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SCIENTIFIC OPINION

Scientific Opinion on the public health hazards to be covered by inspection of meat from sheep and goats[1]

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

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

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

A risk ranking process identified *Toxoplasma gondii* and pathogenic verocytotoxin-producing *Escherichia coli* (VTEC) as the most relevant biological hazards for meat inspection of sheep and goats. As these are not detected by traditional meat inspection, a meat safety assurance system using risk-based interventions was proposed. Further studies are required on *T. gondii* and pathogenic VTEC. If new information confirms these hazards as a high risk to public health from meat from sheep or goats, setting targets at carcass level should be considered. Other elements of the system are risk-categorisation of flocks/herds based on improved Food Chain Information (FCI), classification of abattoirs according to their capability to reduce faecal contamination, and use of improved process hygiene criteria. It is proposed to omit palpation and incision from *post-mortem* inspection in animals subjected to routine slaughter. For chemical hazards, dioxins and dioxin-like polychlorinated biphenyls were ranked as being of high potential concern. 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

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extensive production systems used, and the ranking of chemical substances, which should be regularly updated and include new hazards. Control programmes across the food chain, national residue control plans, feed control and monitoring of environmental contaminants should be better integrated. Meat inspection is a valuable tool for surveillance and monitoring of animal health and welfare conditions. Omission of palpation and incision would reduce detection effectiveness for tuberculosis and fasciolosis at animal level. Surveillance of tuberculosis at the slaughterhouse in small ruminants should be improved and encouraged, as this is in practice the only surveillance system available. Extended use of FCI could compensate for some, but not all, the information on animal health and welfare lost if only visual *post-mortem* inspection is applied.

KEY WORDS

meat inspection, sheep, goats, slaughterhouse, surveillance, contaminants, residues

SUMMARY

Following a request from the European Commission to the European Food Safety Authority (EFSA), the Panel on Biological Hazards (BIOHAZ) was asked to deliver a Scientific Opinion on the public health hazards to be covered by the inspection of meat from sheep and goats. The Panel was supported by the EFSA Panels on Contaminants in the Food Chain (CONTAM) and Animal Health and Welfare (AHAW) in the preparation of this Opinion. Briefly, the main risks for public health that should be addressed by meat inspection were identified and ranked; the strengths and weaknesses of the current meat inspection system were evaluated; recommendations were made for inspection methods fit for the purpose of meeting the overall objectives of meat inspection for hazards currently not covered by the meat inspection system; and recommendations for adaptations of inspection methods and/or frequencies of inspections that provide an equivalent level of protection were made. In addition, the implications for animal health and animal welfare of any changes proposed to current inspection methods were assessed.

Sheep and goats were considered together, unless otherwise stated. Decision trees were developed and used for priority ranking of biological and chemical hazards present in meat from sheep and goats. For biological hazards the ranking was based on the magnitude of the human health impact, the severity of the disease in humans and the evidence supporting the role of meat from sheep and goats as a risk factor for disease in humans. The assessment was focused on the public health risks that may occur through the handling, preparation for consumption and/or consumption of meat from these species. The term 'priority' was considered more appropriate than 'risk' for categorizing the biological hazards associated with meat from small ruminants, given that a significant amount of data on both the occurrence of the hazards and on the attributable fraction of human cases to meat from small ruminants were not available. Risk ranking of chemical hazards into categories of potential concern was based on the outcomes of the national residue control plans (NRCPs), as defined in Council Directive 96/23/EC 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 residues and contaminants in sheep and goats.

Based on the ranking for biological hazards, *Toxoplasma gondii* and pathogenic verocytotoxin-producing *Escherichia coli* (VTEC) were classified as high priority for public health regarding meat inspection of small ruminants. The remaining hazards were classified as low public health relevance, based on available data, and were therefore not considered further. For chemical hazards, dioxins and dioxin-like polychlorinated biphenyls (DL-PCBs) were ranked as being of high potential concern owing to their known bioaccumulation in the food chain, their frequent findings above maximum levels (MLs), particularly in sheep liver, and in consideration of their toxicological profile; all other substances were ranked as of medium or lower concern. It should be noted that the ranking into specific-risk categories of hazards is based on current knowledge and available data and therefore ranking should be updated regularly, taking account of new information and data and including 'new hazards'.

The main elements of the current meat inspection system include analysis of Food Chain Information (FCI), *ante-mortem* examination of animals and *post-mortem* examination of carcasses and organs. The assessment of the strengths and weaknesses of the current meat inspection was based on its contribution to the control of the meat-borne human health hazards identified in sheep and goats. A number of strengths and weaknesses of the current inspection system were identified. Currently, the use of FCI for food safety purposes is limited for small ruminants because the data that it contains is very general and doesn't address specific hazards of public health importance. However, FCI could serve as a valuable tool for risk management decisions and could be used for risk categorisation of farms or batches of animals. To achieve this, the system needs further development to include additional information important for food safety, including definition of appropriate and standardized indicators for the main public health hazards identified above. *Ante-mortem* and *post-mortem* inspections of sheep and goats enable the detection of observable abnormalities and provide a general assessment of animal/herd health, which if compromised may lead to a greater public health risk.

Visual inspection of live animals and carcasses can detect animals heavily contaminated with faeces, which increase the risk for cross-contamination during slaughter and may constitute a food safety risk if the animals are carrying hazards of public health importance. If such animals or carcasses are dealt with adequately, this risk can be reduced. Visual detection of faecal contamination on carcasses can also be an indicator of slaughter hygiene, but other approaches to verify this should be considered. *Post-mortem* inspection can also detect non meat-borne hazards of public health significance, such as *Echinococcus granulosus*, that can be present in carcasses or offal from small ruminants. *Ante-mortem* and *post-mortem* inspection also have the potential to detect new diseases, which may be of direct public health significance. With regard to chemical hazards, it was noted that current procedures for sampling and testing are, in general, well established and coordinated, including follow-up actions subsequent to the identification of non-compliant samples. The regular sampling and testing for chemical residues and contaminants is an important disincentive for the development of undesirable practices and the prescriptive sampling system allows for equivalence in the control of EU-produced sheep and goat meat. The current combination of animal traceability, *ante-mortem* inspection and gross tissue examination can support the collection of appropriate samples for residue monitoring.

The main weakness of *ante-mortem* and *post-mortem* inspection is that they are not able to detect any of the public health hazards identified as the main concerns for food safety. In addition, given that the current *post-mortem* procedures involve palpation and incision of some organs, the potential for cross-contamination of carcasses exists. For chemical hazards, a major weakness is that, with very few exceptions, presence of chemical hazards cannot be identified by current *ante-/post-mortem* meat inspection procedures at the slaughterhouse level and there is a lack of sufficient cost-effective and reliable screening methods. In addition, sampling is mostly prescriptive rather than risk or information based. There is limited ongoing adaptation of the sampling and testing programmes to the results of the residue monitoring programmes, with poor integration between the testing of feed materials for undesirable substances and the NRCPs and sampling under the NRCPs reflecting only a part of testing done by a number of MSs, the results of which should be taken into consideration.

As neither of the main public health hazards associated with meat from small ruminants can be detected by traditional visual meat inspection, other approaches are necessary to identify and control these microbiological hazards. A comprehensive meat safety assurance system for small ruminants, combining a range of preventive measures and controls applied both on the farm and at the slaughterhouse in a longitudinally integrated way, is the most effective approach to control the main hazards in the context of meat inspection.

Information on the biological risks associated with the consumption of meat from sheep or goats 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 *T. gondii* and pathogenic VTEC at flock/herd, live animal and carcass level in individual MSs. Epidemiological and risk assessment studies are also required to determine the specific risk to public health associated with the consumption of meat from small ruminants. If these studies confirm a high risk to public health through the consumption of meat from sheep or goats, 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.

Flock/herd categorisation according to the risk posed by the main hazards is considered an important element of an integrated meat safety assurance system. This should be based on the use of farm descriptors and historical data in addition to batch-specific information. Farm-related data could be provided through farm audits using Harmonised Epidemiological Indicators (HEIs) to assess the risk and protective factors for the flocks/herds related to the given hazards. In addition, classification of abattoirs according to their capability to prevent or reduce faecal contamination of carcasses can be based on two elements: (1) the process hygiene as measured by the level of indicator organisms on the carcasses (i.e. process hygiene criteria); and (2) the use of operational procedures and equipment that reduce faecal contamination, as well as industry led quality systems.

There are a variety of husbandry measures that can be used to control *T. gondii* on sheep and goat farms but at present these are impractical to implement in most farms. A number of post-processing interventions are effective in inactivating *T. gondii* such as cooking, freezing, curing, high pressure and irradiation treatments, although further research is required to validate these treatments in meat from small ruminants. There are also a variety of husbandry measures that can be used to reduce the levels of VTEC on farms, but their efficacy is not clear in small ruminants. There are also a number of challenges that need to be overcome regarding the setting of targets for pathogenic VTEC, including the difficulties in identifying husbandry factors that can be used to classify farms according to pathogenic VTEC risk, the intermittent nature of shedding, and the problems with the interpretation of monitoring results for pathogenic VTEC due to the difficulty to correctly identify pathogenic VTEC. The main sources of VTEC on sheep and goat carcasses are the fleece/hide and the viscera. To control incoming faecal contamination only clean animals should be accepted for slaughter. There are also a number of measures that can help reducing the spillage or leakage of digestive contents onto the carcass, as well as post-processing interventions to control pathogenic VTEC are also available. These include hot water and steam carcass surface treatments.

Risk categorisation of slaughterhouses should be based on trends of data derived from Process Hygiene Assessments and from Hazard Analysis Critical Control Point programmes. Improvement of slaughter hygiene through technological and managerial interventions should be sought in slaughterhouses with repeatedly unsatisfactory performance.

FCI can be improved by including information on participation in quality assurance schemes and by greater feedback to the primary producer, as this would likely result in the production of healthier animals. *Ante-mortem* inspection assesses the general health status of the animals and helps to detect animals heavily contaminated with faeces on arrival at the slaughterhouse, so no adaptations for the existing visual *ante-mortem* inspection are required. Routine *post-mortem* examination cannot detect the meat-borne pathogens of public health importance. Palpation of the lungs, the liver, the umbilical region and the joints, and incision of the liver could contribute to the spread of bacterial hazards through cross contamination. For these reasons, palpation and incision should be omitted in animals subjected to routine slaughter.

Sheep and goat production in the EU is marked by being largely extensive in nature, involving frequent trading of animals and involving nomadic flocks. These differences in husbandry systems and feeding regimes result in different risks for the occurrence of chemical residues and contaminants. Extensive periods on pasture or/as nomadic flocks and the use of slaughter collection dealerships may preclude detailed lifetime FCI. It is recommended regarding chemical hazards, that FCI should be expanded for sheep and goats produced in extensive systems to provide more information on the specific environmental conditions where the animals are produced and that 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 be regularly updated. Control programmes for chemical residues and contaminants should be less prescriptive, with sufficient flexibility to adapt to results of testing, should include 'new hazards', and the test results for sheep and goats should be separately presented. '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. 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 are made in relation to chemical hazards dealing with control measures, testing and analytical techniques and also on data collection and source attribution studies for biological hazards, as well as on methods of detection of viable *T. gondii* in meat and on assessing the effect of the omission of palpation and incision on the risk posed by non-meat-borne zoonoses.

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 related to biological hazards included shorter transport and lairage time, improved collection of Food Chain Information, and omission of palpation and incision in animals subjected to routine slaughter at *post-mortem* inspection. Recommendations on chemical hazards included the ranking system for chemical substances of potential concern and its updating, the use of Food Chain Information to help facilitate risk based sampling strategies, and the inclusion of 'new hazards' in control programmes for chemical residues and contaminants.

From the quantitative assessment, a change to visual only inspection caused a significant reduction of the probability of detection of detectable cases of fasciolosis and tuberculosis in goats. With regard to exotic diseases, clinical surveillance had a greater sensitivity for detecting foot and mouth disease than slaughterhouse surveillance. A change in *post-mortem* protocol to a visual only system did not significantly reduce the detection of any welfare conditions.

Following the qualitative analysis, it was concluded that a change to visual inspection (which implies no palpation) would reduce detection effectiveness for tuberculosis. Surveillance of tuberculosis at the slaughterhouse in small ruminants should be improved and encouraged, as this is in practice the only surveillance system available in these species. The detection of tuberculosis in small ruminants should be adequately recorded and followed at the farm level.

Moving to a visual only meat inspection system would decrease the sensitivity of inspection of fasciolosis at animal level, however it would be sensitive enough to identify most if not all affected herds. Therefore the consequences of the change would be of low relevance. The feedback to farmers of *Fasciola hepatica* detected at meat inspection should be improved, to allow farmer information to support rational on-farm fluke management programmes.

Qualitative analysis suggested that the proposal for shortened transport and lairage time would be beneficial to improving the welfare of small ruminants. Food chain information should include animal welfare status in order to complement the slaughterhouse surveillance systems (*ante-mortem* and *post-mortem* inspection) and the latter could be used to identify on farm welfare status.

Other recommendations on biological and chemical hazards would not have a negative impact on surveillance of animal diseases and welfare conditions.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Regulation (EC) No 854/2004 of the European Parliament and of the Council lays down specific rules for the organisation of official controls on products of animal origin intended for human consumption[4]. 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 jeopardising 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.

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

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 Organisation 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 far animal health and animal welfare of any changes suggested in the light of public health risks to current inspection methods should be considered.

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

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

ASSESSMENT

1. Scope

The scope of the mandate is to evaluate meat inspection in a public health context; animal health and welfare issues are 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 other than those of public health significance but that still compromise the fitness of the meat for human consumption (Regulation (EC) No 854/2004,[5] Annex I, Section II, Chapter V) are outside the scope of the mandate. Examples of these include sexual odour or meat decolouration. 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, hazards representing primarily occupational health risks, the controls related to any hazard at any meat chain stage beyond 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 854/2004[5] 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.

The European Food Safety Authority (EFSA) is requested to issue scientific opinions related to inspection of meat in different species. In addition, technical assistance has been requested on harmonised epidemiological criteria for specific hazards for public health that can be used by risk managers to consider adaptation of the 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 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 was allocated to the Biological Hazards Panel (BIOHAZ), which prepared this scientific opinion with the support of the Animal Health and Welfare (AHAW) and Contaminants in the Food Chain (CONTAM) Panels. In addition, 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 sheep and goats, 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, main outputs from the three working groups (BIOHAZ, CONTAM and AHAW) are presented at the beginning of the document. The scientific justifications for these outputs are found in the various appendices as endorsed by their respective panels, namely biological hazards (Appendix A), chemical hazards (Appendix B), and the potential impact that the proposed changes envisaged by these two could have on animal health and welfare (Appendix C).

[5] 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

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

Conclusions on biological hazards

- Based on the priority ranking, the hazards were classified as follows:
  - *Toxoplasma gondii* and pathogenic verocytotoxin-producing *Escherichia coli* (VTEC)[6] were classified as high priority for sheep/goat meat inspection.
  - The remaining identified hazards, *Bacillus anthracis*, *Campylobacter* spp. (thermophilic) and *Salmonella* spp. were classified as low priority, based on available data.
- As new hazards might emerge and/or hazards that presently are not a priority might become more relevant over time or in some regions, both hazard identification and the risk ranking should be revisited regularly to reflect this dynamic epidemiological situation. Particular attention should be given to potential emerging hazards of public health importance.

Conclusions on 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 for sheep and goats indicated that only 0.41 % of the total number of results was non-compliant for one or more substances listed in Council Directive 96/23/EC. Potentially higher exposure of consumers to these substances from sheep and goat meat takes place only incidentally, as a result of mistakes or non-compliance with known and regulated procedures. Available data however, do not allow for a reliable assessment of consumer exposure.
- Ranking of chemical residues and contaminants in domestic sheep and goats based on pre-defined 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:
  - Dioxins and dioxin-like polychlorinated biphenyls (DL-PCBs) were ranked as being of high potential owing to their known bioaccumulation in the food chain, their frequent findings above MLs, particularly in sheep liver, and in consideration of their toxicological profile.
  - Stilbenes, thyreostats, gonadal (sex) steroids, resorcylic acid lactones and beta-agonists, especially clenbuterol, chloramphenicol and nitrofurans were ranked as being of medium potential concern, as they have proven toxicity for humans, are effective as antibacterial treatments for sheep/goats and as non-compliant samples are found in most years of the NRCPs.

[6] For the purposes of this opinion, human pathogenic VTEC are defined as VTEC capable of causing disease in humans.

- Chloramphenicol and nitrofurans were ranked as being of medium potential concern, as they have proven toxicity for humans, they are effective as antibacterial treatments for sheep/goats and as non-compliant samples are found in most years of the NRCPs.

- Non dioxin-like polychlorinated biphenyls (NDL-PCBs) bioaccumulate, and there is a risk of exceeding the MLs, but they were ranked in the category of medium potential concern, because they are less toxic than dioxins and DL-PCBs.

- The chemical elements cadmium, lead and mercury were allocated to the medium potential concern category taking into account the number of non-compliant results reported under the NRCPs and their toxicological profile.

- All other substances listed in Council Directive 96/23/EC were ranked as of low or negligible potential concern owing 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 2005-2010, and/or to the natural occurrence in sheep and goats of some of these substances.

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 on biological hazards

- Strengths

  - *Ante-mortem* and *post-mortem* inspection of sheep and goats enable the detection of observable abnormalities. In that context, they are an important activity for monitoring animal health and welfare. They provide a general assessment of animal/herd health, which if compromised may lead to a greater public health risk. Visual inspection of live animals and carcasses can also detect animals heavily contaminated with faeces. Such animals increase the risk for cross-contamination during slaughter and may consequently constitute a food safety risk if carrying hazards of public health importance. If such animals or carcasses are dealt with adequately, this risk can be reduced. Visual detection of faecal contamination on carcasses can also be an indicator of slaughter hygiene, but other approaches to verify slaughter hygiene should be considered.

  - *Post-mortem* inspection can also detect non meat-borne hazards of public health significance that can be present in carcasses or offal from small ruminants. *Ante-mortem* and *post-mortem* inspection also have the potential to detect new diseases if these have clinical signs, which may be of direct public health significance.

- Weaknesses

  - Currently, the use of food chain information (FCI) for food safety purposes is limited for small ruminants, mainly because the data that it contains is very general and doesn't address specific hazards of public health importance. However, FCI could serve as a valuable tool for risk management decisions and could be used for risk categorisations of farms or batches of animals. To achieve this, the system needs further development to include additional information important for food safety, including definition of appropriate and standardized indicators for the main public health hazards identified in Section 2 of Appendix A.

- *Ante-* and *post-mortem* inspection is not able to detect any of the public health hazards identified as the main concerns for food safety. It would therefore be expected that more efficient procedures might be implemented to monitor the occurrence of non-visible hazards. In addition, given that the current *post-mortem* inspection procedures involve palpation and incision of some organs, the potential for cross-contamination of carcasses exists.

Conclusions on chemical hazards

- Strengths of the current meat inspection methodology for chemical hazards are as follows:
  - The current procedures for sampling and testing are a mature system, in general well established and coordinated including follow-up actions subsequent to the identification of non-compliant samples.
  - The regular sampling and testing for chemical residues and contaminants in the system is an important disincentive to the development of undesirable practices.
  - The prescriptive sampling system allows for equivalence in the control of EU-produced sheep and goat meat. Any forthcoming measures have to ensure that the control of imports from Third Countries remains equivalent to the controls within the domestic market.
  - The current combination of animal traceability, *ante-mortem* inspection and gross tissue examination can support the collection of appropriate samples for residue monitoring.
- Weaknesses of the current meat inspection methodology for chemical hazards are as follows:
  - A weakness of the system is that presence of chemical hazards cannot be identified by current *ante-/post-mortem* meat inspection procedures at the slaughterhouse level, indicating the need for further harmonization of the risk reduction strategies along the entire food chain.
  - Integration between testing of feed materials for undesirable contaminants and the NRCPs in terms of communication and follow-up testing strategies or interventions is currently limited. Moreover, a routine environmental data flow is not established and keeping habits for sheep and goats provides opportunities for feed coming in without a clear feed chain history.
  - Under the current system, sampling is mostly prescriptive rather than risk- or information-based. It appears that individual samples taken under the NRCP testing programme may not always be taken as targeted samples, as specified under Council Directive 96/23/ EC, but sometimes may be taken as random samples.
  - There is a lack of sufficient cost-effective and reliable screening methods and/or the range of substances prescribed/covered by the testing is sometimes limited.
  - There is limited flexibility to adopt emerging chemical substances into the NRCPs and limited ongoing adaptation of the sampling and testing programme to the results of the residue monitoring programmes. In addition, sampling under the NRCPs reflects only a part of testing done by a number of MSs, the results of which should be taken into consideration.
  - Sheep and goats may not be subject to surveillance over their lifetime at the same level as is the case for other food animal categories such as pigs, poultry and, to a large extent, bovine animals due to the traditional nomadic/outdoor farming systems.

Conclusions on animal health and welfare

- As shown in the COMISURV assessment, a change to visual only inspection would cause a significant reduction in the probability of detection (i.e. non-overlapping 90% probability intervals) of detectable cases of fasciolosis and of tuberculosis in goats.

- Small ruminants are usually not subjected to official tuberculosis eradication campaigns, and farm controls are only performed on premises where cattle and goats are kept together, or in flocks/herds that commercialise raw milk. Surveillance for small ruminant tuberculosis at present relies on meat inspection of sheep and goats slaughtered for human consumption, or other limited diagnostic surveillance activities.

- As is the case with tuberculosis in bovines, the contribution of meat inspection surveillance of tuberculosis in small ruminants is to support the detection of flocks/herds with tuberculosis. Detection of tuberculosis in individual animals is merely the first step in improving the effectiveness of flock/herd surveillance, and for any given flock/herd, the flock/herd sensitivity will increase with the number of animals slaughtered.

- In recent years tuberculosis has been reported in small ruminants in several EU countries and most information derives from recognition of tuberculous lesions at the slaughterhouse and from laboratory reports. Although small ruminants are not considered to represent a significant reservoir of the disease for the persistence of bovine tuberculosis in cattle, it is still possible that infected sheep and goat herds could act as vectors of infection for other domestic and wild animals. Therefore, surveillance and control of tuberculosis in domestic small ruminants does have consequences for the overall surveillance and control of tuberculosis.

- The feedback to farmers of *Fasciola hepatica* detected at meat inspection is low at present and the real risk to animal health/welfare for this disease, caused by a change to a visual only meat inspection method, is probably low.

- Implementation of welfare assessment protocols using appropriate animal based indicators during clinical and slaughterhouse (AMI + PMI) surveillance system would improve the welfare of small ruminants.

- Extended use of food chain information has the potential to compensate for some, but not all, of the information on animal health and welfare that would be lost if visual only *post-mortem* inspection is applied.

- Food chain information is a potentially effective tool to perform more targeted *ante-mortem* and *post-mortem* inspection tasks in the slaughterhouse which may increase the effectiveness of those tasks in detecting conditions of animal health and animal welfare significance.

- The existing ineffective flow of information from primary production to the slaughterhouses and vice versa reduces the ability of detection of animal diseases and animal welfare conditions at the slaughterhouse and as a result it limits possible improvements on animal health and welfare standards at the farm as farmers will not be aware of the slaughterhouse findings.

- The conclusions and recommendations on chemical hazards were reviewed by the AHAW Working Group and none of them were considered to have impact on animal health and welfare surveillance and monitoring.

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 on biological hazards

- As neither of the main public health hazards associated with meat from small ruminants can be detected by traditional meat inspection, other approaches are necessary to identify and control these microbiological hazards. A comprehensive meat safety assurance system for meat from small ruminants, combining a range of preventive measures and controls applied both on the farm and at the slaughterhouse in a longitudinally integrated way, is the most effective approach to control the main hazards in the context of meat inspection.

- Information on the biological risks associated with the consumption of meat from sheep or goats 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 *T. gondii* and pathogenic VTEC at flock/herd, live animal and carcass level in individual Member States. Epidemiological and risk assessment studies are also required to determine the specific risk to public health associated with the consumption of meat from small ruminants.

- In the event that these studies confirm a high risk to public health through the consumption of meat from sheep or goats, 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.

- Flock/herd categorisation according to the risk posed by the main hazards is considered an important element of an integrated meat safety assurance system. This should be based on the use of farm descriptors and historical data in addition to batch-specific information. Farm-related data could be provided through farm audits using Harmonised Epidemiological Indicators (HEIs) to assess the risk and protective factors for the flocks/herds related to the given hazards.

- Classification of abattoirs according to their capability to prevent or reduce faecal contamination of carcasses can be based on two elements: (1) the process hygiene as measured by the level of indicator organisms on the carcasses (i.e. process hygiene criteria); and (2) the use of operational procedures and equipment that reduce faecal contamination, as well as industry-led quality systems.

- As mentioned in Section 4.2 of Appendix A, further studies are necessary to determine with more certainty the risk of acquiring *T. gondii* through consumption of meat from small ruminants. In addition, the lack of tests that can easily identify viable cysts in meat is a significant drawback. Further, if there is a high prevalence in the animal population, this will hamper the development of systems based on risk categorisation of animals. For these reasons, the setting of targets for *T. gondii* is not recommended at the moment.

- There are a variety of animal husbandry measures that can be used to control *T. gondii* on sheep and goat farms but at present these are impractical to implement in most farms. A number of post-processing interventions might be effective in inactivating *T. gondii* such as cooking, freezing, curing and high-pressure and γ-irradiation treatments. However, most of the information available for these treatments originates from research in pigs, so further research is required to validate these treatments in meat from small ruminants.

- There are also a variety of animal husbandry measures that can be used to reduce the levels of VTEC on infected farms, but their efficacy is not clear in small ruminants. In addition, there are a number of challenges that need to be overcome regarding the setting of targets for pathogenic VTEC, including the difficulties in identifying husbandry factors that can be used

to classify farms according to pathogenic VTEC risk, the intermittent nature of shedding, and the problems with the interpretation of monitoring results for pathogenic VTEC due to the difficulty to correctly identify pathogenic VTEC.

- The two main sources of VTEC on sheep and goat carcasses are the fleece/hide and the viscera. To control faecal contamination from the fleece or hide only clean animals should be accepted for slaughter, as currently required by EU legislation. There are also a number of measures that can help reducing the spillage or leakage of digestive contents onto the carcass, particularly rodding of the oesophagus and bagging of the rectum. Post-processing interventions to control VTEC are also available. These include hot water and steam pasteurization.

- Risk categorisation of slaughterhouses should be based on trends of data derived from Process Hygiene Assessments and from Hazard Analysis Critical Control Point programmes. Improvement of slaughter hygiene through technological and managerial interventions should be sought in slaughterhouses with repeatedly unsatisfactory performance.

Conclusions on chemical hazards

- Dioxins and DL-PCBs which accumulate in food-producing animals have been ranked as being of high potential concern. As these substances have not yet been comprehensively covered by the sampling plans of the current meat inspection (NRCPs), they should be considered as 'new' hazards.

- In addition, for a number of chemical elements used as feed supplements and for organic contaminants that may accumulate in food-producing animals only limited data regarding residues in sheep and goats are available. This is the case, in particular, for brominated flame retardants, including polybrominated diphenylethers (PBDEs) and hexabromocyclododecanes (HBCDDs) and perfluorinated compounds (PFCs) including (but not limited to) perfluorooctane sulphonate (PFOS) and perfluorooctanoic acid (PFOA).

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

Conclusions on biological hazards

- FCI can be improved by including information on participation in quality assurance schemes and by giving greater feedback to the primary producer, as this would probably result in the production of healthier animals.

- *Ante-mortem* inspection assesses the general health status of the animals and helps to detect animals heavily contaminated with faeces on arrival at the slaughterhouse. Taking these factors into consideration, and given that current methods do not increase the microbiological risk to public health, no adaptations to the existing visual *ante-mortem* inspection procedure are required.

- Although visual examination contributes by detecting visible faecal contamination, routine *post-mortem* examination cannot detect the meat-borne pathogens of public health importance. Palpation of the lungs, the livers, the umbilical region and the joints and incision of the liver could contribute to the spread of bacterial hazards through cross-contamination. For these reasons, palpation and incision should be omitted in animals subjected to routine slaughter.

Conclusions on chemical hazards

- Sheep and goat production in the EU is marked by being largely extensive in nature, involving frequent trading of animals and nomadic flocks. This involves differences in husbandry systems and feeding regimes resulting in different risks for chemical substances and contaminants. Extensive periods on pasture or/as nomadic flocks and the use of slaughter collection dealerships may preclude detailed lifetime FCI. Similarly, in these situations, the level of feedback from the slaughterhouse and authorities to farmers regarding the results of residue testing may be suboptimal. There is less concern about FCI from dairy sheep and goats as they are reared under more intensive and controlled conditions.

- 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 environmental monitoring.

RECOMMENDATIONS

On biological hazards

- To provide a better evidence base for future risk ranking of hazards, initiatives should be instigated to:

  - improve and harmonise data collection of incidence and severity of human diseases caused by relevant hazards;

  - systematically collect data for source attribution;

  - collect data to identify and risk rank emerging hazards that could be transmitted through handling, preparation and consumption of sheep and goat meat.

- Source attribution studies are needed to determine the relative importance of meat and to ascertain the role of the different livestock species as sources of *T. gondii* and pathogenic VTEC for humans.

- Methods should be developed to estimate the amount of viable *T. gondii* tissue cysts in meat, especially in meat cuts that are commonly consumed.

- The effect of the omission of palpation and incision on the risk posed by non-meat-borne zoonoses such as *Echinococcus granulosus* and *Fasciola hepatica* should be assessed, particularly in those regions where these hazards are endemic.

On chemical hazards

- FCI should be expanded for sheep and goats produced in extensive systems to provide more information on the specific environmental conditions where the animals are produced. It is recommended that sampling of sheep and goats should be based on the risk of occurrence of chemical residues and contaminants and on the completeness and quality of the FCI supplied.

- Regular updating of the ranking of chemical substances in sheep and goats 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 sheep and goat production, and actual occurrence of individual substances in sheep and goats.

- Control programmes for chemical residues and contaminants should be less prescriptive, with sufficient flexibility to adapt to results of testing, should include 'new hazards', and the test results for sheep and goats should be separately presented.

- 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 development of analytical techniques covering multiple analytes and of new biologically based testing approaches should be encouraged and incorporated into the residue control programmes

- For prohibited substances, testing should be directed where appropriate towards the farm level and, in the case of substances that might be used illicitly for growth promotion, control measures, including testing, need to be refocused to better identify the extent of abuse in the EU. In addition, control measures for prohibited substances should not rely exclusively on NRCP testing, but should include veterinary inspection during the production phase and the use of biological methods and biomarkers suitable for the identification of abuse of such substances in sheep and goat production in the EU.

On animal health and welfare

- Data collected during clinical and slaughterhouse (*ante-mortem* and *post mortem* inspection) surveillance systems should be utilised more effectively to improve animal welfare at farm level.

- Slaughterhouse surveillance of tuberculosis in small ruminants should be improved and encouraged, as this is in practice the only surveillance system available. The detection of tuberculosis in small ruminants should be adequately recorded and notified, followed by control measures at the farm level.

- Lack of feedback of *post-mortem* inspection results to the farmer prevents instigation of a fluke management programme, which could be detrimental to animal health and welfare. An improvement in this feedback of information is recommended.

- Welfare surveillance systems should become an integral part of the food chain information.

- An integrated system should be developed whereby food chain information for public health and for animal health and welfare can be used in parallel, more effectively

- Provide farmers with background information on the animal diseases and welfare conditions of key concern that may affect their livestock and why it is important to provide this information to the slaughterhouse through the use of food chain information.

APPENDICES

Appendix A. Assessment on biological hazards

SUMMARY

Following a request from the European Commission, the Panel on Biological Hazards (BIOHAZ) was asked to deliver a Scientific Opinion on the public health hazards to be covered by inspection of meat for 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 for public health that should be addressed by meat inspection were identified and ranked; the strengths and weaknesses of the current meat inspection were evaluated; and recommendations were made for inspection methods capable of meeting the overall objectives of meat inspection for hazards currently not covered by the meat inspection system, as well as recommendations 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 sheep and goats.

The BIOHAZ Panel considered sheep and goats together[7]. A decision tree was used for priority ranking of meat-borne hazards present in meat from sheep and goats. The ranking was based on the magnitude of the human health impact, the severity of the disease in humans and the evidence supporting the role of meat from sheep and goats as a risk factor for disease in humans. The assessment was focused on the public health risks that may occur through the handling, preparation and/or consumption of meat from these species. The term 'priority' was considered more appropriate than 'risk' for categorizing the hazards associated with meat from small ruminants, given that a significant amount of data on both the occurrence of the hazards and on the attributable fraction of human cases to meat from small ruminants were not available.

Based on the priority ranking, the hazards were classified as follows:

- *Toxoplasma gondii* and pathogenic VTEC were classified as high priority for sheep/goat meat inspection.

- The remaining identified hazards, *Bacillus anthracis*, *Campylobacter* spp. (thermophilic) and *Salmonella* spp., were classified as low priority, based on available data.

As new hazards might emerge and/or hazards that presently are not a priority might become more relevant over time or in some regions, both hazard identification and the risk ranking should be revisited regularly to reflect this dynamic epidemiological situation. Particular attention should be given to potential emerging hazards of public health importance.

The main elements of the current meat inspection system include analysis of FCI, *ante-mortem* examination of animals and *post-mortem* examination of carcasses and organs. The assessment of the strengths and weaknesses of the current meat inspection was based on its contribution to the control of the meat-borne human health hazards identified in sheep and goats. A number of strengths and weaknesses of the current system were identified. Currently, the use of food chain information (FCI) for food safety purposes is limited for small ruminants because the data that it contains is very general and doesn't address specific hazards of public health importance. However, FCI could serve as a valuable tool for risk management decisions and could be used for risk categorisation of farms or batches of animals. To achieve this, the system needs further development to include additional information important for food safety, including definition of appropriate and standardized indicators for the main public health hazards identified above.

[7] In this Scientific Opinion, the term small ruminant is used to refer to a combination of sheep and goats.

Ante-mortem and *post-mortem* inspections of sheep and goats enable the detection of observable abnormalities and provide a general assessment of animal/herd health, which if compromised may lead to a greater public health risk. Visual inspection of live animals and carcasses can detect animals heavily contaminated with faeces, which increase the risk for cross-contamination during slaughter and may constitute a food safety risk if the animals are carrying hazards of public health importance. If such animals or carcasses are dealt with adequately, this risk can be reduced. Visual detection of faecal contamination on carcasses can also be an indicator of slaughter hygiene, but other approaches to verify this should be considered. *Post-mortem* inspection can also detect non meat-borne hazards of public health significance, such as *Echinococcus granulosus*, that can be present in carcasses or offal from small ruminants. *Ante-mortem* and *post-mortem* inspection also have the potential to detect new diseases, which may be of direct public health significance.

The main weakness of *ante-mortem* and *post-mortem* inspection is that they are not able to detect any of the public health hazards identified as the main concerns for food safety. In addition, given that the current *post-mortem* procedures involve palpation and incision of some organs, the potential for cross-contamination of carcasses exists.

As neither of the main public health hazards associated with meat from small ruminants can be detected by traditional visual meat inspection, other approaches are necessary to identify and control these microbiological hazards. A comprehensive meat safety assurance system for small ruminants, combining a range of preventive measures and controls applied both on the farm and at the slaughterhouse in a longitudinally integrated way, is the most effective approach to control the main hazards in the context of meat inspection.

Information on the biological risks associated with the consumption of meat from sheep or goats 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 *T. gondii* and pathogenic VTEC at flock/herd, live animal and carcass level in individual MSs. Epidemiological and risk assessment studies are also required to determine the specific risk to public health associated with the consumption of meat from small ruminants. If these studies confirm a high risk to public health through the consumption of meat from sheep or goats, 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.

Flock/herd categorisation according to the risk posed by the main hazards is considered an important element of an integrated meat safety assurance system. This should be based on the use of farm descriptors and historical data in addition to batch-specific information. Farm-related data could be provided through farm audits using Harmonised Epidemiological Indicators (HEIs) to assess the risk and protective factors for the flocks/herds related to the given hazards.

In addition, classification of abattoirs according to their capability to prevent or reduce faecal contamination of carcasses can be based on two elements: (1) the process hygiene as measured by the level of indicator organisms on the carcasses (i.e. process hygiene criteria); and (2) the use of operational procedures and equipment that reduce faecal contamination, as well as industry led quality systems.

There are a variety of husbandry measures that can be used to control *T. gondii* on sheep and goat farms but at present these are impractical to implement in most farms. A number of post-processing interventions are effective in inactivating *T. gondii* such as cooking, freezing, curing, high pressure and irradiation treatments, although further research is required to validate these treatments in meat from small ruminants. There are also a variety of husbandry measures that can be used to reduce the levels of VTEC on farms, but their efficacy is not clear in small ruminants. There are also a number of challenges that need to be overcome regarding the setting of targets for pathogenic VTEC, including the difficulties in identifying husbandry factors that can be used to classify farms according to pathogenic VTEC risk, the intermittent nature of shedding, and the problems with the interpretation of

monitoring results for VTEC due to the difficulty to correctly identify pathogenic VTEC. The main sources of VTEC on sheep and goat carcasses are the fleece/hide and the viscera. To control incoming faecal contamination only clean animals should be accepted for slaughter. There are also a number of measures that can help reducing the spillage or leakage of digestive contents onto the carcass, as well as post-processing interventions to control VTEC are also available. These include hot water and steam pasteurization.

Risk categorisation of slaughterhouses should be based on trends of data derived from Process Hygiene Assessments and from Hazard Analysis Critical Control Point programmes. Improvement of slaughter hygiene through technological and managerial interventions should be sought in slaughterhouses with repeatedly unsatisfactory performance.

FCI can be improved by including information on participation in quality assurance schemes and by greater feedback to the primary producer, as this would likely result in the production of healthier animals. *Ante-mortem* inspection assesses the general health status of the animals and helps to detect animals heavily contaminated with faeces on arrival at the slaughterhouse, so no adaptations for the existing visual *ante-mortem* inspection are required. Routine *post-mortem* examination cannot detect the meat-borne pathogens of public health importance. Palpation of the lungs, the liver, the umbilical region and the joints, and incision of the liver could contribute to the spread of bacterial hazards through cross contamination. For these reasons, palpation and incision should be omitted in animals subjected to routine slaughter.

A series of recommendations were made on data collection, source attribution studies, methods of detection of viable *T. gondii* in meat and on assessing the effect of the omission of palpation and incision on the risk posed by non-meat-borne zoonoses.

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ASSESSMENT

1. Introduction

1.1. Definition of meat inspection and scope of opinion

Assessing current meat inspection systems for sheep and goats with the aim of introducing improvements requires a common understanding of the term "meat inspection". However, as discussed previously (EFSA, 2010, 2011), 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's Code of Hygienic Practice for Meat (CAC/RCP 58–2005)[8]; rather, there are references to elements of the inspection process for meat such as *ante-* and *post-mortem* inspections and food chain information. Consequently, the current understanding of the term *meat inspection* is probably based more on its practical application, and 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 sheep and goats, 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 for important hazards that are not sufficiently covered by the current system. Outside of the scope of the opinion were:

- Microbiological hazards representing only occupational health risks
- Transmissible spongiform encephalopathies (TSEs)
- Issues other than those of public health significance, but which still compromise fitness of meat for human consumption (for example quality issues such as dark firm and dry (DFD) meat).

As the EU Regulations do not include different inspection requirements for sheep and goats, both species are considered together, but any important differences between these species are considered when necessary. In this document, the term small ruminant is used to refer to a combination of sheep and goats.

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 small ruminants, during which experts from several stakeholder organisations 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 when relevant.

Chemical hazards and associated meat safety risks in small ruminants are considered in a separate part of this opinion (see Appendix B). Although highest priority is given to the public health aims of the improvements of the biological/chemical meat safety system, any implications for animal health and welfare of the proposed changes were assessed (see Appendix C). Furthermore, issues related to epidemiological indicators and associated sampling/testing methodologies for hazards dealt with in this opinion were addressed by the Biological Monitoring Unit in a separate document (EFSA, 2013).

1.2. Structure of small ruminant farming systems in the EU

The structure of the EU small ruminants farming industry has already been described in an EFSA opinion (EFSA, 2004). Briefly, sheep farming takes place in many areas of Europe because sheep are

[8] http://www.codexalimentarius.org/download/standards/10196/CXP_058e.pdf

able to live in a wide range of environments, even those hostile for other animals. Goats are generally reared in extensive systems, traditionally in less developed areas, such as mountains or arid regions, and are often reared with sheep, especially in southern Europe. Milk sheep and goats are reared in similar systems, either grazed near the farm or kept housed, with the milk used in most cases for cheese production. Meat production in Europe reflects the diverse farming systems. Lamb[9] meat production originates from sheep milk farms or from farms raising meat breeds. In the Mediterranean countries, the lambs from milk farms are slaughtered at approximately one month of age (suckling lambs, the same applies to goat kids). In some of these countries, lambs from meat breeds are generally slaughtered at 70–100 days of age and represent the majority of total national lamb meat production. In northern countries, the rearing systems usually produce heavier lambs that may be slaughtered at six or more months of age. The proportion of sheep raised for wool production has steadily decreased over time, but it is still significant in parts of the EU. Sheep and goats at the end of their productive life can also be destined for meat production, with the resulting meat usually processed into meat products or exported.

Although the production and consumption of lambs have decreased in recent years, lamb meat continues to be a traditional product consumed in some countries of the EU such as the United Kingdom, Ireland and the Mediterranean countries (Spain, France, Greece and Italy). These countries have the largest populations of sheep in the EU. In general, the southern countries produce lighter carcasses (about 10 kg) than the northern ones (18–20 kg).

1.3. Structure of the processing industry

Sheep are relatively small animals, with a lower yield of meat per carcass and higher slaughter and processing costs per unit of meat produced. As a result, sheep meat is relatively expensive in the market compared with other protein sources. The co-products (e.g. hides, wool, offal, feet, tails, etc.) have a major effect on the prices received by producers, and the impact on the profitability of the enterprise is profound (Byrne et al., 2011). EUROSTAT statistics show that sheep meat production in the EU was over 720 000 tonnes in 2011, with the United Kingdom and Spain as the greatest producers (Figure 1). Goat meat production in the EU is concentrated in the southern European countries, especially Greece and Spain (Figure 2), and accounted for over 57 000 tonnes in 2011. From 2009 to 2010 the number of goats increased by 2.6 % in these Member States (MSs) (European Commission, 2011).

There are many forces instigating change in sheep and goat meat production. Legislative forces present in the hygiene package and microbiological regulation have increased meat hygiene service costs through structural and food safety requirements as well as mandating the provision of traceability and food chain information (Palmer C.M., 2008). Commercial considerations, such as lower co-product returns, higher costs of by-product disposal and the sourcing policies of the multiple retailers (using their market power to control margins) have also put pressure on slaughterhouse profitability (Palmer, 2008). In spite of the EU being only about 80 % self-sufficient in sheep meat, the predictions are that EU sheep numbers are expected to continue to decline over the next 10 years. This problem of falling sheep supplies has led to an overcapacity in the processing sector (Byrne et al., 2011). The effect of this decline is most acute for large slaughterhouses, which can only be run profitably at certain levels of throughput. Given the energy market expectations, greater environmental controls and the pressure on enforcement costs, relief from falling costs looks unlikely (Palmer, 2008).

[9] Lambs are used in this text for illustration purposes. However, the same may also apply to goat kids produced in comparable systems.

