.95	0.98	0.99

1 Red deer (Cervus elaphus).

Shaded rows indicate diseases identified as having a significant reduction in detection probability in the visual only scenario.

When MI surveillance component and surveillance by clinical observation in the field were compared (Stage 3), MI was far more effective for the detection of TB in deer, and in the absence of other surveillance methods its contribution to the overall surveillance should still be regarded as important.

The sensitivity of MI surveillance and clinical surveillance for ASF and CSF is shown in Table 5. Overall, clinical surveillance had a greater sensitivity for detecting ASF or CSF than slaughterhouse surveillance, but sensitivity of MI increased when the number of slaughtered wild boar becomes higher. This indicates that for those countries in Europe with a large farmed wild boar population, clinical surveillance is highly effective for detecting one or more cases of the infection, should it be introduced at a level corresponding to the design prevalence or higher. For countries with high numbers of slaughtered farmed game, the slaughterhouse surveillance would detect these diseases as effectively as clinical surveillance.

**Table 5:** Estimated sensitivity of the slaughterhouse inspection and clinical surveillance components in the detection of swine fevers (classical and African) in wild boar, at three different population sizes.

Population	Slaug	hterhous	se inspec	tion			Clinic	al surve	illance <sup>1</sup>
size (n)		Curren	t	V	isual on	ly			
	0.05	ML	0.95	0.05	ML	0.95	0.05	ML	0.95
100 000	0.14	0.23	0.37	0.13	0.23	0.37	0.98	1.00	1.00
1 000 000	0.77	0.97	0.99	0.77	0.98	0.99	1.00	1.00	1.00
10 000 000	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00

1 Estimates based on the monthly number of slaughtered animals with a design prevalence of 0.2 % at the herd level and 10 % within herd.

ML – Most likely values

## **2.3.** Qualitative assessment of the role of meat inspection in surveillance programmes on selected diseases and welfare conditions

The qualitative assessment involved literature review and expert opinions from the WG members on tuberculosis in farmed deer and farmed wild boar and reindeer diseases and welfare conditions of farmed game.

#### 2.3.1. General overview of tuberculosis in European wildlife and farmed game

TB is a typical multi-host disease, where infection is maintained in a complex matrix of domestic and wild hosts. The goal of TB eradication in cattle requires the development of strategies that reduce pathogen transmission between wildlife and domestic animals and between non-bovine livestock and cattle (O'Reilly and Daborn, 1995). In Europe, three wildlife hosts are regionally defined as maintenance hosts, meaning they are able to maintain and transmit the infection to other species including cattle: the Eurasian badger (Meles meles; mainly in the British Islands), the Eurasian wild boar (mainly in the Iberian Peninsula) and deer of the subfamily Cervinae (red, sika and fallow deer) in several regions (Gortázar et al., 2012). The latter two hosts (or host groups) are also occasionally farmed and thus belong to the farmed game. Throughout Europe, widespread sustained growth in the hunting harvest of red deer and wild boar has occurred, which is consistent with the continued growth of wild ungulate populations and associated social and economic impacts (Sáez-Royuela and Telleria 1986; Milner et al., 2006). Regarding TB, it is important to consider that wild boar and deer are found in different compartments: (1) farms, (2) farm-like (often fenced) hunting estates or preserves where animals are fed, and (3) open (truly wild) populations. The risk of TB is much higher in farmed game than in wildlife conditions. Although the mandate applies only to regular farmed game (i.e. compartment 1), it must be taken into account that this gradient from true farms to true wildlife exists, that movements between compartments occur, and that the limits between compartments are unclear and not harmonised in the different MSs.

TB in wildlife is not notifiable in EU MSs, with the exception of Finland and Sweden, and in the UK in the case of deer (as suspect *post-mortem* lesions). Elsewhere in Europe, TB in wildlife is notifiable only in Norway (EFSA, 2009). Furthermore, wildlife populations (primarily wild boar and deer) are not routinely monitored for mycobacterial infections in all MSs, and results may not always be reported (EFSA, 2009). Consequently, we can have little confidence that TB infection is truly absent in wild mammal populations in many countries, despite the absence of reported cases. Moreover, it has been speculated that, given the current geographical and numerical expansion of wild hosts of TB in parts of Europe and the emergence of risk factors related to habitat change and game management, including farming, fencing and feeding, the importance of wildlife in the epidemiology of *Mycobacterium bovis* infection in domestic animals may continue to grow in the near future (Gortázar et al., 2012).

#### 2.3.2. Tuberculosis in farmed deer

Farmed deer are defined as animals that are farmed for commercial purposes and surrounded by fences or a barrier in order to prevent entry or exit. Deer farming ranges from extensive systems with no segregation by age or sex to highly technical facilities with sex and age segregation and individual identification. Farmed deer are produced for two purposes: for the supply of hunting animals and for the production of game meat. Farms often rear deer for both purposes.

#### 2.3.2.1. Description of the disease and prevalence and relevance in EU

Deer of the subfamily Cervinae are highly susceptible to TB. Although some inter-specific differences in lesion distribution occur, it has been established that investigation of deer for bTB-compatible lesions should include examination of the medial retropharyngeal, left tracheobronchial, mediastinal, mesenteric and ileocaecal lymph nodes. One third of known-infected deer do not show visible lesions. Almost 50 % of confirmed infected deer show generalised TB, defined as lesions occurring in more than one anatomical region (Martín-Hernando et al., 2010).

Wild deer TB has been described in 10 European countries in the last decades, including both Offically Tuberculosis Free (OTF) and non-OTF MSs: Austria, France, Germany, Hungary, Italy, Poland, Portugal, the Republic of Ireland, Spain and the UK (Gortázar et al., 2012). The best-known situation is currently that in Spain, where the mean prevalence of 10-15% of red deer with TB compatible lesions have been reported (Vicente et al., 2006), and local culture-confirmed infection prevalence ranges up to 27 % in red deer and 18 % in fallow deer in parts of the country (Gortázar et al., 2008). Hence, in Spain and Portugal red deer (and locally also fallow deer) are considered an impediment for cattle TB control (Gortázar et al., 2011). Risk assessments in the UK concluded that deer are a potentially significant risk to cattle (Delahay et al., 2007; Ward et al., 2009). This, along with increasing detection of cases in several countries, suggests that the role of deer in TB epidemiology is currently underestimated in some MSs.

Regarding farmed deer, sporadic TB cases have been described in Spain (Fernández-de-Mera et al., 2009), Sweden (cases originating from UK imports) and the UK (Wahlström, 2004). Most likely, the real situation is worse but not properly assessed since no compulsory and harmonised surveillance systems are currently in place (see next Section).

#### 2.3.2.2. Surveillance system currently in place

TB being one of the main animal health concerns in the EU, and deer being a known reservoir host species, it is surprising that no compulsory and harmonised surveillance systems are currently in place. Regarding deer movements, there is as yet no specific legislation relating to intra-community trade in deer, although, with respect to TB, deer must either have come from an officially TB-free holding (based on the requirements for cattle, as defined in Directive 64/432/EEC) or have met defined clinical and testing criteria (no TB case recorded on holding for greater than 42 days, and negative to the tuberculin test in the 30 days prior to dispatch) (More et al., 2009). In Spain, Royal Decree



1082/2009<sup>39</sup> regulates the health requirements for translocation of wild animals (including farmed deer and wild boar). For farmed deer, this decree specifies TB as one of the compulsory diseases to test, and that movement shall not be allowed if TB is present in the farm. The earlier EFSA work on TB in deer (EFSA, 2008), and also that by More et al. (2009) highlighted the difficulty in gaining herd-level confidence of freedom from TB, particularly in areas where there is an ongoing risk of introduction of infection (areas where TB is endemic/present, in wildlife and farmed animals). Unfortunately, no similar regulation exists for other EU MSs. Regarding wildlife, only a few MSs have a formal wildlife disease surveillance scheme allowing the prevalence of TB in hunter-harvested deer to be monitored. Regarding deer farms, TB surveillance is currently hindered by several issues: (1) an insufficient definition of the farms; (2) the absence of any traceability of farm-reared deer in many MSs; and (3) the lack of a formal definition of how this surveillance should be carried out. To overcome these barriers, every MS should set up a proper registry of the existing deer farms (including a proper definition of a deer farm, probably including all fenced populations); all farmed deer should compulsorily be permanently marked (ear tag or microchip) to allow tracing of, at least, their farm of origin, and surveillance based on a combination of skin-testing and post-mortem examination (where applicable) of farmed deer, in combination with disease surveillance in hunter-harvested wild deer, should be set up in a coordinated (harmonised) way.