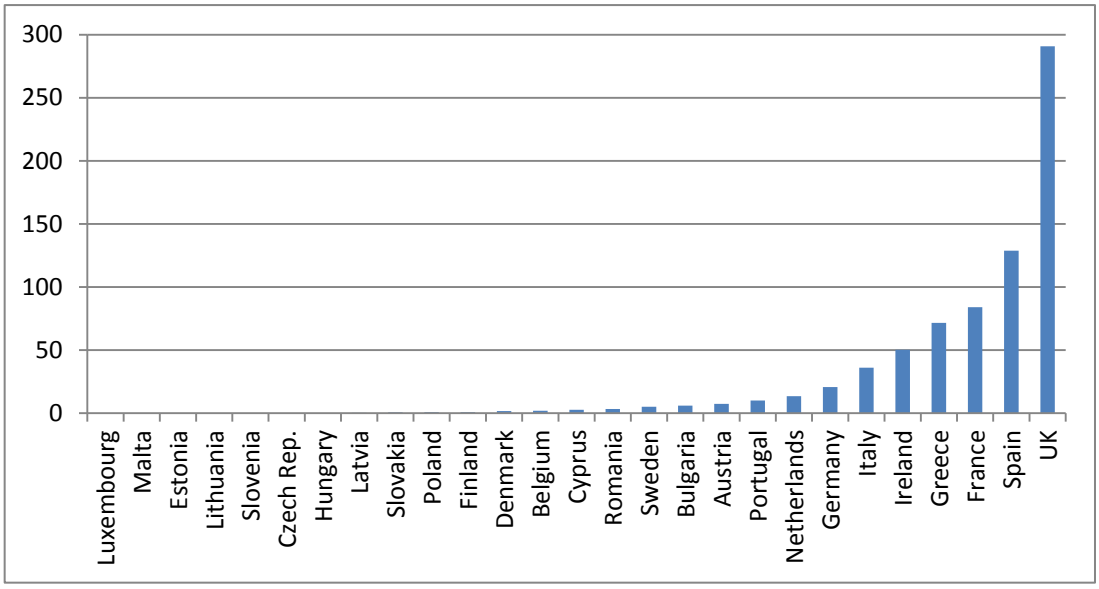

Figure 1: Production of sheep meat, average of 2009, 2010 and 2011, in 1000 tonnes (Statistical database of EUROSTAT,[10] extracted 4 October 2012).

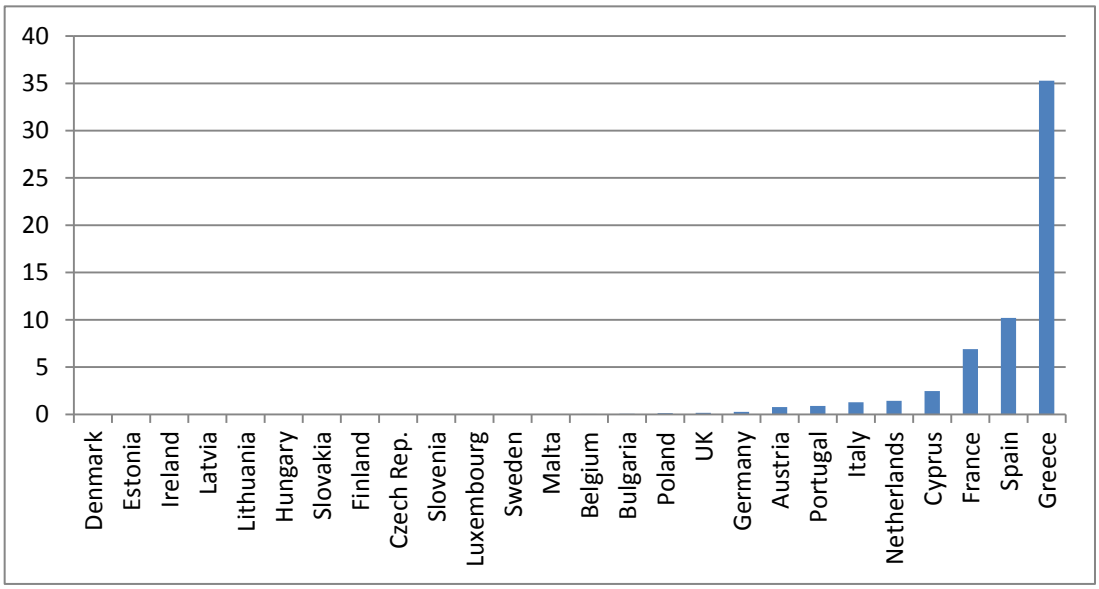

Figure 2: Production of goat meat, average of 2009, 2010 and 2011, in 1000 tonnes (Statistical database of EUROSTAT,[9] extracted 4 October 2012).

The layout and facilities of slaughterhouses as well as slaughtering practices influence the contamination of carcasses. Environmental swab samples from the processing areas in slaughterhouses and cutting plants indicate that there is a strong correlation between the bacterial species and contamination level on sheep carcasses and those of the processing environment (Hauge et al., 2011a) (Loncaric et al., 2009). The slaughter and dressing contamination originates from various sources, including hides, fleece, viscera, knives, equipment, other carcasses and the hands and aprons of the operators and veterinarians, and its avoidance is practically impossible (Hauge et al., 2011a; Norwegian Scientific Committee for Food Safety, 2012). The microbiological quality of the meat produced is influenced by the structure of the premises, the quality of equipment, and the training and skill of operators in complying with good manufacturing practices (EFSA, 2004). Production factors such as seasonal slaughtering, as practised with lambs in countries such as Norway, can influence the

[10] http://epp.eurostat.ec.europa.eu/portal/page/portal/eurostat/home/

availability of skilled personnel competent in good hygiene practices (GHP) (Asheim and Mysterud, 1999). These variations, individually and their combinations, lead to between-slaughterhouse differences in process hygiene performance and, consequently, in the hygienic status of the final carcass. At the end of the slaughter line prior to chilling, process hygiene microbiological criteria, as defined in Regulation (EC) No 2073/2005, verify the effectiveness of each plant's food safety management system (which includes GHP and good manufacturing practices (GMP) prerequisite programmes), based on the principles of hazard analysis and critical control points (HACCP) systems.

Generally, smaller slaughterhouses process much smaller quantities of meat for localised markets and operate at a slower line speed. Operators in such establishments tend to have a wider skill base than their counterparts in large establishments owing to the many varied roles they perform. However, small slaughterhouses have reduced investment capital for expenditure on premises, equipment and staff food safety management training. Disposal of animal by-products and compliance with the microbiological testing Regulation (EC) No 2073/2005 places further financial pressure on these low-throughput businesses. To ameliorate the financial impact of this testing, Article 4 in this regulation states that the frequency of this microbiological sampling may be adapted to the nature and size of the food business, based on a standardised risk assessment and authorised by the Competent Authority. Larger slaughterhouses operate more efficiently, with greater separation of duties and better sampling and food safety oversight. These larger units have larger co-product/by-product markets and therefore produce less waste per animal processed. However, the requirement for high-volume throughput with increased slaughter line speed can impinge on operational hygiene and therefore food safety (Food Standards Agency, 2007a; Palmer, 2008). Such differences in structure and operational practices in the varying sized slaughterhouses can determine the effectiveness of the food safety management system (Motarjemi, 2000).

2. Hazard identification and risk ranking

2.1. Hazard identification

2.1.1. Methodology

A *hazard* is defined by the Codex Alimentarius Commission (CAC) as a "biological, chemical or physical agent or property of food with the potential to cause an adverse health effect". The first step in the hazard identification carried out in this assessment focused on identifying biological hazards occurring in small ruminants and small ruminant meat that can be transmitted to humans, where they may cause disease. Hazards were identified based on evidence found in peer-reviewed literature, textbooks, through reported data (e.g. EU summary reports on zoonoses), previous assessments and EFSA opinions, and the BIOHAZ Panel's and Working Group's expert knowledge.

From this "long" list of identified hazards, the Panel excluded those hazards:

- For which no causal relationship between human infections and the handling, preparation and consumption of meat from small ruminants could be documented through targeted literature reviews.

- Not presently found in the small ruminant population in the EU.

The final "short" list of identified hazards to be included in the priority ranking consisted of hazards occurring in the EU and for which evidence could be found of foodborne transmission through the *handling, preparation and/or consumption* of sheep and goat meat. In the context of this opinion, when referring to *handling and preparation* this should be interpreted as handling of sheep and goat meat that occurs immediately prior to consumption, when these activities are carried out by consumers or professional food handlers.

2.1.2. Results

Based on a review of the scientific literature, a wide range of biological hazards were identified as potential zoonotic hazards related to small ruminants (see Table 1). From these, the majority were considered not to be small ruminant meat-borne pathogens, as no evidence could be found in the literature to support transmission through handling, preparation or consumption of small ruminant meat (for further information on hazards not included see Annex 1, and Section 2.2.3 in this Appendix for those for which evidence for meat-borne transmission was documented).

Other potential pathogenic microorganisms were found not to be relevant as they are not considered to be currently present in small ruminants in Europe (Chandipura virus, *Cryptococcus neoformans* var. *neoformans* and hepatitis E virus), or, if they are, consumption of meat is not considered a significant source of infection. The latter situation applies in particular to *Linguatula serrata*, for which contact with the final host (canids) is the source for the human cases described in Europe. For some of these hazards (e.g. extended-spectrum β-lactamase- (ESBL-)/AmpC-carrying *Escherichia coli*), despite their presence in the animal reservoir, no studies have been conducted to establish whether there is a link between consumption of meat from small ruminants and disease in humans.

The presence of mycobacteria has been previously reported in the small ruminant population in the EU (Domenis et al., 2011; Malone et al., 2003; Marianelli et al., 2010; Shanahan et al., 2011). Despite these reports, evidence of meat-borne transmission of these pathogens to humans from small ruminants is lacking, so this potential pathway of infection remains unproven in the context of livestock processed through the EU meat inspection system. A more detailed discussion on the potential for meat-borne transmission of mycobacteria can be found in the scientific opinion dealing with bovines (EFSA BIOHAZ Panel, 2013).

Table 1: Preliminary (long) list of biological hazards occurring in small ruminants that can be transmitted to humans categorised by whether they are meat-borne and whether they are present in the small ruminant population in the EU.

Hazard	Is there evidence of transmission via consumption of meat from small ruminants?	Present in the small ruminant population in the EU?	Included in assessment?
Bacteria			
Aeromonas spp.	No	Yes	No
Anaplasma phagocytophilum (formerly *Ehrlichia phagocytophila*, *Ehrlichia equi* and *Anaplasma phagocytophila*), Panola Mountain *Ehrlichia*	No	Yes	No
Arcobacter spp.	No	Yes	No
Bacillus anthracis[1]	Yes	Yes	Yes
Bacillus cereus[1]	Yes	Yes	Yes
Borrelia burgdorferi sensu lato	No	Yes	No
Brucella spp.	No	Yes	No
Campylobacter spp. (thermophilic)	Yes	Yes	Yes
Chlamydophila abortus	No	Yes	No
Clostridium botulinum[1]	Yes	Yes	Yes
Clostridium difficile	No	Yes	No
Clostridium perfringens[1]	Yes	Yes	Yes
Corynebacterium pseudotuberculosis	No	Yes	No
Coxiella burnetii	No	Yes	No
Pathogenic verocytotoxin-producing *Escherichia coli*, (VTEC)[2]	Yes	Yes	Yes
Erysipelothrix rhusiopathiae	No	Yes	No
ESBL-/AmpC-carrying bacteria	No	Yes	No
Helicobacter pylori	No	Yes	No
Klebsiella pneumoniae	No	Yes	No
Leptospira spiralis	No	Yes	No
Listeria spp.[1]	Yes	Yes	Yes
Mycobacterium avium subsp. *paratuberculosis*	No	Yes	No
Mycobacterium bovis, M. caprae	No	Yes	No
Salmonella spp.	Yes	Yes	Yes
Staphylococcus aureus (toxin)[1]	Yes	Yes	Yes
Meticillin-resistant *Staphylococcus aureus*	No	Yes	No
Streptococcus suis, *Streptococcus equi* subsp. *zooepidemicus*	No	Yes	No
Yersinia pseudotuberculosis, Y. enterocolitica	No	Yes	No
Fungi			
Candida albicans	No	Yes	No
Cryptococcus neoformans var. *neoformans*	No	No	No
Encephalitozoon cuniculi	No	Yes	No
Enterocytozoon bieneusi	No	Yes	No
Parasites			
Ascaris lumbricoides	No	Yes	No
Babesia divergens, B. microti	No	Yes	No
Coenurus cerebralis	No	Yes	No
Cryptosporidium parvum	No	Yes	No
Cysticercus ovis, C. tenuicollis	No	Yes	No
Dicrocoelium dendriticum	No	Yes	No
Echinococcus granulosus	No	Yes	No
Fasciola hepatica	No	Yes	No

Hazard	Is there evidence of transmission via consumption of meat from small ruminants?	Present in the small ruminant population in the EU?	Included in assessment?
Giardia intestinalis	No	Yes	No
Gongylonema pulchrum ("gullet worm")	No	Yes	No
Linguatula serrata	Yes	Yes	No
Moniezia expansa	No	Yes	No
Sarcocystis spp.	No	Yes	No
Toxoplasma gondii	Yes	Yes	Yes
Trichinella spp.	Yes	No	No
Trichostrongylus spp.	No	Yes	No
Viruses			
Astroviruses	No	Yes	No
Borna disease virus	No	Yes	No
Bovine enterovirus type 1 (BEV-1)	No	Yes	No
Chandipura virus	No	No	No
Crimean Congo haemorrhagic fever virus (CCHFV)	No	No	No
Hepatitis E virus	No	Yes	No
Influenza virus	No	Yes	No
Orfvirus	No	Yes	No
Rabies	No	Yes	No
Rift Valley fever virus	Yes	No	No
Rotavirus	No	Yes	No
Tick-borne encephalitis	No	Yes	No

[1] These hazards are ubiquitous and can potentially be transmitted through consumption, preparation and handling of meat, but it is generally not possible to identify the original source of the contamination.
[2] Human pathogenic verocytotoxin-producing *E. coli*, also known as verotoxigenic *E. coli*, verocytotoxigenic *E. coli*, verotoxin-producing *E. coli* and Shiga toxin-producing *E. coli* (STEC).

The remaining hazards were considered eligible for further assessment and risk ranking (Table 2).

Table 2: Hazards that were considered eligible for further assessment and risk ranking

Hazard
Bacillus anthracis
Bacillus cereus
Campylobacter spp. (thermophilic)
Clostridium botulinum
Clostridium perfringens
Pathogenic VTEC
Listeria monocytogenes
Salmonella spp.
Staphylococcus aureus (toxin producing)
Toxoplasma gondii

2.2. Risk ranking

2.2.1. Methodology

The Panel developed a decision tree that was used for the risk ranking of the small ruminant meat-borne hazards according to their risk of causing infection in humans following the handling, preparation and/or consumption of sheep or goat meat (Figure 3). The CAC defines *risk* as "a function

of the probability of an adverse health effect and the severity of that effect, consequential to one or more hazards in a food". In other words, a foodborne risk is a product of the likelihood of occurrence of the hazard and the magnitude and severity of the consequences of the illness it causes on human health.

This decision tree was adapted from that presented in the scientific opinion on poultry meat inspection (EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM) and EFSA Panel on Animal Health and Welfare (AHAW), 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. This modification was considered appropriate as there was insufficient data at EU level for qualifying carcass prevalence and source attribution for the given hazards. Furthermore, consumption of meat from small ruminants is both lower and unevenly distributed in the EU relative to that of meat from other animal species such as pigs or poultry. Attribution at the population level, as applied in the previous scientific opinions on meat inspection (EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM) and EFSA Panel on Animal Health and Welfare (AHAW), 2011, 2012), may not provide a sufficiently detailed perspective on the relative risk of different hazards in meat from small ruminants. The risk to consumers of meat from these species, rather than to the population as a whole, was therefore assessed. An added consequence is that the categorisation has been reduced from three to two categories (i.e. the medium category is not used in this opinion).

- The term "priority" has replaced the term "risk" used in the pork and poultry opinions. Risk ranking requires a significant amount of data on both the occurrence of the relevant hazards and the fraction of cases of human disease caused by the different hazard–meat species combinations (i.e. source attribution). While 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 small ruminants, for which EU-wide baseline surveys and harmonised monitoring do not 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 meat from small ruminants.

Based on this, the Panel identified the following criteria to be important for determining the final priority category:

Step 1: Identifying and excluding those hazards that are introduced and/or for which the risk for public health requires microbial growth during steps that take place after carcass chilling. The reasons for excluding such hazards from further assessment were that: (1) the scope and target of meat inspection are focused on the food safety risks of the carcasses at the end of slaughter when they are chilled but before they are further processed; and (2) hazards introduced and/or for which the risk relates exclusively to growth during post-chilling processes are better controlled later in the food production chain through, for instance, HACCP programmes.

Step 2: To assess the magnitude of the human health impact, as measured by the reported incidence (notification rate) or number of cases. Where data allowed, the estimated total number of cases was presented, i.e. adjusting for under-reporting. Incidence was considered high if the notification rate in humans at EU level, as reported to ECDC, was equal to or higher than 10 cases in 100 000 population in any given year.

Step 3: To assess the severity of the disease in humans based on mortality. If necessary, severity was also evaluated by comparing disease burden estimates, expressed for example in disability-adjusted life-years (DALYs) per 1 000 cases. The DALY metric quantifies the impact of disease on the health-

related quality of life of acute diseases and sequelae, as well as the impact of premature deaths. Severity was considered high if mortality in humans at EU level, as reported to ECDC, was higher or equal to 0.1 % in more than one year.

Step 4: Evidence supporting the role of meat from small ruminants as a risk factor for disease in humans. For this, the following sources of information were considered:

1. Epidemiological link, based on a significant likelihood that the consumption of meat from the given species is a risk factor for human cases, or on outbreak data

2. Carcass prevalence /farm level prevalence (prevalence studies)

3. Comparative considerations for meat from related species

4. Expert opinion that meat consumption is a risk factor.

The final outcome of this process involved categorising each hazard as high or low priority, as follows:

- The priority was characterized 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 meat from sheep or goats 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 (EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM) and EFSA Panel on Animal Health and Welfare (AHAW), 2012);

- The priority was characterized 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, the evidence available did not identify meat from sheep or goats as an important risk factor for human disease;

- All hazards placed in the low priority category were further evaluated to determine if this was low due to currently controls applied (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 the hazard was further considered and the effect of any recommendations regarding the removal of specific control measures or meat inspection activities on these hazards was assessed and the categorisation of the hazard was reconsidered.

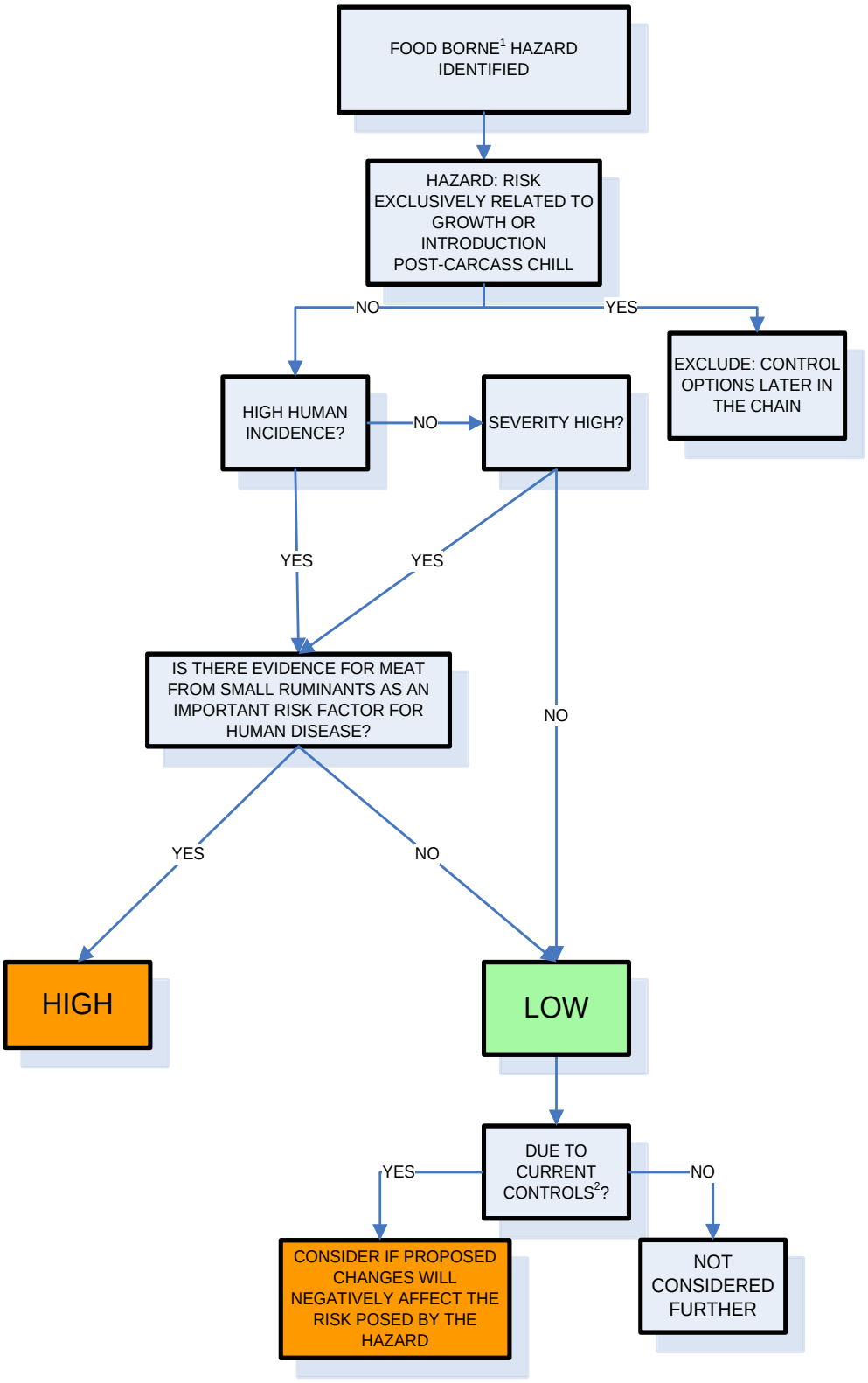

Figure 3: Flowchart for priority ranking different public health hazards.

[1] Risk of infection by handling, preparation or consumption of sheep and/or goat meat.
[2] Current controls: any hazard-specific control measures implemented at farm and/or slaughterhouse level before chilling of the carcasses.

2.2.2. Data employed for the priority ranking of hazards

For the hazards shortlisted (Table 2), data on the incidence and severity in humans and the prevalence of the pathogens in the carcasses of small ruminants were sought to allow the risk from these microbiological hazards to be ranked, based on the decision tree in Figure 3. See Tables 3, 4, 5 and 6 for details.

The data in Table 3 were obtained from The European Surveillance System (TESSy), covering the years 2008, 2009, 2010 and 2011. The data 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; these were specified. 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 seldom reported. The data on severity include as a proxy the proportion of confirmed human cases that died. This information is usually only available in a small proportion of cases. Finally, it has to be kept 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, focus, target groups, etc., in addition to the fact that only a small fraction of diseased patients is sampled and the casual organism typed and reported to the respective national health institutes. Because of all these caveats, the incidence and severity figures quoted here are only approximate and must be considered with caution.

Table 3: Overall human incidence and severity data reported by EU MSs as described in Decision (2119/98/EC) on communicable diseases. Biological hazards in small ruminants that may be transmissible to humans through consumption of meat. Source: TESSy data, extraction carried out on 31 January 2013.

Hazard	Incidence in humans (number of reported confirmed cases per 100 000 EU population[a]; [number of confirmed cases])				Severity in humans (percentage of reported deaths[b]; [number of confirmed cases with information])			
	2008	2009	2010	2011	2008	2009	2010	2011
Bacillus anthracis	< 0.01 [2]	< 0.01 [14]	0.01 [32]	< 0.01 [6]	100.00 [1]	54.55 [11]	37.93 [29]	25.00 [4]
Campylobacter spp. (thermophilic)[c]	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)[d]	0.86 [3 156]	0.97 [3 583]	1.00 [3 656]	2.56 [9 478]	0.15 [1 363]	0.35 [1 701]	0.38 [2 108]	0.75 [7 504]
VTEC (O157)[e]	0.35 [1 683]	0.39 [1 888]	0.31 [1 510]	0.45 [2 195]	0.00 [241]	0.94 [318]	0.56 [536]	0.36 [1 110]
Salmonella spp.[f]	29.46 [132 800]	23.81 [108 977]	21.51 [99 590]	20.37 [94 264]	0.09 [72 837]	0.08 [54 273]	0.13 [46 996]	0.12 [46 808]
Toxoplasma gondii (congenital, i.e. in infants < 1 year)[g]	0.04 [83]	0.10 [306]	0.07 [279]	0.01 [29]	50.00 [2]	9.62 [260]	5.15 [233]	n.a.[h]

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, 2013).
e Portugal not reporting.
f *S. enterica* subsp. *enterica* serovar Typhi and *S.* Paratyphi serovars not included; Netherlands not reporting.
g Seroprevalence. Belgium, Denmark, Greece, Italy, Netherlands, Portugal and Sweden not reporting; Spain reporting through the sentinel system and thus not taken into account. France not reported in 2011 at the time of extraction of these data.
h n.a. = not available.

Data presented in Tables 4–6 are related to flock/herd and carcass prevalence of the hazards identified in sheep and goats. They were obtained from monitoring data as reported by the EU MSs in the frame of the Zoonosis Directive (2003/99/EC), when available. Data reported in the period from 2007 to 2010 were considered. No information was available at carcass level for goats.

In these tables, data described as originating from suspect or selective sampling and from clinical investigations were excluded as they do not, in most cases, represent the actual epidemiological situation. Food samples described as collected for HACCP and own-check purposes were also excluded because the sampling scheme may be biased. Samples included are described as originating from control and eradication plans and monitoring and surveillance; consequently they are supposed to represent the occurrence of the zoonotic agent in the reporting country over the years, based on objective sampling. However, it has to be noted that monitoring and surveillance systems for most of zoonotic agents are not fully harmonised between MSs. Furthermore, data may not necessarily be derived from sampling plans that have a sound statistical design, and may therefore not accurately represent the national situation regarding the true prevalence of zoonoses.

Data in Tables 4 and 6 originate from samples taken from either farms or slaughterhouses, while for Table 5 the samples were taken exclusively at slaughterhouses. The average prevalence was calculated by adding all the sample results across all years and member estates. Data include the maximum and minimum prevalence values from any MS in any year in the period 2004–2011, if at least 25 sample units had been reported.

Table 4: Sheep prevalence estimates for the period 2004–2011 for the different hazards in the EU as reported to EFSA in the frame of the Zoonoses Directive (2003/99/EC) by MSs.

	Flock level			Animal level		
Hazard	**Number of MSs reporting**	**Number of samples**	**Average prevalence % (min–max)**	**Number of MSs reporting**	**Number of samples**	**Average prevalence % (min–max)**
Bacillus anthracis	n.a.[a]	n.a.	n.a.	n.a.	n.a.	n.a.
Campylobacter spp.	3	1 153	8.1 (2.5–13.3)	10	6 633	2.7 (0–7.8)
VTEC (all serotypes)[b]	3	249	11.6 (0–36.4)	12	3 855	4.4 (0–73)
VTEC (*Escherichia coli* O157)	3	249	1.2 (0–13.6)	12	3 855	0.4 (0–0.9)
Salmonella spp.	4	5 580	7.2 (0–45.6)	19	21 129	5.7 (0–100)
Toxoplasma gondii[c]	3	4 679	67.7 (43–74)	20	51 250	28.0 (0–100)

a n.a., no data available.
b Includes those reported as human pathogenic and non-human pathogenic (i.e. no harmonised scheme to discriminate between both, and data available does not preclude that they are not human pathogenic).
c Seroprevalence.

Table 5: Prevalence estimates for the period 2004–2011 for the different hazards in fresh sheep meat in the EU as reported to EFSA in the frame of the Zoonoses Directive (2003/99/EC) by MSs.

	Batch level			Single sample level		
Hazard	**Number of MSs reporting**	**Number of samples**	**Average prevalence % (min–max)**	**Number of MSs reporting**	**Number of samples**	**Average prevalence % (min–max)**
Bacillus anthracis	n.a.[a]	n.a.	n.a.	n.a.	n.a.	n.a.
Campylobacter spp.	2	9	0.0	9	1 852	1.8 (0–5.8)
VTEC (all serotypes)[b]	2	122	0.0	4	248	0.4 (0–2.8)
VTEC (*Escherichia coli* O157)	2	122	0.0	4	248	0.4 (0–2.8)
Salmonella spp.	3	555	0.4 (0–1)	10	1004	0.3 (0–0.5)
Toxoplasma gondii[c]	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

a n.a., no data available.
b Includes those reported as human pathogenic and non-human pathogenic (i.e. no harmonised scheme to discriminate between both, and data available does not preclude that they are not human pathogenic).
c Seroprevalence.

Table 6: Prevalence estimates for the period 2004–2011 for the different hazards in goats in the EU as reported to EFSA in the frame of the Zoonoses Directive (2003/99/EC) by MSs.

	Herd level			Animal level		
Hazard	**Number of MSs reporting**	**Number of samples**	**Average prevalence % (min-max)**	**Number of MSs reporting**	**Number of samples**	**Average prevalence % (min-max)**
Bacillus anthracis	n.a.[a]	n.a.	n.a.	n.a.	n.a.	n.a.
Campylobacter spp.	3	352	3.7 (0–11.5)	7	1 223	4.7 (0–16.8)
VTEC (all serotypes)[b]	3	46	13 (0–13.6)	9	881	10.9 (0–11.8)
VTEC (EHEC O157)	3	46	0	9	881	0.8 (0–1.3)
Salmonella spp.	3	957	3.1 (0.7–10.4)	18	3 149	1.5 (0–7.1)
Toxoplasma gondii[c]	2	491	28.3 (21.6–41.1)	17	6 710	22.0 (0–69.8)

a n.a., no data available.
b Includes those reported as human pathogenic and non-human pathogenic (i.e. no harmonised scheme to discriminate between both, and data available does not preclude that they are not human pathogenic).
c Seroprevalence.

2.2.3. Results of the priority ranking of hazards

Listeria monocytogenes and toxins of *Bacillus cereus*, *Clostridium botulinum*, *Clostridium perfringens* and *Staphylococcus aureus* were all considered to fall within the category of risk related to growth or introduction post-chilling, for different reasons:

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 relevance for public health and thus the risk of disease seems not to be correlated with occurrence in raw meat but rather with improper hygiene and storage that allows the production of toxins. Illness caused by *L. monocytogenes* is usually associated with ready-to-eat products, in which contamination has occurred before or during processing followed by growth during storage at refrigeration temperatures.

Based on incidence and severity in humans (Table 3), flock/herd, animal and carcass prevalence (Tables 4, 5 and 6) and other epidemiological evidence, the hazards in Table 2 were ranked and categorised according to the flowchart in Figure 3, as described in Section 2.2.1 above. A summary of

the outcome is provided in Table 7 at the end of this section. None of the hazards identified as low priority were found to be such owing to currently applied controls.

Bacillus anthracis

This organism has a worldwide distribution, persisting in the soil in the form of extremely resistant spores for many years. Infection is initiated with the introduction of the spore through a break in the skin or entry through the mucosa. After ingestion by macrophages at the site of entry, germination to the vegetative form occurs, followed by extracellular multiplication and capsule and toxin production.

Humans can acquire anthrax by exposure to infected animals, animal products or spores in the soil and, depending on the mode of transmission, can develop one of four distinct clinical forms: respiratory, cutaneous, gastrointestinal and oropharyngeal. Human cases of pulmonary anthrax have been linked to the large-scale processing of hides and wool in enclosed factory spaces, where aerosolised anthrax spores may be inhaled. Humans also acquire the cutaneous form of anthrax from handling contaminated animal products, such as hides, wool and hair. Cases of gastrointestinal anthrax have resulted from the ingestion of raw or undercooked meat (Spickler, 2007) and well-cooked beef from infected animals (Centers for Disease Control and Prevention, 2000). Recently, a case of anthrax possibly acquired through handling or consumption of contaminated beef in a household in Romania has been reported (Popescu et al., 2011). Consumption of meat (including sheep and goat meat) from carcasses of animals showing clinical signs of anthrax, or animals that have died from the disease, is the most reported common route of foodborne infection resulting in gastrointestinal anthrax.

- **Human incidence:** based on EU data, low.

Anthrax has a low human prevalence in the EU (see Table 3 for details). Between 2008 and 2011, the number of anthrax cases reported to the ECDC ranged from two confirmed cases (2008) to 32 (2010). An outbreak of anthrax infection in heroin users in Scotland was reported in December 2009, continuing into 2010 with a total of 55 cases including 21 deaths from the United Kingdom, mainly Scotland and the London area, and Germany. Additional cases have been reported more recently (Grunow et al., 2013).

- **Severity of disease**: based on EU data, high.

The severity of these infections is considered high, and this is supported by the mortality figures in Table 3.

- **Evidence for meat from small ruminants as an important risk factor:** no.

The organism causes a highly infectious notifiable disease in farmed and wild animals that have grazed on contaminated land or ingested contaminated feed (Swartz, 2001). The livestock species most susceptible, in descending order, are cattle, sheep, horses, pigs, goats and camels (Fasanella et al., 2010a). The disease is endemic in most countries in Africa and Asia (Thurnbull, 1998) and in defined regions of other countries. Flooding may often concentrate spores of *B. anthracis* in particular locations. In sheep and goats, the disease is usually peracute, or acute and rapidly fatal, with death occurring in some cases within hours and affected animals showing multiple haemorrhages from natural orifices. Although most cases are found dead without showing premonitory signs, pyrexia with temperatures up to 42° C along with depression, congested mucosae and petechiae may be observed *ante-mortem*. *Post-mortem* findings are characterised by incomplete rigor mortis, widespread ecchymotic haemorrhages and oedema, dark, unclotted blood and blood-stained fluid in body cavities and severe splenomegaly (Quinn et al., 2002). Handling, or direct contact with such animals and carcasses is highly dangerous. Anthrax is now rare in livestock in the EU. The major enzootic areas are Greece, Spain, France and southern Italy (Fasanella et al., 2005; Fouet et al., 2002). A severe outbreak of anthrax occurred in southern Italy in 2004 (Fasanella et al., 2010b). Over 41 days, 81 cattle, 15 sheep, 9 goats, 11 horses and 8 deer died. Also in Italy, an outbreak of anthrax of similar

magnitude was reported among cattle, sheep and horses in 2011[11]. Given the low number of cases of anthrax in the small ruminant population in the EU, the risk of acquiring this disease through consumption of meat from these species can be considered very low.

Based on the data presented and on the above discussions, the BIOHAZ Panel concluded that *B. anthracis* was a low priority hazard with regard to meat inspection of small ruminants. This result is not due to current controls (i.e. any hazard-specific control measures implemented at farm and/or slaughter level before chilling of the carcasses, including current meat inspection procedures).

***Campylobacter* spp. (thermophilic)**

- **Human incidence:** based on EU data, high.

Campylobacteriosis is the most frequently reported zoonotic illness in the EU with a reported incidence of 71.5 confirmed cases per 100 000 in 2011 (Table 3), and it is estimated that there are nine million cases of illness annually in the EU-27 (EFSA Panel on Biological Hazards, 2010).

- **Severity of disease**: as the incidence is high, the severity does not need to be considered.

- **Evidence for meat from small ruminants as an important risk factor:** no.

Campylobacter jejuni is common in the intestines of ruminants of sheep and lambs. The reported prevalence of *Campylobacter* spp. in sheep and goats can be found in Tables 4, 5 and 6. For sheep and at flock level, the prevalence was 8.1 %, while for goats it was 3.7 % (at individual animal level there were 2.7 % and 4.7 %). With regards to carcasses, no data were available for goats. For sheep, the batch prevalence was 0 %, and at individual sample level 1.8 %.

Information from the scientific literature also suggests that *Campylobacter* spp. is often found in small ruminants, with a wide range of prevalences reported. In a study of lambs in the United Kingdom *Campylobacter* spp. was isolated from 92 % of the 360 samples taken from the small intestines (Stanley et al., 1998). On the other hand, Sproston et al. (2011) found this bacterium in just 14 % of fresh faecal samples from 214 sheep on a farm in Scotland. Other studies have reported prevalences somewhere in between these two figures (Milnes et al., 2008; Ogden et al., 2009; Oporto et al., 2011; Rotariu et al., 2009; Schilling et al., 2012). A seasonal variation in prevalence and the number of *Campylobacter* spp. has also been reported in some studies (Milnes et al., 2008; Sproston et al., 2011).

Several studies have investigated the presence of *Campylobacter* spp. in carcasses or meat from small ruminants. Garcia et al. (2010) investigated the presence of *Campylobacter* spp. on 80 sheep carcasses, with a resulting prevalence of 90 %. The authors concluded that the prevalence on carcasses reflected the occurrence of *Campylobacter* spp. in both wool and faeces. However, there is a significant reduction in detection following chilling, probably owing to both the low temperature and drying of the carcass (Norwegian Scientific Committee for Food Safety, 2012). After swabbing of 100 cm^2 around the circum-anal incision of 60 lamb carcasses before chilling *Campylobacter* spp. was isolated from eight (13.3 %) of the carcasses. After a relatively slow chilling process (the air temperature was never below 0 °C) *Campylobacter* spp. was recovered from only one carcass (1.7 %). This study suggests that *Campylobacter* spp. dies during the routine cooling of the carcasses. This theory is supported by the low carcass prevalence found in other studies (0.3 % of 2 226 carcasses, Duffy et al., 2001; 0.4 % of 1 117 carcasses, Phillips et al., 2006; 3 % of 320 carcasses, Bilei et al., 2012) as well as the low prevalence found in meat (0.2 % of 560 samples, Phillips et al., 2006; 7 % of 231 lamb samples—all less than 0.3 MPN/g—Wong et al., 2007; 0.7 % of 1 056 lamb samples, FSA , 2010).

Data from epidemiological or attribution studies suggest that meat from small ruminants plays a minor role as a source of human campylobacteriosis. Gras et al., (2012) estimated that 2.4 % of *C. jejuni* and

[11] See: http://www.oie.int/wahis_2/public/wahid.php/Reviewreport/Review?page_refer=MapFullEventReport&reportid=11003

5 % of *C. coli* cases could be attributed to small ruminants, including through direct contact with animals. Domingues et al. (2012) estimated an odds ratio (OR) of 0.73 (0.50–1.06) for consumption of lamb as a risk factor for sporadic campylobacteriosis. Strachan et al. (2009) attributed between 12–15 % of cases in children under 5 years old to the sheep reservoir, but suggested that "*infection with ruminant strains is likely to occur via an indirect route (e.g., waterborne transmission or direct contact with animals, produce, or raw milk)*". Similarly, Danis et al. (2009) estimated an adjusted matched OR of 11 for contact with sheep as a risk factor for human campylobacteriosis, but consumption of meat from these species was not considered a risk factor. An earlier case-control study in households with primary *Campylobacter* spp. infection in the Netherlands also failed to identify consumption of mutton as risk factor (Oosterom et al., 1984) Finally, people that had consumed mutton were less likely to become ill with *Campylobacter* spp. infection in a prospective case-control study of campylobacteriosis carried out in Norway (Kapperud et al., 2003).

Like their sensitive counterparts, antimicrobial-resistant *Campylobacter* spp. involved in human disease are mostly spread through foods, especially poultry meat. As stated in a previous EFSA opinion (EFSA, 2008), "*a major source of human exposure to fluoroquinolone resistance via food appears to be poultry, whereas for cephalosporin resistance it is poultry, pork and beef that are important, these food production systems require particular attention to prevent spread of such resistance from these sources*". There are no indications that resistant strains behave differently in the food chain compared with their sensitive counterparts, hence there is no need to consider these strains separately in the context of meat inspection.

Based on the presented data, it is concluded that *Campylobacter* spp. are a low public health priority with regard to meat inspection of small ruminants. This ranking is not the result of current controls.

Pathogenic VTEC

Verocytotoxin/Shiga toxin (VT/Stx)-producing *E. coli* (VTEC/STEC) are characterised by the ability to produce potent cytotoxins. Pathogenic VTEC usually also harbour additional virulence factors that are important for the development of the disease in human (EFSA and ECDC, 2012, 2013b). Not all VTEC strains have been associated with human disease and there is no single marker or combination of markers that defines a "pathogenic" VTEC (EFSA Panel on Biological Hazards, 2013). While *stx*2- and *eae* gene-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. For the purposes of this opinion, pathogenic VTEC are defined as VTEC capable of causing disease in humans.

- **Human incidence:** based on EU data, low.

Most reported meat-borne human VTEC infections are sporadic cases. In 2010 (EFSA and ECDC, 2012), the total number of confirmed VTEC cases in the EU was 4 000, representing a 12.0 % increase compared with 2009, with a fatality rate of 0.39 %. Table 3 includes data from TESSy from 2008 to 2011 inclusive. In that period the incidence (all VTEC serotypes) per 100 000 population varied between 0.86 and 2.56. The data are not easily comparable between EU countries, owing to underlying differences in the national surveillance systems. The concentration of laboratory testing on the O157 serogroup means that the proportion of non-O157 strains is largely under-reported (ECDC and EFSA, 2011). Data for 2011 have to be interpreted with caution, as VTEC O104:H4 caused a major outbreak which resulted in 4 321 confirmed cases, including 3 469 cases of VTEC infection and 852 of acute renal failure, known as haemolytic–uraemic syndrome (HUS), with 54 deaths reported in 14 EU countries, the United States and Canada when the epidemic was declared to be over at the end of July 2011 (Karch et al., 2012). It has to be noted, however, that the source of the outbreak was sprouted seeds and not meat.

- **Severity of disease:** based on EU data, high.

Pathogenic VTEC infections can be severe, and are often associated with bloody diarrhoea, but there is a wide clinical spectrum in the association between specific subtypes of pathogenic VTEC and the clinical outcome. Bloody diarrhoea has been shown to be associated with an increased risk of developing HUS and neurological injury, such as paralysis. HUS develops in up to 10 % of patients infected with VTEC O157 and is the leading cause of acute renal failure in young children (EFSA and ECDC, 2012). This is reflected in the severity figures in Table 3 and the corresponding classification in Table 7, which are also supported by high DALY (Havelaar et al., 2012a) and quality-adjusted life-year (QALY) estimates (Hoffmann et al., 2012) published in the literature.

- **Evidence for meat from small ruminants as an important risk factor:** yes.

Pathogenic VTEC can be found in the gut of numerous animal species, but ruminants have been identified as a major reservoir of VTEC that are highly virulent to humans, in particular VTEC O157. Although cattle are considered to be the most important source of human infections caused by VTEC O157, they have also been isolated from the intestinal contents of sheep and goats. Food of small ruminant origin has been reported as a source for human VTEC infections (Kosmider et al., 2010; Schimmer et al., 2008; Werber et al., 2007). Transmission occurs through consumption of undercooked meat, unpasteurised dairy products, or water and vegetables contaminated by faeces of carriers. Person-to-person transmission has also been documented (Rey et al., 2006). Data reported in the frame of the Zoonoses Directive (2003/99/EC) from 2004 to 2011 can be found in Tables 4–6. For all VTEC serotypes, the reported prevalence was 11.6 % and 4.4 % for sheep at flock and individual animal level, respectively. For goats, the figures were 13.0 % and 10.9 %. Prevalences for VTEC O157 were much lower across the board.

Isolation of *E. coli* O157 from goats has been reported in studies from several countries, with isolation rates ranging between 2 % and 89 % (Cortes et al., 2005; Keen et al., 2006; Orden et al., 2008; Orden et al., 2003; Schilling et al., 2012). VTEC strains have also been detected in sheep, with a similarly wide range of prevalence figures (Milnes et al., 2008; Oporto et al., 2008; Prendergast et al., 2011; Pritchard et al., 2009; Schilling et al., 2012; Sekse et al., 2011). Thus it is clear that small ruminants can play an important role by shedding these pathogens in the faeces (Blanco et al., 2003; La Ragione et al., 2009). The prevalence can be influenced by the sampling and testing methodology, but these studies nevertheless clearly indicate that pathogenic VTEC is present in the small ruminant population in the EU.