#### 2.3.2.3. Impact of proposed changes on surveillance and control

Current deer meat inspection at slaughter is similar to the inspection of bovines, as defined in Regulation (EC) 854/2004 (see also Table 2). The changes proposed by the BIOHAZ Panel are to cease palpation and incision, largely because the main identified food-borne hazard (*Toxoplasma gondii*) is not detectable by meat inspection and incision might cause cross-contamination of carcasses by enterobacteria. The efficacy of MI procedures for detecting *M. bovis* infection may be influenced by many factors, related to the pathobiology of the infection, the intensity of inspection, the skills and dedication of the inspector, and other variables such as the speed of the chain, etc. (Corner, 1994). In the current EU MI procedure for deer (the same as in bovines), tasks aimed at detecting suspected tuberculous lesions include visual inspection and palpation of the lungs, and palpation and incision of relevant lymph nodes (e.g. mediastinal, tracheobronchial and medial retropharyngeal lymph nodes). If palpation of lungs and lymph nodes and incision of lymph nodes are omitted, small suspect lesions in these organs may go undetected.

It is generally accepted that the sensitivity of the current MI system for detection of TB is low. If the current MI system were to be changed to a visual only system, this could further reduce the sensitivity of detection, making the system inefficient and unreliable for surveillance (Wahlström, 2004). To assess the impact of changes on the overall MI sensitivity, the approach followed was to review recent scientific information to obtain estimates of the sensitivity of detection of TB by MI, and factors affecting it.

According to a review carried out by EFSA (2008), the sensitivity of deer necropsy for detecting TB is 81 %, while the sensitivity of deer meat inspection is 62 %. The key factors affecting sensitivity are the number of animals inspected and the degree of detail and time during the inspection (i.e. larger numbers and less time per carcass in meat inspection than in necropsy (More et al., 2009). However, recent studies in natural *M. bovis*-infected deer have shown that detailed examination by necropsy (including palpation and incision) may detect only 68 % (fallow deer) and 71 % (red deer) of animals with culture-confirmed *M. bovis* infection (Martín-Hernando et al., 2010). By contrast, Jaroso et al. (2010) recorded TB-compatible lesions by necropsy in 20 of 21 (95 %) fallow deer with culture-confirmed *M. bovis* infection, and Rohonczy et al. (1996) recorded TB-compatible lesions by inspection in 68 of 73 (93 %) elk and red deer with culture-confirmed *M. bovis* infection. Hence, the

<sup>&</sup>lt;sup>39</sup>http://rasve.mapa.es/publica/programas/NORMATIVA%20Y%20PROGRAMAS%5CPROGRAMAS%5CFAUNA%20SIL VESTRE%5CPLAN%20NACIONAL%20DE%20VIGILANCIA%20SANITARIA%20EN%20FAUNA%20SILVESTR E\_2011.PDF).



sensitivity of inspection is highly variable and will depend also on the characteristics of each animal population.

#### 2.3.3. Tuberculosis in farmed wild boar

Farmed wild boar are defined as animals farmed for commercial purposes and surrounded by fences or a barrier in order to prevent entry or exit. Wild boar farming ranges from extensive systems with no segregation by age or sex to highly technical facilities with sex and age segregation and individual identification. Farmed wild boar is produced for two purposes: for the supply of hunting animals and for the production of game meat. Farms often rear wild boar for both purposes.

#### 2.3.3.1. Description of the disease and prevalence and relevance in EU

Wild boar TB must be suspected if necrotic or calcified granulomatous lesions are detected in the mandibular lymph nodes. This organ is affected in over 90 % of known-infected wild boar with visible lesions. In addition to those wild boar presenting visible lesions, another 20 % of known-infected wild boar have no visible lesions. Close to 60 % of known-infected wild boar with visible lesions present generalised lesions, meaning that lesions are present in more than one region i.e. head, thorax, abdomen (Martín-Hernando et al., 2007). However, even generalised TB in farmed wild boar rarely causes visible loss of body condition.

Wild boar TB has been reported in the last decades in at least 10 European countries: Bulgaria, Croatia, France, Germany, Hungary, Poland, Portugal, Slovakia, Spain and the UK (Gortázar et al., 2012). Wild boar experience much higher levels of exposure than deer (Vicente et al., 2006). *M. bovis* prevalences in wild boar, as estimated by culture, ranged from 46 to 52 % in three different surveys in the Iberian Peninsula (Gortázar et al., 2008, Santos et al., 2009), where this host is considered the main driver of wildlife TB and a key factor in hindering cattle TB eradication (Naranjo et al., 2008).

Risk factors for wild boar TB include fencing and artificial feeding to maintain high densities and spatial concentrations of wild ungulates in farms and farm-like environments, which increase the probability of transmission (Vicente et al., 2007).

#### 2.3.3.2. Surveillance system currently in place

As already described for deer, no formal TB surveillance exists for free-living or for farmed wild boar. Regarding wild populations, the TB prevalence of hunter-harvested animals can easily be assessed by different means including lesion detection and antibody detection (Boadella et al., 2011). However, only France, Italy and Spain regularly monitor their wild ungulates for mycobacterial infections and report the results to EFSA (EFSA, 2009).

Regarding farmed wild boar, TB is, unfortunately, not among the diseases that are routinely tested in pig and wild boar farms. Hence, meat inspection is the only potential current source of information on TB distribution and prevalence. Skin testing is rarely used in farmed wild boar (Jaroso et al., 2010), and enzyme-linked immunosorbent assays (ELISAs) are available but not extensively used (Boadella et al., 2011).

Regarding wild boar farms, and similarly to what was described above for deer farms, TB surveillance is currently hindered by several facts: (1) an insufficient definition of the farms; (2) the absence of any traceability of farm-reared wild boar in many MSs; and (3) the lack of a formal definition of how this surveillance should be carried out. To overcome these barriers, every MS should set up a proper registry of the existing wild boar farms (including a proper definition of a wild boar farm, probably including all fenced populations); all farmed wild boar should compulsorily be permanently marked (ear tag or microchip) to allow tracing back at least their farm of origin, and surveillance based on a combination of live testing and *post-mortem* examination of farmed wild boar, in combination with disease surveillance in hunter-harvested free living wild boar, should be set up in a coordinated (harmonised) way.



#### 2.3.3.3. Impact of proposed changes on surveillance and control

Current wild boar meat inspection at slaughter is similar to that for swine (see Table 3). The changes proposed by the BIOHAZ Panel are to cease palpation and incision, largely because the main identified food-borne hazards (*Salmonella* and *Toxoplasma gondii*) are not detectable by meat inspection and incision might cause cross-contamination of carcasses by enterobacteria. Changes proposed by COMISURV include poor condition as an indicator for TB.

However, eliminating palpation and incision would be strongly detrimental to the likelihood of detecting TB. The significance of TB in swine is probably underestimated (Di Marco et al., 2012) and, as seen above, TB is a frequently detected problem in wild boar, including farmed wild boar. The effect of TB on wild boar body condition is not consistent. This means that poor condition should not be used as an indicator of TB in wild boar.

#### 2.3.4. Reindeer

In the COMISURV assessment, only farmed deer was considered. As reindeer (*Rangifer tarandus*) was included in the risk assessment by the BIOHAZ Panel, the possible impact of proposed changes in MI on the surveillance of animal disease and welfare conditions was also considered by experts. The PMI procedure for small ruminants as prescribed in Regulation (EC) 854/2004 is also used for reindeer.

Reindeer (*Rangifer tarandus*) is mainly farmed in northern regions of Norway, Sweden and Finland. Since they are kept at low stocking densities and in sub-Arctic environmental conditions, the number of diseases affecting them and their prevalence is very low. For instance, enterobacteria such as *Salmonella* or pathogenic *E. coli* or *Yersinia* are virtually absent (e.g. Kemper et al., 2006) or occur at low prevalence (e.g. *Campylobacter*; Hänninen et al., 2002), and antibodies against *Toxoplasma gondii* are 10–100 times lower in reindeer than in other deer from southern latitudes (e.g. Oksanen et al., 1997). With *M. bovis* infection, it is exceedingly rare in reindeer (Palmer et al., 2006). Hydatidosis, another disease that can be recognised at MI, is occasionally detected at slaughter of reindeer (Kummeneje, 1980). However, the detection probability of hydatid cysts (analysed in COMISURV report for red deer) was not significantly affected by a change to a visual only system. Therefore, the same is to be expected for reindeer. Hence, it is not expected that changes in MI will significantly affect the surveillance of animal diseases in farmed reindeer.