Table 5 includes data from official monitoring of sheep carcasses. The reported prevalence was 0 % at batch level and 0.8 % at individual carcass level (0.2 % for VTEC O157). The scientific literature also indicates that sheep and goat carcasses or meat can be contaminated with VTEC, albeit generally at lower levels compared with those in the animal reservoir. At the higher end of the range, Barlow et al. (2006) in Australia and Zweifel et al. (2003) in Switzerland reported prevalences around 40 % in carcasses and lamb cuts. Brooks et al. (2001) reported a prevalence of 17 % in lamb cuts in New Zealand and other, less recent, studies reported much lower prevalence—between 0 % and 4 % (Doyle and Schoeni, 1987; Heuvelink et al., 1999; Pierard et al., 1997; Samadpour et al., 1994). It has to be noted that this variation in prevalence could be a result of the different testing methodologies used (e.g. use of polymerase chain reaction (PCR) testing), and the fact that not all these VTEC isolates would necessarily be pathogenic to humans.

A case-control study on risk factors for human VTEC in Germany identified lamb as an important risk factor for human infection (Werber et al., 2007). Consumption of dry cured sausages made with sheep meat was identified as the cause of an outbreak of VTEC O103:H25 infection in humans (Schimmer et al., 2008; Sekse et al., 2009). In the latter study, bacteria with the same properties, including identical DNA profiles, were found in five dry cured sausage products and sheep meat used as raw material in sausage production and were identical to the isolates from patients. *E. coli* with the same virulence genes, serotypes, biochemical characteristics and DNA profiles as those found in patients from the *E. coli* O103:H25 outbreak, were detected in sheep from 29 of 491 farms in Norway (Brandal et al., 2010). More recent research in Norway and Spain comparing virulence characteristics between strains

isolated from humans and sheep has suggested that the latter can be an important reservoir for pathogenic VTEC (Brandal et al., 2012; Sanchez et al., 2012).

The evidence arising from epidemiological or source attribution studies points to a minor role for meat from small ruminants as a source of human cases of VTEC, although the model used in this study was found to underestimate the observed prevalence of VTEC in lamb, so this attribution estimate should be interpreted with caution (Kosmider et al., 2010).

Based on the data (see Table 7) and the assessment presented above, the BIOHAZ Panel concluded that pathogenic VTEC can be considered to be of high priority for meat inspection of small ruminants given the relatively high prevalence of this hazard in the small ruminant population, the epidemiological links to outbreaks in humans and the severity of the disease in humans.

***Salmonella* spp.**

- **Human incidence:** based on EU data, high.

In the EU, *S. enterica* subsp. *enterica* serovar Enteritidis and *S.* Typhimurium are the serovars most frequently associated with human illness, although the number of reported cases of *S.* Enteritidis has more than halved since 2006. Human *S.* Enteritidis cases are most commonly associated with the consumption of contaminated eggs and poultry meat, while *S.* Typhimurium cases are mostly associated with the consumption of contaminated pig, poultry and bovine meat. Human salmonellosis is the second-ranking foodborne disease reported in the EU and most European countries, exceeded only by campylobacteriosis (EFSA, 2008; EFSA and ECDC, 2013b). A total of 94 264 confirmed cases were reported from 27 EU MSs in 2011 through TESSy, corresponding to a notification rate of 20.37 confirmed cases per 100 000 (Table 3, which also includes data on the severity of human disease). Accounting for under-reporting, it is estimated that there are six million cases of this illness annually in the EU-27 (EFSA, 2011; Havelaar et al., 2012b).

- **Severity of disease**: as the incidence is high, the severity does not need to be considered.

- **Evidence for meat from small ruminants as an important risk factor:** no.

The common reservoir of *Salmonella* spp. is the intestinal tract of a wide range of domestic and wild animals, which results in a variety of foodstuffs, of both animal and plant origin, as sources of human infections. The organism may be transmitted through direct contact with infected animals or between humans or from faecally contaminated environments.

In animals, subclinical infections are common. The organism may easily spread between animals in a herd or flock without detection, and animals may become intermittent or persistent carriers. Fever and diarrhoea due to *Salmonella* spp. infection are more common in sheep, cattle and horses, whereas goats, pigs and poultry usually show no signs of infection (EFSA and ECDC, 2013b). Sheep and goats have been shown to be potential carriers and symptomless shedders of *Salmonella* spp. (Bonke et al., 2012), although infection by this hazard has sometimes caused outbreaks of abortion in sheep (Clark et al., 2004). *S.* Dublin, *S.* Abortusovis and *S.* Typhimurium were the *S. enterica* serotypes most frequently associated with disease in sheep.

The variant, *S. enterica* subsp. *diarizonae* IIIb 61.k:1,5, (7), which might be referred to as "the sheep variant" owing to its adaption to sheep, is endemic in sheep in several regions of the world such as the United Kingdom (Hall and Rowe, 1980) and Norway (Norwegian Scientific Committee for Food Safety, 2008) in Europe and Canada (Greenfield et al., 1973; Pritchard, 1990) and the United States (Weiss et al., 1986). However, the overall conclusion is that *S. enterica* subsp. *diarizonae* IIIb 61.k:1,5, (7) is very rarely demonstrated as a cause of human infections, including in those areas in which the endemic prevalence in sheep is high such as the United Kingdom and Norway ((Norwegian Scientific Committee for Food Safety, 2008). Another *Salmonella* spp. variant well adapted to sheep,

causing abortion and death of ewes, is *S*. Brandenburg, which is endemic in the South Island of New Zealand (Sabirovic, 2002), but its human health relevance seems to be limited.

EU monitoring data for sheep and goats are presented in Tables 4–6, which contain data collected by MSs from 2004 to 2011. The prevalence reported in both herds and individual animals is 7.2 % and 5.7 %, respectively, for sheep and 3.1 % and 1.5 % for goats. Although *Salmonella* spp. is commonly found in live sheep or goats at variable prevalence levels (Bonke et al., 2012; Duffy et al., 2009; Duffy et al., 2010; Hjartardottir et al., 2002; Moriarty et al., 2011; Zweifel et al., 2004), there is a more limited number of studies looking at the occurrence of *Salmonella* spp. in sheep and goats carcasses. A prevalence of 0. 3% was reported in individual sheep carcasses in the EU monitoring (see Table 5). Bilei et al. (2012) reported a prevalence of 0.6 % in 320 sheep carcasses in Italy, Duffy et al. (2010) reported 1.3 % in 164 sheep carcasses in Australia, Duffy et al. (2001) reported 1.5 % from 5 042 carcasses in the United States, Phillips et al. (2001) reported 0.1 % in 917 carcasses and Vanderlinde et al. (1999) reported 5.7 % of 470 carcasses in Australia. At the same time, a number of studies could not find any *Salmonella* spp. in sheep carcasses: in the United States, Edrington et al. (2009) in 56 lamb carcasses sampled; Hanzelyova and Gamcikova (2009) in carcass samples from 90 sheep in Slovakia; Martineli et al. (2009) in 60 lamb carcasses in Brazil; and Phillips et al. (2006) in 1 117 carcasses in Australia. For goats, the data are a lot more limited, with only Duffy et al. (2009), looking specifically at goat processing, reporting *Salmonella* spp. in 29 % of 121 carcasses in Australia.

Some outbreaks linked to meat from small ruminants can be found in the scientific literature (Evans et al., 1999; Hess et al., 2008; Synnott et al., 1993). These involved unusual consumption patterns (e.g. raw lamb liver) or cross-contamination of raw food ingredients (e.g. yoghurt relish contaminated with carcass blood), therefore it is unclear how significant these events are when assessing the role of sheep or goat meat as a source of *Salmonella* spp. infection. Data from epidemiological or source attribution studies suggest that the role of meat from small ruminants as a vehicle for *Salmonella* spp. infection is limited. A systematic review of case-control studies carried out by Domingues et al. (2012) did not identify meat from small ruminants as a risk factor for sporadic salmonellosis. Similarly, King et al. (2011) did not identify sheep or goat meat as risk factors for outbreaks of salmonellosis in New Zealand. A source attribution study in Europe using outbreak data estimated the proportion of salmonellosis cases attributed to lamb to be 0.1 % (Pires et al., 2010). Similar studies in New Zealand (Mullner et al., 2009) and Latin America and the Caribbean (Pires et al., 2012) also concluded that lamb and mutton are estimated to be minor sources of *Salmonella* spp. infection with 1.4 % and 0 % of cases apportioned respectively.

The occurrence of antimicrobial resistance among zoonotic *Salmonella* spp. is an increasing problem. Antimicrobial-resistant *Salmonella* spp. involved in human disease are, like *Salmonella* spp. in general, mostly spread through foods, predominantly poultry meat, eggs, pork and beef (Hald et al., 2007). As there are no indications that resistant strains behave differently from their sensitive counterparts in the food chain, there is no need to consider these strains separately in the context of meat inspection. Fluoroquinolone and cephalosporin resistance are currently considered to be those of most public health concern. Meat, particularly poultry meat and pork, is recognised as an important source of human exposure to fluoroquinolone-resistant *Salmonella* spp., and high levels of ESBL-/AmpC-producing *Salmonella* spp. have also been reported in poultry in some EU MSs (EFSA and ECDC, 2013a). Such resistant strains may or may not be associated with a significant level of human infection, depending on the pathogenicity of the strains involved and the opportunity for them to contaminate the food chain (Butaye et al., 2006; de Jong et al., 2012; EFSA Panel on Biological Hazards, 2011c; Rodriguez et al., 2012). The control of antimicrobial-resistant bacteria in food including poultry meat is further complicated by the fact that resistance mechanisms can be located on mobile genetic elements such as plasmids and thereby be transferred between different bacterial species, for instance between generally apathogenic *E. coli* and *Salmonella* spp.

Based on the data (see Table 7) and the assessment presented above, the BIOHAZ Panel concluded that the risk arising from consumption of meat from small ruminants with regards to *Salmonella* spp.

is of low priority for meat inspection of small ruminants. This ranking is not the result of current controls.

Toxoplasma gondii

- **Human incidence:** based on EU data on congenital toxoplasmosis, low.

Toxoplasmosis can be contracted by the oral ingestion of oocysts present in cat faeces and the environment, or tissue cysts present in the meat of infected animals (Tenter et al., 2000). In pregnant women, the parasite can cause congenital infections (abortion, stillbirth, mortality and hydrocephalus in newborns or retinochoroidal lesions leading to chronic ocular disease) and complications (lymphadenopathy, retinitis or encephalitis) in immunocompromised individuals such as organ graft recipients and individuals with acquired immune deficiency syndrome (AIDS) or cancer (EFSA, 2007b). In immune-competent individuals, 80–90 % of cases of *Toxoplasma gondii* infection are asymptomatic, and the majority of the remainder have only mild, self-limiting symptoms. Thus, reports of acute symptomatic *T. gondii* infection (toxoplasmosis) do not provide a reliable basis for assessing overall disease incidence. Given these limitations, the incidence of human disease caused by toxoplasmosis is rare (Table 3).

The prevalence of antibodies to *T. gondii* in the general population provides an alternative for estimating the number of cases and disease burden (Food Standards Agency, 2011). *T. gondii* seroprevalence is known to vary geographically and with age (Montoya and Liesenfeld, 2004). Although antibodies are found in 20–40 % of adults in the United Kingdom, seroprevalence is higher in Central Europe, and similar or lower in Scandinavia (11–28 %). Climate and consumption of raw meat, meat from animals farmed outdoors or frozen meat may be factors that contribute to these variations (Kijlstra and Jongert, 2008). Seropositivity also varies within countries, being highest in those from rural or small town backgrounds and lowest in those from urban or suburban areas (Food Standards Agency, 2011). Data showing the variation in seropositivity with age are available from a number of countries. For example, in the Netherlands, it was found to range from 20 % at 25 years of age to 60 % at 50 years (EFSA, 2007b; Hofhuis et al., 2011). There is evidence of a sharp decrease in seroprevalence over the last 40 years in many populations. For example, in 1960 there was a reported seroprevalence of 82 % in France, falling to 44 % in 2003 (AFSSA, 2005). This decrease is in part attributable to a decrease in infection in childhood, probably associated with increased standards of living, and has also been linked to changes in meat husbandry and consumption.

- **Severity of disease**: based on EU data for congenital toxoplasmosis, high.

Owing to the lifelong impact of symptoms related to toxoplasmosis, the burden of disease is high. Mead et al. (1999) showed that *T. gondii* ranked fourth in hospitalisations and third concerning deaths when compared with other foodborne pathogens. More recent research ranked *T. gondii* among the highest in population burden estimates (DALY or QALY) among 14 foodborne pathogens from both an individual and a population perspective (Havelaar et al., 2012a; Hoffmann et al., 2012).

- **Evidence for meat from small ruminants as an important risk factor:** yes.

The relative role of *T. gondii* oocysts in the environment versus tissues cysts in meat and meat products as a source of infection for humans could not be determined by laboratory tests until recently. Hill et al. (2011) have developed a test to identify a sporozite specific antigen which will be a useful tool in providing information on the relative importance of oocysts as the agent of infection. Until this recent development, source attribution information came from epidemiological studies. In Europe, three large case-control studies have pinpointed uncooked meat as the most important risk factor for pregnant women (Baril et al., 1999; Cook et al., 2000; Kapperud et al., 1996).

With regard to the prevalence in the animal population, despite *T. gondii* infection being a major cause of abortion and stillbirth in sheep and goats in the EU, most infections exist subclinically in

flocks/herds (Dumetre et al., 2006). In response to natural infection, seropositive sheep have been shown to harbour infectious parasites as tissue cysts (Dubey et al., 2008; Kijlstra and Jongert, 2008; Opsteegh et al., 2011). Antibodies to *T. gondii* and tissue cysts persist in infected sheep (Dubey, 2009). This implies that serological tests can be used to estimate the number of animals carrying *T. gondii* tissue cysts in the meat and thereby indicate the risk for public health (Opsteegh et al., 2010b). Seroprevalence increases with increasing age (Dubey, 2009; Halos et al., 2010), and sheep and goats are identified as the main source of infected meat in southern European countries (Berger et al., 2007; Dumetre et al., 2006). Seroprevalence of *T. gondii* in sheep can range from 4 % to 92 % in certain European countries (EFSA, 2007b). Limited data available in slaughtered sheep report seropositive rates of 16–66 % in Europe (Dumetre et al., 2006; Tenter et al., 2000). Seroprevalence in farmed goats in Europe ranges from 4 % to 77 % (EFSA, 2007b). No data have been published about seroprevalence in slaughtered goats in Europe, but findings in goats in non-European countries range from 0 % to 40 % (EFSA, 2007b; Tenter et al., 2000). Data reported by EU member states under the Zoonoses Directive (2003/99/EC), showing a relatively high seroprevalence for this hazard in flocks/herds and individual animals, can be found in Tables 4–6.

Notwithstanding this, significant uncertainty remains regarding this hazard. The prevalence of toxoplasmosis in humans and its importance in terms of overall disease burden still requires research. Despite the development of recent laboratory procedures, the proportion of human toxoplasmosis attributable to the consumption of sheep meat is unknown. Furthermore, the relationship between seropositivity in sheep and the number of viable tissue cysts in edible tissue has yet to be established (Food Standards Agency, 2011). These uncertainties hinder the development of control procedures for this hazard.

With regard to the role of meat from small ruminants as a risk factor for human toxoplasmosis, a prospective case-control study designed to identify preventable risk factors for *T. gondii* infection in pregnancy, conducted in Norway (Kapperud et al., 1996) found eating raw or undercooked mutton to be independently associated with an increased risk of maternal infection (OR = 11.4, $p = 0.005$). In the case-control study carried out by Baril et al. (1999), an odds ratio of 3.1 was estimated for the consumption of undercooked or raw mutton/lamb. The same odds ratio was obtained for the consumption of undercooked or raw mutton/lamb in the study carried out in 2000 (Cook et al.). In addition, raw or undercooked lamb meat is considered a delicacy in certain countries, such as France, and is therefore considered an important source of infection in that country (AFSSA, 2005). This has been recently corroborated by a report of an outbreak of toxoplasmosis linked to the consumption of undercooked lamb (Ginsbourger et al., 2012).

Given its high seroprevalence in sheep and goat meat and the correlation of human infection to animal incidence, *T. gondii* in sheep and goat meat was considered by the Panel to be of high priority for meat inspection of small ruminants within the EU (see Table 7).

Table 7: Priority ranking of hazards according to the categorisation in Figure 1 (decision tree).

Hazard	High notification rate in humans	High severity (% deaths over confirmed cases)	Evidence of meat from small ruminants as a risk factor for human disease	Priority category	Due to current controls
Criteria	(High, > 10/100 000)	High, > 0.1 % in more than one year			
Bacillus anthracis	No	Yes	No	Low	No
Campylobacter spp. (thermophilic)	Yes	(No)	No	Low	No
Pathogenic VTEC	No	Yes	Yes	High	No
Salmonella spp.	Yes	(No)	No	Low	No
Toxoplasma gondii	No	Yes	Yes	High	No

2.3. Conclusions and recommendations

Based on the priority ranking, the hazards were classified as follows:

- *T. gondii* and pathogenic VTEC were classified as high priority for sheep/goat meat inspection.
- The remaining identified hazards, *B. anthracis*, *Campylobacter* spp. (thermophilic) and *Salmonella* spp., were classified as low priority, based on the available data.

As new hazards might emerge and/or hazards that presently are not a priority might become more relevant over time or in some regions, both hazard identification and the risk ranking should be revisited regularly to reflect this dynamic epidemiological situation. Particular attention should be given to potential emerging hazards of public health importance that arise only in small ruminants.

To provide a better evidence base for future risk ranking of hazards, initiatives should be instigated to:

- Improve and harmonise data collection of incidence and severity of human diseases caused by relevant hazards.
- Systematically collect data for source attribution.
- Collect data to identify and risk rank emerging hazards that could be transmitted through handling, preparation and consumption of sheep and goat meat.

3. Assessment of strengths and weaknesses of current meat inspection

3.1. General background

Protection of public health is the top priority objective of meat inspection. The origin of Western European meat inspection goes back to the end of the 19th century, when it became obvious that meat could play a role in the transmission of disease, particularly tuberculosis, and that the trade in animals, meat and meat products needed some sort of safety and quality assurance (Johnson, 2009; Theves, 2002; von Ostertag, 1892). The first meat inspection act was drawn up in 1900 by Professor Ostertag at the University of Berlin. There is no doubt that the meat inspection procedures were highly risk based at that time.

Ever since, an *ante-mortem* and *post-mortem* inspection has been carried out at individual animal level in cattle and it has been extended to other species. The *ante-mortem* inspection is a simple clinical examination aimed at identifying sick or abnormal animals, as well as assessing the level of cleanliness of the animals entering the slaughtering 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. *Post-mortem* inspection is laborious and expensive.

The previous situation of slaughtering a few animals originating from a farm has evolved into large numbers of uniform, relatively young and healthy animals presented for slaughter, which have a common genetic background and prior history. At the same time, it is common to find mixed batches of animals arriving at the slaughterhouse, having been assembled at markets and where several farms have each contributed a few animals. Transport can also increase the level and/or duration of shedding of pathogens, as well as the surface contamination of animals with pathogens via animal–animal or animal environment–animal contacts in the vehicle, at the market or in the lairage. Therefore, it can be assumed that the food/meat safety risks increase as the number/frequency of movements of animals between farm and slaughter increases (Scientific Committee on Veterinary Measures relating to Public Health (SCVMPH), 2003).

The current state of meat inspection in the EU and six selected exporting countries outside the EU has been reviewed and summarised recently in an external report.[12] For further, more detailed information on the current EU meat inspection system, the reader is referred to that report.

Still, irrespective of the meat inspection procedures in place, it is well recognised that small ruminants presented at slaughter can be carriers of zoonotic microorganisms (see Section 2.2.3 above), which cannot be detected during *ante-* and *post-mortem* inspections. In the following section, an assessment of the strength and weaknesses of the current practices for protection of public health will be given.

3.2. Food chain information

3.2.1. Description

The food chain information (FCI) principle includes a flow of information from farm to slaughterhouse in order to help classify the batch of animals 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 sheep or goats. Regulation (EC) No 2074/2005 also requires the feedback of information from slaughterhouse to farmers, describing also the information that has to be provided (Appendix to Annex I of the Regulation).

[12] http://www.efsa.europa.eu/en/supporting/pub/190e.htm

FCI is recorded at the flock/batch level and its minimum content is described in Regulation (EC) No 853/2004. FCI related to primary production of flocks or herds is based on a farmer's declaration. Most MSs have made available a standardised FCI declaration form to farmers (e.g. Ireland, the United Kingdom, Italy, France). FCI must be checked for completeness and content as part of *ante-mortem* inspection. In theory, FCI may be used to adapt *ante-* and/or *post-mortem* inspections.

3.2.2. Strengths

FCI serves as a channel of communication between the primary producer and the inspectors at the slaughterhouse. This, theoretically, facilitates the process of evaluating the health of incoming batches and prevents 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 (occurrence of disease, veterinary treatments, specific laboratory testing).

The main benefit of the food chain information is that it may create an 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.

3.2.3. Weaknesses

In practice, *ante-* or *post-mortem* inspections of sheep and goats are rarely adapted to take account of FCI. The main reason that current FCI is insufficiently utilised is because of the lack of adequate and harmonised indicators that could help in classifying the animals according to the risk to public health they may pose. The food safety relevance of FCI is often limited because the data that it contains is very general and does not address specific hazards of public health importance. Also, farmers might not be in a position to properly assess the presence of relevant hazards.

Feedback of the results of the meat inspection process to farmers is not implemented in all MSs to the full extent foreseen in the legislation. The flow of information back to the farm is not straightforward in the absence of a fast and reliable animal movement tracing system, e.g. through the use of electronic individual animal identification linked to a database containing information on the movements of animals (e.g. change of farm, last farm). For example, in Ireland between 15 % and 50 % of small ruminants come to the slaughterhouse from assembly centres or markets (EFSA, 2012). In this case, it is difficult to consider a batch of small ruminants as an epidemiological unit. Good feedback to farmers also requires harmonisation of the reasons for condemnation and the systematic use of the same terminology for each reason for condemnation.

3.3. *Ante-mortem*

3.3.1. Description

The *ante-mortem* clinical examination is carried out to evaluate the health and welfare of the animals, and to prevent sick or abnormal animals entering the slaughterhouse. This is a visual-only inspection, consisting of the identification of clinical signs of a disease and an assessment of the cleanliness of the incoming animals. It is performed at the individual level in sheep and goats.

3.3.2. Strengths

The public health-related strengths of *ante-mortem* inspection include inspection of individual animals for signs of disease and animal identification. *Ante-mortem* inspection also helps in identifying dirty animals, as required by current legislation. Regulation (EC) No 852/2004, Annex I requires primary producers to ensure the cleanliness of animals going to slaughter. Regulation (EC) No 853/2004 Annex II, Section II states that food business operators, operating slaughterhouses, must have HACCP-based intake procedures to guarantee that each animal or, where appropriate, each lot of

animals accepted on to the slaughterhouse premises are clean. Regulation (EC) No 854/2004, Annex I, Section II, Chapter III states that animals with hides, skins or fleeces posing an unacceptable risk of contamination to meat during slaughter cannot be slaughtered for human consumption unless they are cleaned beforehand.

Adjustments can be made to the slaughter process depending on how dirty the batch of sheep or goats is. Current pre-slaughter control procedures include: rejection of dirty lots, washing of animals, fleece/hide trimming or clipping (at the farm or at the slaughterhouse, either pre- or post-slaughter), and slaughter of dirty animals at the end of the day (Byrne et al., 2007). Dirty animals that are presented for slaughter are rejected at *ante-mortem* inspection until their fleece/hide condition improves. Suppliers are sometimes penalised financially through reduced price and the cost imposed by remedial actions required to improve fleece/hide condition. Certain countries have adopted such measures as part of a "clean livestock policy". These policies were adopted to meet the requirements of the hygiene package and have proved to be effective in reducing the risk posed by dirty sheep (see Section 4.4.2 below).

3.3.3. Weaknesses

From a public health perspective, *ante-mortem* examination is of no value in the detection of toxoplasmosis in small ruminants, as animals infected with this previously identified hazard do not show clinical signs. Despite the HACCP-based intake procedures guaranteeing the health, welfare and cleanliness of animals going for slaughter, it is difficult to identify animals infected with pathogenic VTEC and other enteric pathogens. Supplying clean animals reduces, but does not prevent, the possibility of introducing this invisible hazard as infected animals are asymptomatic transient shedders (Duffy, 2003).

3.4. *Post-mortem*

3.4.1. Description

Post-mortem inspection of carcasses is designed to detect and withdraw from the food chain any carcass or part thereof that has grossly identifiable abnormalities that could affect its meat safety or wholesomeness. The meat inspector examines external and internal surfaces of the carcass 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. These procedures are described in Annex I, Section IV, Chapter II of Regulation (EC) No 854/2004. Palpation is compulsory for liver, lungs and their lymph nodes. In addition, palpation is mandatory for the umbilical region and joints in young animals. Incision is currently required only for the gastric surface of the liver.

This procedure can be reduced to a visual-only inspection for sheep less than a year old or goats less than six months of age, if certain conditions are met, as stated in Regulation (EC) No 1244/2007, amending Regulation (EC) No 2074/2005, in the spirit of a risk-based inspection. It is unclear to what extent this derogation is currently used as intended. A more thorough examination, involving palpation and incision of other organs, is performed if abnormalities are detected during visual inspection. Table 1 in Annex 2 summarises these requirements for *post-mortem* inspection.

Ultimately, the production of safe food is the responsibility of the food business operator (FBO) as defined by Regulation (EC) No 178/2002. The FBO must assure process control by the application of a food safety management system based on the HACCP principles and containing a prerequisite programme to safeguard GMP and GHP. Regulation (EC) No 2073/2005 (as amended by Regulation (EC) No 1441/2007) sets microbiological criteria for indicator organisms (process hygiene criteria, PHC) in foodstuffs to be complied with by the FBO. The microbiological criteria of this regulation are used to validate and verify the effective functioning of the FBO's hygiene system.

3.4.2. Strengths

Post-mortem inspection enables, to a certain extent, detection of lesions related to animal health and welfare, which are not dealt with in this part of the document (see Appendix C). For 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 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 to be present in the carcass.

Classic zoonotic diseases, such as tuberculosis, which can be detected by *post-mortem* examination, are now controlled in many areas where modern systems of animal husbandry, disease control and animal health care were introduced. Hence, the ability of current *post-mortem* inspection to detect lesions caused by mycobacteria is only relevant in regions where they are present.

Post-mortem inspection can also detect other non meat-borne hazards of public health significance that can be present in carcasses or offal from small ruminants. Examples of these hazards are *Echinococcus granulosus* and trematode parasites such as *Fasciola hepatica*. Acquisition of these parasites by humans occurs when subjects inadvertently swallow eggs or cysts attached to tainted vegetation or by drinking contaminated water containing free-floating eggs (*E. granulosus*) or cysts (*F. hepatica*) (Fried and Abruzzi, 2010). From the public health standpoint, only *E. granulosus* is still relatively important in some MSs (EFSA and ECDC, 2013b), while trematode parasites are less commonly reported in humans in the EU. Meat inspection contributes to the monitoring of these parasites as they are routinely detected during *post-mortem* examination of sheep and goats. 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 these parasites, compared with control measures elsewhere (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. Nevertheless, the importance of meat inspection as a monitoring tool has been stressed previously (EFSA, 2010).

The slaughter of sheep involves greater challenges than the slaughter of cattle and pigs since the animal is relatively small and has a wool fleece increasing the risk of surface contamination at dehiding (Buncic, 2006). As mentioned in Section 1.3 of this Appendix, many challenges are posed by the processing procedure at the slaughterhouse, which has a direct effect on the final microbial disposition of the carcass (e.g. line speed, operational hygiene, equipment and training) (Hansson, 2001; Palmer, 2008). In this context, the mandatory bacteriological analysis of carcasses to evaluate slaughter process hygiene is important. The maximum acceptable microbiological values are set in the PHC for the indicators mentioned in Regulation (EC) No 2073/2005. Some risks determined at *post-mortem* examination are under the direct influence of the processor and can be ameliorated by corrective action procedures. In the case of the identified hazard, pathogenic VTEC, *post-mortem* corrective actions may include clipping after stunning and bleeding, adjustments to operational hygiene practices, slowing the slaughter line down and/or adding extra personnel at certain carcass dressing stations, with feedback to producers (see Section 4.4.2 below). The competent authority also verifies the FBO's responsibility to produce safe food, as mandated by Regulation (EC) No 178/2002, through audit and inspection of the slaughterhouse's food safety management system. In terms of the slaughter process, PHC are end-product criteria. Compliance with these criteria, in Regulation (EC) No 2073/2005, is one aspect of system compliance verification carried out by the competent authority. More details about PHC can be found in Section 4.4.2.3.

3.4.3. Weaknesses

Potential threats to public health associated with slaughtered sheep or goats including agents such as pathogenic VTEC and *T. gondii* are carried by animals without signs or lesions. Current meat inspection is not designed to detect or eliminate these agents. Sometimes, cysts of *T. gondii* can be macroscopically visible but it is impossible to distinguish them from *Sarcocystis* cysts, except cysts of

S. ovifelis. Visible meat quality-related abnormalities are detectable at *post-mortem* inspection, but these are not important for human health (see Table 8). 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*, *S. aureus*), but, as explained in Section 2 of this Appendix, the risk to public health arising from these hazards is not considered to be important and is mostly related to occupational exposure or the way the meat is handled after it leaves the slaughterhouse. Other conditions that result in condemnation of offal or carcasses are parasitic lesions. These parasites (*C. tenuicollis*, *Sarcocystis*, *Fasciola*, *Dicrocoelium*, etc.) are not transmissible via meat consumption. In cases where these abnormalities are observed, the meat must be removed as unfit for human consumption on aesthetic or meat quality grounds.

Table 8: Micro-organisms most frequently associated with abnormalities routinely detected at sheep and goat *post-mortem* examination.

Condition/abnormality	Microorganisms commonly isolated	References
Abnormal colour	–	
Abnormal odour	–	
Abscesses (localised/hepatic /injection)	*Staphylococcus aureus*, *Corynebacterium pseudotuberculosis*, *Arcanobacterium pyogenes*, *Streptoccocous* spp.	Jackman and Hathaway (2010)
Anaemia	–	
Backleg/gangrene	*Clostridium chauvoei* type B	Lewis (2000) Scharko et al. (2012)
Caseous lymphadenitis	*Corynebacterium pseudotuberculosis*	Baird (2007) Fontaine and Baird (2007)
Cirrhosis	–	
Contamination	*Salmonella* spp., *Escherichia coli* (VTEC), *Clostridium* spp., *Campylobacter* spp., *Yersinia* spp., *Listeria* spp., *Giardia* spp., *Cryptosporidium parvum*	Biss and Hathaway (1998) EFSA (2004) Jackman and Hathaway (2010)
Cysticercosis	*Cysticercus ovis*, *Cysticercus tenuicollis*	
Enteritis	*Cryptosporidium parvum*, *Eimeria* spp. (*E. crandallis*, *E. ovinoidallis*), rotavirus, coronavirus, parasitic gastroenteritis (*Nematodirus* spp., *Haemonchus* spp., *Ostertagia* spp., *Trichostrongylus* spp., *Fasciola hepatica*)	Mitchell and Linklater (1983) Aitken (2007) West et al. (2002) EFSA (2004) Malone et al. (2010)
Fascioliasis	*Fasciola hepatica*	
Fly strike	*Lucilia sericata*, *Lucilia cuprina*, *Wohlfahrtia magnifica*	Wall (2012)
Hydatidosis	*Echinococcus granulosus*	
Joint lesions	*Arcanobacterium pyogenes*, *Escherichia coli*, *Erysipelothrix rhusiopathiae*, *Fusobacterium necrophorum*, *Staphylococcus aureus*, *Streptococcus* spp.	EFSA (2004) Watkins (2007) Thompson (2008)
Lameness	*Arcanobacterium pyogenes*, *Dichelobacter nodosus*, *Fusobacterium*, *Necrophorum*, spirochetes, *Staphylococcus aureus*	Green et al. (2011) Hodgkinson (2010) Winter and Clarkson (2012) Winter (2009)
Mastitis	*Staphylococcus aureus*, *Mannheimia hemolytica*, *Streptoccocus* spp., *Escherichia coli*	Watkins and Jones (2007) Contreras et al (2007)
Melanosis	–	

Condition/abnormality	Microorganisms commonly isolated	References
Metritis	*Arcanobacterium pyogenes*, *Escherichia coli*	Tzora et al. (2002) Mavrogianni and Brozos (2008)
Oedema/emaciation	–	
Pericarditis	*Salmonella* spp., *Clostridium* spp., *Pasteurella* spp.	Jubb and Kennedy (1972) Cebra and Cebra (2012)
Peritonitis	*Salmonella* spp., *Clostridium* spp.	Jubb et al. (2007) Jackman and Hathaway (2010)
Pleurisy / pneumonia	Parainfluenza 3 virus, *Mycoplasma* spp. (*M. ovipneumonia*, *M. mycoides*), *Pasteurella multocida*, *Mannheimia haemolytica*	Martin (1996) EFSA (2004) Goodwin-Ray (2006) Jackman and Hathaway (2010)
Sheep scab	*Psoroptes ovis*	
Suspect fever / septicaemia	*Salmonella* spp., *Clostridium* spp., *Escherichia coli*	Jackman and Hathaway (2010) West et al (2002)
Suspect Pyaemia/generalised abcessation	*Staphylococcus aureus*, *Corynebacterium pseudotuberculosis*, *Arcanobacterium pyogenes*, *Streptoccocous* spp.	Jackman and Hathaway (2010)
Trauma (bruising, fractures, dislocations)	–	
Toxaemia	–	
Tumours	–	

The potential for cross-contamination of carcasses exists whenever palpation and/or incision methods are used in the inspection process. Palpation of the liver, the lungs, the umbilical region and the joints, and the incision of the gastric surface of the liver during the *post-mortem* examination of sheep and goats could contribute to the spread of the bacterial hazards of public health importance in small ruminants through cross-contamination. The importance of cross-contamination is not clear in small ruminants, although it has been considered important in other species (Walker et al., 2000). However, it should be borne in mind that incision is compulsory only for the liver, whereas in cattle and pigs incision of muscle is also required, so the level of contamination is likely to be smaller in small ruminants than in these species. Current legislation foresees more detailed palpation and incision if abnormalities are detected during visual inspection. This could also facilitate cross-contamination of normal carcasses with microbiological hazards of public health importance.

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

The legislation on official controls on fresh meat from 2004 (Regulation (EC) 854/2004, Annex I) has a more horizontal approach than the former one (Council Directive No 432/1964, amended by Council Directives No 497/1991 and No 498/1991 and has also in theory a risk-based approach. However, the main experiences are that alternative control regimes, such as visual control of young animals (sheep of less than a year old and goats less than six months old) are not implemented due to the fact that the gains are limited due to:

- The threshold in terms of implementation of quality assurance systems and extra procedures at herd level is too high

- Lack of practical FCI

- Logistical challenges connected to the *post-mortem* meat inspection procedures as some flocks/herds are certified for visual control while others are not due to the fact that alternative control methods are not accepted by some importing countries outside the EU.

3.5. Conclusions and recommendations

Ante-mortem and *post-mortem* inspections of sheep and goats enable the detection of observable abnormalities. In that context, they are an important activity for monitoring animal health and welfare. They provide a general assessment of animal/herd health, which if compromised may lead to a greater public health risk. Visual inspection of live animals and carcasses can also detect animals heavily contaminated with faeces. Such animals increase the risk for cross-contamination during slaughter and may consequently constitute a food safety risk if carrying hazards of public health importance. If such animals or carcasses are dealt with adequately, this risk can be reduced. Visual detection of faecal contamination on carcasses can also be an indicator of slaughter hygiene, but other approaches to verify slaughter hygiene should be considered.

Post-mortem inspection can also detect non meat-borne hazards of public health significance that can be present in carcasses or offal from small ruminants. *Ante-mortem* and *post-mortem* inspection also have the potential to detect new diseases if these have clinical signs, which may be of direct public health significance.

Currently, the use of food chain information for food safety purposes is limited for small ruminants, mainly because the data that it contains is very general and doesn't address specific hazards of public health importance. However, FCI could serve as a valuable tool for risk management decisions and could be used for risk categorisation of farms or batches of animals. To achieve this, the system needs further development to include additional information important for food safety, including definition of appropriate and standardised indicators for the main public health hazards identified above (Section 2 of this Appendix).

Ante- and *post-mortem* inspection is not able to detect any of the public health hazards identified as the main concerns for food safety. It would therefore be expected that more efficient procedures might be implemented to monitor the occurrence of non-visible hazards. In addition, given that the current *post-mortem* procedures involve palpation and incision of some organs, there is potential for cross-contamination of carcasses.

4. Recommended inspection methods for the main public health hazards related to meat from small ruminants that are not addressed by current meat inspection

4.1. Introduction

As identified by priority ranking earlier in this opinion, the principal biological hazards associated with meat from small ruminants are *T. gondii* and pathogenic VTEC. The ranking presented in Section 2 of this Appendix classified all other hazards in the low-risk category. This ranking is provisional because of the limited information available for some of the hazards. Neither of the principal hazards identified can be detected by traditional meat inspection, which is focused on 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 sheep or goats and their carcasses is possible only through laboratory testing. The occurrence and levels of *T. gondii* and pathogenic VTEC on carcasses are highly variable depending on various factors, including particularly: (i) their occurrence in the sheep and goat population before slaughter and the application and the effectiveness of related pre-slaughter controls strategies; (ii) the extent of direct and/or indirect faecal cross-contamination during slaughter line operation (this does not apply to *T. gondii*); and (iii) the application and the effectiveness of possible interventions to eliminate/reduce them on carcasses (e.g. decontamination). Therefore, as far as the presence of these pathogens in/on carcass meat is concerned, the risk reduction strategies, and related controls, are focused on these three aspects.

Changes are therefore necessary to identify and control microbiological hazards, and this can be most readily achieved by improved use of FCI and interventions based on risk. Control measures for pathogenic VTEC at the slaughterhouse 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 meat safety assurance system for the main public health hazards related to meat from small ruminants

A comprehensive meat safety assurance system for meat from small ruminants, combining a range of preventive measures and controls applied both on the farm and at the slaughterhouse in a longitudinally integrated way, is the most effective approach to control the main hazards in the context of meat inspection. The main responsibility for such a system should be allocated to FBOs, whereby compliance is to be verified by the competent authority.

The setting up of such a comprehensive meat safety assurance system at EU level is dependent on the availability of reliable information on the biological risks associated with the consumption of meat from these species. As indicated in the priority ranking section of this opinion (Section 2 of this Appendix), information on the biological risks associated with the consumption of meat from sheep or goats is sometimes scant and unreliable. Consequently, in order to facilitate decision making, harmonised surveys are required to establish values for the prevalence of the main hazards *T. gondii* and pathogenic VTEC at flock/herd, live animal and carcass level in individual MSs. Epidemiological and risk assessment studies are also required to determine the specific risk to public health associated with the consumption of meat from small ruminants.

In the event that these studies confirm a high risk to public health through the consumption of meat from sheep or goats, consideration should be given to the setting of clear and measurable EU 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 small ruminants. The use of specific hazard-based targets (i.e. pathogenic VTEC or *T. gondii* related) for chilled carcasses provides:

1. Measurable and transparent focus for the abattoir meat safety assurance system.

2. Information (as a "benchmark") on what has to be achieved at earlier steps in the food production chain.

3. Information for the purpose of consumer exposure assessment for each hazard.

4. Measurable aim for the meat industry in the context of global pathogen reduction programmes.

For all these reasons, the chilled carcass targets have to be specific hazard based. This, however, may not be always practical (e.g. in very low hazard prevalence situations). Therefore, proper functioning of meat safety quality assurance systems may not rely exclusively on hazard-based testing of the final carcass but on the general hygiene of the slaughter process. This issue is discussed further in the following sections.

Further information on the development of targets 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) and EFSA Panel on Animal Health and Welfare (AHAW), 2011) and the EFSA opinion on meat inspection of poultry (EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM) and EFSA Panel on Animal Health and Welfare (AHAW), 2012). In addition, information on harmonised epidemiological indicators (HEIs) and related methodologies for the main hazards that can be used in studies to establish prevalence of the main pathogens to establish targets for carcasses and performance criteria for slaughterhouses, as well as targets for incoming small ruminant animals, is provided in the EFSA report (EFSA, 2013). Therefore, this opinion should be used in combination with that report.

4.2.1. Farm elements of a meat safety assurance system

At farm level, the primary goal is reduction of risk for the main hazards, which can be achieved through preventive measures such as flock/herd health programmes, including biosecurity and good farming practices (GFPs) that specifically address the hazards identified in Section 2 of this Appendix. Husbandry practices will vary considerably for small ruminants, particularly, the intensity of the rearing system. So, although it is not possible to detect any of the main foodborne zoonotic infections visually at the farm, there are known risk factors that are likely to increase the risk of infection with the main hazards.

An important element of an integrated meat safety assurance system is considered to be risk categorisation of flocks or herds based on the use of farm descriptors and data on clinical disease and use of antimicrobials, in addition to data provided by ongoing monitoring of high-risk hazards that constitute the FCI. Such data could be provided through farm audits using HEIs to assess the risk and preventive factors for the flocks or herds related to each of the prioritised microbiological hazards (see EFSA report, (2013)). Ongoing monitoring could be put in place for particular pathogens at EU level if, following the completion of the prevalence studies described earlier, these pathogens are identified as presenting a high risk. An assessment of the historical data over a time period could also be used for adjusting the sampling frequency of the main hazards in order to focus control efforts where the risk is highest.

A structured approach to gathering more detailed farm information should become an additional farm-related element of the FCI that, in combination with the monitoring results for the main hazards, should form the basis for the risk categorisation of the farms. The frequency of monitoring in higher risk farms could be adapted in a cost-effective manner, e.g. there would be no need to sample every batch of animals to be slaughtered if the result is very likely to be "high risk" or "very low risk". Thus, animals from higher risk farms could be systematically directed to, for example, logistic slaughter, or specific treatments such as decontamination at the slaughterhouse, until these high-risk farms demonstrated a decreased risk following the implementation of adequate on-farm measures. This system could act as an incentive for the primary producer to improve farm standards by means of reduced monitoring costs associated with low-risk status.

4.2.2. Slaughterhouse elements of a meat safety assurance system

At slaughterhouse level, the primary goal is risk reduction for the main hazards that can be achieved through integrated programmes based on GMP, GHP and HACCP, including the use of PHC:

- Logistic slaughter based on the risk categorisation of the slaughtered batches; this could be slaughter of higher risk animals at the end of the day.

- Hygienic practices and technology-based measures aimed at avoiding direct and indirect cross-contamination with the main hazards.

- Interventions such as the scheduling of higher risk animals for carcass decontamination or for risk-reducing processes such as heat treatment to reduce pathogenic microorganisms or freezing-based treatments to eliminate parasites such as *T. gondii*.

Enteric pathogens are carried in the gastrointestinal tract and/or on the fleece of sheep and goats presented for slaughter, and carcass meat becomes contaminated as a result of direct or indirect cross-contamination that is highly dependent on slaughterhouse technology and the skills of the operators. Technical aspects of individual steps of the slaughter process for small ruminants may vary considerably. The order of the processing steps at the slaughterhouse is generally as follows: transport/lairaging—stunning—bleeding—skinning—evisceration—chilling.

Each of these steps contributes differently to the final microbial load of the carcass. Cross-contamination between animals can occur from transport and lairaging and during the slaughter process. Contamination occurs particularly during skinning and evisceration. The slaughter of sheep involves greater challenges than the slaughter of cattle and pigs since the animal is relatively small and has wool. "*During sheep de-pelting, it is difficult to achieve the low contamination rates capable of being achieved during cattle de-hiding, as the animal is smaller, the fleece is longer and there is a much greater chance of fleece inrolling and contacting the carcass. Therefore, overall, de-skinning is a 'dirtier' procedure in small ruminants than in larger ones*" (Buncic, 2006). Chilling can help to control the numbers of pathogenic and spoilage microorganisms on carcasses.