#### 2.3.5. Welfare conditions

#### 2.3.5.1. Farmed deer

Farmed deer have been traditionally killed on the farm by shooting with free bullets, but nowadays most are transported to dedicated slaughterhouses (Weeks, 2000). Specific handling facilities and management procedures are required for deer as loading, transport and unloading are stressful procedures (Fletcher, 1988; Goddard, 1998; Grigor et al., 1998a, b, c, d). The principles of deer handling have been described by several authors (Matthews, 2000). Confinement in isolation or with unfamiliar deer has been found to be aversive and therefore considered as factors contributing to stress (Pollard et al., 1993).

Nevertheless, farmed deer are prone to trauma and injury during herding on the farm, loading, transport, unloading, lairage and pre-slaughter handling. A survey carried out in a farmed deer slaughterhouse in New Zealand to ascertain the animal welfare-related carcass defects detectable at *post-mortem* meat inspection revealed that 26.9 % of (n = 4762) carcasses had wounds and bruises (Selwyn and Hathaway, 1990). Bruising received during transport may be a consequence of movements caused by fatigue and stress during the journey (Jago et al., 1997). Rate of carcass bruising has been used as an index of pre-slaughter stress in deer, as well as of poor handling, management and transportation (Jago et al., 1993). Hindquarters or hocks are usually mainly affected (Jago et al., 1996). Stags were significantly more affected than hinds, and increasing downgrading of stags during the rut appeared to be great. A higher rate of bruising was reported in leaner animals. Increased bruising was

significantly related to different farms and carrier companies, poor driving techniques and road conditions, increasing journey length, and sometimes, with overnight lairage (Jago et al., 1996; Pollard et al., 1998). Trauma, injury and bruising can be detected during slaughterhouse surveillance and the proposed change to visual only inspection is not expected to affect the detection levels for these welfare conditions.

WDS occurs mainly in late winter and is well known to deer farmers in New Zealand, Australia and Europe (Sanford et al., 1993). Deer, especially stags, have a very low energy reserve in winter because of their late autumn rut, and while establishing dominance and mating stags may lose up to two kilograms of body weight per day, leading to extremely poor body condition, which can be detected during routine AMI.

#### 2.3.5.2. Farmed wild boar

At present, farmed wild boar can be slaughtered on the farm, sent to a multi-species slaughterhouse or transported to a specialist slaughterhouse. It has been reported that there are only few slaughterhouses licensed to slaughter farmed wild boar and the geographical location of wild boar farms bears little relationship to abattoir distribution, at least in the UK. This inevitably leads to long transport distance and duration for some animals (Bornett-Gauci et al., 2006). Although the animal welfare consequences of loading, transport, unloading and pre-slaughter handling in slaughterhouses are not documented, farmed wild boar can be prone to injury and trauma.

Trauma, injury and bruising occurring in wild boars can be detected during slaughterhouse surveillance and the proposed change to visual only inspection is not expected to affect the detection levels for these welfare conditions.

#### 2.3.5.3. Farmed reindeer

Reindeer were also traditionally slaughtered in the field at the site of selection, but the implementation of new meat hygiene legislation in Sweden requires that they are slaughtered in designated slaughterhouses and, therefore, transported over long distances (Malmfors and Wiklund, 1996). The method of catching and manual handling (catching with lassoes or manual catching) of reindeer can result in struggling, which can lead to trauma and injuries.

Manual handling and restraint have been found to be stressful to reindeer, and it has been demonstrated that animals selected for slaughter can be herded onto the vehicle without restraint (Wiklund et. al., 2001). Andersen (1978) stated that non-slippery and even surfaces during catching are very important to avoid injury to the reindeer and recommended that reindeer intended for slaughter be collected in a group the day before transport, so that it would be easier to move them towards and onto the vehicle. Reindeer do not lie down during transport but maintain a stance with legs at an angle and heads held low, using these as a balance pole. This means that reindeer need more floor space than might be expected from their body size. However, Andersen (1978) stated, that there was a difference in posture during transport differs depending on sex. Females lay down before males, thus increasing their risk of being trodden on and it was recommended, in addition, that the sexes be separated during transport. Adult reindeer can have antlers and this will also affect space requirements, as well as grouping on the vehicle. There are limits to transport distance when no feed is offered, and mortalities of up to 25 % were observed for transports of reindeer from Russia to Norway (EFSA, 2004). Clearly, poor handling and transport conditions can increase the prevalence of trauma and injuries in reindeer.

Trauma, injury and bruising occurring in reindeer can be detected during slaughterhouse surveillance and the proposed change to visual only inspection is not expected to affect the detection levels for these welfare conditions.



## **3.** Implications for surveillance and monitoring for farmed game health and welfare of changes to meat inspection as proposed by the CONTAM Panel

The conclusions and recommendations from the CONTAM Panel refer to areas such as the ranking of chemical substances of potential concern; sampling, which should be based on the types and likelihood of occurrence of chemical residues and contaminants and on the completeness and quality of the FCI supplied; and the inclusion of new hazards in control programmes for residues and contaminants (see CONTAM Appendix B for full details). None of these were considered to have impact on animal health and welfare surveillance and monitoring.



#### **CONCLUSIONS AND RECOMMENDATIONS**

#### CONCLUSIONS

- A significant difference in the effectiveness between the current and the visual only meat inspection scenarios was seen for tuberculosis in deer, with a significant reduction in the probability of detection of this disease for the visual only meat inspection. No difference in detection effectiveness was observed for the other diseases and welfare conditions analysed for farmed red deer and farmed wild boar.
- When slaughterhouse surveillance component and clinical surveillance were compared, slaughterhouse surveillance was found to be far more effective for the detection of tuberculosis in farmed red deer. In the absence of other surveillance methods, its contribution to the overall surveillance should be regarded as important.
- Overall, clinical surveillance in farmed wild boar had a greater sensitivity for detecting African Swine Fever and Classical Swine Fever than slaughterhouse surveillance, but sensitivity of meat inspection was found to increase when the number of slaughtered farmed wild boar became higher.
- Meat inspection is a useful tool for tuberculosis detection in both farmed deer and farmed wild boar, and the only realistic tool for surveillance in farmed wild boar. Given the relevance of farmed deer and farmed wild boar in tuberculosis epidemiology, and given the fact that many cases of confirmed infection only show small local lesions, eliminating palpation and incision would be strongly detrimental for the likelihood of detecting tuberculosis through meat inspection.
- In contrast with other large animals such as cattle or pigs, farmed deer and farmed wild boar currently lack traceability in many Member States. This lack impedes tracing back any detected tuberculosis cases to the farm of origin.
- Also in contrast with most other farming systems, deer and wild boar farms still lack a proper registry in several Member States, and the definition of a deer farm or wild boar farm is not homogeneous through the Member States.
- Farmed deer and farmed wild boar can act as tuberculosis reservoirs, owing to this, any reduction in the detection due to changes in the *post-mortem* inspection procedures, will have consequences for the overall surveillance of tuberculosis.
- It is not expected that changes in meat inspection (from current to visual only) will significantly affect the surveillance of animal diseases in farmed reindeer.
- Winter death syndrome in farmed deer and trauma and injury occurring in farmed deer, farmed reindeer and farmed wild boar can be detected during routine slaughterhouse surveillance systems. The proposed changes to meat inspection are not expected to affect the detection levels for these welfare conditions.
- The conclusions and recommendations on chemical hazards were reviewed by the AHAW Working Group experts and none of them were considered to have an impact on animal health and welfare surveillance and monitoring.

#### RECOMMENDATIONS

- Acknowledging that meat inspection is a useful tool for tuberculosis detection in farmed deer and farmed wild boar, that both groups of farmed game are relevant as *Mycobacterium bovis* maintenance host and that many cases of confirmed infection only show small local lesions, it is recommended to maintain palpation and incision both for deer and for wild boar.
- Given the current lack of individual traceability in farmed deer and wild boar, and considering that this lack likely impedes tracing back any detected tuberculosis cases to the farm of origin,



it is recommended to set up proper animal identification schemes throughout the Member States.