Decontamination treatments for carcasses might be used to reduce the levels of enteric pathogens and can be divided into physical and chemical treatments. Physical interventions include water-based treatments, irradiation, ultrasound or freezing. Hot water, steam and irradiation effectively reduce the bacterial load. Chemical interventions such as treatments with acetic and lactic acid reduce the bacterial load, as observed in poultry (Loretz et al., 2010). Some combinations of treatments further enhance the reductions (Loretz et al., 2010). Freezing and γ-irradiation can also be effective in eliminating *T. gondii* in carcasses. However, some of these methods are limited by their practicability, regulatory requirements or acceptability to consumers (ACMSF, 2005). Thus, the best way to achieve reductions in carcass contamination is likely to come either from physical decontamination treatments or from technological developments in the process that are designed to improve hygiene, as long as they are acceptable to the industry and the consumer.

Each slaughterhouse can be viewed as unique, owing to differences in species slaughtered, logistics, processing practices, plant layout, equipment design and performance, standardised and documented procedures, personnel motivation and management, and other factors. These variations individually and in combination lead to between-slaughterhouse differences in risk-reduction capacity and, consequently, in the microbiological status of the final carcass. Hansson (2001) indicated that there was a significantly greater amount of aerobic bacteria in ruminant carcasses slaughtered at low-capacity slaughterhouses than in high-capacity slaughterhouses. This difference in carcass microbiological status can be accounted for by better separation of low- and high-risk areas, less variation in evisceration techniques, uniformity of the animals slaughtered, increased specialisation of labour and equipment, and improved measures taken to prevent contamination through effective operational hygiene practices in high-volume slaughter establishments (Hogue et al., 1993; Rahkio and

Korkeala, 1996). Consequently, a risk categorisation of slaughterhouses is also possible, based on the assessment of individual hygiene process performance. For that, a standardised methodology and criteria for the assessment of process hygiene is a prerequisite.

In respect to process hygiene, differentiation of abattoirs in current EU regulation is based on the use of process hygiene criteria providing two categories: "acceptably" and "unacceptably" performing abattoirs. However, this differentiation is based solely on carcass testing, and so does not differentiate the abattoirs in terms of the processes but only the end products. More in-depth differentiation, even within each of the two global categories of abattoirs, would have been possible if improved process hygiene assessment methodology and indicators were used. The main guiding principle (Koutsoumanis and Sofos, 2004) in abattoir process hygiene differentiation is that abattoir PHC need to address the initial level of a hazard and the reduction of that hazard during the production process. In the process of creating PHC for abattoirs, the possibilities that need to be considered are whether they should be linked to individual stages of the process (e.g. reduction of occurrence/level of indicator organisms or hazards at a selected one or more specific steps along the slaughter line) or only related to the starting and the end point of the process (e.g. reduction of the occurrence/level in/on the final carcass meat compared with that in/on incoming animals).

This risk categorisation of slaughterhouses is already taking place in the EU in the context of the implementation of Regulation (EC) No 882/2004 on official controls, and the accompanying guidelines set out in Commission Decision 2007/363/ EC of 21 May 2007.[13] These established that the national control plans should indicate the risk categorisation, if any, assigned to the various activities subject to official controls. In this regard, a guideline[14] for the application of the regulations on official controls has been set out in Italy, where criteria for plant categorisation based on risk are defined, with the aim of:

- Establishing the frequency of the official controls on the basis of pre-defined and objective criteria.
- Carrying out the official controls using homogeneous criteria for plants with a comparable risk profile.

These criteria take six parameters into account:

1. The structural characteristics of the plant, (including the maintenance)
2. The capacity of the slaughterhouse
3. The products' characteristics
4. The operational hygiene practices
5. The HACCP implementation level
6. The results of previous control activities.

These criteria could serve as an example for future risk categorisation of slaughterhouses based on the specific hazards previously described.

[13] 2007/363/EC: Commission Decision of 21 May 2007 on guidelines to assist Member States in preparing the single integrated multi-annual national control plan provided for in Regulation (EC) No 882/2004 of the European Parliament and of the Council.

[14] Official Memorandum of Italian Minister of Health: Prot. n. DGSAN/3/6238/A, 31st May 2007: "Guideline on official controls under the Regulations (EC) No 882/2004 and 854/2004" (Circolare del Ministero della Salute Prot. DGSAN/3/6238/P del 31/05/2007 "Linee guida per il controllo ufficiale ai sensi dei Regolamenti CE 854/2004 e 882/2004)".

Food safety management systems can combine official control and supervision based on compulsory requirements prescribed by law (HACCP, traceability, FCI, etc.), and private quality assurance schemes. Besides those aspects included in the legislation, abattoirs can voluntarily implement their own quality requirements in the form of certification schemes. Certification of production processes is based on the auditing and approval by accredited third-party organisations on an accredited standard. These schemes include official requirements but also pay attention to additional, more stringent, quality and safety aspects of the processes and products. At the slaughterhouse, standards are implemented for animal welfare and hygiene, slaughtering, dressing and evisceration, hygiene control, carcass quality and grading, storage conditions, carcass cutting and processing, etc.

The adherence to certification schemes reassures stakeholders (suppliers, clients), government and consumers of the quality and safety of their products, with a view to meeting market demands and consumer satisfaction. Retailers and manufacturers are increasingly demanding that their suppliers hold an approved certification. In this sense slaughterhouses are becoming increasingly important throughout supply chains in integrated food safety management systems. Some examples of quality assurance schemes are the International Standards Organisation (ISO) 22000, Food Safety System Certification (FSSC) 22000, International Food Standard (IFS), British Retail Consortium (BRC) and GlobalGap.

In summary, classification of abattoirs according to their capability to prevent or reduce faecal contamination of carcasses can be based on two elements: (i) the process hygiene as measured by the level of indicator organisms on the carcasses (i.e. process hygiene criteria); and (ii) the use of operational procedures and equipment that reduce faecal contamination (as described in Section 4.4.2.2 above), as well as industry-led quality systems. Information about the risk categorisation of slaughterhouses could be then considered with the FCI when assessing the risk arising from incoming animals.

4.3. Specific inspection and control methods for *T. gondii* in the integrated system

4.3.1. On farm

Herbivorous animals most likely contract *T. gondii* infection via ingestion of pasture, hay, forage, feed or surface water contaminated with oocysts shed by infected cats (Skjerve et al., 1998; Tenter et al., 2000). Oocysts are very resistant and can survive a range of temperatures in the environment. 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 sterilised feed and bedding, and not allowing sheep and goats outdoor access; however, such husbandry practices are not economically viable in most EU commercial sheep and goat enterprises (Kijlstra and Jongert, 2009). Removing cats from the farm surroundings, or vaccinating cats, could theoretically lead to a reduction of the oocyst load in the neighbourhood of the farm. In reality, most of these measures would not be practical to implement in most situations at the moment.

Theoretically, vaccines against *T. gondii* could potentially be targeted in a number of directions, for example: (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; (iii) prevention of infection or at least of clinical disease in humans (EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM) and EFSA Panel on Animal Health and Welfare (AHAW), 2011). Currently, the only vaccine commercially available is a live *T. gondii* vaccine for sheep, based on the attenuated S48 strain of the parasite. This vaccine is usually applied as a preventive measure to young sheep to reduce the risk of abortion in adult ewes. Vaccination reduces 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 (Hiszczynska-Sawicka et al., 2011). An oral vaccine composed of live bradyzoites from

an oocyst-negative mutant strain (T-263) has been effective in preventing oocyst shedding by cats in experimental trials but a vaccine for cats is not yet commercially available (Innes et al., 2009). While 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 due to 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). For this reason, the development of vaccines that prevent *T. gondii* infection in ruminants and/or cats is recommended.

Surveillance and monitoring of *T. gondii* in animals preharvest is essential in the control of this parasite, something that is currently not addressed effectively within the EU (EFSA, 2007b; Opsteegh et al., 2010b). The most feasible surveillance method is the use of indirect serological tests (e.g. enzyme-linked immunosorbent assay, ELISA) on live sheep and goats for the detection of *T. gondii* antibodies, as seropositivity has been correlated with tissue cyst presence in non-vaccinated animals (Buxton, 1998; Conde de Felipe et al., 2007; Dubey, 2009; Opsteegh et al., 2010b). However, a more practical solution is taking a blood sample during bleeding of the animal at the slaughterhouse, or even freezing a piece of meat and collecting the meat juice during thawing. Studies have indicated regional differences in seroprevalence in small ruminants which can be accounted for by differences in environmental contamination or by factors that influence the level of exposure of sheep to the environment, such as age and farm management (Alvarado-Esquivel et al., 2012; Opsteegh et al., 2010b). Monitoring programmes could help in the risk assessment and categorisation of small ruminants with regard to *T. gondii* at the slaughterhouse as part of the FCI provided. For more details on the different options for indicators of the presence of *T. gondii* we refer the reader to the technical specifications on harmonised epidemiological indicators for biological hazards to be covered by meat inspection of small ruminants (EFSA, 2013).

A study from the south-western region of Norway suggests that there are some limitations in the use of categorisation of lambs if there are many flocks positive for *T. gondii* (Nordic Council of Ministers, 2006). Of the 117 flocks sampled in 2004, 98 were also sampled in 2005 to investigate how reliable historical data could be in this context. In total, only 59 % of the flocks that had antibodies against *T. gondii* in 2004 were positive in 2005. Moreover, if there are many positives (in this case 87 % positive herds in 2004 and 77 % positives in 2005) the treatment of large numbers of carcasses to eliminate *T. gondii* is not a cost-effective risk management tool. A surveillance study by García Bocanegra et al. (2012) indicates that there is a similar high seroprevalence in goats, with antibodies against *T. gondii* being detected in 25.1 % of goats and 72.2 % goat herds.

With this background of high *T. gondii* prevalence in the national flocks and herds of small ruminants, a more realistic approach could be to focus the efforts in setting up a system to identify negative flocks/herds instead. For example, animals raised exclusively indoors and under controlled husbandry conditions (which would need to include for example the exclusion of cats from the farms and the absence of contamination of feed, bedding and water with *T. gondii* oocysts) would present a much lower risk with regards to *T. gondii*. When these husbandry conditions are combined with serological testing and the selection of young animals for slaughter, the production of *T. gondii*-free meat should be a feasible goal. This meat could be then used for either subpopulations at greater risk (e.g. pregnant women or immunocompromised people), or for the elaboration of particular dishes that require little cooking of the meat (e.g. agneau rosé in France). At the moment, this system might be practical to implement only for some intensive farms dedicated to milk or cheese production in some MSs. A more detailed explanation about how harmonised epidemiological indicators could help setting up this system is provided in the accompanying report on these indicators mentioned above (EFSA, 2013).

4.3.2. At the slaughterhouse

There is no way to distinguish *T. gondii*-infected meat carcasses from uninfected carcasses during meat inspection (Dubey et al., 2002). Similarly, current process hygiene criteria do not address the risk arising from this hazard (or any non-enteric hazard). The presence of *T. gondii* tissue cysts can be determined only by laboratory methods, particularly by using serological methods. This can be done on farm or at the slaughterhouse. Studies on PCR methods to detect and quantify *T. gondii* in meat samples have shown promise with detection sensitivities comparable to those of bioassay (Opsteegh et al., 2010a). Studies using such laboratory techniques allow epidemiological studies to be conducted to determine the seroprevalence of toxoplasmosis in ovine meat and the risks such meat poses to human health (EFSA, 2007b; Opsteegh et al., 2010b). Additional information on sampling and testing methodologies to detect *T. gondii* can be found in the EFSA report on harmonised epidemiological indicators for sheep and goats (2013).

Given that *T. gondii* cannot be horizontally transmitted between ruminants, there is no issue of between-animal cross-contamination with *T. gondii* at slaughter, and therefore separating sheep and goats from negative and positive flocks or herds during transport, lairage and on the slaughter line would not have any impact on the levels of *T. gondii*.

4.3.2.1. Post-processing interventions

Studies have indicated that *T. gondii* tissue 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 treatment and curing (addition of salt combined with drying) (Table 9). Heat treatment is the most secure method to inactivate the parasite; however, freezing would probably be the most practical risk management option to control *T. gondii* for the meat industry (Kijlstra and Jongert, 2008). Most of the information available for these treatments originates from research in pigs, so further research is required to validate these treatments in meat from small ruminants. These treatments would be particularly appropriate for meat cuts that are intended to be consumed rare.

Table 9: Interventions available to inactivate *T. gondii* tissue cysts.

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 3 days	El-Nawawi et al. (2008)
	Sheep	–20 °C for at least 54 hours	Lunden and Uggla (1992)
Curing or applying salt solutions	Swine	> 2 % salt for at least 7 days at 20 °C	Hill et al. (2004) Dubey (1997)
	Sheep	Salt and sugar[a] for at least 64 hours at 4 °C	Kijlstra and Jongert (2008) Lunden and Uggla (1992)
High pressure treatment	Swine	300 Mpa for at least 90 seconds	Aymerich et al. (2008) Lindsay et al. (2006)
γ-irradiation	Swine	75–100 krad	El-Nawawi et al. (2008)

a From Lunden and Uggla (1992): "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."

4.4. Specific inspection and control methods for pathogenic VTEC in the integrated system

The ranking presented in Section 2 of this Appendix classified pathogenic VTEC as high risk. However, it is important to note that measures aimed at controlling this hazard will also probably be effective in reducing the level of other enteric pathogens such as *Salmonella* spp. or *Campylobacter* spp.

4.4.1. On farm/food chain information

Control of pathogenic VTEC at farm level is complicated by the fact that animals are asymptomatic carriers of these organisms, thus without an active monitoring programme there is no way of knowing which animals are infected and/or shedding at any given time. Control activities must therefore be directed at the flock or herd. Good management practices such as maintaining stable rearing groups, keeping a closed herd and preventing young animals from having contact with older animals all decrease the spread of VTEC on and between farms.

A number of studies have reported reductions in bacterial contamination and, in particular, in *E. coli* O157:H7 levels on carcasses by reducing the level of fleece/hide contamination (Hadley et al., 1997; Longstreeth and Udall, 1997). In this context, the provision of a dry lying area for sheep improves hygiene. In outdoor rearing systems, this is achieved by access to sheltered free-draining land, avoiding access to wet or boggy areas. The housed rearing environment is more easily controlled by the producer. The shelter provided, in addition to the effect of good-quality bedding and the ability to influence access to food/water in the housed system, result in pre-slaughter housing being recommended as a clean fleece policy control measure (Food Standards Agency, 2007b). Other husbandry practices such as internal parasite control, effective mineral supplementation, regular dagging/crutching and the planned pre-slaughter preparation by the producer can have an impact on the on-farm clean sheep policy (Food Standards Agency, 2007b; Pugh and Baird, 2011). Although no such information is available for goats, it is probably safe to assume that these principles would also work in this species.

Controlling diet and feeding before slaughter to minimise digestive upset is essential in ensuring that animals are clean prior to slaughter. The provision of a high-fibre, nutritionally balanced diet, with easily digestible protein, helps develop good faecal consistency (Collis et al., 2004; Pugh and Baird, 2011). Lush grass, contaminated water sources, overfertilised grassland, excessive concentrate supplementation and root/forage crop consumption prior to slaughter are dietary causes of fleece contamination (Food Standards Agency, 2007b). In addition, in a recent review, Pointon et al., (2012), considered the impact of pre-slaughter feed curfews of cattle, sheep and goats on food safety and carcass hygiene in Australia. The authors examined the ecology of *Salmonella* spp. and *E. coli* and the efficacy of on-farm withholding of feed, carried out to reduce soiling during transport, in terms of microbial reduction. They suggested that, to minimise carcass contamination with *Salmonella* spp. and generic *E. coli*, the animals should be fasted before transport only for a period sufficient to complete faecal expulsion, i.e. 24 hours, but not exceeding 48 hours, and they concluded that the implementation of these practices as good agricultural practice is likely to improve the effectiveness in terms of reducing pathogens on the carcasses.

Good management of animal waste is also essential to prevent spread and cross-infection of other animals. Animal waste from animals housed indoors generally accumulates as slurry or farmyard manure. VTEC survive for extended periods in faecal, slurry, soil and water environments (Besser et al., 2001; Bolton et al., 1999; Bolton et al., 2012; Fremaux et al., 2008; Himathongkham et al., 1999; Hutchison et al., 2005a; Hutchison et al., 2005b; Islam et al., 2004; McGee et al., 2001; O'Neill et al., 2011). Current control measures to reduce the pathogen risk in animal waste can be applied before, during or after spreading manure. Pre-spreading controls include the provision of proper storage facilities for animal waste to prevent leakage of waste into ground water, and keeping animals away from slurry pits or dung heaps. Spreading should not take place in conditions where contamination of a water course is more likely to occur. After manure is spread, the land should not be used for grazing for a certain amount of time (at least one month or until all visible signs of animal waste have disappeared in the case of grazing (Hutchison et al., 2000).

Despite there being a range of on-farm measures to control VTEC at farm level, the efficacy of such measures in reducing the prevalence (or load) of pathogenic VTEC in small ruminants is not clear.

Transport has also been identified as a risk factor for hide cleanliness (Animalia, 2007; Byrne et al., 2007; Food Standards Agency, 2007b). In compliance with Council Regulation (EC) No 1/2005 on the protection of animals during transport and related operations, livestock should be carried in well-ventilated, clean vehicles, at the correct stocking density, with the provision of shelter, bedding and access to food and water where appropriate. These measures, particularly relating to vehicle facilities, design and journey distances directly affect fleece/pelt cleanliness. Industry standards on stocking densities during transport and lairage also facilitate the requirements of clean livestock policies (Anonymous, 2009; Minihan et al., 2003).

Section 4.2.1 above indicated that categorisation of flocks or herds according to risk can be an important element of an integrated meat safety assurance system. However, for pathogenic VTEC there are a number of challenges that need to be overcome for this approach to be feasible, including the difficulties in identifying husbandry factors that can be used to classify farms according to pathogenic VTEC risk, the intermittent nature of shedding, and the problems with the interpretation of monitoring results for VTEC due to the difficulty of correctly identifying pathogenic VTEC.

4.4.2. At the slaughterhouse

4.4.2.1. *Ante-mortem*

The two main sources of enteric bacteria on sheep and goat carcasses are the fleece/hide and the viscera, but contamination from the former is more common. A number of studies have established a relationship between the dirtiness of sheep at the time of slaughter and the amount of contamination, and therefore the amount of pathogenic bacteria transferred to the carcass during skinning (Duffy et al., 2000; Gerrand, 1975; Hauge et al., 2011a; Longstreeth and Udall, 1997). This relationship is addressed by legislation at the production and processing level, within the hygiene package, as previously mentioned in Section 3.3.2. To meet this requirement for clean fleece/hides, some MSs have adopted formalised "clean livestock policies" to categorise livestock including sheep and goats at *ante-mortem* examination, thereby placing the responsibility of presenting clean animals for slaughter with the producer and the processor (Byrne et al., 2007; Hauge et al., 2011a). Pre-slaughter washing of sheep is widely used in New Zealand (Biss and Hathaway, 1995), together with routine shearing at high-risk sites.

The Clean Livestock Policy adopted by the Food Standards Agency in the United Kingdom has had considerable success in meeting the requirements of the hygiene package. It is based on a visual inspection during unloading or lairaging and the categorisation of the animals as acceptable for slaughter, acceptable for slaughter following shearing or clipping (conducted at the primary producers expense), and unsuitable for slaughter. Extra time spent in lairage, clipping, subsequent reduction in slaughter line speed, separate processing or excessive trimming and rejection of animals all incur additional costs to producers and processors (Food Standards Agency, 2007b). Similarly, in 2006, the Norwegian meat industry also adopted national guidelines for good hygiene slaughter practices regarding the categorisation of fleece cleanliness for sheep (Hauge et al., 2011a). The policy coordinators, in both the United Kingdom and Norway, communicate the risk of contaminated sheep to the sheep producer, suggesting various husbandry practices, handling methods and pre-slaughter preparation to limit contamination prior to slaughter (Animalia, 2007; Food Standards Agency, 2007b).

As part of the Norwegian Clean Sheep Policy, developed by the associations of producers and slaughterers, sheep are shorn in the slaughterhouses. If they do not become visually clean after shearing or they are already shorn on farm and are contaminated after shearing, the carcasses of these animals are processed in a separate line. This separate processing may include heat treatment of meat products and processing into a restricted range of products, with the farmers receiving a lower price (a reduction of 10–15 % in the carcass value). Hauge et al. (2011a) demonstrated that the measures taken as part of the Norwegian policy decreased the risks posed by carcasses and thereby validated the use of such clean sheep policies.

The influence of animal cleanliness on small ruminant carcass contamination was investigated by several authors in Australia, Canada, New Zealand, Ireland and Norway (Biss and Hathaway, 1996a, 1996b, 1996c; Duffy et al., 2000; Gill, 2004; Hauge et al., 2011a; Sumner et al., 2003), but there is contradictory evidence on the impact of measures to improve fleece cleanliness on microbiological contamination of lamb carcasses. Roberts (1980) and Field et al. (1992) found no effect of shearing of sheep on carcass contamination. Some more recent studies have reported that shearing of sheep decreased carcass surface bacterial counts (Biss and Hathaway, 1996a; Collis et al., 2004; Schroder and Ring, 1998). In a study carried out in Norway by Hauge et al. (2011a) a significantly lower level of aerobic plate count (APC) and *E. coli* was found on carcass surfaces from shorn lambs when compared with unshorn lambs at skinning. At this sampling point, shearing proved to be effective for reducing microbial loads on carcasses. Results in this study showed a trend of increasing contamination of carcasses with increasing duration of the time between shearing and slaughter. Sheep shorn immediately before slaughter yielded carcasses with the lowest microbial loads with respect to APC. The *E. coli* results were less definitive, but a similar trend was demonstrated. Biss and Hathaway (1996b), investigating the effect of pre-slaughter washing of lambs on the microbiological and visible contamination of the carcasses at four slaughterhouses in New Zealand, showed that total aerobic bacteria and *E. coli* contamination was greater on carcasses that had been washed before slaughter, irrespective of wool length, and it was generally higher on carcasses derived from woolly lambs than those derived from shorn lambs. Other researchers have found that pre-slaughter washing of sheep will only have positive effects if the washed animals are allowed sufficient time to dry before they are slaughtered (Newton et al., 1978; Patterson and Gibbs, 1978).

Many studies have reported difficulties in making valid microbiological comparisons associated with differences in slaughter hygiene due to individual operators, uneven distribution of microorganisms on carcasses, variations between groups of animals, day-to-day variations, and seasonal variations (Biss and Hathaway, 1996b; Hauge et al., 2011a; Ingram and Roberts, 1976). This may explain the conflicting results obtained in relation to the effect of shearing or washing on carcass contamination in such studies.

Irrespective of this conflicting evidence about how to best ensure that incoming animals are clean, it seems necessary to continue accepting only clean animals for slaughter as currently required by EU legislation, as it can be assumed that the dirtier the animals are in terms of faecal material, the higher the risk of cross-contamination of the slaughterline environment, including the carcasses.

4.4.2.2. *Post-mortem*

As mentioned above, a second source of enteric bacteria on carcasses are the viscera. During carcass dressing, bacteria are transferred from the gastrointestinal tract to the carcass directly by contact with gut spillage or indirectly via contaminated hands, knives, other equipment and the air. In general, prerequisite GMP and GHP implemented to reduce bacterial contamination will also prevent or reduce carcass contamination with pathogenic VTEC, *Salmonella* spp. and other pathogens. During evisceration, the abdominal cavity is opened using a knife and the connective tissue joining the bung and the viscera to the carcass is cut. Rodding (sealing the oesophagus with a crocodile clip, plastic ring or starch cone) may be performed to prevent leakage. The spread of faecal material from the rectum can be prevented or reduced by bagging and tying the bung.

The current throat sticking practice in halal slaughter (cutting of blood vessels, oesophagus and trachea)[15] limits the effect of rodding as the leakage from the oesophagus occurs before rodding can be applied. If a sticking method such as chest sticking is applied, the effect of rodding will be greater as the oesophagus remains intact, with reduced leakage from the oesophagus until rodding is performed as one of the first steps after bleeding. Using this method, contamination from the oesophagus of wool, skinned surfaces and the abdominal and chest cavity, in addition to the operator's hands, equipment, walls and floor, will be avoided to a high degree.

[15] Allowed as per Article 7 (a), Chapter IV, 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.

The effect of bagging on the level of *E. coli* on sheep carcasses has been previously investigated (Norwegian Scientific Committee for Food Safety, 2012). Although the numbers of carcasses were limited, based on relevant 100-cm^2 sampling sites (circum-anal incision and pelvic duct), it could be concluded that the use of the plastic bag technique during circum-anal incision and removal of the rectum results in a 1 to 2 log reduction in *E. coli* (Figure 4). If a plastic bag is not used and the rectum is inserted in the abdomen, the chances of contamination are larger.

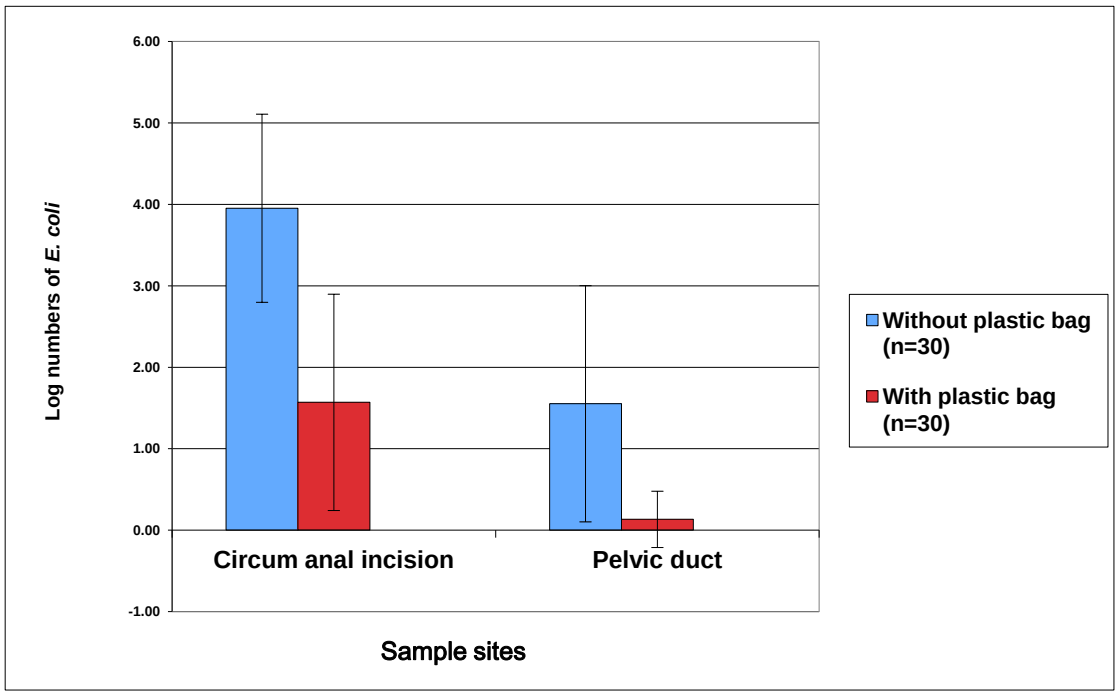

Figure 4: The average numbers and standard deviations of *E. coli* per 100-cm^2 sample sites on lamb carcasses (Norwegian Scientific Committee for Food Safety, 2007).

The hygienic effect of rodding and bagging will depend on the operator's experience at these critical hygienic positions.

Skinning and evisceration may also be designated as critical control points (CCPs) as part of the HACCP programme, the critical limit for both being zero visible faecal contamination on the carcasses. Monitoring occurs at the trimming stand where every carcass is visually inspected. This inspection may be facilitated using the online monitoring system described by Tergney and Bolton (2006). When faeces or faecal stains are detected they are immediately removed by trimming. The cause of the breach in hygiene should also be investigated, and secondary corrective actions require retraining of personnel, replacement of knives, etc.

4.4.2.3. Process hygiene criteria

Setting and using indicators/criteria for "process hygiene" of slaughterhouses is an integral part of the meat safety assurance system, which targets specifically contamination of the carcasses with enteric pathogens. According to the Regulation on microbiological criteria, a microbiological criterion means a criterion defining the acceptability of a product, a batch of foodstuffs or a process, based on the absence, presence or number of microorganisms, and/or on the quantity of their toxins/metabolites, per unit(s) of mass, volume, area or batch. PHC included in Regulation (EC) No 2073/2005 are defined as criteria indicating the acceptable functioning of the production process. They give guidance on the acceptable implementation of pre-requisite programmes (GMP/GHP) and HACCP-based systems to ensure hygienic functioning of slaughterhouse processes and are applicable only to the product at the

end of the manufacturing process (final carcass after dressing but before chilling), and not to products placed on the market.

In EU countries, PHC involve the evaluation of indicators of overall contamination (total viable count of bacteria), indicators of contamination of enteric origin (*Enterobacteriaceae*) and *Salmonella* spp. prevalence. Bacteriological analysis of carcasses, as outlined in this regulation, is carried out by the FBO. It involves pooled samples from four risk-assessed sampling sites on each of five sampled carcasses. This must be carried out weekly or, depending on the previous results, once a fortnight. PHC set an indicative microbial contamination value above which corrective actions are required by the FBO in order to maintain the hygiene of the process in compliance with EU food law. These corrective actions should include the improvement of slaughter hygiene and the review of process controls. The PHC communicate the expected outcome of a process, but they neither characterise nor differentiate between the processes themselves. Process compliance must be verified by audits of HACCP plans and inspections of processing procedures. The competent authority carries out this role on behalf of the member state as defined by Regulation (EC) No 854/2004.

As PHC verifies the hygienic functioning of the process 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 security due to the statistical limitations 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 hazards (e.g. *T. gondii*), PHC does 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 without other aspects of EU food legislation, in particular HACCP principles and official controls to FBOs' compliance (EFSA, 2007c).

With current EU legislation, one element of the PHC indicates the maximum acceptable prevalence of *Salmonella* spp. on carcasses at the end of the slaughter line. The inclusion of this pathogen as a process hygiene criterion for carcasses highlights the importance of *Salmonella* spp. as a foodborne pathogen in the EU and the need for good hygiene measures for controlling it in the abattoir. However, the use of this hazard presents some problems, because the *Salmonella* spp. occurrence on carcasses depends not only on process hygiene performance of a given abattoir, but also on the *Salmonella* spp. carriage by incoming animals (or lack of it). Hence, when slaughtering batches that are *Salmonella* spp. free or that have a low prevalence, such PHC will be satisfied even if the actual process hygiene is inadequate—and vice versa. On the other hand, the current EU *Salmonella*-based process hygiene criterion *partly* has the nature of a *Salmonella*-related target to be achieved by abattoirs. The important difference is that with the current EU PHC the hazard is measured on the carcass before chilling, while with the target-based concept the hazard is measured on the chilled carcass (i.e. just before dispatch onwards to the meat chain). However, the chilled carcass is better suited for assessing consumer exposure, and for the hazard-related target concept, as the prevalence/levels of microbial hazards on the carcass may change during chilling. Furthermore, these current *Salmonella*-related EU criteria for chilled carcasses are not clearly linked to other *Salmonella*-related criteria/targets at preceding and/or consecutive steps of the meat chain.

In addition, current EU-legislated PHC for abattoirs actually do not provide information on ratios between initial contamination associated with incoming animals versus final contamination associated with carcasses, i.e. on the actual capacity of the process to reduce the incoming contamination, but only on the process outcomes. When the main purpose is to microbiologically characterise the abattoir process itself, which is the subject of this subsection and a prerequisite for related differentiation of abattoirs, this is a significant weakness of the current EU-legislated PHC.

These shortcomings could be addressed by the setting of specific targets for pathogenic VTEC, as described in Section 4.2 above, instead of using *Salmonella* spp. in PHC. In addition, to measure the performance of the slaughter line, PHC based on indicator organisms should be implemented, measuring microbial loads in at least two stages of the processing line. This would allow

determination of the ratio between indicator organisms on pre-chill carcasses and those found in incoming animals, for a given batch. The PHC is considered to be a key component of the proposed meat safety assurance system so, in that context, careful consideration would need to be given to issues such as the number of samples taken per week, the areas where those samples are taken from (both in carcasses and incoming animals) and the need for regulatory auditing of the process hygiene assessment (which may include microbial testing, as well as record verification).

This more accurate information based on trends of data derived from process hygiene assessments and from HACCP programmes would enable differentiation ("risk categorisation") of abattoirs with respect to pathogenic VTEC which, in turn, would enable different risk management options for different risk categories of abattoirs to be used, including:

- Optimisation of balancing pathogenic VTEC risk categories of small ruminants with risk categories of abattoirs where they are to be slaughtered.
- Optimisation of the decision whether/where additional pathogenic VTEC risk-reducing interventions are to be applied (e.g. carcass decontamination step).
- More stringent requirements for monitoring/verification/auditing programmes for higher risk abattoirs.
- More reliable feedback to the farm of origin on the root of problems with pathogenic VTEC on carcasses of small ruminants.
- Clearer identification of slaughterhouses where improvement of the slaughtering practices and/or technology is needed.

4.4.2.4. Post-processing interventions

Small ruminants represent a reservoir of enteric pathogens. In that context, the slaughtering of sheep involves greater challenges because the animal is relatively small and has a wool fleece, thus increasing the risk of surface contamination at dehiding (Buncic, 2006), which might result in suboptimal hygiene during slaughtering compared with the slaughtering of cattle. Technological and operational shortcomings, such as a too high line speed, no rodding and bagging and the use of seasonal workers not sufficiently trained for the purpose, are reported as additional challenges in some abattoirs (Norwegian Scientific Committee for Food Safety, 2012). Accordingly, interventions such as surface pasteurisation using hot water might be considered as one of several options to reduce the bacterial contamination on carcasses. Hot water at 72–85 °C achieves a 1.0 to 2.8 $\log_{10}$ reduction in colony-forming units (CFUs)/cm^2 in *Salmonella* spp. on beef carcasses (Arthur et al., 2008; Cutter and Rivera-Betancourt, 2000). In a study by Hauge et al. (2011b) 210 lamb carcasses were subjected to hot water pasteurisation at 82 °C for eight seconds. The reduction in *E. coli* just after pasteurisation was 99.5 %, corresponding to 1.85 log CFUs/cm^2, and after 24 hours' storage 2.02 log CFUs/cm^2. Accordingly, surface pasteurisation of sheep carcasses might represent an important and efficient step (CCP) to reduce VTEC on the carcasses and the risk of disease among consumers. An automatic surface pasteurisation step is easy to control by measurement of time/temperature, and these results, together with the quality of the process water, might be documented on display and/or on hard copy. The pasteurisation step might be recognised as a CCP in a HACCP concept.

Steam treatment is also allowed in the EU and has been found to reduce bacterial contamination in sheep carcasses by a $\log_{10}$ CFUs/cm^2, both in *Enterobacteriaceae* (Milios et al., 2011) and aerobic plate counts (James et al., 2000). Greater reductions of up to 4.0 $\log_{10}$ CFUs/cm^2 have been described when using a combination of steam and a hot water wash in sheep carcasses (Dorsa et al., 1996). Similar effects have been observed with *Salmonella* spp. counts in beef carcasses, achieving reductions of < 0.7 to 4.8 $\log_{10}$ CFUs/cm^2 (Phebus et al., 1997; Retzlaff et al., 2005). Surface pasteurisation can also be achieved by manual steam vacuum technology. However, the use of this

technology depends on skilled and responsible operators, and will require close supervision in order to ensure the pasteurisation procedure is correctly applied to the whole carcass. The use of manual steam vacuum was evaluated in a Norwegian slaughterhouse, showing a real reduction (median of 1.10 log CFUs/cm^2)(Hassan, 2008).

Surface pasteurisation of ruminant carcasses is an option that allows dealing with carcasses presenting greater risk, such as emergency slaughtered carcasses or unclean carcasses, without the need, for example, to apply a heat treatment on these carcasses.

Although not permitted in the EU, a range of specific interventions are applied in US slaughter plants targeting enteric pathogens such as pathogenic VTEC and *Salmonella* spp. These include the application of organic acids. The application of acetic acid to beef carcasses will reduce *E. coli* counts by 1.0–3.7 $\log_{10}$ CFUs/cm^2 (Sofos and Smith, 1998). Significant reductions achieved with lactic acid have also been described (EFSA Panel on Biological Hazards, 2011).

4.5. Conclusions and recommendations

Conclusions

As neither of the main public health hazards associated with meat from small ruminants can be detected by traditional meat inspection, other approaches are necessary to identify and control these microbiological hazards. A comprehensive meat safety assurance system for meat from small ruminants, combining a range of preventive measures and controls applied both on the farm and at the slaughterhouse in a longitudinally integrated way, is the most effective approach to control the main hazards in the context of meat inspection.

Information on the biological risks associated with the consumption of meat from sheep or goats 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 *T. gondii* and pathogenic VTEC at flock/herd, live animal and carcass level in individual MSs. Epidemiological and risk assessment studies are also required to determine the specific risk to public health associated with the consumption of meat from small ruminants.

In the event that these studies confirm a high risk to public health through the consumption of meat from sheep or goats, 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.

Flock/herd categorisation according to the risk posed by the main hazards is considered an important element of an integrated meat safety assurance system. This should be based on the use of farm descriptors and historical data in addition to batch-specific information. Farm-related data could be provided through farm audits using HEIs to assess the risk and protective factors for the flocks/herds related to the given hazards.

Classification of abattoirs according to their capability to prevent or reduce faecal contamination of carcasses can be based on two elements: (i) the process hygiene as measured by the level of indicator organisms on the carcasses (i.e. PHC); and (ii) the use of operational procedures and equipment that reduce faecal contamination, as well as industry-led quality assurance systems.

As mentioned in Section 4.2, further studies are necessary to determine with more certainty the risk of acquiring *T. gondii* through consumption of meat from small ruminants. In addition, the lack of tests that can easily identify viable cysts in meat is a significant drawback. Furthermore, if there is a high prevalence in the animal population, this will hamper the development of systems based on risk categorisation of animals. For these reasons, the setting of targets for *T. gondii* is not recommended at the moment.

There are a variety of animal husbandry measures that can be used to control *T. gondii* on sheep and goat farms but at present it would not be practical to implement them on most farms. A number of post-processing interventions might be effective in inactivating *T. gondii* such as cooking, freezing, curing and high-pressure and γ-irradiation treatments. However, most of the information available for these treatments originates from research in pigs, so further research is required to validate these treatments in meat from small ruminants.

There are also a variety of animal husbandry measures that can be used to reduce the levels of VTEC on infected farms, but their efficacy is not clear in small ruminants. In addition, there are a number of challenges that need to be overcome regarding the setting of targets for pathogenic VTEC, including the difficulties in identifying husbandry factors that can be used to classify farms according to pathogenic VTEC risk, the intermittent nature of shedding, and the problems with the interpretation of monitoring results for VTEC due to the difficulty of correctly identifying pathogenic VTEC.

The two main sources of VTEC on sheep and goat carcasses are the fleece/hide and the viscera. To control faecal contamination from the fleece or hide only clean animals should be accepted for slaughter, as currently required by EU legislation. There are also a number of measures that can help to reduce the spillage or leakage of digestive contents onto the carcass, particularly rodding of the oesophagus and bagging of the rectum. Post-processing interventions to control pathogenic VTEC are also available. These include hot water and steam pasteurisation.

Risk categorisation of slaughterhouses should be based on trends of data derived from Process Hygiene Assessments and from Hazard Analysis Critical Control Point programmes. Improvement of slaughter hygiene through technological and managerial interventions should be sought in slaughterhouses with repeatedly unsatisfactory performance.

Recommendations

Source attribution studies are needed to determine the relative importance of meat, as well as to ascertain the role of the different livestock species as a source of *T. gondii* and pathogenic VTEC.

Methods should be developed to estimate the amount of viable *T. gondii* tissue cysts in meat, especially in meat cuts that are commonly consumed.

5. Recommend adaptation of inspection methods that provide an equivalent protection for current hazards

5.1. Food chain information

The main rationale behind the concept of FCI is that animals sent 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. Although Regulation (EC) No 853/2004 mentions the basic requirements for FCI, these are very general and as a consequence the information reported in FCI is rarely used as described above (Section 3.2.3 of this Appendix).

There are a number of ways in which FCI could be improved. As explained in Section 4.2.1 above, more specific information about the main hazards could be used for assessing the risks associated with batches of animals arriving at the slaughterhouse, resulting in a classification according to these risks. To achieve this, the system needs further development to include additional information important for food safety, including the definition of appropriate and standardised indicators for the main public health hazards identified in Section 2 of this Appendix.

In addition, membership of quality assurance schemes and certification systems can have a positive impact on public health by contributing to the overall health of the animals sent to slaughter. Certification procedures at farm level are voluntary tools to ensure compliance with given standards and regulations in the quality assurance system. They are aimed at achieving continuous improvement in production standards by monitoring quality assurance standards or criteria. Audits or inspections of farms ensure that the animal (final product) is being raised and handled in accordance with the standards or guidelines, which producers should adhere to. The main areas covered by the standards include usually animal health, welfare and hygiene, identification and traceability, adequate and prudent use of medicines and chemicals at farm level, safety of feed and water, environmental guidelines, hygiene of personnel, processes and infrastructure, and preparation of animals for slaughter. The standards should be regularly updated in line with changes in legislation and with scientific developments. Certifications are issued by independent agencies or bodies which confirm that an auditing process has been passed. Farmers can also adopt other schemes such as the Guides to Good Farming Practices, recommendations of best practice published by international bodies (i.e. World Organisation for Animal Health (OIE) and the Food and Agriculture Organization of the United Nations (FAO)).

Adherence to such quality schemes and guidelines at farm level has multiple benefits, providing slaughterhouse operators with useful information about animals intended to be slaughtered and could be integrated in the FCI. It also increases farmers' responsibilities and has a beneficial influence on meat safety and quality. Schemes such as the Beef and Lamb Quality Assurance Scheme in Ireland cover a broad area, relating to animal identification and animal health and welfare, and contribute to ensuring that healthy animals enter the slaughterhouse. 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.

EU Regulations (EC) No 854/2004 and (EC) No 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 and pneumonia. However, as mentioned previously, use of this information to produce healthier animals would have indirect benefits for public health. From discussions with stakeholders, it is clear that feedback to the producers is very limited in most MSs and that there is considerable room for improvement in that area (see the report from the technical hearing on meat inspection of small ruminants[16]).

[16] Available at: www.efsa.europa.eu/en/supporting/pub/373e.htm

5.2. *Ante-mortem* inspection

Ante-mortem inspection assesses the general health status of the animals on arrival at the slaughterhouse. 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, 2011b). Measures to keep the transport-lairaging period as short as possible may be beneficial in terms of reducing cross-contamination with these enteric pathogens.

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

5.3. *Post-mortem* inspection

In the inspection procedure for sheep and goats, as set out in EU Regulation (EC) No 854/2004, carcasses are subject to visual inspection only. Incision is mandatory for the gastric surface of the liver. Palpation is mandatory for the lungs, bronchial and mediastinal lymph nodes, the liver and its lymph nodes. In addition, palpation is mandatory for the umbilical region and joints of young animals.

Palpation of lungs, liver, umbilical region and joints, and incision of the liver could contribute to the spread of bacterial hazards through cross-contamination. Although the importance of such cross-contamination has not been studied in small ruminants, it has been considered important in other species (EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM) and EFSA Panel on Animal Health and Welfare (AHAW), 2011; Walker et al., 2000).

The pathogens of importance for public health cannot be detected by routine *post-mortem* examination. Consequently, palpation of liver, lungs, the umbilical region and joints and incision of the gastric surface of the liver do not contribute to preventing the risk to public health arising from the meat-borne hazards identified in this opinion.

For these reasons, palpation and incision should be omitted in animals subjected to routine slaughter.

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.

The 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 can be ensured through a meat quality assurance system and not through the official meat safety assurance system including meat inspection. Any handling should be performed on a separate line and accompanied by laboratory testing as required.

Palpation and incision currently assist in the identification of zoonootic pathogens that are not meat borne, such as *Echinococcus granulosus*, *Fasciola hepatica* (although cysts are usually visible before incisions are made) and *Mycobacterium bovis*. The removal of palpation and incision as a requirement in the *post-mortem* procedure in small ruminants could have a significant effect on monitoring *Echinococcus*, in particular, as meat inspection is the principal method of detection of this pathogen (EFSA, 2010). In countries where hazards such as *Echinococcus* are present it might be appropriate to conduct a risk assessment to evaluate the benefits to public health of stopping cross-contamination through palpation and incision of viscera with those obtained through monitoring of these non-meat-borne zoonotic hazards.

5.4. Conclusions and recommendations

FCI can be improved by including information on participation in quality assurance schemes and by giving greater feedback to the primary producer, as this would probably result in the production of healthier animals.

Ante-mortem inspection assesses the general health status of the animals and helps to detect animals heavily contaminated with faeces on arrival at the slaughterhouse. Taking these factors into consideration, and given that current methods do not increase the microbiological risk to public health, no adaptations to the existing visual *ante-mortem* inspection procedure are required.

Although visual examination contributes by detecting visible faecal contamination, routine *post-mortem* examination cannot detect the meat-borne pathogens of public health importance. Palpation of the lungs, the liver, the umbilical region and the joints and incision of the liver could contribute to the spread of bacterial hazards through cross-contamination. For these reasons, palpation and incision should be omitted in animals subjected to routine slaughter.

The effect of this omission on the risk posed by non-meat-borne zoonoses such as *E. granulosus*, *F. hepatica* and *M. bovis* should be assessed, particularly in those countries where these hazards are prevalent.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

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

- Based on the priority ranking, the hazards were classified as follows:
  - *T. gondii* and pathogenic verocytotoxin-producing *Escherichia coli* (VTEC) were classified as high priority for sheep/goat meat inspection.
  - The remaining identified hazards, *B. anthracis*, *Campylobacter* spp. (thermophilic) and *Salmonella* spp., were classified as low priority, based on the available data.
- As new hazards might emerge and/or hazards that presently are not a priority might become more relevant over time or in some regions, both hazard identification and the risk ranking should be revisited regularly to reflect this dynamic epidemiological situation. Particular attention should be given to potential emerging hazards of public health importance.

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

Strengths

- *Ante-mortem* and *post-mortem* inspection of sheep and goats enable the detection of observable abnormalities. In that context, they are an important activity for monitoring animal health and welfare. They provide a general assessment of animal/herd health, which if compromised may lead to a greater public health risk. Visual inspection of live animals and carcasses can also detect animals heavily contaminated with faeces. Such animals increase the risk for cross-contamination during slaughter and may consequently constitute a food safety risk if carrying hazards of public health importance. If such animals or carcasses are dealt with adequately, this risk can be reduced. Visual detection of faecal contamination on carcasses can also be an indicator of slaughter hygiene, but other approaches to verify slaughter hygiene should be considered.
- *Post-mortem* inspection can also detect non-meat-borne hazards of public health significance that can be present in carcasses or offal from small ruminants. *Ante-mortem* and *post-mortem* inspection also have the potential to detect new diseases if these have clinical signs, which may be of direct public health significance.

Weaknesses

- Currently, the use of food chain information (FCI) for food safety purposes is limited for small ruminants, mainly because the data that it contains is very general and doesn't address specific hazards of public health importance. However, FCI could serve as a valuable tool for risk management decisions and could be used for risk categorisation of farms or batches of animals. To achieve this, the system needs further development to include additional

information important for food safety, including definition of appropriate and standardised indicators for the main public health hazards identified in Section 2 of this Appendix.

- *Ante-* and *post-mortem* inspection is not able to detect any of the public health hazards identified as the main concerns for food safety. It would therefore be expected that more efficient procedures might be implemented to monitor the occurrence of non-visible hazards. In addition, given that the current *post-mortem* procedures involve palpation and incision of some organs, there is potential for cross-contamination of carcasses.

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.

- As neither of the main public health hazards associated with meat from small ruminants can be detected by traditional meat inspection, other approaches are necessary to identify and control these microbiological hazards. A comprehensive meat safety assurance system for meat from small ruminants, combining a range of preventive measures and controls applied both on the farm and at the slaughterhouse in a longitudinally integrated way, is the most effective approach to control the main hazards in the context of meat inspection.

- Information on the biological risks associated with the consumption of meat from sheep or goats 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 *T. gondii* and pathogenic VTEC at flock/herd, live animal and carcass level in individual Member States. Epidemiological and risk assessment studies are also required to determine the specific risk to public health associated with the consumption of meat from small ruminants.

- In the event that these studies confirm a high risk to public health through the consumption of meat from sheep or goats, 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.

- Flock/herd categorisation according to the risk posed by the main hazards is considered an important element of an integrated meat safety assurance system. This should be based on the use of farm descriptors and historical data in addition to batch-specific information. Farm-related data could be provided through farm audits using Harmonised Epidemiological Indicators (HEIs)[17] to assess the risk and protective factors for the flocks/herds related to the given hazards.

- Classification of abattoirs according to their capability to prevent or reduce faecal contamination of carcasses can be based on two elements: (i) the process hygiene as measured by the level of indicator organisms on the carcasses (i.e. Process Hygiene Criteria); and (ii) the use of operational procedures and equipment that reduce faecal contamination, as well as industry-led quality assurance systems.

- As mentioned in Section 4.2 of Appendix A, further studies are necessary to determine with more certainty the risk of acquiring *T. gondii* through consumption of meat from small ruminants. In addition, the lack of tests that can easily identify viable cysts in meat is a significant drawback. Furthermore, if there is a high prevalence in the animal population, this will hamper the development of systems based on risk categorisation of animals. For these reasons, the setting of targets for *T. gondii* is not recommended at the moment.

[17] As described in EFSA (2013)

- There are a variety of animal husbandry measures that can be used to control *T. gondii* on sheep and goat farms, but at present these would not be practical to implement on most farms. A number of post-processing interventions might be effective in inactivating *T. gondii* such as cooking, freezing, curing and high-pressure and γ-irradiation treatments. However, most of the information available for these treatments originates from research in pigs, so further research is required to validate these treatments in meat from small ruminants.

- There are also a variety of animal husbandry measures that can be used to reduce the levels of VTEC on infected farms, but their efficacy is not clear in small ruminants. In addition, there are a number of challenges that need to be overcome regarding the setting of targets for pathogenic VTEC, including the difficulties in identifying husbandry factors that can be used to classify farms according to pathogenic VTEC risk, the intermittent nature of shedding, and the problems with the interpretation of monitoring results for VTEC due to the difficulty of correctly identifying pathogenic VTEC.

- The two main sources of VTEC on sheep and goat carcasses are the fleece/hide and the viscera. To control faecal contamination from the fleece or hide only clean animals should be accepted for slaughter, as currently required by EU legislation. There are also a number of measures that can help to reduce the spillage or leakage of digestive contents onto the carcass, particularly rodding of the oesophagus and bagging of the rectum. Post-processing interventions to control VTEC are also available. These include hot water and steam pasteurisation.

- Risk categorisation of slaughterhouses should be based on trends of data derived from Process Hygiene Assessments and from Hazard Analysis Critical Control Point programmes. Improvement of slaughter hygiene through technological and managerial interventions should be sought in slaughterhouses with repeatedly unsatisfactory performance.

TOR 4 Recommend adaptations of inspection methods and/or frequencies of inspections that provide an equivalent level of protection within the scope of meat inspection or elsewhere in the production chain that may be used by risk managers in case they consider the current methods disproportionate to the risk, e.g. based on the ranking as an outcome of terms of reference 1 or on data obtained using harmonised epidemiological criteria (see Annex 2[18]). When appropriate, food chain information should be taken into account.

- FCI can be improved by including information on participation in quality assurance schemes and by giving greater feedback to the primary producer, as this would probably result in the production of healthier animals.

- *Ante-mortem* inspection assesses the general health status of the animals and helps to detect animals heavily contaminated with faeces on arrival at the slaughterhouse. Taking these factors into consideration, and given that current methods do not increase the microbiological risk to public health, no adaptations for the existing visual *ante-mortem* inspection are required.

- Although visual examination contributes by detecting visible faecal contamination, routine *post-mortem* examination cannot detect the meat-borne pathogens of public health importance. Palpation of the lungs, the liver, the umbilical region and the joints, and incision of the liver could contribute to the spread of bacterial hazards through cross-contamination. For these reasons, palpation and incision should be omitted in animals subjected to routine slaughter.

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

RECOMMENDATIONS

- To provide a better evidence base for future risk ranking of hazards, initiatives should be instigated to:
  - improve and harmonise data collection of incidence and severity of human diseases caused by relevant hazards
  - systematically collect data for source attribution
  - collect data to identify and risk rank emerging hazards that could be transmitted through handling, preparation and consumption of sheep and goat meat.
- Source attribution studies are needed to determine the relative importance of meat, as well as to ascertain the role of the different livestock species, as a source of *T. gondii* and pathogenic VTEC for humans.
- Methods should be developed to estimate the amount of viable *T. gondii* tissue cysts in meat, especially in meat cuts that are commonly consumed.
- The effect of the omission of palpation and incision on the risk posed by non-meat-borne zoonoses such as *E. granulosus* and *F. hepatica* should be assessed, particularly in those regions where these hazards are endemic.

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ANNEXES

Annex 1. Additional information on hazards excluded from the priority ranking

Assessment of the importance of the hazards in Table 1 with regard to their potential as zoonotic agents that can be transmitted via consumption of meat from small ruminants.

Bacteria

- *Aeromonas*

These bacteria are considered zoonotic, although this characteristic has only been documented in fish. Transmission via consumption of meat from small ruminants has not been reported, despite Aeromonas being detected in lamb and meat products and having the potential to be a foodborne pathogen (Daskalov, 2006).

- *Anaplasma phagocytophilum* (formerly *Ehrlichia phagocytophila*, *Ehrlichia equi* and *Anaplasma phagocytophila*), Panola Mountain *Ehrlichia*

These obligate intracellular bacteria are found in sheep, cattle, horses and dogs, as well as deer and rodents in Europe (Kalinova et al., 2009), and although they cause human disease, this illness is rare (Scharf et al., 2011). They are transmitted by ticks of the genus *Ixodes*, therefore they do not present a risk to humans via consumption of sheep meat.

- *Arcobacter* spp.

The genus *Arcobacter* includes species that can be defined as aerotolerant *Campylobacter*-like organisms. They were first isolated from aborted bovine foetuses. Information on the real prevalence and clinical importance of *Arcobacter* is limited because of the absence of routine testing protocols and the fact that most laboratories do not use appropriate culture conditions or do not identify isolates to species level. Small ruminants have been found to be carriers of these bacteria (De Smet et al., 2011) in Europe. Recent reports suggest that arcobacters, especially *A. butzleri*, may be involved in human enteric disease, although the evidence is not conclusive (Houf, 2009). There are no specific epidemiological data establishing a link between *Arcobacter* infection with consumption of meat from small ruminants. In addition, the public health significance of *Arcobacter* remains unclear.

- *Borrelia burgdorferi sensu lato*

Borrelia are transmitted by ticks of the genus *Ixodes*, and infect a wide range of hosts including sheep, although their contribution to the maintenance of *B. burgdorferi* is still not clear (Mannelli et al., 2012). Although present throughout Europe, currently there is no evidence that *Borrelia* can be transmitted via consumption of meat.

- *Brucella*

Sheep and goat brucellosis is a zoonotic infection. Brucellosis is caused by some bacterial species belonging to the genus *Brucella*. Of the six species known to cause disease in humans *B. melitensis* affects goats and sheep, their specific animal reservoir. Humans are usually infected from direct contact with infected animals or via contaminated food, typically raw milk, cheese made thereof or other milk products such as cream and ice cream. Meat is not considered a source of infection since muscle tissue contains low concentrations of *Brucella* organisms and the survival time in meat seems extremely short. The number of organisms per gram of muscle is small and rapidly decreases as the pH of the meat drops. *Brucella* spp. die off rapidly when incubated at 37º C in a medium at pH < 5 (ICMSF (International Commission on Microbial Specifications for Food), 1996). An exception in survival behaviour seems to be frozen carcasses, in which the organism can survive for years.

- *Chlamydophila abortus*

C. abortus is known to be transmissible from animals to humans, causing significant zoonotic infections. *C. abortus* causes the enzootic abortion of ewes (ovine enzootic abortion), which has become recognised as a major cause of loss in sheep (and goats) in Europe, North America and Africa. (Pospischil, 2006). Most cases of *C. abortus* infection are directly associated with exposure to infected sheep or goats, with transmission most probably occurring by mouth following the handling of an infected ewe or lamb or of contaminated clothing (Longbottom and Coulter, 2003). The role of meat from small ruminants in the epidemiology of human infection with *C. abortus* is nevertheless unclear.

- *Clostridium difficile*

C. difficile is a species of anaerobic, spore-forming gram-positive bacteria that causes severe diarrhoea and other intestinal disease when competing bacteria in the gut flora have been eliminated by antibiotic treatment. There are reports of *C. difficile* being isolated from small ruminants (Hunter et al., 1981; Koene et al., 2012; Rieu-Lesme and Fonty, 1999; Saif and Brazier, 1996). However, there is to date no indication of meat-borne transmission to humans.

- *Corynebacterium pseudotuberculosis*

C. pseudotuberculosis is the causative agent of caseous lymphadenitis in small ruminants. These bacteria are commonly found in Europe in the ruminant population. Cases of human lymphadenitis have been described previously (Peel et al., 1997), although transmitted via occupational exposure and not through consumption of meat.

- *Coxiella burnetii*

C. burnetti has been isolated from a large range of animals including farm animals (e.g. cattle, sheep and goats), wildlife and arthropods. It has a near-worldwide distribution. *C. burnetti* causes Q fever in humans, in whom it was traditionally considered an occupational disease in farm and abattoir workers. Airborne transmission is also important, and has played a major role in recent outbreaks. The meat-borne transmission route has so far not been identified as a possibility (Georgiev et al., 2013).

- *Erysipelothrix rhusiopathiae*

E. rhusiopathiae is a ubiquitous bacterium which can cause polyarthritis in sheep and lambs. It can also infect humans, in whom it causes either cutaneous (localised or general) or septicaemic disease (Wang et al., 2010). Humans usually acquire the infection through contact with infected animals, i.e. erysipelas is considered an occupational disease. Meat from small ruminants has not been identified as a vehicle for human infection.

- ESBL/AmpC-gene carrying *Escherichia coli*

ESBLs may be defined as plasmid-encoded enzymes found in the *Enterobacteriaceae* that confer resistance to a variety of ß-lactam antibiotics, including penicillins, and second-, third- and fourth-generation cephalosporins. In contrast, AmpC β-lactamases are intrinsic cephalosporinases found on the chromosomal DNA of many gram-negative bacteria, which confer resistance to penicillins, second- and third-generation cephalosporins, including β-lactam/inhibitor combinations, and cefamycins (cefoxitin), but usually not to fourth-generation cephalosporins. A growing number of these AmpC enzymes are now plasmid-borne (EFSA Panel on Biological Hazards, 2011c). A targeted literature search found references that reported the presence of ESBL/AmpC-gene carrying *Enterobacteriaceae* (Geser et al., 2012; Snow et al., 2011) in small ruminants but none indicated transmission of these enzymes to humans via consumption of meat from sheep or goats.

- *Helicobacter pylori*

H. pylori was previously known as *Campylobacter pylori* (it is taxonomically related to *Campylobacter* spp. and belongs to the family *Helicobacteraceae*). Infection of the stomach by

H. pylori is associated with several alterations in gastric mucosal cell proliferation, and disorders such as chronic gastritis, gastric ulcers, duodenal ulcers and stomach cancer. Colonisation of the stomach by *H. pylori* is well established and the bacterium is able to withstand digestive enzymes and concentrated hydrochloric acid. *H. pylori* is believed to be transmitted orally but no food has been as yet identified as a source. No reservoir other than the human gastric mucosa has been identified for *H. pylori*. Plonka et al. (2006) suggest a zoonotic link to sheep, but no evidence of meat-borne transmission is presented.

- *Klebsiella pneumoniae*

Although the isolation of *K. pneumoniae* from small ruminants' meat has been described (Brahmbhatt, 2000; Sharma et al., 2003), no evidence for meat-borne transmission of this pathogen to humans could be found.

- *Leptospira spiralis*

L. spiralis has been reported in the small ruminant population in Europe and elsewhere (Bisias et al., 2010; Savalia et al., 2008; Seixas Melo et al., 2010); however, although it has been considered a potential occupational hazard (Heuer et al., 2010), there is no current evidence that it can be transmitted to humans via consumption of meat from small ruminants.

- *Mycobacterium avium* subsp. *paratuberculosis*

M. avium subsp. *paratuberculosis* (*Map*), which causes chronic enteritis in all ruminants, is the most prevalent mycobacterium found in small ruminants within the *M. avium* complex (MAC). MAC includes eight mycobacteria species and several subspecies with different degrees of pathogenicity, a broad host range and environmental distribution in numerous biotopes including the soil, water, aerosols, etc. (Alvarez et al., 2011; Biet et al., 2005). A link between *Map* and the human chronic enteritis, Crohn's disease, has been speculated and supported by several lines of evidence, such as the demonstration of *Map*-specific sequences in Crohn's disease-affected tissues. However, at present, there is no agreed consensus on any aetiological role for *Map* in Crohn's disease (Chiodini, 2000; Waddell et al., 2008; Wagner et al., 2013) and no evidence that it presents a risk via consumption of meat or meat products.

- *Mycobacterium bovis*, *Mycobacterium Mycobacterium*

The presence of mycobacteria has been previously reported in the small ruminant population in the EU (Domenis et al., 2011; Malone et al., 2003; Marianelli et al., 2010; Shanahan et al., 2011). Despite these reports, evidence of meat-borne transmission of these pathogens to humans from small ruminants is lacking, so this potential pathway of infection remains unproven in the context of livestock processed through the EU meat inspection system.

- Meticillin-resistant *Staphylococcus aureus* (MRSA)

MRSA has been isolated from most food-producing animals and from most meats, as well as from milk including sheep and lamb meat. Where MRSA CC398 prevalence is high in food-producing animals, people in contact with these live animals (especially farmers and veterinarians, and their families) are at greater risk of colonisation and infection than the general population. Food may be contaminated by MRSA (including CC398): eating and handling contaminated food is a potential vehicle for transmission. There is currently no evidence for increased risk of human colonisation or infection following contact or consumption of food contaminated by CC398 both in the community and in hospital (EFSA, 2009).

- *Streptococcus suis*, *Streptococcus equi* subsp. *zooepidemicus*

Streptococcus spp. have been isolated in small ruminants, most commonly in milk or mastitis samples (Pisoni et al., 2009; Zdragas et al., 2005). Zoonotic transmission has been described (Poulin and Boivin, 2009), but there is no evidence to date that it can cause meat-borne disease in humans.

- *Yersinia pseudotuberculosis, Yersinia enterocolitica*

Foodborne yersiniosis is caused primarily by *Yersinia enterocolitica*, with *Y. pseudotuberculosis* representing a low fraction of isolates (less than 1 %) from human cases reported (EFSA and ECDC, 2013b). The majority of isolates of *Y. enterocolitica* isolated from food and environmental sources are non-pathogenic types, and therefore discrimination between pathogenic and non-pathogenic strains for humans is necessary. No reports of *Y. pseudotuberculosis* have been published of isolates in food items tested during 2008–2011 (EFSA and ECDC, 2012, 2013b). Pigs are considered to be the primary reservoir for the human pathogenic types of *Y. enterocolitica*, and they can be isolated from the oral cavity, the submaxillary lymph nodes, the intestine and faeces (Nesbakken, 2006). *Y. enterocolitica* is found in small ruminants, and is considered to be responsible for certain infections in sheep and goats such as enteritis (Arnold et al., 2006; Fearnley et al., 2005; Fredriksson-Ahomaa et al., 2006; Fukushima et al., 1993; Gourdon et al., 1999; Krogstad, 1974; McNally et al., 2004; Milnes et al., 2008; Philbey et al., 1991; Slee and Button, 1990; Slee and Skilbeck, 1992; Soderqvist et al., 2012; Wojciech et al., 2004).

McNally et al. (2004) investigated the relationship between livestock (sheep, cattle and pigs) carriage of *Y. enterocolitica* and human disease with inconclusive results. The majority of the strains isolated from animal reservoirs differ from clinical strains found in humans, biochemically and serologically. So far pigs are the only species pinpointed as being significant reservoirs for pathogenic *Y. enterocolitica*. There is no evidence that sheep and goats are important animal reservoirs for strains involved in human cases, although Slee and Button (1990) reported the infection of an animal attendant in connection with an outbreak of *Y. enterocolitica* infection in a goat herd in Norway. No evidence that *Yersinia* spp. present a risk via consumption of meat or meat products from sheep or goats is currently available.

Fungi

- *Candida albicans*

C. albicans is a fungus that is the causal agent of opportunistic oral and genital infections in humans and has also been isolated from sheep and goats, for example in milk samples of goats suffering from mastitis (Langoni et al., 2006) or from sheep droppings (Nardoni et al., 2002). No evidence to date could indicate transmission of this fungus to humans via consumption of meat.

- *Cryptococcus neoformans* var. *neoformans*

Cryptococcosis is a rare disease in animals in Europe. A few cases have been described in sheep and goats (lung and mammary gland) in Australia. The source of microorganisms is largely environmental. No cases of transmission from animal to animal or from animal to man or from man to man (except corneal transplant) have been described (Acha and Szyfres, 2001). *C. neoformans* is therefore currently considered not relevant in the EU sheep and goat population and not transmissible via meat.

- *Encephalitozoon intestinalis, Encephalitozoon cuniculi*

Species of microsporidia infecting humans have been identified in water sources as well as in wild, domestic, and food-producing farm animals, raising concerns for waterborne, foodborne, and zoonotic transmission (Didier, 2005).

No evidence could be found in the literature of meat-borne transmission of this hazard from small ruminants to humans.

- *Enterocytozoon bieneusi*

E. bieneusi, the species now known to be the most frequent in microsporidial infections of humans, was not discovered until 1985. *E. bieneusi* has recently been found in the faeces of animals, including pigs, rhesus macaques, cats and cattle. However, the potential reservoirs and the mode of transmission

of this pathogen are still unknown (Dengjel et al., 2001). Phylogenetic analysis revealed the lack of a transmission barrier between *E. bieneusi* from humans and animals (cats, pigs and cattle). Thus, *E. bieneusi* appears to be a zoonotic pathogen." (Dengjel et al., 2001). However, no evidence could be found in the literature for meat-borne transmission of this hazard from small ruminants to humans.

Parasites

- *Ascaris lumbricoides*

Parasites of the genus *Ascaris* have very occasionally reported in sheep. However, the transmission of these parasites to humans is via ingestion of eggs that are excreted in faeces of the definite hosts (e.g. in pigs *A. sum* and in and humans *A. lumbricoides*), therefore there is currently no evidence of a link between human ascariasis and the consumption of ruminant meat.

- *Babesia divergens*, *Babesia microti*

Babesia spp. are vector-mediated parasites, and are transmitted by hard ticks (e.g. *Ixodes*, *Dermacentor*, *Rhipicephalus* and *Hyaloma* spp.). In Europe, they are found in cattle and rodents, although they have also been reported in sheep ((Sreter et al., 2005). Human babesiosis is rare in Europe, and only transmitted via tick bites, i.e. there have been no reports of meat-borne transmission to humans from animals.

- *Coenurus cerebralis* (*Taenia multiceps*)

Cerebral coenurosis is caused by the metacestode stage of the cestode *T. multiceps*, which has canids as the final host. Both humans and sheep are intermediate hosts in the life cycle of this parasite, which is present in parts of Europe (Scala and Varcasia, 2006). Infection occurs by ingestion of vegetables or water contaminated with the tapeworm eggs shed by the final host. Meat has not been recorded as being involved in transmission of this parasite.

- *Cryptosporidium parvum*

Cryptosporidiosis in humans is usually linked to consumption of contaminated water or contact with infected animals, mainly cattle but also young sheep and goats. Although its presence in meat is considered possible, a quick review of the literature did not reveal any evidence describing the isolation in meat or any outbreaks caused by consumption of meat from small ruminants.

- *Cysticercus ovis*, *Cysticercus tenuicollis*

C. ovis and *C. tenuicollis* are the larval stages of *Taenia ovis* and *Taenia hydatigena* respectively, found in the intestines of canids. Humans can act as intermediate hosts for these cysticerci, but cases are very rare. Consumption of meat is not associated with the transmission of these parasites, but they are targeted during meat inspection because cysticerci are visible and render the meat unfit for human consumption on quality grounds.

- *Dicrocoelium dendriticum*

D. dendriticum is a parasite from the Trematoda class that can be found in small ruminants in the EU. Together with *Fasciola hepatica*, they are considered as economically significant parasites of livestock, including sheep and goats, although both species are known to cause foodborne infections. Acquisition of this parasite by humans can occur when subjects inadvertently ingest infested second intermediate hosts (ants) (Krauss et al., 2003), but there is no evidence of meat being a vehicle for transmission of *D. dendriticum* to humans.

- *Echinococcus granulosus*

E. granulosus is a small tapeworm that causes hydatid disease, or cystic echinococcosis, in humans. There were 530 human cases of echinococcosis reported in 2011 due to *E. granulosus*, i.e. 85.1 % of

cases for which the *Echinococcus* species had been determined (EFSA and ECDC, 2013b). The definitive hosts are dogs and other canids, and ungulates (sheep, goats, pigs, horses, etc.) are the intermediate hosts. Other mammals, including humans, can also act as intermediate hosts, and can play a role in the transmission cycle (intermediate hosts) or are dead ends of the development (aberrant hosts). 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. This usually occurs via the ingestion of contaminated food (especially vegetables) or water, and also through accidental soil ingestion or by acquiring the eggs directly from the coat of the definitive host. Meat, however, has not been identified as a vehicle for transmission of *E. granulosus*.

- *Fasciola hepatica*

The trematode *Fasciola* is a parasite of herbivores that can infect humans accidentally, and is commonly found in Europe. Humans can become infected by ingesting freshwater plants or water containing metacercariae (Fried and Abruzzi, 2010). There is currently no evidence of meat-borne transmission of this parasite to humans.

- *Giardia intestinalis*

G. intestinalis is a ubiquitous protozoan parasite with global distribution, which infects humans as well as a wide range of other mammals. *G. intestinalis* is excreted in faeces, and it is transmitted to humans via contaminated water or fresh vegetables. No evidence is available for a role for meat from small ruminants in transmitting this parasite to humans.

- *Gongylonema pulchrum*

G. pulchrum, along with most other *Gongylonema* nematodes, has a broad natural host range that includes ruminants, pigs, rabbits and others. The vector and intermediate host for *G. pulchrum* infections are coprophagous insects (dung beetles and cockroaches). Transmission to humans is usually the result of unsanitary conditions resulting in the accidental ingestion of infected vectors. The ingested larva infects the upper oesophagus, develops and matures into adult worms after two subsequent moulting stages, then migrates into the buccal cavity where it lays eggs. On the basis of the information available from the scientific literature, *G. pulchrum* should not be considered for risk ranking as it is not transmitted via consumption of meat.

- *Linguatula serrata*

L. serrata is a cosmopolitan zoonotic parasite with its adult form occurring in the nasal and respiratory passages of canids as the definitive hosts, while its immature stages localise in the mesenteric lymph nodes, liver, spleen, lungs, and, rarely, in other organs, such as the ocular region of herbivorous intermediate hosts. Humans can behave as both intermediate and final host and are infected by visceral and nasopharyngeal linguatulosis. Consumption of infected, improperly cooked viscera of the intermediate hosts, including sheep, goats, cattle, camels or other herbivores, containing the larval stages of this parasite is a potential source of infection of human beings with the nasopharyngeal form of linguatulosis. However, nasopharyngeal secretions or faeces of carnivores containing eggs of *Linguatula* are the main sources for infecting human beings with the visceral form of this infection (Oryan et al., 2011; Tappe and Buettner, 2009). Most of the literature is from Iran, also Turkey, India and Romania, although sporadic cases have also been reported in Germany (Tappe et al., 2006) and Austria (Koehsler et al., 2011). Owing to the low number of human cases reported in the literature, it is assumed that this parasite is not widely distributed at the moment in the small ruminant population in the EU. Further, recent reports of human cases are linked to transmission from the final host (i.e. canids) and not through consumption of meat from small ruminants.

- *Moniezia expansa*

M. expansa is a tapeworm that inhabits the small intestine of ruminants. The life cycle also involves oribatid (soil) mites as intermediate hosts. It was not considered a zoonotic parasite, but there has been

at least one report of human infection with *M. expansa* (el-Shazly et al., 2004). Meat is not suspected as the vehicle for infection.

- *Sarcocystis* spp.

Sarcocystis spp. are coccidian protozoans that infect humans and have a worldwide distribution. Although theoretically *Sarcocystis* spp. that infect small ruminants could also infect humans as the final host, the main source of human infection are the cattle and pig species, *S. hominis* and *S. suihominis* respectively. Although present in Europe, the prevalence of small ruminant *Sarcocystis* is not known (Martinez-Navalon et al., 2012). There are no reports of human sarcosporidiosis attributed to consumption of meat from small ruminants in the EU.

- *Trichinella* spp.

Although rare, cases of trichinellosis in humans caused by ingestion of this parasite in sheep meat have been described in the literature (Wang and Cui, 2001; Zheng et al., 2008). Similarly, *Trichinella* has also reportedly been found in small ruminants (Cui et al., 2005; Wang et al., 2007). All these articles originated from outside Europe, with all the references made to trichinellosis in small ruminants in Europe concerning experimental infections only. For this reason, it can be concluded that the role of small ruminants in the epidemiology of human trichinellosis is very small in Europe, if it does indeed contribute at all to human infection.

- *Trichostrongylus* spp.

Trichostrongyles are parasites of ruminants, usually found in the abomasum and small intestine. They have a worldwide distribution, including Europe, where they have been reported in the small ruminant population (Cringoli and Rinaldi, 2003; Idris et al., 2012; Pavlovic et al., 2012). Human infections are usually reported in persons that live in close quarters with the animals or by handling faecal material (Krauss et al., 2003; Wall et al., 2012). Meat-borne transmission has not been reported as a pathway for human infection.

Viruses

- Astroviruses

Virus of the family *Astroviridae* are associated with gastroenteritis in birds and mammals, including small ruminants and humans. Although a potential zoonotic link has been suggested (Jonassen et al., 2001), information available in the scientific literature does not point at potential transmission of astroviruses to humans via consumption of meat.

- Borna disease virus (BDV)

BDV infections can result in neurological disease that mainly affects horses and sheep in certain areas of Germany (Bilzer et al., 1996; Durrwald, 1993; Grabner and Fischer, 1991; Ludwig et al., 1985). The endemic area also includes areas of Switzerland, Austria and the Principality of Liechtenstein (Caplazi et al., 1999; Weissenbock et al., 1998). BDV received worldwide attention when it was reported that sera and/or cerebrospinal fluids from neuropsychiatric patients can contain BDV-specific antibodies. As infected animals produce BDV-specific antibodies only after virus replication, it was assumed that the broad spectrum of BDV-susceptible species also includes man. However, reports describing the presence of other BDV markers, i.e. BDV-RNA or BDV-antigen, in peripheral blood leucocytes or brain tissue of neuropsychiatric patients are highly controversial and, therefore, the role of BDV in human neuropsychiatric disorders is questionable (Richt and Rott, 2001). In any case, no evidence of meat-borne transmission has been found.

- Bovine enterovirus type 1

There is a lack of clarity in relation to the taxonomy of bovine enterovirus (BEV). While it appears that BEV may be zoonootic, based on a serological survey in Turkey, and that sheep and goats in

Europe are infected, it is likely that the main source of infection for humans is contact with infected animals and/or material contaminated with faeces of infected animals. On the basis of the information obtained from the scientific literature, it is proposed that BEV should not be considered for risk ranking.

- Chandipura virus

Chandipura virus, a member of the *Rhabdoviridae* family and *Vesiculovirus* genus, has recently emerged as a human pathogen associated with a number of outbreaks of acute encephalitis in different parts of India (Basak et al., 2007). The virus closely resembles the vesicular stomatitis virus, and there are reports of antibody detection in small ruminants, also in India (Joshi et al., 2005). There are no reports of this virus being present in the EU or being able to be transmitted to humans via food. The information available in the scientific literature for this virus in the small ruminant reservoir is very limited.

- Crimean Congo haemorrhagic fever virus (CCHFV)

CCHF is a tick-borne disease that can also be transmitted to humans through contact with infected tissues or blood from affected (viraemic) livestock, including sheep. Cases of CCHF have been reported in butchers and abattoir workers (Ergonul, 2006) as well as health care workers, therefore it can be considered an occupational disease. Currently, there is no evidence of meat-borne transmission, and it has been reported that "*meat itself is not a risk because the virus is inactivated by post slaughter acidification of the tissues and would not survive cooking in any case*." (Ergonul, 2006).

- Hepatitis E (HEV)

HEV has been found in both livestock, especially pigs, and humans in Europe. The epidemiology of HEV is complex, and a foodborne transmission of HEV from animal products (e.g. pork and pork products) to humans is an emerging concern. However, only very few systematic studies have been performed so far, therefore the importance of specific food items has not been sufficiently substantiated. Although the presence of HEV antibodies in sheep has been previously reported in Europe (Peralta et al., 2009), there is no evidence that meat from small ruminants has played a role in transmitting the virus to humans (EFSA Panel on Biological Hazards, 2011a).

- Influenza virus

The presence of influenza virus has been occasionally reported in small ruminants (Abubakar et al., 2008; Shukla and Negi, 1984; Zupancic et al., 1992). Although no information is available for small ruminants, the safety of meat from pigs infected with influenza has been previously assessed, and it was found that these viruses are not known to be transmissible to humans through the consumption of meat (FAO/WHO/OIE, 2009).

- Orf

Orf, also known as contagious ecthyma, is caused by a parapoxvirus and is commonly found in the small ruminant population in Europe. This virus is transmitted to humans through direct contact with infected animals and thus is considered an occupational disease (Uzel et al., 2005). Meat-borne transmission has not been reported to date.

- Rabies

Small ruminants are susceptible to infection with rabies virus, which is present in the wild animal reservoir in Europe (mainly in bats and wild canids). Cases of rabies in sheep and goats have been occasionally reported in Europe (Maciulskis et al., 2005; Mudura et al., 2007), and although experimental oral transmission has been described (Bell and Moore, 1971; Fischman and Ward, 1968), transmission of this virus to humans through the consumption of meat from small ruminants has not been reported to date.

- Rift Valley fever virus

This RNA virus of the family *Bunyaviridae* causes disease in cattle, sheep and goats, and is transmitted to humans by a wide range of mosquitoes, as well as by handling diseased animals (Davies and Martin, 2006). Contact with and consumption of meat, as well as other animal products, has been identified as a risk factor for human infection (Anyangu et al., 2010; Mohamed et al., 2010). The presence of this virus has not been reported in Europe so far (EFSA Panel on Animal Health and Welfare (AHAW), 2013).

- Rotavirus

Rotaviruses are responsible for causing enteritis and diarrhoea in young livestock, including sheep and goats, as well as in humans. Some studies that used gene sequencing point to a common evolutionary origin for rotavirus strains found in small ruminants and those found in humans (Ghosh et al., 2010; Matthijnssens et al., 2009). This could suggest that there is potential for zoonotic transmission between livestock and humans, or at least that some exchange of viruses has occurred in the past (Nakagomi et al., 1992). It is, however, unclear if meat-borne transmission is possible, as there are no data in the literature reporting this possibility.

- Tick-borne encephalitis (TBE)

TBE is an infection caused by flavivirus found in both wild and domestic animals in Europe, including small ruminants. Humans acquire the infection following the bite of an infected tick. Transmission via aerosol and direct contact is also possible, as well as by consuming fresh milk from infected animals. However, transmission via consumption of meat has not been described (Krauss et al., 2003).

Annex 2. Specific requirements for small ruminants in EU legislation on meat inspection (Regulation (EC) No 854/2004)

Table 1: 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[b]	
	Throat		V[b]
	Mouth		V[b]
	Tongue		V[b]
	Retropharyngeal lymph node		V[b]
	Parotid lymph node		V[b]
Lungs	Lungs	V+P	I
	Trachea	V	I
	Bronchial lymph nodes	P	I
	Mediastinal lymph nodes	P	I
Heart	Heart	V	I
	Pericardium	V	I
Diaphragm	Diaphragm	V	
Liver	Liver	V + P+I	
	Hepatic lymph nodes	V + P	
	Pancreatic lymph nodes	V + P	
Gastro-intestinal tract	Oesaphagus	V	I
	Gastro-intestinal tract	V	
	Mesentery	V	
	Gastric lymph nodes	V	
	Mesenteric lymph nodes	V	
Spleen	Spleen	V	P
Kidneys	Kidneys	V	I
	Renal lymph nodes		I
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.

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 meat from sheep and goats. Such substances may occur as residues in edible tissues from 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 and feed additives. A multi-step approach was used for the ranking of 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 only 0.41 % of the total number of results was non-compliant for one or more substances listed in Council Directive 96/23/EC. Potentially higher exposure of consumers to these substances from sheep and goat meat takes place only incidentally, as a result of mistakes or non-compliance with known and regulated procedures. The available aggregated data indicate a low number of samples that were non-compliant with the current legislation. However, in the absence of substance- and/or species-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 as reported from 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 sheep and goat carcasses. Taking into account these criteria, the individual compounds were ranked into four categories denoted as being of high, medium, low and negligible potential concern.

Dioxins and dioxin-like polychlorinated biphenyls (DL-PCBs) were ranked as being of high potential concern owing to their known bioaccumulation in the food chain, the frequent findings above maximum levels (MLs), particularly in sheep liver, and in consideration of their toxicological profile.

The following substances were ranked in the category of medium potential concern: stilbenes, thyreostats, gonadal (sex) steroids, resorcylic acid lactones and beta-agonists (especially clenbuterol) because of their toxicity for humans, their efficacy as growth promoters in sheep and goats and the incidence of non-compliant results; chloramphenicol and nitrofurans because they have proven toxicity for humans, are effective as antibacterial treatments for sheep/goats and non-compliant samples are found in most years of the NRCPs; non-dioxin-like polychlorinated biphenyls (NDL-PCBs) because, while they bioaccumulate and there is a risk of exceeding the MLs, they are less toxic than dioxins and DL-PCBs; and the chemical elements cadmium, lead and mercury because of the number of non-compliant results reported under the NRCPs and their toxicological profile.

Residues originating from other substances listed in Council Directive 96/23/EC were ranked as of low or negligible potential concern.

The CONTAM Panel emphasises that this ranking into specific categories of potential concern is based on the current knowledge regarding toxicological profiles, usage in sheep and goat production

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 current procedures for sampling and testing are, in general, well established and coordinated, including follow-up actions subsequent to the identification of non-compliant samples. The regular sampling and testing for chemical residues and contaminants is an important disincentive for the development of undesirable practices and the prescriptive sampling system allows for equivalence in the control of EU-produced sheep and goat meat. The current combination of animal traceability, *ante-mortem* inspection and gross tissue examination can support the collection of appropriate samples for residue monitoring. Nevertheless, a major weakness is that, with very few exceptions, presence of chemical hazards cannot be identified by current *ante-/post-mortem* meat inspection procedures at the slaughterhouse level and there is a lack of sufficient cost-effective and reliable screening methods. In addition, sampling is mostly prescriptive rather than risk or information based. There is limited ongoing adaptation of the sampling and testing programmes to the results of the residue monitoring programmes, with poor integration between the testing of feed materials for undesirable substances and the NRCPs and sampling under the NRCPs reflecting only a part of testing done by a number of MSs, the results of which should be taken into consideration.

The CONTAM Panel was also asked to identify and recommend inspection methods for new hazards. As dioxins and DL-PCBs have not yet been comprehensively covered by the sampling plans of the current meat inspection, they should be considered as 'new' hazards as they have been ranked as being of high potential concern. Moreover, for other organic contaminants that may accumulate in food-producing animals and for a number of chemical elements used as feed supplements, only limited data regarding residues in sheep and goats are available. This is the case, in particular, for brominated flame retardants, including polybrominated diphenylethers (PBDEs) and hexabromocyclododecanes (HBCDDs) and perfluorinated compounds (PFCs) including (but not limited to) perfluorooctane sulphonate (PFOS) and perfluorooctanoic acid (PFOA).

The CONTAM Panel concludes that sheep and goat production in the EU is marked by being largely extensive in nature, involving frequent trading of animals and nomadic flocks. These differences in husbandry systems and feeding regimes result in different risks for the occurrence of chemical residues and contaminants. Extensive periods on pasture or/as nomadic flocks and the use of slaughter collection dealerships may preclude detailed lifetime food chain information (FCI). The CONTAM Panel recommends that FCI should be expanded for sheep and goats produced in extensive systems to provide more information on the specific environmental conditions where the animals are produced and that 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 substance into categories of potential concern, which needs to be regularly updated. Control programmes for chemical residues and contaminants should be less prescriptive, with sufficient flexibility to adapt to results of testing, should include 'new hazards', and the test results for sheep and goats should be separately presented. 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 development of analytical techniques covering multiple analytes and of new biologically based testing approaches should be encouraged too and incorporated into the residue control programmes. For prohibited substances, testing should be directed where appropriate towards the farm level and, in the case of substances that might be used illicitly for growth promotion, control measures, including testing, need to be refocused to better identify the extent of abuse in the EU.

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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 SHEEP AND GOATS

1. Introduction

Meat inspection in the EU is specified in Regulation (EC) No 854/2004.[19] 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 in meat that could be potentially harmful for consumers. This aspect is not fully addressed by the current procedures. For the purposes of this document 'chemical residues' refer to chemical compounds which result from the intentional administration of legal or illegal pharmacologically active substances while 'chemical contaminants' refer to chemical compounds originating from the environment.

This document aims to identify undesirable or harmful chemical residues and contaminants that may occur in meat from sheep and goats 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.[20] These findings, together with the characteristics of the individual substances and the likelihood that a substance will occur in meat from sheep or goats 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.

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. Domestic sheep and goats in Europe

1.1.1. Domestic sheep

Sheep (*Ovis aries*) were domesticated from ancestral subspecies of wild mouflon approximately 9 000 years ago in south-west Asia, and by 5 000 years ago, sheep had been transported throughout Europe. Today, over 850 sheep breeds are recognised worldwide, and Europe supports a greater number of breeds than any other continent. Sheep are raised for three main purposes: meat, milk and wool. Therefore, a range of different breeds have been developed over centuries to suit the land and weather and husbandry conditions in different areas of the EU. In mountain and arid areas, for example, sheep are bred for hardiness and self-reliance (e.g. Scottish Blackface). They must be able to survive poor weather and thrive on poor grazing. Lowland or grassland breeds, on the other hand (e.g. Suffolk and Texel), usually do not cope as well with bad weather or poor-quality feed, but produce higher numbers of lambs that are often better suited for meat production. Most lambs are born in late winter or spring. Many lambs are born outside, particularly those in mountain flocks. Indoor lambing is also common, particularly for lowland flocks. Good housing facilities and management are important in order to prevent disease and heat stress problems. Most meat-breed sheep are slaughtered and presented for meat inspection as younger stock "lambs" from ten weeks up to one year. In

[19] 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. OJ L 139, 30.4.2004, 206–320. Corrected version in OJ L 226, 25.6.2004, p. 83–127.

[20] Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC. OJ l 125, 23.5.96, p. 10–32.

accordance with Commission Regulation (EC) No 1244/2007,[21] a "young ovine animal" means an ovine animal of either gender, not having any permanent incisor teeth erupted and not older than 12 months.