- Considering that deer and wild boar farms often lack a proper registry in several Member States and also considering that the definition of a deer farm or wild boar farm is not homogeneous throughout the Member States, it is recommended that all fenced deer or wild boar populations should be defined as game farms. All game farms should be registered in each Member State.
- Given the importance of tuberculosis in farmed game, including deer and wild boar, it is recommended to set up a homogeneous tuberculosis testing scheme. This scheme could be based on live-testing and meat inspection.
- In view of the fact that farmed deer and farmed wild boar act as tuberculosis reservoirs, premises where these two animal species are kept should be included in the national tuberculosis monitoring and control programmes.



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#### **GLOSSARY AND ABBREVIATIONS**

AHAW	Animal Health and Welfare
ASF	African swine fever
AMI	Ante-mortem inspection
BIOHAZ	Biological Hazards Panel
CONTAM	Contaminants in the Food Chain Panel
CSF	Classical swine fever
EFSA	European Food Safety Authority
ELISA	Enzyme-linked immunosorbent assays
EU	European Union
FCI	Food chain information
FMD	Foot and mouth disease
GI	Gastro intestinal
Ι	Incision
MI	Meat inspection
ML	Most likely (equivalent to mode)
MS	Member state
Р	Palpation
PMI	Post-mortem inspection
ТВ	
	Tuberculosis
V	Tuberculosis Visual inspection
V	Visual inspection

All cases: the combination of detectable cases (mild and typical) and non-detectable cases.

**Case-finding capacity**: characteristic of a surveillance system for endemic disease, describing the ability of the system to identify infected or affected herds or individuals, so that a control action can (potentially) be taken. The detection fraction is a measure of the case-finding capacity.

Case type: includes detectable (mild or typical cases) and non-detectable cases.

Clinical surveillance: surveillance based on clinical observations in the field.

Combined inspection: taking into account ante-mortem and post-mortem inspection.

**Component sensitivity**: the probability that one or more infected animals will be detected by the surveillance component during a specified time period, given that the disease is present at a level defined by the design prevalence.

**Detectable cases**: all cases that are detectable by routine meat inspection procedures. They will express a range of combinations of clinical and pathological signs. A proportion of detectable cases will fit the definition of the typical case and a proportion will be milder cases.

**Detection effectiveness**: the proportion of animals with lesions (i.e. detectable by visual inspection, palpation and/or incision) that are actually detected.

**Detection fraction**: the proportion of infected or affected units that are successfully detected by the surveillance system.

**Mild cases**: the mild case of a disease or condition is the form that could be seen at the early stages of the disease or at some point between the subclinical and the fully developed (i.e. "typical") form. A mild case is neither typical nor subclinical. The animal will probably present more subtle signs than in a typical case. Mild cases fit the mild case definition validated by experts.

**Monitoring**: investigating samples or animals in order to obtain information about the frequency of disease or infection as it varies in time and/or space.

**Non-detectable cases**: cases that are beyond the detection capacity of current meat inspection protocols. These will often be early cases at a stage where distinct clinical signs have not yet developed, but they can be cases with mild infection that leads to only subclinical conditions, and without pathological lesions detectable by meat inspection.

Non-overlapping probability intervals: indicate that scenarios differ significantly from each other.

**Overall surveillance system**: includes several components, such as slaughterhouse surveillance and clinical surveillance.

Slaughterhouse surveillance: surveillance by meat inspection in slaughterhouses.

**Stage 2**: assessment of the probability of detection at meat inspection. The objective of Stage 2 modelling was to estimate case type-specific (for typical and mild cases) as well as overall probabilities of detection at meat inspection.

**Stage 3**: an assessment of the relative effectiveness of meat inspection within the overall surveillance system by comparing meat inspection with other available surveillance methods.

**Typical cases**: cases that are, by definition, detectable cases and which express more developed clinical signs than mild cases. They fit the typical case definition provided by the experts, which is defined as signs and/or lesions that are expected to be observed in more than 60 % of affected or infected of animals seen at the slaughterhouse.