Sheep have also been raised for milk production for thousands of years. The East Friesian type is one of the most common and productive breeds of dairy sheep. Europe's commercial dairy sheep industry is concentrated in the countries on or near the Mediterranean Sea. Most of the sheep milk is used to produce cheese, such as feta, ricotta, Manchego and Pecorino Romano. In France, the Lacaune is the breed of choice for making Roquefort cheese. Dairy sheep kept on small farms are milked seasonally by hand but more modern sheep dairies use sophisticated machinery for milking. Ewes are milked once or twice per day. Sheep are also widely kept for wool production, particularly in the United Kingdom and Spain. Wool may range from fine or medium fibre diameter to specialised breeds producing wool for carpets. Some flocks may be kept for both meat and wool production purposes.

Meat from older sheep carcasses (mutton), derived from cull adult sheep from the dairy or wool industries, is tougher and is not as widely consumed as fresh meat, but may also be used in sausage production.

1.1.2. Domestic goats

Goats have been associated with man in a symbiotic relationship for up to 10 000 years. The goat eats little, occupies a small area and each produces enough milk to sustain a family. In Europe, goat farming is strongly oriented towards milk production, which is mostly used for cheese production. It has been estimated that the EU has 1.6 % of the world's goat population, but it produces 13.2 % of goat milk and 2.0 % of goat meat generated in the world annually (Casey, 2005). During the last ten years, the overall EU goat count has diminished. In France, Greece and Spain, annual goat milk production is 580, 510, and 420 million litres, respectively, which comprises 83 % of the total goat milk produced in the EU. France produces a great number of goat's milk cheeses, especially in the Loire Valley, with examples of French chèvre including Bucheron. Like sheep, dairy goats kept on small farms are milked seasonally by hand but modern goat dairies use more sophisticated machinery for milking. Does are milked once or twice per day.

Goats produced for fibre are not common in Europe, but small local flocks occur in many Member States (MSs). The fibre taken from an Angora goat breed is called mohair. A single goat produces between four and five kilograms of hair per year, shorn twice a year. Cashmere is the valuable fine undercoat found to varying degrees and qualities on all goats, except the Angora. It grows as a winter down which is shed in early spring, when it is harvested by either shearing or combing.

Goat meat or chevron is not widely consumed in the EU. Specialised larger goat meat breeds such as the Boer goat are currently only held in small local herds, but crosses of a Boer sire and a cashmere-type breed dam can also be used to provide a suitable carcass. These meat-line goats can grow to slaughter weight (25–30 kg) in approximately six to nine months on low-quality feeding. Again, the meat from older goat carcasses derived from the cull goats from dairy or fibre industries tends to be very tough. Meat from older male goats ('billy' goats) can have an offensive odour.

The extensive farming practices and generally low economic value of sheep and goats mean that veterinary treatment of individual animals is often limited. Sheep and goats are often exposed to parasites, which explain the necessary use of anti-parasitic programmes for the flocks. Other veterinary interventions follow normal clinical practice, such as the use of registered mastitis treatments for milking animals, with appropriate withdrawal periods and residue monitoring.

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

It is important to note that, despite recent developments towards large milking goat holdings, sheep and goat production in the EU largely remains extensive[22] in nature, involving frequent trading of animals and nomadic flocks. This involves varied husbandry systems and feeding regimes resulting in different risks for chemical substances and contaminants.

Sheep and goat populations in the EU as reported by EUROSTAT are presented in Table 1.

Table 2: Population figures for sheep and goats in the EU27[a] from 2002 to 2010. Data source: Statistical database of EUROSTAT, Agriculture, Agricultural products, Animal Production, Livestock, Sheep and Goats population. Units: 1 000 heads (animals).

	2010	2009	2008	2007	2006	2005	2004	2003	2002
Sheep	86 905	89 681	92 782	97 660	97 709	98 241	100 212	100 473	98 964
Goats	13 244	12 896	11 334	13 113	13 100	12 918	13 305	13 470	13 769

[a]EU27, data from the current 27 MSs were included for all years.

1.2. Procedures in the current meat inspection of domestic sheep and goats

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). There are concerns about slaughter outside licensed premises where animals are not subject to appropriate meat inspection.

1.2.1. *Ante-mortem* inspection and food chain information

Since January 2010, a mandatory identification of small ruminants has been implemented in the EU by Regulation (EC) No 21/2004.[23] Domestic sheep and goats may be presented for slaughter in small numbers or even as individuals. Visual *ante-mortem* inspection is carried out at the level of the individual animal.

Extensive periods on pasture or as nomadic flocks, sale at open markets of many sheep and goats, and the presence of slaughter collection dealerships that may combine small numbers of animals purchased from several farmers, means that there is a level of concern that food chain information (FCI) shared between farmers and the slaughterhouse (where residue data are managed), may be suboptimal. Similarly, in these situations, the level of feedback from the slaughterhouse and authorities to farmers regarding the results of residue testing may be suboptimal. Here the individual identification of animals, which has now become mandatory, may contribute to more transparency in the future. There is less concern about FCI from dairy sheep and goats as they are reared under more intensive and controlled conditions. 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 veterinary medicinal products (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.

[22] Note that for the purpose of this opinion, intensive farming applies to animals housed during their productive life and fed with compound feed (often supplemented with roughage and concentrates) while extensive farming applies to animals primarily kept outdoors at pasture.

[23] Council Regulation (EC) No 21/2004 of 17 December 2003 establishing a system for the identification and registration of ovine and caprine animals and amending Regulation (EC) No 1782/2003 and Directives 92/102/EEC and 64/432/EEC. OJ L 5, 9.1.2004, pp. 8–17.

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. An exception is the mandatory sampling of adult animals for transmissible spongiform encephalopathies (TSEs). In contrast to bovine animals, TSE testing is not directed at individual animals, but is based on a region and animal stock related monitoring system.

Visual inspection of the carcass (and offals) may allow, in some cases, for the identification of gross alterations in carcass conformation (e.g. abscesses or deposits) and organ-specific lesions in kidneys, liver, lungs or other organs that might be indicative of recent use of VMPs (with the possibility of non-compliance with withdrawal periods) or acute or chronic exposure to toxic substances. In most cases, exposure to chemical compounds 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 visual inspection of ovine and caprine carcasses. Therefore, the meat inspection approach based on "detect and immediately eliminate", used for biotic (microbiological) hazards in slaughterhouses, is generally not applicable to abiotic hazards.

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

1.3. Current legislation

Council Directive 96/23/EC 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 programme, also referred to as the National Residue Control Plan (NRCP, for defined groups of substances.[24] 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 Commission Regulation (EU) No 37/2010,[25] with the maximum residue levels (MRLs) for pesticides as set out in Regulation (EC) No 396/2005,[26] or with the maximum levels (MLs) for contaminants as laid down in Commission Regulation (EC) No 1881/2006.[27] This means that in the national monitoring plans, the MSs should target those groups of animals/gender/age combinations in which the probability of finding residues is highest. This approach differs from random sampling, in which the objective is to gather statistically representative data, for instance to evaluate consumer exposure to a specific substance.

The minimum number of animals to be checked for all kind of residues and substances must be at least equal to 0.05 % of sheep and goats over three months of age slaughtered the previous year, with the following breakdown (further details on Group A and B compounds is presented in Section 2.1):

[24] Commission Staff Working Document on the Implementation of National Residue Monitoring Plans in the Member States in 2009 (Council Directive 96/23/EC). Available from http://ec.europa.eu/food/food/chemicalsafety/residues/workdoc_2009_en.pdf

[25] 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, pp. 1–72.

[26] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue level 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, pp. 1–16.

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

- Group A:[28] 0.01 % of total samples
  - Each sub-Group A must be checked each year using a minimum of 5 % of the total number of samples to be collected for Group A.

The balance is allocated according to the experience and background information of the MS.

- Group B: 0.04 % of the total samples
  - 30 % must be checked for Group B1 substances
  - 30 % must be checked for Group B2 substances
  - 10 % must be checked for Group B3 substances.

The balance must be allocated according to the situation of the MS.

In the case of imports from third countries, Chapter VI of Council Directive 96/23/EC describes the system to be followed to ensure an equivalent level of control on such imports. In particular it specifies (i) 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 to the Council Directive, (ii) that such guarantees must have an effect at least equivalent to those provided for in Council Directive 96/23/EC, (iii) 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[29] and the checks provided for in Directives 90/675/EEC[30] and 91/496/EEC,[31] and (iv) 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 consequence of non-compliant results

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

- suspect sampling
- 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 Council Directive 96/23/EC)

[28] See Section 2.1 for detailed description of group A and B as defined by the Council Directive 96/23/EC.
[29] 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, pp. 1–14.
[30] 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, pp. 7–33.
[31] 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, pp. 56–68.

- 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 Council Directive 96/23/EC)
- samples taken where the veterinarian suspects, or has evidence of, illegal treatment or non-compliance with the withdrawal period for an authorised veterinary medicinal product (Article 24 of Council 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 Council 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 in the farm of origin, such as verification of records and additional sampling
- hold animals in 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 Council 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 requisites for self-monitoring and co-responsibility on the part of operators.

In accordance with Article 9, chapter III of Council 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.

Farmers and food processors (including 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 authorised 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 chapter 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. Resorcyclic acid lactones, including zeranol

A.5. Beta-agonists

A.6. Compounds included in Annex IV to Council Regulation (EEC) No 2377/90 of 26 June 1990[32] (repealed by Commission Regulation (EC) 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

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

[32] 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, 1–8.

a) organochlorine compounds, including polychlorinated biphenyls (PCBs)

b) organophosphorus compounds

c) chemical elements

d) mycotoxins

e) dyes

f) others

For sheep and goats, analysis for chemical residues and contaminants for all of the above substances is required under Council Directive 96/23/EC with the exception of B2f—Other pharmacologically active substances, 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 sheep and goats, 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 are prohibited for use in food-producing animals, corresponding to Group A substances in Council Directive 96/23/EC
- veterinary drugs, also denoted VMPs, 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 the list of Group A substances comprises 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, anti-parasitic agents and other pharmacologically active substances) and authorised feed additives used 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 Regulation (EC) No 470/2009[33] 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.[34] 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. Compounds for which no toxicological ADI can be established are excluded from approval. 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

[33] 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, 11–22.

[34] 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, 29–43.

compliance. The list of allowed substances is presented as Annex, Table 1 of Commission Regulation (EC) No 37/2010 and in the Community Register of Feed Additives; it should be noted that for most feed additives listed as allowed for use, no MRL is required.

With regard to antibacterial 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 (see Appendix A of the BIOHAZ Panel).

A **third group** of chemical substances that may occur in edible tissues of sheep and goats are contaminants that may enter the animal's body mainly via feed, ingested soil, 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,[35] listing the undesirable substances in feed and feed materials and presenting maximum content in feed materials or complete feedingstuffs. In a recent re-assessment of these undesirable substances in animal feeds, the 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 that are directly excreted into milk and eggs.

2.2.1. Statutory limits

Article 2 of Council Regulation (EEC) No 315/93[36] of 8 February 1993 laying down Community procedures for contaminants in food stipulates that, where necessary, maximum tolerances for specific contaminants shall be established. Subsequently, 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, amended by Commission Regulation (EU) No 1259/2011.[37] Regarding sheep, MLs were established for lead, cadmium, dioxins,[38] the sum of dioxins and DL-PCBs and for the sum of six NDL-PCBs. There are no specific provisions for goats.

[35] Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed. OJ L 140, 30.5.2002, pp. 10–22.
[36] Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food. OJ L 37, 13.2.1993, pp. 1–3.
[37] Commission Regulation (EU) 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, pp. 18–23.
[38] The term "dioxins" used in this opinion refers to the sum of polychlorinated dibenzo-*p*-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs).

Table 3: Contaminants currently included in Regulation (EC) No 1881/2006[39] (as amended) in sheep. There are no specific provisions for goats.

Contaminant	MLs	Health-based guidance values/MOE approach	Assessments: Reference
Dioxins and dioxin-like PCBs	*Dioxins* Meat, fat and meat products: 2.5 pg WHO-TEQ/g fat Liver and derived products: 4.5 pg WHO-TEQ/g fat *Dioxins + DL-PCBs* Meat, fat and meat products: 4.0 pg WHO-TEQ/g fat Liver and derived products: 10.0 pg WHO TEQ/g fat	TWI: 14 pg/WHO-TEQ/kg b.w.	SCF, 2001
Non dioxin-like PCBs (sum of PCBs 28, 52, 101, 138, 153 and 180)	Meat, fat and meat products: 40 ng/g fat Liver and derived products: 40 ng/g fat		EFSA, 2005a
Cadmium	Meat: 0.050 mg/kg wet weight Liver: 0.50 mg/kg wet weight Kidney: 1.0 mg/kg wet weight	TWI: 2.5 µg/kg b.w.	EFSA, 2009a; EFSA CONTAM Panel, 2011a
Lead	Meat: 0.10 mg/kg wet weight Offal: 0.50 mg/kg wet weight	MOE approach	EFSA CONTAM Panel, 2010

PCB, polychlorinated biphenyl; ML, maximum level; b.w., body weight; MOE, margin of exposure; WHO, World Health Organization; TEQ, toxic equivalent; TWI, tolerable weekly intake.
Note: Besides the above MLs, Regulation (EC) No 1881/2006 also sets MLs for raw milk and dairy products of bovine animals.

Recently, the MLs for dioxins and the sum of dioxins and 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 TEQs using the WHO-TEF_{2005}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, 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, 2005a) for various kinds of foodstuffs following the same food categorisation as for dioxins and the sum of dioxins and DL-PCBs.

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.[40] Owing to the fact that their sources are

[39] 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.
[40] Commission Recommendation of 23 August 2011 on the reduction of the presence of dioxins, furans and PCBs in feed and food (2011/516/EU). OJ L 218, 24.8.2011, pp. 23–25.

generally different, separate action levels for dioxins and DL-PCBs were established. The action levels for meat and meat products of sheep are 1.75 pg WHO-TEQ/g fat for dioxins and 1.75 pg WHO-TEQ/g fat for DL-PCBs.

In cases where levels of dioxins and/or DL-PCBs in excess of the action levels are found, it is recommended that MSs, 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 NDL-PCBs.

Maximum residue levels for certain elements in sheep and goats are also 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, related to 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 non-compliant with the current legislation
- evaluation of the likelihood that specific residues or contaminants, including 'new hazards', may be present in sheep and goat carcasses
- consideration of the toxicological profile for chemical substances.

2.3.1. Outcome of the national residue monitoring plans 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 sheep and goats from 2005 to 2010 are presented in Tables 3–5. 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 as (i) a follow-up to the occurrence of a non-compliant result, and/or (ii) on suspicion of illegal treatment at any stage of the food chain, and/or (iii) on suspicion of non-compliance with the withdrawal periods for authorised VMPs (Articles 5, 11 and 24 of Council 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.[41] 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 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

[41] 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.

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[42]) 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 sheep and goats, such as chloramphenicol, nitrofurans and their metabolites, and medroxyprogesterone acetate, MRPLs have been established (Commission Decision 2003/181/CE[43]).

It should be noted that information on the number of total analyses performed for an individual substance is only transmitted by those MSs that were reporting at least one non-compliant result for that substance. Therefore, it is not possible to extract from the data supplied complete information on the individual substances from each sub-group tested or 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/sub-groups and therefore the number of substance groups/sub-groups tested is higher than the total number of samples collected from sheep and goats. 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, in some cases, no information is available on the nature of the positive samples (i.e. whether this refers to muscle, liver, kidney, skin/fat or other samples) and these results often give no indication of the actual measured concentrations of residues or contaminants. As a result, in the absence of substance-specific information and the actual concentration of a residue or contaminant measured, these data do not allow for an assessment of consumer exposure. In addition, particularly in the case of prohibited substances, much of the testing may be done in matrices such as urine, faeces and hair and so no data on residue levels in edible tissues are available. Another problem with interpreting the data provided arises from the failure to clearly identify in all cases (i) the proportion of total samples tested that are of sheep and that are of goat and (ii) whether a particular non-compliant result refers to a sample from a sheep or from a goat.

In spite of the limitations highlighted above, an overall assessment of these data indicates that the percentage of non-compliant results is of a low order of magnitude compared with the total number of samples tested.

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

[43] Commission Decision of 13 March 2003 amending Decision 2002/657/EC as regards the setting of MRPLs for certain residues in food of animal origin (2003/181/EC) OJ L 71, 15.3.2003, pp. 17–18.

Table 4: Non-compliant (NC) results[a] for prohibited substances (Group A) in sheep and goats reported from national residue monitoring plans, 2005–2010 (targeted sampling). Information extracted from the reports published by the European Commission.[b] In brackets: number of MSs providing NC data.

Substance	2010 (EU27)		2009 (EU27)		2008 (EU27)		2007 (EU27)		2006 (EU27)		2005 (EU25)	
Sub-group	**NC**	**Total**	**NC**	**Total**	**NC**	**Total**	**NC**	**Total**	**NC**	**Total**	**NC**	**Total**
A1 Stilbenes	0	537	0	559	0	450	0	514	0	565	0	579
A2 Thyreostats	2 (1)	243	8 (2)	280	2 (2)	222	5 (1)	357	0	363	0	493
Thiouracil	2 (1)		8 (2)		2 (2)		5 (1)		0		0	
A3 Steroids	7 (2)	1 112	43 (3)	1 177	50 (1)	1 058	12 (1)	1 148	16 (1)	1 156	34 (1)	1 161
17-α-nortestosterone	3 (1)		0		0		0		0		0	
Boldenone (boldenone-α)	0		12 (1)		23 (1)		0		0		0	
Epinandrolone	4 (1)		2 (1)		0		0		0		0	
Nandrolone	0		29 (2)		0		0		16 (1)		34[c] (1)	
Nortestosterone cypionate	0		0		27 (1)		12 (1)		0		0	
A4 Resorcylic acid lactones (RALs)	0	524	1 (1)	560	2 (1)	453	3 (2)	543	0	588	1 (1)	615
α-Zeralanol (zeranol)	0		1 (1)		1 (1)		1 (1)		0		0	
β-Zearalanol (taleranol)	0		0		1 (1)		2 (2)		0		0	
Zearalanone	0		0		0		0		0		1 (1)	
A5 Beta-agonists	0	1 397	0	1 590	0	1 274	0	1 553	0	1 688	3 (1)	2 068
Clenbuterol	0		0		0		0		0		3 (1)	
A6 Annex IV compounds	1 (1)	1 990	7 (3)	2 078	2 (2)	1 193	1 (1)	1 924	3 (2)	2 008	8 (3)	1 846
Chloramphenicol	0		1 (1)		1(1)		1 (1)		3 (2)		5 (1)	
Nitrofurantoin/AHD	0		0		0		0		0		1 (1)	
Furazolidone/AOZ	1 (1)		0		0		0		0		0	
Nitrofurazone/SEM	0		4 (1)		1(1)		0		0		2 (2)	
Ronidazole	0		2 (1)				0		0			

[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]Naturally-occurring hormones. No evidence of misuse was proved after investigations.

Table 5: Non-compliant (NC) results[a] for veterinary medicinal products (antibacterial substances and other veterinary drugs, Group B1 and B2) in sheep and goats reported from national residue monitoring plans, 2005–2010 (targeted sampling). Information extracted from the reports published by the European Commission.[b] In brackets: number of MSs providing NC data.

Substance	2010 (EU27)		2009 (EU27)		2008 (EU27)		2007 (EU27)		2006 (EU27)		2005 (EU25)	
Sub-group	**NC**	**Total**	**NC**	**Total**	**NC**	**Total**	**NC**	**Total**	**NC**	**Total**	**NC**	**Total**
B1 Antibacterials	26 (7)	9 657	32 (5)	11 164	34 (7)	7 237	29 (3)	11 407	32 (6)	11 715	50(9)	12 320
Antibacterials (unspecified)	0		0		1 (1)		0		1 (1)		8 (2)	
Aminoglycosides												
Dihydrostreptomycin	2 (2)		0		1 (1)		0		0		1 (1)	
Gentamicin	0		1 (1)		0		0		0		0	
Neomycin C	2 (1)		1 (1)		0		0		0		0	
Streptomycin	0		0		0		0		2 (1)		0	
Fluoroquinilones												
Ciprofloxacin	1 (1)		0		0		0		0		1 (1)	
Enrofloxacin	1 (1)		2 (1)		0		0		1 (1)		1 (1)	
Macrolides												
Tulathromycin	0		1 (1)		0		0		0		0	
Tylosin, Tylosin A	0		0		0		0		0		2 (1)	
Penicillin												
Amoxycillin	1 (1)		0		0		1 (1)		0		0	
Sulphonamides												
Sulphadiazine	7 (1)		13 (2)		24 (4)		18 (4)		17 (2)		19 (2)	
Sulphadimethoxine	1 (1)		3 (1)		6 (1)		0		4 (1)		4 (1)	
Sulphadimidine	4 (1)		0		1 (1)		0		0		0	
Sulphamethazine	0		0		0		0		1 (1)		1 (1)	
Sulphamethoxyoyridazin	0		0		0		1 (1)		0		0	
Sulphamerazine	1 (1)		0		0		0		0		0	
Sulphamonomethoazole	1 (1)		0		0		0		0		0	
Sulphaquinoxaline	0		0		0		0		1 (1)		0	
Sulphadimidine	0		0		0		0		1 (1)		1 (1)	
Tetracyclines												
Chlortetracylcine	2 (1)		6 (1)		1 (1)		3 (1)		2 (1)		5 (2)	
Doxycycline	0		0		0		1 (1)		0		1 (1)	
Oxytetracycline	3 (3)		5 (3)		0		4 (2)		2 (2)		6 (3)	
Tetracycline	0		0		0		1 (1)		0		0	
B2a Anthelmintics	7 (4)	2 875	9 (3)	3 239	4 (4)	1 810	2 (2)	3 147	2 (2)	3 140	4 (2)	2 940
Avermectin B1	0		0		0		1 (1)		0		0	
Closantel	4 (1)		2 (1)		0		0		0		0	
Doramectin	1 (1)		1 (1)		0		0		0		0	

Table 5: Continued.

Substance Sub-group	2010 (EU27)		2009 (EU27)		2008 (EU27)		2007 (EU27)		2006 (EU27)		2005 (EU25)	
	NC	Total	NC	Total	NC	Total	NC	Total	NC	Total	NC	Total
Eprinomectin	1 (1)		0		0		0		0		0	
Fenbendazole	0		1 (1)		0		0		0		1 (1)	
Ivermectin	0		1 (1)		0		1 (1)		1 (1)		1 (1)	
Levamisole	0		0		1(1)		0		0		0	
Oxfendazole (sulfon)	1 (1)		1 (1)		2 (2)		0		1 (1)		2 (1)	
Triclbendazole	0		0		1 (1)		0		0		0	
Rafoxanide	0		3 (1)		0		0		0		0	
B2b Anticoccidials	4 (3)	1 035	0	853	4 (3)	332	0	823	0	757	0	518
Decoquinate	1 (1)		0		0		0		0		0	
Monensin	1 (1)		0		1 (1)		0		0		0	
Robenidine	1 (1)		0		1 (1)		0		0		0	
Salinomycin	1 (1)		0		0		0		0		0	
Semduramicin	0		0		2 (1)		0		0		0	
B2c Carbamates and pyrethroids	0	590	0	1 135	0	369	0	1 131	0	1 112	0	936
B2d Sedatives	0	600	0	579	0	414	0	497	0	431	0	464
B2e NSAIDs	1 (1)	480	1 (1)	490	1 (1)	451	0	474	2 (2)	429	3 (2)	409
Antipyrin-4-methylamino	1 (1)		0		1 (1)		0		0		0	
Diclofen (diclofenac)	0		1 (1)		0		0		0		0	
Flunixin-meglumine	0		0		0		0		1 (1)		2 (1)	
Sodium salicylate	0		0		0		0		1 (1)		0	
Tolfenamic acid	0		0		0		0		0		1 (1)	
B2f Other	0	409	0	621	1(1)	589	0	702	0	693	1 (1)	520
Dexamethasone	0		0		0		0		0		1 (1)	
Methylprednisolone	0		0		1 (1)		0		0		0	

[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[a,b] for other substances and environmental contaminants (Group B3) in sheep and goats reported from national residue monitoring plans, 2005–2010 (targeted sampling). Information extracted from the reports published by the European Commission.[c] In brackets: number of MSs providing NC data.

Substance Sub-group	2010 (EU27)		2009 (EU27)		2008 (EU27)		2007 (EU27)		2006 (EU27)		2005 (EU25)	
	NC	Total	NC	Total	NC	Total	NC	Total	NC	Total	NC	Total
B3a Organochlorine compounds	8 (1)	1 487	0	1 065	3 (3)	2 179	7 (3)	1 143	7 (3)	1 073	9 (2)	1 060
Dioxins (WHO-PCDD/F-TEQ)	4 (1)		0		0		0		0		0	
Dioxins and DL-PCBs (WHO-PCDD/F-PCB-TEQ)	4 (1)		0		1 (1)		1 (1)		0		0	
PCBs sum	0		0		0		4 (1)		3 (2)		0	
DDT sum (DDE, DDD)	0		0		1 (1)		0		1 (1)		2 (1)	
γ-HCH (HCH, lindane)	0		0		0		0		1 (1)		1 (1)	
HCH-α	0		0		0		0		0		3 (2)	
HCH-β	0		0		1 (1)		2 (1)		2 (2)		3 (2)	
B3b Organophosphorous compounds	1 (1)	1 102	2 (2)	1 094	0	401	0	1 090	2 (2)	1 037	0	1 042
Chlorpyrifos	0		1 (1)		0		0		0		0	
Diazinon	1 (1)		1 (1)		0		0		2 (2)		0	
B3c Chemical elements	21(7)	957	22 (6)	1 010	23	975	56 (7)	1 187	18 (6)	1 094	24 (8)	982
Cadmium	13 (6)		9 (4)		16 (5)		38 (6)		12 (4)		19 (5)	
Copper	1 (1)		0		0		0		0		0	
Lead	7 (3)		5 (3)		4 (2)		14 (2)		5 (3)		5 (4)	
Mercury	0		8 (1)		3 (1)		3 (2)		0		0	
Zinc	0		0		0		1 (1)		1 (1)		0	
B3d Mycotoxins	0	270	1 (1)	252	0	329	0	281	1(1)	357	0	164
Aflatoxin B1	0		1 (1)		0		0		0		0	
Ochratoxin A	0		0		0		0		1 (1)		0	
B3e Dyes	0	0	0	0	0	0	0	0	0	0	0	0
B3f Other	0	45	0	68	0	56	0	69	0	77	0	16

[a]One sample can be non-compliant for more than one substance.
[b]National tolerance levels are applied by individual MSs for contaminants where no EU maximum levels have been established.
[c]Published at http://ec.europa.eu/food/food/chemicalsafety/residues/control_en.htm

A summary of the data presented in the previous tables (Tables 3–5) shows that 619 of the 152 143 (0.41 %) samples analysed in the EU NRCPs during the period 2005–2010 were non-compliant for one or more substances listed in Annex I of Council Directive 96/23/EC. Further details are presented in Table 6. 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. For example, for B3 substances, there were 207 non-compliant results in 176 non-compliant samples.

Table 7: Overview of non-compliant (NC) samples[a] as reported in the NRCPs[b] for the period 2005–2010 in the EU.

Period 2005–2010	Group A	Group B1-B2	Group B3	Total
Total samples analysed[c]	32 502	99 167	20 474	152 143
Farm level	4 738	2 786	834	8 358
Slaughterhouse level	27 764	96 381	19 640	143 785
Total NC samples	208	235	176	619
Farm level	3	22	4	29
Slaughterhouse level	205	213	172	590

[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 3–5 provide the results for sampling and testing carried out by MSs under the terms of Council Directive 96/23/EC within the NRCPs. However, there may be other chemical substances of relevance for control in sheep and goats, particularly in the case of contaminants, which are not included in the NRCPs at all or which are not systematically covered by the NRCPs. Some of these substances are addressed further under TOR 3 of this opinion ('New Hazards').

2.3.2. Analysis of the data

Of the total number of samples taken for analysis during the period 2005–2010, 5.5 % were taken at farm level while the remaining 94.5 % were taken at slaughterhouse level. No information on the types of animals sampled is readily available. Results indicate that:

- 0.41 % of the total samples were non-compliant for one or more substances, with 0.64 %, 0.24 % and 0.86 % being non-compliant for Group A, Group B1/B2 and Group B3 substances, respectively.

- 0.35 % of all samples taken at farm level were non-compliant for one or more substances, with 0.06 %, 0.79 % and 0.48 % being non-compliant for Group A, Group B1/B2 and Group B3 substances, respectively.

- 0.41 % of all samples taken at slaughterhouse level were non-compliant for one or more substances, with 0.74 %, 0.22 % and 0.88 % being non-compliant for Group A, Group B1/B2 and Group B3 substances, respectively.

The highest proportion of non-compliant results overall (0.86 %) was for Group B3 substances, contaminants, representing largely exceedances of the MLs/MRLs specified for these substances. The proportions of non-compliant results overall for Group A, prohibited substances (0.64 %), and for Group B1/B2 substances, VMPs (0.24 %) represent largely illicit use of prohibited substances and exceedances of the MRLs specified for VMPs, respectively.

An analysis of the results for sampling at farm level compared with slaughterhouse level indicates that for prohibited substances (Group A) the rate of non-compliant results determined for sampling at farm level is considerably lower than that for sampling at slaughterhouse level. The majority (90 %) of

samples found to be non-compliant for prohibited substances relate to those having anabolic effects (thyreostats, steroids, zeranol, beta-agonists) and only a minority (10 %) were non-compliant for substances such as chloramphenicol, nitrofurans and nitroimidazoles. While the incidence of non-compliant results from farm level sampling is low, 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) the rate of non-compliant results determined at farm level is markedly higher than for sampling at slaughterhouse level. However, 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 rate of non-compliant results determined for sampling at slaughterhouse level is almost twofold higher than for sampling at farm level. Indeed, 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.

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

In conclusion, this compilation of data clearly indicates the low prevalence of abiotic hazards (residues and contaminants) in edible tissues of sheep and goats. Only 0.41 % of the total number of analysed samples was non-compliant for one or more substances listed in Annex I of Council Directive 96/23/EC. Based on these results, it can be concluded that potentially higher exposure of consumers to these substances from edible tissues of sheep and goats takes place only incidentally, as a result of mistakes or non-compliance with known and regulated procedures. The available aggregated data indicate the number of samples that were non-compliant with the current legislation. However, in the absence of species- and 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.

While the data from the annual NRCP testing by MSs indicate a relatively low incidence of non-compliant results for sheep and goats, there may be human health concerns regarding certain contaminants. For example, an evaluation undertaken by EFSA (EFSA CONTAM Panel, 2011b) on the risk to public health related to the presence of high levels of dioxins and dioxin-like PCBs in liver from sheep (and deer) concluded that regular consumption of sheep liver would result, on average, in an approximate 20 % increase of the median background exposure to dioxins and dioxin-like PCBs (DL-PCBs) for adults. The study also concluded that on individual occasions, consumption of sheep liver could result in high intakes exceeding the tolerable weekly intake (TWI), and that the frequent consumption of sheep liver, particularly by women of child-bearing age and children, may be a potential health concern.

2.4. Criteria used for the evaluation of the likelihood of the occurrence of residues or contaminants[44] in sheep and goats

Independent from the occurrence data as reported from the NRCPs, each substance or group of chemical substances that may enter the food chain was also evaluated for the likelihood that potentially toxic or undesirable substances might occur in sheep and goat carcasses.

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 sheep and goats (suitability for sheep and goat production; commercial advantages)
- the potential availability of the substance(s) for illicit or non-compliant usage in sheep and goat production (allowed usage in third countries; availability in suitable form for use in sheep and goats; 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 sheep and goats based on the kinetic data (pharmacokinetic and withdrawal period data; persistence characteristics; special residue issues, e.g. bound residues of nitrofurans)
- toxicological profile and nature of hazard and the relative contribution of residues in sheep and goats to dietary human exposure.

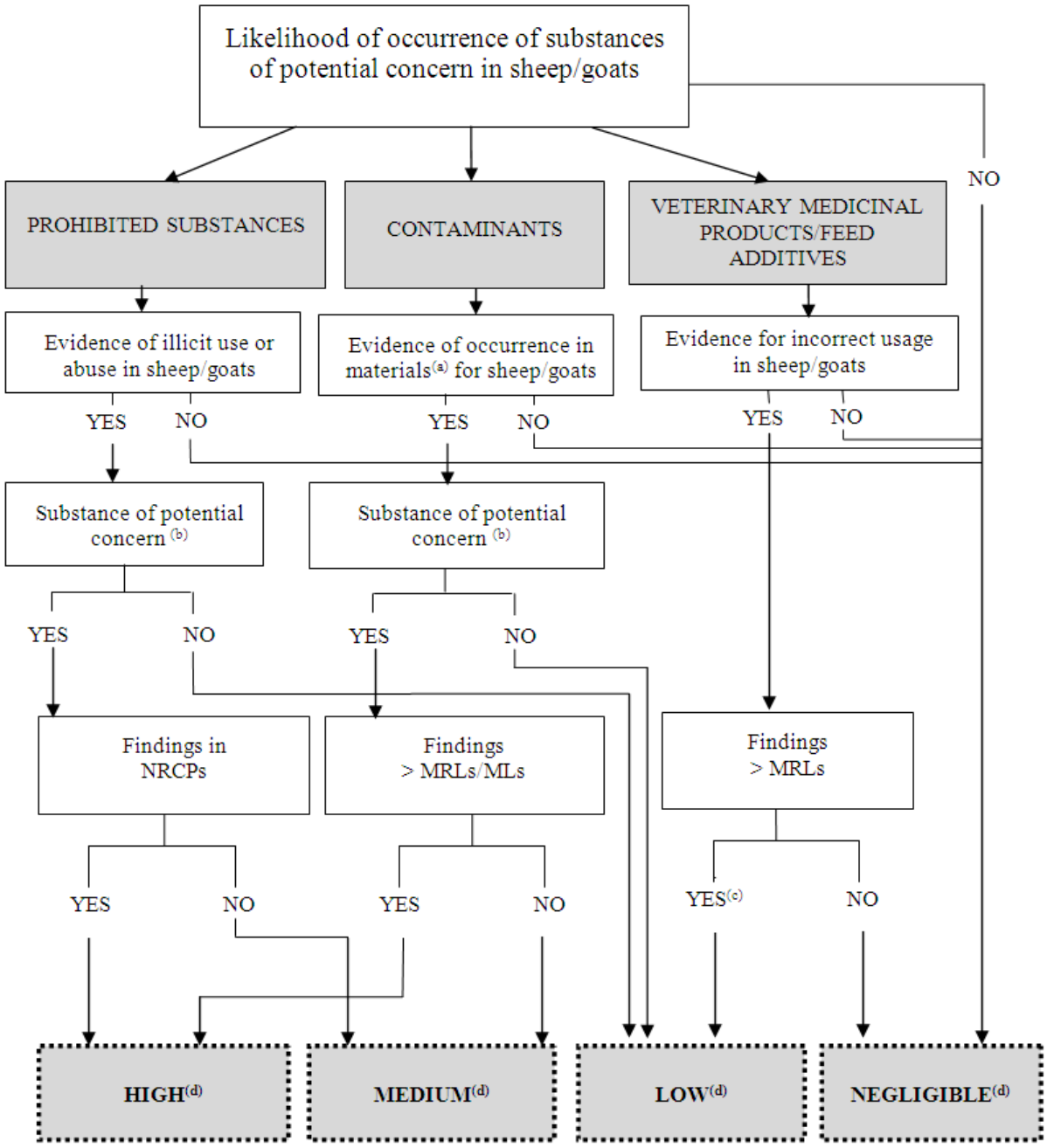
For contaminants, the following criteria were considered:

- the prevalence (where available) of occurrence of the substances in animal feeds/forages and pastures, and of the specific environmental conditions in which the animals are raised
- the level and duration of exposure, tissue distribution and deposition including accumulation in edible tissues of sheep and goats
- toxicological profile and nature of hazard and the relative contribution of residues in sheep and goats to dietary human exposure.

2.4.1. 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 sheep and goats and the toxicological profile of the substances were considered in the development of the general flow chart, presented in Figure 1.

[44] Note that residues comprise both prohibited substances and veterinary medicinal products/feed additives. Contaminants refer to any substance not intentionally added to feed or food.



ML, maximum level; MRL, maximum residue limits; 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 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 the next 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 sheep and goats.

2.4.2. Outcome of the ranking of residues and contaminants of potential concern that can occur in sheep/goat carcasses

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

Category 1—Negligible potential concern

Substance irrelevant in sheep/goat production (no known use at any stage of production); no evidence for illicit use or abuse in sheep/goats; not or very seldom associated with exceedances in MRLs in NRCPs; no evidence of occurrence as a contaminant in feed for sheep/goats.

Category 2—Low potential concern

VMPs/feed additives which have an application in sheep/goat production, residues above MRLs are found in control plans, but substances are of low toxicological concern;[45] 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 sheep/goats.

Category 3—Medium potential concern

Contaminants and prohibited substances to which sheep/goats 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 sheep/goats; contaminants generally not found in concentrations above the MRL/MLs in edible tissues of sheep/goats.

Category 4—High potential concern

Contaminants and prohibited substances to which sheep/goats 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 sheep/goats; evidence for ongoing occurrence and exposure of sheep/goats to feed contaminants.

2.4.2.1. Substances classified in the category of high potential concern

2.4.2.1.1. Contaminants: dioxins, dioxin-like polychlorinated biphenyls (DL-PCBs)

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

(a) Dioxins

Dioxins are persistent organochlorine contaminants that are not produced intentionally and 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 and high lipophilic properties, they bioaccumulate in the food chain and are stored in fatty tissues of animals and humans. The major pathway of 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, kaolinitic clay containing potato peel or mixing of compound feed

[45] 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.

with contaminated fatty acids. 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.

Monitoring programmes also demonstrated that certain food commodities, such as sheep liver can have high dioxin levels even when not affected by specific contamination sources. In 2011, the CONTAM Panel delivered a scientific opinion on the risk to public health related to the presence of high levels of dioxins and DL-PCBs in liver from sheep and deer (EFSA CONTAM Panel, 2011b). EFSA evaluated, *inter alia*, the dioxin and PCB results from 332 sheep liver and 175 sheep meat samples submitted by eight European countries. Almost all sheep meat samples were below the relevant MLs set by Regulation (EC) No 1881/2006. However, the corresponding liver samples from the same sheep in more than half of the cases exceeded the relevant maximum levels considerably. This finding is likely to be associated with differences in the level of biotransformation enzymes in sheep compared with bovine animals.

Dioxins have a long half-life and are accumulated in various tissues. The findings of elevated levels in food are of public health concern owing to their potential effects on liver, thyroid, immune function, reproduction and neurodevelopment (EFSA, 2005a, 2010). The available data indicate that a substantial part of the European population is in the range of or already exceeding the TWI for dioxins and DL-PCBs. A report on "Monitoring of Dioxins and PCBs in Food and Feed" (EFSA, 2012) estimated that between 1.0 % and 52.9 % of individuals were exposed above the TWI of 14 pg TEQ/kg body weight (b.w.) for the sum of dioxins and DL-PCBs. In addition to milk and dairy products and fish and seafood, meat and meat products also contributed significantly to total exposure. Owing to the high toxic potential of dioxins and the incidence of samples of sheep meat and sheep liver exceeding the maximum limits, efforts need to be undertaken to reduce exposure where possible.

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

(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 physicochemical 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 Council Directive 96/59/EC,[46] MSs were required to take the necessary measures to ensure that used PCBs are disposed off and equipment containing PCBs is 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. On the other hand, monitoring programmes also demonstrated that certain food commodities, such as sheep liver can have high PCB levels even when not affected by specific contamination sources. This was demonstrated by EFSA in its scientific opinion on the risk to public health related to the presence of high levels of dioxins and PCBs in liver from sheep and deer (EFSA CONTAM Panel, 2011b). EFSA evaluated, *inter alia*, the dioxin and PCB results from 332 sheep liver and 175 sheep meat samples submitted by eight European countries. For sheep liver, the mean upper bound concentration for DL-PCBs (expressed as $WHO\text{-}TEQ_{1998}$) was 11.2 (range: 0.10–198.2) pg WHO-TEQ/g fat. The corresponding levels in sheep meat were considerably lower: 1.29 (range: 0.08–11.29) pg WHO-TEQ/g fat (EFSA CONTAM Panel, 2011b).

[46] 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.

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 neurodevelopment). This group of PCBs is therefore called "dioxin-like 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" (see below).

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

2.4.2.2. Substances classified in the category of medium potential concern

2.4.2.2.1. Prohibited substances: stilbenes, thyreostats, gonadal (sex) steroids, resorcylic acid lactones, beta-agonists, chloramphenicol and nitrofurans

(a) Stilbenes

The toxicity of stilbenes is well established (for review see Waltner-Toews and McEwen, 1994) and this has led to their prohibition for use as growth promoters in animals in most countries, based also on their involvement in the baby food scandal in the late 1970s (Loizzo et al., 1984). In particular, diethylstilbestrol is a proven human genotoxic carcinogen (Group I IARC (International Agency for Research on Cancer)) (IARC, 2012), while sufficient evidence for hexestrol and limited evidence for dienestrol for carcinogenicity in animals were found (IARC, 1979). Diethylstilbestrol is associated with cancer of the breast in women who were exposed while pregnant, and also causes adenocarcinoma in the vagina and cervix of women who were exposed *in utero*; finally, a positive association has been observed between exposure to diethylstilbestrol and cancer of the endometrium, and between *in utero* exposure to diethylstilbestrol and squamous cell carcinoma of the cervix and cancer of the testis. In 1981, the use of stilbenes in all species of food-producing animals was prohibited in the European Community by Directive 81/602/EEC.[47]

Diethylstilbestrol, and other stilbenes such as hexestrol and dienestrol, are likely to be available on the black market and, therefore, might be available for illicit use in sheep and goats. No non-compliant results for stilbenes in sheep and goat samples have been reported from the European NRCPs 2005–2010, indicating that abuse of stilbenes in sheep and goat production in the EU is unlikely.

Considering that stilbenes have proven toxicity for humans, these substances are ranked as of medium potential concern. However, considering that there is no evidence for current use of stilbenes in sheep and goat production and that no non-compliant results have been found over a number of years of NRCP testing, control measures for stilbenes might be focused on identifying any potential future abuse of these substances in sheep and goat production in the EU.

(b) Thyreostats

Thyreostats are a group of substances that inhibit the thyroid function, resulting in decreased production of the thyroid hormones triiodothyronine (T3) and thyroxine (T4). Enlargement of the thyroid gland has been proposed as a criterion to identify illicit use of these compounds (Vos et al., 1982; Vanden Bussche et al., 2009). They are used in human and in non-food-producing animal medicine to deal with hyperthyroidism. The use of thyreostats for animal fattening is based on weight gain caused by filling of the gastrointestinal tract and retention of water in muscle tissues (Courtheyn et al., 2002). Synthetic thyreostats include thiouracil, methylthiouracil, propylthiouracil, methimazole,

[47] Council Directive 81/602/EEC of 31 July 1981 concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action. OJ L 222, 7.8.1981, pp. 32–33.

tapazol (methylmercaptoimidazole) and mercaptobenzimidazole (MBI). Use of synthetic thyreostats in food-producing animals has been prohibited in the EU since 1981 (Council Directive 81/602/EC).

Naturally occurring thyreostats include thiocyanates and oxazolidine-2-thiones, which are present as glucosinolates in plant material such as in the seeds of *Cruciferae*, like rapeseed (EFSA, 2008b; Vanden Bussche et al., 2009). Evidence for the occurrence of thiouracil in urine of cattle fed on a cruciferous-based diet has been demonstrated (Pinel et al., 2006).

Thyreostats are very widely available on the black market so there is the possibility for illicit use in sheep/goat production. The results from the European NRCPs 2005–2010 show that sheep/goat samples were found to be non-compliant for thyreostats (17 non-compliant results out of the total 1 958 samples analysed for thyreostats). However, it has been shown that the source of the generally low levels of thiouracil determined in urine samples may be from exposure of animals through their diet (Le Bizec et al., 2011). Some MSs reporting the highest numbers of non-compliant samples for thiouracil state that "the presence of thiouracil in low concentrations may be due to the animals eating cruciferous plant material" and "in line with scientific evidence, the competent authority has concluded that the residues resulted from dietary factors".

Thyreostats have been considered to be carcinogenic and teratogenic. While the *in utero* exposure to methimazole or propylthiouracil has been associated with *aplasia cutis* and a number of other congenital defects (Löllgen et al., 2011; Rodriguez-Garcia et al., 2011), an IARC evaluation found inadequate evidence in humans, but limited evidence (in the case of methimazole) and sufficient evidence (in the case of thiouracil, methylthiouracil and propylthiouracil) in experimental animals for carcinogenicity (IARC, 2001; EFSA 2008b).

Thyreostats are prohibited substances owing to their potential toxicity to humans and their efficacy as growth promoters in sheep/goats, but considering that the non-compliant results that have been found in most years of NRCP testing have been attributed largely to a dietary source, these substances are ranked as of medium potential concern. Control measures for thyreostats might focus on identifying potential abuse of these substances in sheep and goat production in the EU.

(c) Gonadal (sex) steroids

A broad range of steroids derived from oestrogens, androgens and progestagens are available and have been used as growth-promoting agents in food-producing animals. There is an extensive body of animal production research demonstrating the efficacy of anabolic steroids, often in combination treatments of an oestrogen and an androgen (or progestagen), as growth promoters. All use of steroids as growth-promoting agents in food-producing animals is banned according to Council Directive 96/22/EC, as amended by Directives 2003/74/EC[48] and 2008/97/EC.[49] The latter included 17β-oestradiol in the list of prohibited substances owing to its demonstrated tumour-promoting (epigenetic) and tumour initiating (genotoxic) properties (Russo et al., 2003). Certain uses of 17β-oestradiol, progesterone and medroxyprogesterone acetate in sheep and/or goats are allowed for therapeutic or zootechnical purposes only (Commission Regulation (EU) No 37/2010).

There is evidence that anabolic steroids are of economic value for farmers as animals respond to their application with increased growth rate and feed conversion efficiency. Anabolic steroids are widely available on the black market so there is the possibility for illicit use in sheep and goat production. The results from the NRCPs 2005–2010 show several sheep and goat samples non-compliant for anabolic steroids. Because of the potential occurrence of some of these substances endogenously, particularly substances such as alpha-boldenone, epinandrolone and the natural hormones, it is difficult to establish

[48] Directive 2003/74/EC of the European Parliament and of the Council of 22 September 2003 amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists. OJ L 262, 14.10.2003, pp. 17–21.

[49] Directive 2008/97/EC of the European Parliament and of the Council of 19 November 2008 amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists. OJ L 318, 28.11.2008, p. 9–11.

an accurate estimate for the level of abuse of anabolic steroids in European sheep and goat production from these data. There are divergent views on the potential adverse effects for the consumer from residues of anabolic steroids in edible tissues of treated animals. There is concern regarding the carcinogenic effects of oestrogenic substances, and the long-term effects of exposure of prepubescent children to oestrogenic substances. In 1999 the Scientific Committee on Veterinary measures relating to Public Health (SCVPH) performed an assessment of the potential risks to human health from hormone residues in bovine meat and meat products (SCVPH, 1999, 2000, 2002), particularly as regards the three natural hormones (17β-oestradiol, testosterone, progesterone) and the three synthetic analogues (zeranol, trenbolone acetate, melengestrol acetate) that may be legally used as growth promoters in third countries. It was concluded that, taking into account both the hormonal and non-hormonal toxicological effects, the issues of concern include neurobiological, developmental, reproductive and immunological effects, as well as immunotoxicity, genotoxicity and carcinogenicity. In consideration of concerns relating to the lack of understanding of critical developmental periods in human life as well as uncertainties in the estimates of endogenous hormone production rates and metabolic clearance capacity, particularly in prepubertal children, no threshold level and therefore no ADI could be established for any of the six hormones. According to IARC, 17β-oestradiol and steroidal oestrogens are classified as proven human carcinogens (Group 1), androgenic (anabolic) steroids as probably carcinogenic to humans (Group 2A); for most progestagens, evidence for human carcinogenicity is inadequate while that for animals varies from sufficient to inadequate (IARC, 2012).

Notwithstanding the toxicological profile of gonadal (sex) steroids, owing to the low prevalence of non-compliant samples from confirmed illicit use in the NRCPs, these substances are ranked as of medium potential concern.

(d) Resorcylic acid lactones (RALs)

In the EU, zeranol was evaluated together with other hormonal growth promoters by the SCVPH (SCVPH 1999, 2000, 2002). In these scientific opinions it was concluded that, taking into account both the hormonal and non-hormonal toxicological effects, no ADI could be established for any of the six hormones, including zeranol. Use of zeranol as a growth promoter in cattle production was widespread in some MSs prior to its prohibition in Europe in 1985. Zeranol is widely available as a commercial product and is used extensively in third countries. Hence it is readily available on the market and there is the possibility for its illicit use in cattle production in the EU.

Zeranol is derived from, and can also occur as, a metabolite of the mycotoxin zearalenone, produced by *Fusarium* spp.

The results from the European NRCPs 2005–2010 show sheep/goat samples non-compliant for resorcylic acid lactones (a total of seven non-compliant results out of the total 3 283 samples analysed). However, it has been shown that the source of the generally low levels of zeranol and its metabolites determined in these samples may be from exposure of sheep/goats to the mycotoxin zearalenone through their diet (EFSA, 2004a). Some MSs reporting non-compliant results for zeranol and its metabolites state that "the residue was found to be as a result of feed contamination on the farm" and it was "probably attributable to mycotoxin contamination of feed".

RALs are prohibited substances owing to their potential toxicity to humans and their efficacy as growth promoters in sheep and goats, but considering that the non-compliant results that have been found in some years of NRCP testing have been attributed largely to a dietary source, these substances are ranked as of medium potential concern. Control measures for RALs might focus on identifying potential abuse of these substances in sheep and goat production in the EU.

(e) Beta-Agonists

Beta-Agonists, or β-adrenergic agonists, have therapeutic uses as bronchodilatory and tocolytic agents. A wide range of beta-agonists have been developed, such as clenbuterol, salbutamol, cimaterol,

terbutaline, ractopamine, etc., and all of these are prohibited for use as growth-promoting agents in food-producing animals in the EU. Salbutamol and terbutaline are licensed human medicines indicated for treatment of asthma and bronchospasm conditions and for prevention of premature labour, respectively. One of the beta-agonists, clenbuterol, is licensed for therapeutic use in cattle (as a tocolytic agent) and in the treatment of obstructive airway conditions in horses (Commission Regulation (EU) No 37/2010). Other beta-agonists, such as ractopamine, have been approved for use in food-producing animals in a number of third countries.

Treatment of sheep with beta-agonists, such as clenbuterol, results in increased muscle mass and increased carcass leanness (Baker et al., 1984). The commercial benefits of using beta-agonists in sheep and goat production, particularly lambs, combined with the availability of these substances, indicates that illicit use of beta-agonists as growth promoters cannot be excluded. An outbreak of collective food poisoning from the ingestion of lamb meat containing residues of clenbuterol has been reported in Portugal; symptoms shown by the intoxicated people may be generally described as gross tremors of the extremities, tachycardia, nausea, headaches and dizziness (Barbosa et al., 2005).

In the light of the known adverse biological effects of beta-agonists in humans, particularly clenbuterol, and the efficacy of such drugs as repartitioning agents in sheep/goats, but considering that no non-compliant results for sheep/goats have not been found in the NRCPs since 2005, these substances currently are ranked as of medium potential concern.

(f) Chloramphenicol

Chloramphenicol is an antibiotic substance, first used for the treatment of typhoid in the late 1940s. Chloramphenicol may produce blood dyscrasias in humans, particularly bone marrow aplasia, or aplastic anaemia, which may be fatal. 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 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 a long-term treatment with chloramphenicol, IARC classified chloramphenicol as Group 2A (probably carcinogenic to humans) substance (IARC, 1990). Based on these evaluations, the use of chloramphenicol in food-producing animals is prohibited within the EU to avoid the exposure of consumers to potential residues in animal tissues, milk and eggs. Consequently, chloramphenicol is included in Table 2 of Commission Regulation (EU) No 37/2010 (previously Annex IV of Council Regulation (EEC) No 2377/90).

Until its prohibition, chloramphenicol was used on food-producing animals, including sheep and goats, for treatment of *Salmonella* infections and for prevention of secondary bacterial infections. Currently, chloramphenicol, which is licensed for use as a broad-spectrum bacteriostatic antibacterial in pets and non-food-producing animals in the EU, is used also in some third countries for food-producing animals. Hence, chloramphenicol may be available on the black market for illicit use in sheep/goat production. However, the availability for use on food-producing animals of related substances with similar antibacterial properties, thiamphenicol and florfenicol (with no toxicological concern), should mitigate the illicit use of chloramphenicol in sheep/goat production as these alternative drugs are available as prescription medicines. Non-compliant results for chloramphenicol in sheep/goats have been reported in most years' results from the European NRCPs 2005–2010 (11 non-compliant results), indicating that abuse of chloramphenicol in sheep/goat production in Europe may be a continuing occurrence.

Chloramphenicol has proven toxicity for humans and is effective as an antibacterial treatment for sheep/goats but, considering that lower numbers of non-compliant results have been found in recent years of the NRCP testing, chloramphenicol currently is ranked as of medium potential concern.

(g) Nitrofurans

Nitrofurans, including furazolidone, furaltadone, nitrofurantoin and nitrofurazone, are very effective antimicrobial agents that, prior to their prohibition for use on food-producing animals in the EU in 1995, were widely used on livestock (cattle, sheep/goats, pigs, sheep and goats), in aquaculture and in bees. Various nitrofuran antimicrobials are still applied in human medicine particularly for the treatment of urinary tract infections. A characteristic of nitrofurans is the short half-life of the parent compounds and the formation of covalently bound metabolites which, under the acidic conditions of the human stomach, may be released as active agents (Hoogenboom et al., 1992). These covalently bound metabolites are used as marker residues for detecting the illicit use of nitrofurans in animal production. It should be noted that the metabolite semicarbazide (SEM) has been shown not to be an unambiguous marker for abuse of the nitrofuran drug nitrofurazone because the SEM molecule may occur from other sources (Hoenicke, et al., 2004; Sarnsonova et al., 2008; Bendall, 2009).

Nitrofurans are effective in treatment of bacterial and protozoal infections, including coccidiosis, in food-producing animals. Although prohibited for use on food-producing animals in many countries, nitrofurans are likely to be available on the black market for illicit use in sheep/goat production. Non-compliant results for nitrofurans in sheep/goats have been reported in most years' results from the European NRCPs 2005–2010, indicating that abuse of nitrofurans in sheep/goat production in Europe is a continuing occurrence. A metabolite of furazolidone that can be released from covalently bound residues in tissues has been shown to be mutagenic and may be involved in the carcinogenic properties of the parent compound (EMEA, 1997a).

Nitrofurans have proven toxicity for humans and are effective as antibacterials for sheep and goats but, considering that non-compliant results, other than for the marker residue SEM, are found only sporadically in the NRCP testing, these substances currently are ranked as of medium potential concern.

2.4.2.2.2. Contaminants: non dioxin-like PCBs (NDL-PCBs), chemical elements and mycotoxins

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

In its risk assessment the CONTAM Panel decided to use the sum of the six PCB congeners (-28, -52, -101, -138, -153 and -180) as the basis for their evaluation, because these congeners are appropriate indicators for different PCB patterns in various sample matrices and are most suitable for a potential concern assessment of NDL-PCBs on the basis of the available data. Moreover, the Panel noted that the sum of these six indicator PCBs represents about 50 % of total NDL-PCBs in food (EFSA, 2005a). Harmonised European maximum levels for NDL-PCBs in different food categories including meat, meat products and liver of sheep applied from 1 January 2012.

Levels for the sum of the above six NDL-PCBs in 146 sheep meat and 257 sheep liver samples were reported by eight MSs to EFSA following a call for data. Levels in meat samples ranged from 0.51 to 162.2 (mean 13.1, median 8.46) µg/kg fat. Levels in the liver samples ranged from 0.41 to 350.5 (mean 26.8, median 14.6) µg/kg fat (EFSA CONTAM Panel, 2011b).

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

(b) Chemical elements (heavy metals: cadmium, mercury and lead)

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. Kidney tissue from sheep forms a specific dietary component in many European cultures. Exposure of animals is commonly related to contaminated feed materials, despite older reports of accidental intoxication of animals from other sources (paints, batteries). The CONTAM Panel has issued within the framework of the re-evaluation of undesirable substances in animal feeds according to 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. Most of the non-compliant results were for kidney samples with some non-compliant results for muscle and liver being reported.

Mercury (EFSA, 2008a, EFSA CONTAM Panel, 2012a) exists in the environment as elemental mercury, inorganic mercury and organic mercury (primarily methylmercury). Methylmercury bioaccumulates and biomagnifies along the aquatic food chain. The toxicity and toxicokinetics of mercury in animals and humans depends on its chemical form. Elemental mercury is volatile and mainly absorbed through the respiratory tract, whereas its absorption through the gastrointestinal tract is limited (10–30 %). Following absorption, inorganic mercury distributes mainly to the kidneys and, to a lesser extent, to the liver. The critical effect of inorganic mercury is renal damage. In contrast, in animals, as in humans, methylmercury and its salts are readily absorbed in the gastrointestinal tract (> 80 %) and rapidly distributed to all tissues, although the highest concentrations are also found in the kidneys.

Data from MSs indicated the presence of mercury in animal feeds, but the measured concentrations remained below the maximum content for feed materials (0.1 mg/kg feed according to Directive 2002/32/EC). Human exposure is predominantly associated with fish consumption; sheep and goat meat and offal are assumed to contribute only to a minor extent to human exposure (FAO/WHO, 2011). For sheep and goats, there are no harmonised EU MLs for mercury other than in the Pesticides Regulation (EC) No 396/2005, as amended.

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 sheep and goat meat and offal to human exposure is limited.

Given the toxicological profile of these elements and the fact that cadmium accumulates in animals and humans, these three elements have been allocated to the group of substances of medium potential health concern.

2.4.2.3. Substances classified in the category of low potential concern

2.4.2.3.1. Prohibited substances: nitroimidazoles, chlorpromazine

(a) Nitroimidazoles

The 5-nitroimidazoles, dimetridazole, metronidazole and ronidazole, are a group of drugs having antibacterial, antiprotozoal and anticoccidial properties. Owing to the potential harmful effects of these

drugs on human health (EMEA, 1997b)—carcinogenicity, mutagenicity, genotoxicity and the occurrence of covalent binding to macromolecules of metabolites with an intact imidazole structure—their use in food-producing animals is prohibited in the EU, United States, China, and other countries.

Nitroimidazoles had been used as veterinary drugs for the treatment of cattle, pigs and sheep and goats. Although prohibited for use on food-producing animals, not only in the EU but also in many third countries, nitroimidazoles are likely to be available on the black market for illicit use in animal production, particularly as drugs such as metronidazole are readily available as human medicines. However, there are no clinical conditions in sheep/goats for which nitroimidazoles are particularly appropriate. Non-compliant results (two) for nitroimidazoles in sheep/goats have been reported only in one year and from one MS from the European NRCPs 2005–2010, suggesting that abuse of nitroimidazoles in sheep/goat production in Europe is not widespread.

Considering that nitroimidazoles have proven toxicity for humans and that they may be effective as antibacterial/antiprotozoal treatments for sheep/goats, these substances might be ranked as of medium potential concern. However, as only occasional non-compliant results have been found over a number of years of NRCP testing, nitroimidazoles currently are ranked as of low potential concern.

(b) Chlorpromazine

Chlorpromazine is a sedative and is also used against motion sickness and as an anti-emetic in pets. Its use is banned in food-producing animals, including sheep/goats. Chlorpromazine is likely to be available as a black market substance for illicit use in sheep/goat production. No non-compliant results for chlorpromazine were reported from the NRCP for the period 2005–2010, indicating that the substance may not be rarely used illicitly in sheep/goat production in the EU. Chlorpromazine is used as an antipsychotic drug in human therapy and has long-term persistence in humans and numerous side effects, including the more common ones of agitation, constipation, dizziness, drowsiness, etc. (EMEA, 1996).

Chlorpromazine may be effective as a tranquilliser for sheep/goats but, since no non-compliant results have been found over a number of years of NRCP testing, chlorapromazine currently is ranked as of low potential concern.

2.4.2.3.2. Contaminants: organochlorine pesticides, organophosphorus compounds, and natural toxins

(a) Organochlorine compounds

Organochlorine pesticides, such as dichlorodiphenyltrichloroethane (DDT) and its metabolites, hexachlorocyclohexanes (HCHs), dieldrin, toxaphene and others have been assigned to the category of contaminants of low potential concern. Occurrence of residues of these substances has declined over the years, because of their long-standing ban, and relatively low levels in animal products can be expected, as shown by results from the NRCPs 2005–2010, which indicate that 17 results out of the total of 8 007 samples tested for the category of organochlorine compounds were non-compliant for organochlorine pesticides.

(b) Organophosphorus compounds

Organophosphorus compounds are classified in Council Directive 96/23/EC as Group B3b contaminants, although they may be used also as VMPs for the therapy of parasitic infestations of sheep and goats. However, their probably infrequent use and short half-life results in these compounds being assigned to the category of low potential concern, or even negligible potential concern where MRLs are not exceeded. Results from the NRCPs from 2005–2010 indicate that 5 results out of the total of 5 766 samples tested for the category of organophosphorus compounds were non-compliant.

(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 intoxication in humans and animals following ingestion of contaminated food or feed materials.

Mycotoxins evaluated by the CONTAM Panel as undesirable contaminants in animal feeds, including aflatoxins (EFSA, 2004b), deoxynivalenol (EFSA, 2004c), fumonisins (EFSA, 2005b) and zearalenone (EFSA, 2004a), T-2 toxin (EFSA CONTAM Panel, 2011c), ergot alkaloids (EFSA CONTAM Panel, 2012b) may pose a risk for animal health and productivity when present in feed materials that are used for sheep and goat animals over an extended period of time. However, most of the known mycotoxins are efficiently degraded by the rumen microflora and have a short biological half-life. Hence, even if residues of mycotoxins are occasionally detected in animal tissues (monogastric animal species) they do not contribute significantly to human exposure, which is mainly related to the consumption of cereal products, nuts and spices.

Considering that some mycotoxins like aflatoxins have proven toxicity for humans, some of these substances might be ranked as of medium potential concern. However, since non-compliant results have been found incidentally (two out of 1 655 samples) over a number of years of NRCP testing, these substances currently are ranked as of low potential concern.

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

Plants used as feed materials may contain undesirable substances such as toxic secondary metabolites and/or botanical impurities. 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 Directive 2002/32/EC). The evaluations addressed plant metabolites such as glucosinolates (EFSA, 2008b), saponins (EFSA, 2009b), pyrrolizidine alkaloids (EFSA, 2007a; EFSA CONTAM Panel, 2011d), 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). Although 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. The limited data on the kinetics of these metabolites does not preclude in all cases a transfer from the feed into animal tissues under certain circumstances of exposure. For example, residues of gossypol in meat of cattle (and sheep) were demonstrated under experimental conditions (feeding of cotton meal as the main feed component), but such residues are not expected under the conditions of European farming, where cotton seeds or cotton seed by-products are infrequently used and only with limited inclusion rates in feed (EFSA, 2008e). Other natural substances, such as the fungal metabolite (mycotoxin) zearalenone, are intensively metabolised in the rumen and following absorption in the liver and other animal tissues, and this may explain certain non-compliant analytical results. Zearalanol (zeranol) is one of these metabolites and which is used in certain third countries as a growth-promoting agent owing to its oestrogenic activity (see Section 2.3.5.2.1 (d)). This applies also to certain thiocyanates and oxazolidinethiones, originating from glucosinolates produced by a broad variety of plants of the Brassicaceae family. They target different steps in the synthesis of thyroid hormones, leading eventually to hypothyroidism and enlargement of the thyroid gland (goitre) (EFSA, 2008b). Again, these natural products may explain some of the non-compliant results found in NRCP testing where treatment of animals with antithyroid agents (thyreostats) has been suspected.

Recently, an increasing use of herbal remedies, given as so-called alternatives to antibiotics for animals, has been reported also in ruminants. Many of the herbal products contain biologically active substances that are also addressed in the list of undesirable plant metabolites. However, the remedies are given in low concentrations (lower than the larger amount that could be ingested with feed), and for a limited period. Although specific data are lacking, it seems unlikely that residues of these

compounds may be found in edible tissues of slaughtered animals. Such substances, therefore, are placed in the category of low potential concern within the current classification.

2.4.2.3.3. VMPs and feed additives above MRLs

VMPs, such as antimicrobials, anti-coccidials and anti-parasitics, are used commonly on sheep and goats for prophylactic purposes, particularly prior to turning animals out to grazing (anti-parasitic treatments). Therapeutic use of VMPs, particularly antimicrobials, may occur in response to diagnosis of infection in individual animals or in the flock.

In general, VMPs, except the substances allocated to Annex Table 2 of Regulation (EC) No 37/2010, are categorised as being of low potential concern because they have all been subjected to pre-marketing approval which specifies ADIs, and MRLs, with the aim of guaranteeing a high level of safety to the consumer. Where exceedances of MRLs are found in the residue monitoring programmes (i.e. 203 non-compliant results out of the 63 500 samples analysed for antibacterials, 28 non-compliant results for anthelmintics out of the 17 151 samples analysed, and eight non-compliant results out of the 4 318 samples analysed for anti-coccidials), these are typically of an occasional nature that is not likely to constitute a concern to public health. Despite only two non-compliant results being reported out of the 3 534 samples analysed for corticosteroids, there is concern about their potential illicit use, particularly in fattening lambs.

2.4.2.4. Substances classified in the negligible potential concern category

In the negligible potential concern category are the dyes and the prohibited substances, colchicine, dapsone, chloroform and *Aristolochia* spp.

2.4.2.4.1. Prohibited substances: colchicine, dapsone, chloroform and *Aristolochia* spp.

(a) Colchicine

Colchicine is a plant alkaloid that has been used in veterinary medicine to treat papillomas and warts in cattle and horses by injection at the affected area. A possible contamination of food with colchicine has been identified through consumption of *Colchicum autumnale* in forage by animals such as cattle or sheep and, in this context, colchicine has been determined in milk of sheep after exposure to *C. autumnale* (Hamscher et al., 2005). Colchicine is genotoxic and teratogenic and may have toxic effects on reproduction.

No non-compliant results for colchicine in sheep/goats have been reported from the European NRCPs 2005–2010; however, it is probable that testing for this substance may not be included in monitoring programmes in many countries.

In the absence of the absence of evidence for use of colchicine in sheep/goats colchicine currently is ranked as of negligible potential concern.

(b) Dapsone

Dapsone is a drug used in humans and formerly in veterinary medicine: in human medicine it is used for treatment of leprosy, malaria, tuberculosis and dermatitis; and in veterinary medicine it is used as an intramammary treatment for mastitis, for oral treatment of coccidiosis and for intra-uterine treatment of endometriosis. Following scientific assessment by the Committee for Medicinal Products for Veterinary Use (CVMP), a provisional MRL of 25 µg/kg parent drug was established for muscle, kidney, liver, fat and milk for all food-producing animals (EMEA, 1999). Further information on teratogenicity and reproductive effects for dapsone was required but, when this was not provided, the substance was recommended for inclusion in Annex IV to Council Regulation (EEC) No 2377/90 (now Annex, Table 2, of Commission Regulation (EC) No 37/2010). More recently, the CVMP has reviewed the alleged mutagenicity of dapsone in the context of its occurrence as an impurity in VMPs containing sulphonamides and concluded that it is not genotoxic (CVMP, 2012), and EFSA has issued

a scientific opinion on the product as a food-packaging material (compound 15267), proposing an acceptable level of 5 mg/kg food (EFSA, 2005c).

No non-compliant results for dapsone in sheep/goats have been reported from the European NRCPs 2005–2010. However, a review of testing carried out in MSs during 2008 by the EU Reference Laboratory AFSSA (Agence Française de Sécurité Sanitaire des Aliments, Fougères, France) found that testing for dapsone in sheep/goats was carried out in only two MSs.

In the absence of evidence for use of dapsone in sheep and goats, dapsone currently is ranked as of negligible potential concern.

(c) Chloroform and *Aristolochia* spp.

In the negligible potential concern category are the prohibited substances, chloroform and plant remedies containing *Aristolochia* spp., as these are not relevant to sheep/goat production and there is no evidence for use of these substances in sheep/goat production.

2.4.2.4.2. VMPs below MRLs: carbamates and pyrethroids, sedatives

VMPs used in sheep and goat production but with no evidence for residues above MRLs being found in monitoring programmes and VMPs irrelevant for sheep and goat 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 sheep for control of environmental infections, such as lice eggs in buildings. There are no recent incidents of non-compliant results reported in NRCP testing in sheep and goats during the period 2005–2010, resulting in these substances being assigned 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 sheep, goats and other animal species for sedation and analgesia during surgical procedures or for euthanasia. They are rarely used in sheep and goats. No non-compliant results were found in the NRCP testing for the period 2005–2010. Due 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. However, it should be noted that testing for this category of substances is not required under the provisions of Council Directive 96/23/EC.

2.4.2.4.3. Contaminants: dyes

There are no indications for use of dyes such as (leuco-)malachite green in sheep and goat animals. Testing of sheep and goat animals for this group of substances is not required under Council Directive 96/23/EC2.

A summary of the outcome of the ranking is presented in Table 7.

Table 8: Ranking of chemical residues and contaminants in sheep/goats based on pre-defined criteria and taking into account the findings from the NRCPs for the period 2005–2010.

Group / Potential concern category	Prohibited substances	VMPs and licensed feed additives	Contaminants
Category1 **Negligible potential concern**	• *Aristolochia spp.* • Chloroform • Colchicine • Dapsone	• VMPs below MRLs	• Dyes
Category 2 **Low potential concern**	• Chlorpromazine • Nitroimidazoles	• VMPs exceeding MRLs, including corticosteroids	• Organochlorine pesticides • Organophosphorus compounds • Chemical elements (feed supplements) • Natural toxins (mycotoxins and PSMs)
Category 3 **Medium potential concern**	• Stilbenes • Thyreostats • Steroids • Resorcylic acid lactones • β-agonists • Chloramphenicol • Nitrofurans		• NDL-PCBs • Chemical elements (cadmium, mercury and lead)
Category 4 **High potential concern**			• Dioxins • DL-PCBs

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

2.4.2.5. Future aspects

The ranking into specific categories of potential concern of prohibited substances, VMPs and contaminants presented in this section applies exclusively to sheep and goats and is based on current knowledge regarding the toxicological profiles, usage in ovine animal production, 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.

2.4.2.5.1. New hazards

Another element of future aspects is the issue of 'new hazards'. In this context, 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 are scarce. It does not imply that there is evidence for an increasing trend in the concentration of these compounds in food or in human samples. Examples are brominated flame retardants, such as polybrominated diphenyl ethers (PBDE) and hexabromocyclododecanes (HBCDDs) or perfluorinated compounds (PFC), such as perfluorooctane sulphonate (PFOS) and perfluorooctanoic acid (PFOA).

(a) Polybrominated diphenyl ethers

In 2011, EFSA performed a risk assessment on polybrominated diphenyl ethers (PBDEs) in food (EFSA CONTAM Panel, 2011e). PBDEs are additive flame retardants which are applied in plastics, textiles, electronic castings and circuitry. PBDEs are ubiquitously present in the environment and likewise in biota and in food and feed. Eight congeners were considered by the CONTAM Panel to be

of primary interest: BDE-28, -47, -99, -100, -153, -154, -183 and -209. The highest dietary exposure is to BDE-47 and -209. Toxicity studies were carried out with technical PBDE mixtures or individual congeners. The main targets were the liver, thyroid hormone homeostasis and the reproductive and nervous system. PBDEs are not genotoxic. The CONTAM Panel identified effects on neurodevelopment as the critical endpoint, and derived benchmark doses (BMDs) and their corresponding lower 95 % confidence limit for a benchmark response of 10 %, the $BMDL_{10}$, 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, 1 700 µg/kg b.w. Owing to the limitations and uncertainties in the current database, the Panel concluded that it was inappropriate to use these BMDLs to establish health based guidance values, and instead used a margin of exposure (MOE) approach for the health risk assessment. As the elimination characteristics of PBDE congeners in animals and humans differ considerably, the Panel used the body burden as the 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 ovine meat and ovine-derived products to total human exposure is currently not known. As these compounds bioaccumulate in the food chain, they deserve attention and should be considered for inclusion in the NRCPs.

(b) Hexabromocyclododecanes (HBCDDs)

In 2011, EFSA delivered a risk assessment on HBCDDs in food (EFSA CONTAM Panel, 2011f). HBCDDs are additive flame retardants, primarily used in expanded and extruded polystyrene used as construction and packing materials, and in textiles. Technical HBCDD consists predominantly of three stereoisomers (α-, β- and γ-HBCDD). Also δ- and ε-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 α-, β- and γ-HBCDD as of primary interest. As 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 $BMDL_{10}$ of 0.79 mg/kg b.w. Owing 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. As the elimination characteristics of HBCDDs in animals and humans differ, the Panel used the body burden as the starting point for the MOE approach. The CONTAM Panel concluded that current dietary exposure to HBCDDs in the EU does not raise a health concern.

The occurrence data reported to EFSA have shown that HBCDDs could be detected in a limited number of meat samples. As the total number of sheep and goat meat samples analysed for HBCDDs are sparse and thus the current knowledge about the prevalence and their levels in edible tissues of ovine animals is limited, their inclusion into NRCPs even as a temporary measure should be considered.

(c) 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 widely found in the environment. In 2008, EFSA delivered a risk assessment on PFOS and PFOA in food (EFSA, 2008g). The CONTAM Panel established a TDI for PFOS of 150 ng/kg b.w. per day, and a TDI for PFOA of 1.5 µg/kg b.w. per day. A few data indicated the occurrence of PFOS and PFOA in meat samples. However, owing 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. A recent study in which contaminated

feed was fed to sheep demonstrated the transfer of PFOS, PFOA and various other PFCs with different chain lengths into milk and meat of the sheep (Kowalczyk et al., 2012). As PFCs have found widespread use and ubiquitous distribution in the environment, but representative data on their occurrence in meat are still limited, an intensified monitoring of these compounds in tissues as well as feed should be considered.

(d) Chemical elements (feed supplements)

Besides the heavy metals discussed in Section 2.4.2.2.2, attention should be given also to those compounds that may be used as feed supplements (e.g. copper, selenium, zinc). The correct use of these supplements cannot be guaranteed. Although supplementary feeding to sheep and goats at pasture with trace elements is practised, supplements for sheep are not permitted to contain copper. However, the risk of copper supplementation cannot be ruled out on mixed livestock farms where supplements containing copper for other livestock, e.g. pigs or calves, may be given in error to sheep, resulting in undesirable residues in animal organs, such as the liver. Sheep are particularly susceptible to copper toxicity; goats appear to be able to tolerate higher intakes (Underwood and Suttle, 1999). In the absence of supplementation, the main source of copper is the pasture, the uptake of which is a complex interaction between the copper, molybdenum and sulphate levels in the plants and the grass plants themselves. For example, sheep that consume excess subterranean clover (*Trifolium* spp.) will develop chronic copper accumulation in their tissues as a result of the copper/molybdenum balance in the clover (Radostits et al., 2007). There are also large differences between breeds in susceptibility to copper toxicity (Underwood and Suttle, 1999).

Only a single non-compliant result (265 mg/kg copper in lamb liver), was reported for copper in sheep tissues in 2010 and none from 2005 to 2009. There are no harmonised levels for copper in animal tissues in the EU other than in the pesticides Regulation (EC) No 396/2005.

A closer communication of results from official feed control seems essential to decide whether or not analytical monitoring of residues in slaughter animals needs to be directed to these substances that might be overused or mistakenly used in sheep or goat feeds.

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

In light of the existing Regulations and the daily practice of the control of residues/chemical substances in sheep/goat carcasses, 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:

- The current procedures for sampling and testing are a mature system, well established and coordinated, and subject to regular evaluation that is in place across EU MSs, with residue testing that 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. The residue monitoring programmes 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 (see Annex 1).

- There are well-developed systems and follow-up actions subsequent to the identification of non-compliant samples. As indicated in Section 1.4, follow-up on non-compliant samples is typically through intensified sampling (suspect sampling), withholding of slaughter and/or of carcasses subject to positive clearance as compliant, and on-farm investigations potentially leading to penalties and/or criminal prosecutions.

- The regular sampling and testing for chemical residues is a disincentive for the development of bad practices. There is constant development of new approaches in sampling and testing methodologies, particularly in the area of prohibited substances, directed at identifying illicit use of such substances in animal production; for example, use of samples other than edible tissues, such as excreta, eyes, fibre, etc. that demonstrate enhanced residue persistence characteristics, and use of indirect testing procedures, such as genomics, proteomics and metabolomics, to identify treated animals.

- The prescriptive sampling system allows for equivalence in the control of EU-produced sheep/goat meat. Any forthcoming measures have to ensure that the control of imports from third countries remains equivalent to the controls within the domestic market (this issue is addressed further in TOR 4).

- The current combination of animal traceability, *ante-mortem* inspection and gross tissue examination can support the collection of appropriate samples for residue monitoring. However, any indication of misuse or abuse of pharmacologically active substances through visual assessment needs to be confirmed by chemical analysis for potential residues.

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:

- Presence of chemical hazards cannot be identified by current *ante-*/*post-mortem* meat inspection procedures at the slaughterhouse level, indicating the need for further harmonisation of the risk reduction strategies along the entire food chain.

- At present, there is poor integration between the testing of feed materials for undesirable contaminants and the NRCPs in terms of communication and follow-up testing strategies or interventions. Moreover, a routine environmental data flow is not established and keeping habits for sheep and goats provide opportunities for feed coming in without a clear feed chain history.

- Under the current system, sampling is mostly prescriptive rather than risk or information based. It appears that individual samples taken under the NRCP testing programme may not always be taken as targeted samples, as specified under Council Directive 96/23/EC, but sometimes may be taken as random samples.

- There is a lack of sufficient cost-effective and reliable screening methods and/or the range of substances prescribed/covered by the testing is sometimes limited.

- There is limited flexibility to adopt new chemical substances into the NRCPs and limited ongoing adaptation of the sampling and testing programme to the results of the residue monitoring programmes.

- The sampling under the NRCPs reflects only a part of testing done by a number of MSs and, therefore, data from the NRCPs may not provide the most complete information for certain categories of substances.

- Sheep and goats may not be subject to surveillance over their lifetime at the same level as is the case for other food animal categories such as pigs, poultry and, to a large extent, bovine animals owing to their traditional nomadic/outdoor farming systems.

4. TOR 3: New hazards

Current monitoring of residues and contaminants in edible tissues of slaughter sheep/goats 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 high potential concern for consumers.

However, considering the recent information available from the re-assessment of undesirable substances in the food chain, covered by more recent EFSA opinions from the CONTAM Panel, additional compounds have been identified that require attention. Prominent examples of such substances are and DL-PCBs, which were identified as compounds of high potential concern as they bioaccumulate in the food chain, are likely to be found in sheep/goat carcasses and have a toxicological profile that points towards public health concerns even at low (residue) concentrations. In addition, it has been shown that these substances are found in edible tissues of sheep, particularly in sheep liver. Other halogenated substances such as brominated flame retardants, including polybrominated diphenylethers (PBDEs) as well as hexabromocyclododecanes (HBCDDs) and perfluorinated compounds (PFCs), such as PFOS and PFOA have a different toxicological profile. These compounds 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 of sheep and goats is limited. Chemical elements, such as copper, selenium and zinc, given as feed supplements may be mistakenly provided to sheep and goats resulting in undesirable residues in animal organs, such as the liver.

Inclusion of these various substances in the NRCPs (even as a temporary measure) should be considered together with an intensified monitoring of feed materials for the presence of these compounds, to support forthcoming decisions on whether or not these substances require continued monitoring either in feed materials and/or in slaughter animals.

Due to the nature of the husbandry systems applied, sheep and goats are more likely to be exposed to environmental contaminants than other livestock. Therefore, any incident giving rise to contamination of the environment may be noted primarily in animals kept outdoors, i.e. in sheep and goats.

5. TOR 4: Adaptation of inspection methods

It is important to note that sheep and goat production in the EU is marked by being largely extensive in nature, involving frequent trading of animals and nomadic flocks. This involves differences in husbandry systems and feeding regimes resulting in different risks from chemical substances and contaminants. Extensive periods on pasture or/as nomadic flocks, sale at open markets of many sheep and goats, and the presence of slaughter collection dealerships that may combine small numbers of animals purchased from several farmers, means that there is a level of concern that FCI shared between farmers and the slaughterhouse (where residue data is managed), may be suboptimal. Similarly, in these situations, the level of feedback from the slaughterhouse and authorities to farmers regarding the results of residue testing may be suboptimal. Here the individual identification of animals, which has now become mandatory, may contribute to more transparency in the future. There is less concern about FCI from dairy sheep and goats if they are reared under more intensive and controlled conditions.

FCI should be expanded for sheep and goats produced in extensive systems to provide more information on the specific environmental conditions where the animals are produced. It is recommended that sampling of sheep and goats should be based on the risk of occurrence of chemical residues and contaminants and on the completeness and quality of the FCI supplied. To achieve this, 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. It should be noted that for the small ruminant chains more environmental information should be provided. 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. Moreover, the combination of data from both sheep and goats into one data set is based on the assumption that both food chains are identical. In many cases such an assumption is not justified. A separation of records for both species is recommended.

In addition, there is a need to develop new approaches to chemical residues and contaminants testing. Recent developments in chemical analytical techniques allow the simultaneous measurement of a broad range of substances. Analytical techniques covering multiple analytes should be encouraged too and incorporated into feed quality control and national residue control programmes. Application of such validated methods for multi-residue analyses comprising veterinary drugs, pesticides and natural and environmental contaminants should be encouraged.

For prohibited substances, testing should be directed towards the farm level. One of the limitations of the currently applied analytical strategies is the generally poor sensitivity of some screening methods, resulting in the potential failure to detect residues in the low µg/kg range and, therefore, to identify non-compliant samples. New approaches including molecular biological techniques for the identification of indirect biomarkers of exposure in animals, as well as the development of reliable *in vitro* assays based on the biological action(s) of the compounds under analysis, are considered to be of additional value. Such approaches may help in detecting molecules of unknown structure or that are not included in the NRCPs but share a common mechanism of action, thereby better orienting and rationalising the subsequent chemical analysis.

In the case of many of the substances that might be used illicitly for growth-promoting purposes in sheep and goat production, the results of NRCP testing show no non-compliant results (e.g. stilbenes) or indicate that reported non-compliant results may be attributable to dietary sources (e.g. thyreostats, zeranol) or are the result of endogenous production (e.g. gonadal (sex) steroids). Therefore, future NRCP testing relating to such substances needs to be reduced and/or refocused, in terms of the range of analytes tested and the appropriateness of samples taken for testing, to better identify the extent of abuse of growth-promoting substances in sheep and goat production in the EU. In addition, control measures for such substances must not rely exclusively on NRCP testing, but should include veterinary inspection/police activities along the food chain directed at identifying abuse of such substances in sheep and goat production in the EU.

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

CONCLUSIONS AND RECOMMENDATIONS

This section contains conclusions derived from the material 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 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

- As a first step in the identification and ranking of chemical substances of potential concern, the CONTAM Panel considered the substances listed in Council Directive 96/23/EC and evaluated the outcome of the National Residue Control Plans (NRCPs) 2005–2010. The CONTAM Panel noted that only 0.41 % of the total number of results was non-compliant for one or more substances listed in Council Directive 96/23/EC. Potentially higher exposure of consumers to these substances from sheep and goat meat takes place only incidentally, as a result of mistakes or non-compliance with known and regulated procedures. The available aggregated data indicate a low number of samples that were non-compliant with the current legislation. However, in the absence of substance- and/or species-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 included the identification of substances that that are found in other testing programmes and that bioaccumulate in the food chain, substances with a toxicological profile of concern, and the likelihood that a substance under consideration will occur in sheep and goat carcasses. Taking into account these criteria the individual compounds were ranked into four categories denoted as being of high, medium, low and negligible potential concern.

- The highest overall proportion of non-compliant results under the NRCPs were for Group B3 substances, contaminants (0. 86 %) representing largely exceedances of the maximum residue limits/maximum levels (MRLs/MLs) specified for these substances. The proportion of non-compliant results overall for Group A substances, prohibited substances (0.64 %) and for Group B1/B2 substances, veterinary medicinal products (VMPs) (0.24 %) represent largely illicit use and exceedances of the MRLs, respectively.

- Dioxins and dioxin-like polychlorinated biphenyls (DL-PCBs) were ranked as being of high potential concern owing to their known bioaccumulation in the food chain, their frequent findings above MLs, particularly in sheep liver, and in consideration of their toxicological profile.

- Stilbenes, thyreostats, gonadal (sex) steroids, resorcylic acid lactones and beta-agonists, especially clenbuterol, were ranked as being of medium potential concern because of their toxicity for humans, their efficacy as growth promoters in sheep and goats and the incidence of non-compliant results.

- Chloramphenicol and nitrofurans were ranked as being of medium potential concern, as they have proven toxicity for humans, they are effective as antibacterial treatments for sheep/goats and as non-compliant samples are found in most years of the NRCPs.

- Non-dioxin-like polychlorinated biphenyls (NDL-PCBs) bioaccumulate, and there is a risk of exceeding of the MLs, but they were ranked in the category of medium potential concern, because they are less toxic than dioxins and DL-PCBs.

- The chemical elements cadmium, lead and mercury were allocated to the medium potential concern category taking into account the number of non-compliant results reported under the NRCPs and their toxicological profile.

- Residues originating from other substances listed in Council Directive 96/23/EC were ranked as of low or negligible potential owing 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 2005–2010, and/or to the natural occurrence in sheep and goats of some of these substances.

- The low potential concern category includes nitroimidazoles chlorpromazine, organochlorine pesticides, organophosphorus compounds, natural toxins, as well as and VMPs exceeding MRLs.

- In the negligible potential concern category are the prohibited substances colchicine, dapsone, chloroform and *Aristolochia* spp., the dyes, as well as VMPs occurring below MRLs.

- The CONTAM Panel emphasises that this ranking into specific categories of potential concern is based on the current knowledge regarding toxicological profiles, usage in sheep and goat production and occurrence as contaminants or chemical residues, as demonstrated by the data from the NRCPs for the 2005–2010 period.

RECOMMENDATIONS

- Future monitoring programmes should be based on the system for the ranking of chemical compounds into potential concern categories as presented in this document.

- Regular updating of the ranking of chemical compounds in sheep and goats 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 sheep and goat production, and actual occurrence of individual substances in sheep and goats.

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

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

- The current procedures for sampling and testing are a mature system, in general well established and coordinated including follow-up actions subsequent to the identification of non-compliant samples.

- The regular sampling and testing for chemical residues and contaminants in the system is an important disincentive to the development of undesirable practices.

- The prescriptive sampling system allows for equivalence in the control of EU-produced sheep and goat meat. Any forthcoming measures have to ensure that the control of imports from third countries remains equivalent to the controls within the domestic market.

- The current combination of animal traceability, *ante-mortem* inspection and gross tissue examination can support the collection of appropriate samples for residue monitoring.

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

- A weakness of the system is that presence of chemical hazards cannot be identified by current *ante-/post-mortem* meat inspection procedures at the slaughterhouse level, indicating the need for further harmonisation of the risk reduction strategies along the entire food chain.

- Integration between testing of feed materials for undesirable contaminants and the NRCPs in terms of communication and follow-up testing strategies or interventions is currently limited. Moreover, a routine environmental data flow is not established and keeping habits for sheep and goats provides opportunities for feed coming in without a clear feed chain history.

- Under the current system, sampling is mostly prescriptive rather than risk or information based. It appears that individual samples taken under the NRCP testing programme may not always be taken as targeted samples, as specified under Council Directive 96/23/ EC, but sometimes may be taken as random samples.

- There is a lack of sufficient cost-effective and reliable screening methods and/or the range of substances prescribed/covered by the testing is sometimes limited.

- There is limited flexibility to adopt emerging chemical substances into the NRCPs and limited ongoing adaptation of the sampling and testing programme to the results of the residue monitoring programmes. In addition, sampling under the NRCPs reflects only a part of testing done by a number of MS, the results of which should be taken into consideration.

- Sheep and goats may not be subject to surveillance over their lifetime at the same level as is the case for other food animal categories such as pigs, poultry and, to a large extent, bovine animals owing to their traditional nomadic/outdoor farming systems.

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

- Dioxins and DL-PCBs which accumulate in food-producing animals have been ranked as being of high potential concern. As these compounds have not yet been comprehensively covered by the sampling plans of the current meat inspection (NRCPs), they should be considered as 'new' hazards.

- In addition, for a number of chemical elements used as feed supplements and for organic contaminants that may accumulate in food-producing animals only limited data regarding residues in sheep and goats are available. This is the case, in particular, for brominated flame retardants, including polybrominated diphenylethers (PBDEs) and hexabromocyclododecanes (HBCDDs) and perfluorinated compounds (PFCs) including (but not limited to) PFOS and PFOA.

RECOMMENDATION

- Control programmes for residues and contaminants 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 TOR 1 or on data obtained using harmonised epidemiological criteria. When appropriate, food chain information should be taken into account

CONCLUSIONS

- Sheep and goat production in the EU is marked by being largely extensive in nature, involving frequent trading of animals and nomadic flocks. This involves differences in husbandry systems and feeding regimes resulting in different risks for chemical substances and contaminants. Extensive periods on pasture or/as nomadic flocks and the use of slaughter collection dealerships may preclude detailed lifetime FCI. Similarly, in these situations, the level of feedback from the slaughterhouse and authorities to farmers regarding the results of residue testing may be suboptimal. There is less concern about FCI from dairy sheep and goats as they are reared under more intensive and controlled conditions.

- 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 environmental monitoring.

RECOMMENDATIONS

- FCI should be expanded for sheep and goats produced in extensive systems to provide more information on the specific environmental conditions where the animals are produced. It is recommended that sampling of sheep and goats should be based on the risk of occurrence of chemical residues and contaminants and on the completeness and quality of the FCI supplied.

- There is a need for an improved integration of sampling, testing and intervention protocols for domestic sheep and goats across the food chain, NRCPs, feed control and environmental monitoring.

- The development of analytical techniques covering multiple analytes and of new biologically based testing approaches should be encouraged and incorporated into feed quality control and chemical residue/contaminants testing in the NRCPs.

- The combination of data from both sheep and goats into one data set assumes that both food chains are identical, which is not the case. A separation of test records for both species is recommended.

- For prohibited substances, testing should be directed where appropriate towards the farm level. Future NRCP testing relating to substances that might be used illicitly for growth promoting purposes needs to be refocused to better identify the extent of abuse in the EU. In addition, control measures for prohibited substances should not rely exclusively on NRCP testing, but should include veterinary inspection during the production phase and the use of biological methods and biomarkers suitable for the identification of abuse of such substances in sheep and goat production in the EU.

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ANNEXES

Annex 1. 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 veterinary drugs and contaminants (Group B substances). For Group A substances, liquid or gas chromatographic separation with mass spectrometry (MS) or infra red (IR) 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 liquid or gas chromatographic separation with MS or IR spectrometric detection, suitable confirmatory techniques for Group B substances may include liquid chromatography (LC) with diode-array or fluorescence detection for appropriate molecules, two-dimensional thin layer chromatography (2-D TLC) with full-scan ultraviolet visible (UV/VIS) detection, and GC-ECD (electron capture detector), 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, 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 and trueness/recovery.

The analytical requirements for the determination of dioxins, DL-PCBs and NDL-PCBs are laid down in Commission Regulation (EC) No 252/2012.[50] Following a criteria approach analyses can be performed with any appropriate method, provided the analytical performance criteria are fulfilled. While methods, such as GC-MS and 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 ELISA, 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

[50] 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, DL-PCBs and NDL-PCBs in certain foodstuffs and repealing Regulation (EC) No 1883/2006. OJ L 84, 23.3.2013, pp. 1–22.

extract is tested for inhibition of bacterial growth. If, after a specific period of incubation, the sample 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 that 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 maximum residue limit 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 are examples of these advances. Such combinations 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 utilised to study the $^{13}C/^{12}C$ ratio of substances in urine samples, where, for example, such $^{13}C/^{12}C$ ratio differs significantly between endogenous (or natural) testosterone and exogenous (or synthetic) testosterone.

ABBREVIATIONS

ADI	Acceptable daily intake
BIOHAZ Panel	EFSA Panel on Biological Hazards
$BMDL_{10}$	Benchmark dose lower confidence limit for a benchmark response of 10 %
b.w.	Body weight
CONTAM Panel	EFSA Panel on Contaminants in the Food Chain
CVMP	Committee for Medicinal Products for Veterinary Use
DDT	Dichlorodiphenyltrichloroethane
DL-PCB	Dioxin-like PCB
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
HBCDD	Hexabromocyclododecanes
HCH	Hexachlorocyclohexanes
IARC	International Agency for Research in Cancer
ML	Maximum level
MOE	Margin of exposure
MRL	Maximum residue limit
MRPL	Minimum Required Performance Limit
MS	Member State
NC	Non-compliant
NDL-PCB	Non-dioxin-like PCB
NRCP	National residue control plan
NSAID	Non-steroidal anti-inflammatory drug
PBDE	Polybrominated diphenyl ether
PCB	Polychlorinated biphenyl
PCDD	Polychlorinated dibenzo-*p*-dioxin
PCDF	Polychlorinated dibenzofuran
PFC	Perfluorinated compound
PFOA	Perfluorooctanoic acid
PFOS	Perfluorooctane sulphonate
PSM	Plant secondary metabolites
RAL	Resorcylic acid lactone
SCF	Scientific Committee on Food

SCVPH	Scientific Committee on Veterinary measures relating to Public Health
SEM	Semicarbazide
T3	Triiodothyronine
T4	Thyroxine
TEQ	Toxic equivalent
TSE	Transmissible spongiform encephalopathy
TWI	Tolerable weekly intake
VMP	Veterinary medicinal product
WHO	World Health Organization

Appendix C. Assessment on animal health and welfare

SUMMARY

Meat inspection, comprising both *ante-mortem* and *post-mortem* inspection, is recognised as a valuable tool for surveillance and monitoring of animal diseases and welfare conditions, and helps in the recognition of outbreaks of existing or new disorders or disease syndromes, in situations where clinical signs are not detected on-farm. Meat inspection represents a practical way to evaluate the welfare of small ruminants on-farm, and the only way to evaluate their welfare during transport and associated handling. Changes in the meat inspection system may negatively affect the efficiency of the surveillance and monitoring of animal diseases and welfare conditions. The focus of the Animal Health and Welfare (AHAW) Panel was to assess the implications for surveillance of animal health and welfare of the changes proposed to the current small ruminants meat inspection system by the Biological Hazards (BIOHAZ) and Contaminants in the Food Chain (CONTAM) Panels. Briefly, the recommendations of the BIOHAZ Panel were related to (i) shorter transport and lairaging, (ii) improved collection of food chain information to provide information for categorisation of farms, which can be used for e.g. risk-based *ante-mortem* inspection, logistic slaughter and/or decontamination, (iii) omission of palpation and incision in animals subjected to routine slaughter at *post-mortem* inspection (if necessary, detailed inspection with potential use of palpation and incision should be carried out separately). The CONTAM Panel recommendations included (i) the ranking system for chemical substances of potential concern and its updating, (ii) the use of FCI to help facilitate risk-based sampling strategies, and (iii) the inclusion of new hazards in control programmes for chemical residues and contaminants.

To assess the impact of proposed changes to the current meat inspection on the overall sensitivity for surveillance and control of animal diseases and welfare conditions, the results and conclusions of a quantitative assessment, carried out by an external consortium (COMISURV) under an EFSA procurement, were analysed. This report assessed the impact of a change from the current small ruminant meat inspection to a visual only system in terms of detection efficiency of a list of twenty selected diseases and welfare conditions of sheep and goats. Additional information from scientific literature and other recent assessments were also taken into account by experts to assess the impact of proposed changes on the detection probability and overall surveillance of animal diseases and welfare conditions.

A change to visual only inspection caused a significant reduction in the probability of detection (i.e. non-overlapping 90 % probability intervals) of detectable cases of fasciolosis and tuberculosis in goats (Stage 2).

With regard to exotic diseases, clinical surveillance (Stage 3) had a greater sensitivity for detecting foot and mouth disease than slaughterhouse surveillance, and the sensitivity increased with an increase in population size. This indicates that for those countries in Europe with a large sheep population, clinical surveillance is highly effective for detecting at least one case of foot and mouth disease in an infected sheep. For countries with high slaughter numbers of sheep, slaughterhouse surveillance would be almost equally efficient in detecting the disease. A change in *post-mortem* protocol to a visual only system did not significantly reduce the detection of any welfare conditions.

In recent years tuberculosis has been reported in small ruminants in several EU countries and most information derives from recognition of tuberculosus lesions at the slaughterhouse and from laboratory reports. According to Regulation (EC) 854/2004, current inspection in small ruminants aimed at detecting tuberculosis includes visual inspection and palpation of the lungs and respiratory lymph nodes. A change to visual inspection would imply abandoning palpation, which is the reason for this reduced detection. Surveillance of tuberculosis at the slaughterhouse for small ruminants should be improved and encouraged, as this is in practice the only surveillance system available. The detection of tuberculosis in small ruminants should be adequately recorded and followed at the farm level.

Liver examination at slaughter is the most direct, reliable, and cost-effective technique for the diagnosis of fasciolosis. Moving to a visual only meat inspection system would decrease the sensitivity of inspection of fasciolosis at the animal level; however, it would be sensitive enough to identify most if not all affected herds. Therefore the consequences of the change would be of low relevance. The feedback to farmers of *Fasciola hepatica* detected at meat inspection should be improved, to allow farmer information to support rational on-farm fluke management programmes.

Quantitative analysis indicated that the proposed changes to the meat inspection system would not affect detection of welfare conditions; however, for leg and foot disorders and sheep scab a combination of the two surveillance components (clinical surveillance and meat inspection) were found to be more effective than either one of the surveillance component on its own. Qualitative analysis suggested that the proposal for shortened transport and lairage time would be beneficial to improving the welfare of small ruminants.

Food chain information should include animal welfare status in order to complement the slaughterhouse surveillance systems (*ante-mortem* and *post-mortem* inspection) and the latter could be used to identify on-farm welfare status.

Other recommendations on biological and chemical hazards would not have a negative impact on surveillance of animal diseases and welfare conditions.

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1. Introduction

In this mandate, the AHAW Panel and the *ad hoc* working group (WG) are focusing 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 (CONTAM) Panels. "Implications for animal health and welfare" relates specifically to monitoring and surveillance of animal diseases and welfare conditions 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 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 in the 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. Further, MI offers the only opportunity 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 also play a role in surveillance and monitoring of the welfare of farmed animals, and, moreover, it is the only place to assess poor welfare during the transport of animals to the slaughterhouse.

Small ruminants are subjected to different periods of feed and water restriction, handling and transport prior to arrival at the slaughterhouse. AMI begins with the observation of animals at the time of unloading from the transport vehicle and the purpose is to determine whether animal welfare has been compromised in any way on the farm and during handling and transport. Welfare conditions such as fitness to travel, prevalence of injury, lameness and exhaustion, and the cleanliness of the animals are ascertained during AMI. Certain other welfare conditions such as bruising may not always be detectable during AMI, but become visible during routine PMI. Welfare conditions related to foot and leg disorders would be detectable only if the animals are observed during walking, e.g. unloading or moving to lairage pens, and are also less likely to be detected by visual examination during PMI. When MI detects apparent defects or abnormalities, incision of the relevant joints, tendons and/or muscles could be necessary to determine the presence as well as the severity of foot and leg disorders.

2. Implications for surveillance and monitoring for small ruminant health and welfare of changes to meat inspection as proposed by the BIOHAZ Panel

2.1. The proposed BIOHAZ Panel changes

The proposed modifications to the MI system that may have implications for animal health and welfare (see BIOHAZ Appendix A for full details), include:

- Shorter transport and lairaging, which may be beneficial in terms of reducing cross-contamination of pathogens *Salmonella* spp. and human pathogenic *Escherichia coli* (see BIOHAZ Appendix A, Section 5.2).

- The changes to address prioritised hazards not currently detected by MI will focus on improved collection and use of relevant food chain information (FCI), including the use of harmonised epidemiological indicators, to provide information for categorisation of farms, which can be used for, for example, risk-based AMI, logistic slaughter and/or decontamination (see BIOHAZ Appendix A, Sections 4 and 5.1).

- Omission of palpation and incision in animals subjected to routine slaughter at PMI. If abnormalities are detected during visual inspection, palpation and incision should be carried

out separately from the routine inspection of carcasses to prevent cross-contamination) (see BIOHAZ Appendix A, Section 5.3).

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.

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 small ruminants MI (Hardstaff 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.
- 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 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 small ruminant 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. A total of twenty conditions (eleven diseases and nine welfare conditions) 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 small ruminants was developed. A definition of a typical and a mild case for each of the diseases and welfare conditions listed in Table 1 was provided by the COMISURV experts.

Typical cases were by definition detectable cases and express more developed clinical signs than mild cases. Typical cases were defined as the clinical signs and/or lesions that are expected to be observed in more than 60 % of affected or infected small ruminants arriving at slaughter.

The mild case of a disease or welfare condition is the form that could 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 echinococcosis would show hydatid cysts in the liver and in the lungs, and a mild case would have a low number of small cysts in liver and lungs.

The proportion of affected animals presenting as typical or mild cases, as well as the non-detectable fraction was estimated (see COMISURV report for details).

The most likely detection probability, as well as 5th and 95th percentiles (the probability intervals) of the output distribution of AMI, PMI, and AMI and PMI combined were derived for each of the conditions in Table 1, both prior to and following suggested changes to the MI system as proposed by the BIOHAZ Panel. The inspection protocols in the current and visual only systems are compared in Table 2.

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).

Table 1: List of diseases and welfare conditions in small ruminants identified by the AHAW WG for consideration in the assessment conducted by COMISURV.

Disease or welfare condition		**Stage 2[a]**	**Stage 3[b]**
Exotic	Bluetongue (BT)	X	
	Foot and mouth disease (FMD)	X	X
	Rift Valley fever (RVF)	X	
Endemic	Tuberculosis (TB) in goats	X	
	Caseous lymphadenitis	X	
	Echinococcosis/hydatidosis	X	
	Fasciolosis	X	X
	Lower respiratory tract infection	X	X
	Lungworm	X	
	Orf	X	
	Pulmonary adenomatosis/Maedi–Visna	X	
Welfare	Diarrhoea/soiling	X	
	Partial vaginal prolapse/hernia	X	
	Arthritis	X	
	Bruising	X	
	Broken bones	X	
	Leg and foot disorders including foot rot	X	X
	Poor body condition	X	
	Sheep scab	X	X

Mastitis	X	

a Stage 2—all diseases and welfare conditions listed were evaluated with regards to their probability of being detected at MI.
b Stage 3—for selected diseases and welfare conditions, surveillance by MI was to be compared with clinical surveillance.

As inspection tasks aimed to detect Orf do not change in a visual-only system, Orf was not further discussed.

Table 2: Inspection requirements for small ruminants according to Regulation (EC) No 854/2004 (V, visual inspection; P, palpation; I, incision). Grey boxes indicate inspection points where the visual-only scenario implies a change to current procedures.

Inspection step		Inspection procedure	
		Current	**Visual only**
***Post-mortem* inspection**			
Whole carcass	External surface	V	V
Head[a]	Head	V[a]	V[a]
	Tongue	V[e]	V[e]
	Mouth	V[e]	V[e]
	Throat	V[e]	V[e]
	Retropharyngeal and parotid lymph nodes	V[e]	V[e]
Lungs	Lungs	V + P + I[d]	V
	Trachea	V + I[d]	V
	Bronchial and mediastinal lymph nodes	V + P + I[d]	V
Oesophagus		V + I[d]	V
Heart	Heart	V + I[d]	V
	Pericardium	V	V
Diaphragm		V	V
Liver	Liver	V + P + I	V
	Hepatic and pancreatic lymph nodes	V + P	V
Gastrointestinal tract	Gastrointestinal tract	V	V
	Mesentery	V	V
	Gastric and mesenteric lymph nodes	V	V
Spleen		V + P[c]	V
Kidneys	Kidneys	V + I[b]	V
	Renal lymph nodes	V + I[b]	V
Mammary glands	Udder	V	V
	Supra-mammary lymph nodes	V	V
Genital organs		V	V
Pleura		V	V
Peritoneum		V	V
Umbilical region		V + P + I[d]	V
Joints (young)		V + P + I[d]	V
Synovial fluid		V	V

a Not required if not intended for human consumption.
b Incision if necessary.
c Palpation if necessary.
d Incision if in doubt.
e Examine if in doubt.

In addition, for three of the selected diseases and two welfare conditions, considered to be more adversely affected in terms of probability of detection following the proposed changes to the MI system, further modelling 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 MI system (referred to as Stage 3 in the COMISURV report). The objective for exotic diseases (i.e. foot and mouth disease (FMD), was to evaluate the probability of detecting at least one

infected case of infected small ruminants by slaughterhouse inspection relative to other surveillance system components (component sensitivity), which for the purpose of this opinion was clinical surveillance.

For endemic diseases (fasciolosis, lower respiratory tract infection) and welfare conditions (leg and feet disorders including foot rot, sheep scab) the objective was to calculate the case-finding capacity i.e. the proportion of infected or affected animals detected by the surveillance components (detection fraction) during both slaughterhouse and clinical surveillance.

Note that the word surveillance as used in this opinion does not imply that any action is taken to capture, or act upon, the information that is collected. It merely points to the potential of these systems to be used for such purposes.

2.2.2. Results and discussion

The detection probability for each disease and condition using the current MI system and the visual only system is shown in Table 3 (detectable cases) and Table A of Annex 1 (all cases, including subclinical cases not detectable at slaughterhouse).

A change to visual only inspection caused a significant reduction in the probability of detection (i.e. non-overlapping 90 % probability intervals, Stage 2) during MI of detectable cases of fasciolosis (with a 28 % reduction in detection probability) and tuberculosis (TB) in goats (24 %) (Table 3). When all cases were considered (see Annex 1, Table A), the change to a visual only PMI protocol resulted in a clear reduction in the detection probability of three diseases, TB in goats (with a 30 % reduction in detection fraction), fasciolosis (28 %) and pulmonary adenomatosis/Maedi–Visna (15 %)), although none of these reductions was significant when the overlap of probability intervals was considered.

Values for the probability of detection at AMI and for the two proposed PMI scenarios for all cases (detectable and non-detectable cases combined) were also determined for welfare conditions (Table 3 and Annex 1, Table A, respectively). The probability of detection was significantly higher for AMI than PMI for broken bones, diarrhoea, leg and foot disorders, partial prolapses/hernias and sheep scab. A change in PMI protocol to a visual only system did not significantly reduce the detection of any welfare conditions. PMI had a significantly higher probability of detection than AMI for mastitis.

Combined slaughterhouse probabilities of detection were higher for detecting cases of many welfare conditions than when the slaughterhouse inspection components were considered separately (Table 3 and Annex 1, Table A). Where this was not the case, i.e. the detection probability of the combined MI process yielded equal values as either AMI or PMI on its own. This was due to the fact that the experts had agreed that the respective welfare condition could not be detected at all with the one of the two MI steps. Therefore the results of the combined MI are solely based on the results of either AMI or PMI.

For three welfare conditions (arthritis, broken bones and poor body condition), the PMI of detectable cases with visual only protocol also reduced the detection probability, although this was not significant.

When considering all cases (Annex 1, Table A), the probability of detection for the combined inspection was lower than for detectable cases. The change in PMI protocols led to a slight reduction in the detection probability of two welfare conditions (arthritis and poor body condition), yet none of these reductions were significant when the overlap of probability intervals was considered.

Table 3: The probability of detection for **all detectable cases** of diseases and welfare conditions at AMI, PMI (two proposed scenarios—current and visual) inspection scenarios with the most likely (ML), 5th and 95th percentiles.

Disease or welfare condition		AMI			PMI						Combined AMI and PMI					
					Current			Visual			Current			Visual		
		0.05	ML	0.95	0.05	ML	0.95	0.05	ML	0.95	0.05	ML	0.95	0.05	ML	0.95
Exotic	BT	0.27	0.42	0.63	0.11	0.16	0.25	0.07	0.11	0.16	0.46	0.64	0.77	0.39	0.57	0.72
	FMD	0.09	0.15	0.31	0.00	0.02	0.05	0.00	0.00	0.00	0.10	0.19	0.34	0.09	0.15	0.31
	RVF	0.36	0.48	0.59	0.23	0.32	0.42	0.23	0.32	0.42	0.71	0.82	0.86	0.71	0.82	0.86
Endemic	TB in goats	0.16	0.22	0.31	0.50	0.59	0.69	0.33	0.40	0.50	0.74	0.84	0.90	0.55	0.64	0.72
	Caseous lymphadenitis	0.07	0.14	0.23	0.56	0.63	0.77	0.49	0.59	0.68	0.69	0.83	0.89	0.62	0.76	0.81
	Echinococcosis	0.00	0.00	0.00	0.82	0.89	0.93	0.71	0.79	0.86	0.82	0.89	0.93	0.71	0.79	0.86
	Fasciolosis	0.02	0.03	0.07	0.89	0.92	0.95	0.63	0.66	0.69	0.94	0.96	0.98	0.67	0.69	0.74
	Lower respiratory tract infection	0.33	0.46	0.55	0.41	0.50	0.61	0.41	0.50	0.61	0.91	0.95	0.98	0.91	0.95	0.98
	Lungworm	0.19	0.25	0.30	0.44	0.50	0.56	0.44	0.51	0.56	0.69	0.75	0.80	0.69	0.73	0.80
	Orf disease	0.51	0.59	0.72	0.09	0.13	0.17	0.00	0.00	0.00	0.67	0.76	0.82	0.51	0.59	0.72
	Pulmonary adenomatosis/ Maedi–Visna	0.42	0.56	0.67	0.21	0.32	0.39	0.18	0.24	0.35	0.76	0.86	0.92	0.72	0.81	0.87
Welfare conditions	Arthritis	0.32	0.43	0.52	0.19	0.26	0.36	0.14	0.20	0.26	0.59	0.71	0.78	0.53	0.65	0.70
	Broken bones	0.76	0.95	0.98	0.49	0.65	0.65	0.27	0.50	0.49	0.90	0.98	0.99	0.86	0.97	0.99
	Bruising	0.04	0.09	0.16	0.80	0.87	0.92	0.80	0.87	0.92	0.92	0.96	0.99	0.92	0.96	0.99
	Diarrhoea or soiling	0.58	0.66	0.72	0.07	0.10	0.14	0.06	0.09	0.13	0.70	0.77	0.81	0.69	0.77	0.80
	Leg and foot disorders	0.34	0.45	0.54	0.11	0.14	0.17	0.11	0.14	0.17	0.49	0.59	0.66	0.49	0.59	0.66
	Mastitis	0.09	0.15	0.25	0.42	0.53	0.63	0.42	0.53	0.63	0.56	0.69	0.79	0.56	0.69	0.79
	Partial vaginal prolapse/hernia	0.43	0.51	0.62	0.01	0.02	0.06	0.01	0.02	0.06	0.45	0.56	0.65	0.45	0.56	0.65
	Poor body condition	0.39	0.49	0.57	0.30	0.35	0.42	0.29	0.34	0.40	0.81	0.84	0.87	0.79	0.82	0.85
	Sheep scab	0.49	0.62	0.71	0.00	0.01	0.01	0.00	0.00	0.01	0.50	0.63	0.71	0.50	0.63	0.71

Shaded rows indicate diseases identified as having a significant reduction in detection probability in the visual-only scenario.

For the two welfare conditions (leg and foot disorders and sheep scab) included in the overall surveillance analysis (Stage 3), a combination of the two surveillance components (clinical surveillance and MI) was found to be more effective (detecting a higher fraction of affected animals) than either one of the surveillance component on its own. However, the change in PMI protocol did not greatly affect the detection fraction of these welfare conditions (Table 4).

Table 4: The detection fractions for clinical surveillance and combined slaughterhouse and clinical surveillance for endemic diseases: fasciolosis and lower respiratory tract infection and welfare conditions: leg and foot disorders and sheep scab.

	Disease or welfare condition	Clinical surveillance only			Combined slaughterhouse and clinical surveillance					
					Current			Visual only		
		5 %	ML	95 %	5 %	ML	95 %	5 %	ML	95 %
Endemic	**Fasciolosis**	0.072	**0.094**	0.127	0.356	**0.451**	0.510	0.356	**0.450**	0.510
Endemic	**Lower respiratory diseases**	0.037	**0.048**	0.065	0.182	**0.225**	0.253	0.169	**0.194**	0.236
Welfare	**Leg and foot disorders**	0.064	**0.081**	0.101	0.153	**0.193**	0.223	0.153	**0.186**	0.223
Welfare	**Sheep scab**	0.157	**0.237**	0.300	0.211	**0.312**	0.377	0.210	**0.298**	0.376

ML –Most likely values

With regard to epizootic diseases, clinical surveillance (detection of clinical signs) had a greater sensitivity for detecting FMD than slaughterhouse surveillance, and the sensitivity increased with an increase in population size (Table 5, Stage 3). A change to a visual only system would not have a negative impact on sensitivity of detection.

Table 5: The slaughterhouse and clinical surveillance sensitivities for FMD, by different population sizes.

Population size (*n*)	Clinical surveillance			Slaughterhouse inspection					
				Current			Visual only		
	5 %	ML	95 %	5 %	ML	95 %	5 %	ML	95 %
100 000	0.320	**0.613**	0.801	0.006	**0.016**	0.043	0.006	**0.016**	0.043
1 000 000	0.979	**1.000**	1.000	0.059	**0.181**	0.358	0.059	**0.157**	0.358
10 000 000	1.000	**1.000**	1.000	0.457	**0.961**	0.988	0.446	**0.983**	0.989

ML –Most likely values

2.3. Qualitative assessment of the role of meat inspection in surveillance programmes on selected diseases and welfare conditions

A qualitative assessment was conducted, based on a literature review and expert opinion from the WG members, for the diseases identified as having a significant reduction in detection probability of detectable cases in the quantitative assessment of the COMISURV report (TB in goats and fasciolosis) and welfare conditions.

2.3.1. Tuberculosis in domestic small ruminants

2.3.1.1. Description of the disease and prevalence and relevance in EU

As in bovines, tuberculosis in small ruminants is a chronic infection, caused by *Mycobacterium bovis* and *Mycobacterium caprae*[51] (Aranaz et al., 2003, Crawshaw et al., 2008), and has also zoonotic implications. The pathological and histological findings in sheep and goats are similar to those seen in cattle (Marianelli et al., 2010). In the EU, TB in small ruminants has been considered a rare disease for many years, limited to some Mediterranean countries, and mainly to goats (Gutiérrez et al., 1995). However, in recent years, TB has been reported in both goats and sheep in several EU countries, such as Portugal (Quintas et al., 2010), Spain (Gutiérrez et al., 1995, Liébana et al., 1998; Alvarez et al., 2008, Mendoza et al., 2012), Ireland (Sharpe et al., 2010; Shanahan et al., 2011) and the United Kingdom (Daniel et al., 2009; van der Burgt et al., 2010). These reports highlight the possible role of domestic goats and sheep as reservoirs of TB, and the need to re-evaluate the evidence for *M. bovis* (and *M. caprae*) transmission among cattle and small ruminants. At least in goats, TB may also cause production losses due to clinical signs of respiratory disease, cough, anorexia, fall in milk production and weight loss, as described by Bernabé et al. (1991) and Crawshaw et al. (2008).

Crawshaw et al. (2008) and Quintas et al. (2010) described the main pathological lesions in goats in the lungs in the form of abscesses (2–10 cm in size) with yellowish white, caseous or caseocalcareous lesions. Lesions are also seen in the retropharyngeal, mediastinal or mesenteric lymph nodes and in liver, spleen and udder. Lesions is sheep are very similar to those in goats, ranging from encapsulated, mineralised foci to extensive, soft, caseous tissue in the thoracic and abdominal cavities. Submandibular, mesenteric and mediastinal lymph nodes are enlarged and contain caseous, gritty nodules. Soft, caseous lesions and encapsulated, calcified tubercles are also present in the lungs and liver (Marianelli et al., 2010).

There are no prevalence data about TB in small ruminants in the EU, and most information derives from recognition of tuberculosus lesions at the slaughterhouse and from laboratory reports. The database for animal tuberculosis within the context of the Spanish national programme for eradication of bovine tuberculosis included 1 078 isolates from domestic goats (Rodriguez-Campos et al., 2012) from 1996 until 2011 in the national territory, with goats being the second species after cattle in the number of isolates, and before wild boar (n = 618) and red deer (n = 282).

2.3.1.2. Surveillance system currently in place

Surveillance for small ruminant TB at present relies on MI of sheep and goats slaughtered for human consumption, diagnostic surveillance of carcases submitted to veterinary pathology laboratories, and attending private veterinary surgeons reporting any suspect clinical cases or fatalities (Daniel et al., 2009). In general, small ruminants are not subjected to official TB eradication campaigns; however, sheep and goats may undergo a bovine tuberculin skin test for detecting TB infection if located on premises where bTB has been confirmed in cattle (subject to findings of a veterinary risk assessment), or if *M. bovis* infection has been confirmed in the sheep/goat flock/herd itself. If goats are kept together with cows, such goats must be inspected and tested for TB. Furthermore, given that milk has, over time, been the most significant human zoonotic source of *M. bovis*, Regulation (EC) 853/2004[52] requires that raw milk produced from goats and sheep comes from herds/flocks subjected to a TB control plan, approved by the national competent authority. MI in these herds/flock acts as an extra control in the herd/flock control programmes.

At present, MI of sheep/goats is defined by Regulation (EC) 854/2004. It involves a visual inspection of the lungs, trachea and oesophagus, with palpation of the lungs and the bronchial and mediastinal lymph nodes. In the event of doubt, these organs and lymph nodes must be incised and examined.

[51] Both *M. bovis* and *M. caprae* cause tuberculosis in bovines and other species, including humans. Further in the text, only *M. bovis* is mentioned, but any reference to *M. bovis*, unless the contrary is specified, also includes *M. caprae*.

[52] 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, pp. 55–205.

Therefore routine inspection, unlike inspection for bTB in the bovine, does not differ substantially from the visual only MI being proposed. Information regarding the presence of TB is not specifically recorded at PMI.

2.3.1.3. Sensitivity

The COMISURV report relating to the contribution of meat inspection to animal health surveillance in sheep and goats investigated the probability of detection of specific diseases and welfare conditions for three scenarios: one for inspection tasks as currently required by the legislation; one with visual inspection only; and one in which risk categorisation based on a hypothetical public health risk formed the basis for subsequent inspections. According to the COMISURV report, the most likely values for the proportion of non-detectable, mild and typical cases elicited by experts for TB in goats were 0.35, 0.45 and 0.20, respectively. The PMI had a significantly higher probability of detection of TB in goats than AMI for detectable cases and all cases, and the reduction in the probability of detection of TB in goats was significant for visual only PMI. The probability of detection (most likely values) of TB in goats (Table 3 for detectable cases and Annex 1, Table A for all cases) for combined AMI and PMI was 0.84 (0.47 for all cases) changing to 0.64 (0.40 for all cases) for visual only, which represents a 24 % reduction.

As is the case with bTB in bovines, the contribution of MI surveillance of TB in small ruminants is to support the detection of flocks/herds with TB, and the detection of individual animals with TB is merely the first step in improving herd surveillance. Since more than one sheep or goat per flock/herd is likely to be slaughtered per time period (e.g. per year), the flock/herd probability of detection is a function of the individual animal sensitivity, the number of animals slaughtered from the herd and the within-herd prevalence of TB. For any given flock/herd, the flock/herd sensitivity will increase with the number of animals slaughtered. Officially Tuberculosis Free (OTF) status, however, is not available for small ruminants as it is for bovine herds, so the herd status is important in controlling TB in small ruminants, but not in substantiating freedom from TB.

2.3.1.4. Impact of proposed changes on surveillance and control

For TB in goats, the results from the COMISURV report suggest that a change from the current inspection to visual only will reduce the probability of detection for detectable cases.

A qualitative risk and benefit assessment for visual only PMI of cattle, sheep, goats and farmed/wild deer, commissioned by the UK Food Standards Agency (FSA) (FSA, 2013a), considered the absolute and relative animal health risk of TB in small ruminants as negligible when moving to a visual only PMI system when compared with the current legal requirements of inspection for sheep and goats (Regulation (EC) 854/2004).

The main reason to reach this conclusion is that the current legal PMI requirements for small ruminants are mainly visual and do not require the incision of the lungs. Incision of lymph nodes are required if in doubt after the initial visual inspection. Considering that the majority of positive submissions to government labs in the United Kingdom are associated with lesions in the mediastinal and bronchial lymph nodes, it is likely that the most frequent TB-like lesions in small ruminants (as described above) are not detected under the current traditional PMI requirements, which are initially visual, and therefore nor would be by visual only inspection. This lack of sensitivity is aggravated by the current commercial speed of slaughtering lines and the limited time available to carry out the inspection of carcases and offal.

In the United Kingdom, TB in non-bovine farmed animals is rare. Small ruminants are not considered to represent a significant reservoir of the disease for other animals or to be of any significance in the persistence of bTB in cattle. Although small ruminants are considered as spillover hosts, it is still possible that severely infected sheep and goats could act as vectors of infection for other domestic and wild animals. In these circumstances, on-farm identification of possible sick small ruminants by

farmers and a differential diagnosis from other respiratory disease and necropsy examination of lungs and relevant lymph nodes by farm veterinarians are the most effective control activities.

2.3.2. Fasciolosis

2.3.2.1. Description of the disease and prevalence and relevance in EU

Fasciolosis (liver fluke) in small ruminants has a world wide distribution and is caused by the trematode parasite, *Fasciola hepatica*. The direct losses due to fasciolosis are mortality, liver condemnation and reduced growth rate. Disease results from the migration of large numbers of immature flukes through the liver, from the presence of adult flukes in the bile ducts, or both. Liver fluke can infect all grazing animals, but is most pathogenic in sheep (Armour, 1991). The incidence of liver fluke is inextricably linked to high rainfall and is particularly prevalent in years when summer rainfall is high, which facilitates the survival and proliferation of the snail intermediate host and infective parasite stages present in the environment (Ollerenshaw, 1959). Changes in recent epidemiological patterns, due to climate change, have resulted with increasing prevalence in northern European countries and the survival of fluke on pasture over winter, exposing sheep to infection for long periods (Daniel and Mitchell, 2002). There have been increasing reports of liver fluke disease over the last decade in countries such as the United Kingdom and Ireland, most likely due to higher than average rainfall and temperatures through the seasons, and greater stock movements (Taylor, 2012). In southern European regions, for example in Spain, the infection of snails could occur throughout the year, with a higher infection rate at the end of summer–autumn and at the end of the winter, and sheep eliminating eggs throughout the year (Manga et al., 1990). Prevalence studies in the north-west of Spain have indicated a liver fluke infection rate of approximately 56 % of sheep flocks (Ferre et al., 1995).

2.3.2.2. Surveillance system currently in place

Regulation (EC) 854/2004 requires that domestic sheep and goats going for human consumption must have visual inspection of the liver and the hepatic lymph nodes, palpation of the liver and its lymph nodes, and incision of the gastric surface of the liver to examine the bile ducts.

Liver examination at slaughter is the most direct, reliable, and cost-effective technique for diagnosis of fasciolosis (Urquhart et al., 1996). Reliance upon clinical signs to diagnose fasciolosis may result in low detection rates (Rojo-Vázquez et al., 2012). MI is a convenient means of confirming a suspected herd or flock infestation, assessing the extent of infestation or determining the effectiveness of anthelmintic treatment (Kissling and Petrey, 1989). PMI can confirm acute and sub-acute liver damage with liver enlargement, caused by the presence of immature flukes. Animals suffering from chronic fasciolosis show a deterioration of the carcass, cholangitis, biliar occlusion and hepatic fibrosis with adult fluke present in bile ducts. Besides the liver, other organs and structures can be found damaged, such as periportal and mesenteric lymph nodes that are enlarged and exhibit a brownish colour (Rojo-Vázquez et al., 2012). McKenzie's study (1987) compared the New Zealand inspection procedure (observation and palpation of livers) with the European Community procedure (observation and incision through the gastric surface of liver to examine the bile ducts) and found that the New Zealand method detected fewer truly infected livers, but misdiagnosis by inspectors gave more false-positives. The gastric surface incision procedure has a specificity of 100 % and sensitivity of 93.08 % to 99.42 % (Kissling and Petrey, 1989). This underlines their importance in animal disease surveillance and the importance of the present MI technique in liver fluke surveillance.

2.3.2.3. Impact of proposed changes on surveillance and control

Effective disease monitoring systems are essential to the provision of reliable information on diseases to producers, thereby protecting a nation's agricultural system and its potential for production (Glosser, 1988). Information on fluke infestation at herd level allows farmers to develop and implement control programmes that can attempt to reduce risk factors and recommend the use of drugs in a more strategic fashion (Fairweather, 2011). Edwards et al., (1999) demonstrated that one-third of

farmers would improve their animal husbandry if informed of the MI findings for their lambs. The COMISURV report on the contribution of MI to animal health surveillance determined that there would be a significant difference in detection rates between the current and the visual only MI techniques (a probability of 0.96 of all detectable cases by current method compared with 0.69 by the visual only method). A reduction in liver fluke surveillance by the use of a less sensitive MI procedure will reduce the quality of information available for producers and thereby directly impact animal health and welfare.

2.3.3. Welfare conditions

The quantitative analysis (see COMISURV report) of detection levels for welfare conditions indicated that none of them will be significantly affected by the proposed changes to MI. However, the results also revealed that when both AMI and PMI were considered, the probability of detection was high for most welfare conditions. It was also evident that detection of two welfare conditions, i.e. leg and foot disorders (including foot rot) and sheep scab, would be more effective when a combination of clinical and slaughterhouse surveillance systems are used.

Leg and foot disorders in sheep are caused by either infectious conditions, i.e. interdigital dermatitis (also known as scald), foot rot, contagious ovine digital dermatitis, or non-infectious conditions such as white line disease (shelly hoof), granulomas, foot abscesses, interdigital fibromas, and foreign bodies such as thorns, wire or soil balls (Kaler and Green, 2008; Conington, et al., 2010a, 2010b; FAWC, 2011). Overgrown and misshapen hooves are also attributed to lameness in sheep and erysipelas can cause outbreaks of lameness in lambs. The importance of routine feet examination in sheep health management is well documented (Hodgkinson, 2010).

The Farm Animal Welfare Council (FAWC) suggested that there is adequate legal protection for sheep suffering from lameness as the European transport regulation EC/1/2005[53] prohibits the transport of unfit animals, and specifically includes those that are "injured or present physiological weaknesses or pathological processes" and, in particular, are "unable to move independently without pain or to walk unassisted". The FAWC also recommended that the surveillance of lameness in sheep should be undertaken by the UK government, in conjunction with farm assurance schemes, to determine trends in lameness over time, which would also apply to other MSs where the prevalence of lameness is high (e.g. more than 2 % of flocks being affected at national level).

Lameness in dairy goats is also a common welfare problem and abnormalities detected in the United Kingdom were horn separation, white line lesions, slippering, abscess of the sole, foreign bodies and granulomatous lesions (Hill et al., 1997). Interdigital dermatitis has also been reported to be the cause of lameness in goats kept indoors in Greece (Christodoulopoulos, 2009).

Sheep scab is a skin disease caused by the mite *Psoroptes ovis* and has been widely prevalent in Europe. It is a major animal welfare, husbandry and economic problem (Bisdorff et al., 2006; Bisdorff and Wall, 2008).

The objectives of the AMI in the current hygiene legislation, Regulation (EC) 854/2004, are to determine:

- conditions that may might adversely affect human or animal health, paying particular attention to the detection of zoonotic diseases and animal diseases for which animal health rules are laid down in EU legislation, and
- whether there is any sign that welfare has been compromised.

[53] Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 Official Journal L 003, 05/01/2005 pp. 1–37.

Implementation of welfare assessment protocols using appropriate animal based indicators during clinical and slaughterhouse (AMI + PMI) surveillance systems would improve the welfare of small ruminants. These welfare surveillance systems should become an integral part of the food chain information (FCI).

Sheep are thought to be tolerant of being transported and deprived of food and water for long periods (Knowles et. al., 1998). It is a common practice by farmers to withdraw food on the farm for several hours prior to transport of sheep / lambs to auction markets or slaughterhouses, primarily to reduce soiling. However, dehydration can be a welfare problem during long transport distances/times, especially in high ambient temperatures (Knowles, 1998). Recovery from the effects of food and water deprivation is a very slow process and therefore lairage appears to be of very little benefit. In this regard, full recovery from 14 hours of transport has been shown to take up to 144 hours (Knowles, 1998). Owing to these, the BIOHAZ Panel's proposal for shortened transport and lairage time would be beneficial to animal welfare.

2.4. Food chain information

The EU Regulation (EC) No 852/2004[54] on the hygiene of foodstuffs requires slaughterhouse operators to request FCI declarations to ensure animals entering the food chain are safe for human consumption. FCI is also a good source of information to facilitate the detection in the slaughterhouse of abnormalities indicative of animal health and welfare conditions. FCI is recorded at the flock/herd level, and its minimum content is described in Regulation (EC) No 853/2004. FCI related to primary production of small ruminant herds/flocks is based on a farmer's declaration. Most MSs have made available to farmers a standardised FCI declaration form. A whole-chain approach to food safety, animal health and animal welfare requires slaughterhouse operators to be provided by livestock producers with information about their animals consigned to slaughter. Based on the FCI provided food business operators (FBOs) can assess potential hazards presented by the animals and are required to act upon any information recorded on the FCI declaration as part of their hazard analysis and critical control point (HACCP) plan. This helps the slaughterhouse operator to organise slaughter operations and to ensure that no animals affected by disease or certain veterinary medicines enter the food chain. Quality assurance schemes at primary producer level are voluntary tools operated by independent agencies or bodies to ensure compliance with given standards and regulations. These schemes increase farmers' responsibilities with regard to animal health and welfare and have potential for integration within the FCI provided (OIE, 2006).

The FCI also assists risk management to determine the required inspection procedures and should be analysed by risk management and used as an integral part of the inspection procedures.

The value of the FCI in guiding risk management to discriminate between animals subsequently going through different types of inspection procedures should be evaluated. As for any evaluation of (pre-) screening procedures, the sensitivity and specificity of the classification should be estimated. Priority should be given to improving test sensitivity, noting that (pre-) screening tests should preferably produce few false negative classifications for the sake of animal disease detection and surveillance. Test specificity will largely be an economical parameter, since the subsequent inspection of all "FCI-positive" animals or groups should detect any false positives not correctly identified during the FCI pre-screening.

Regulation (EC) No 854/2004 requires that data from the AMI and PMI at the slaughterhouse is delivered back to the farmer/producer when the inspections reveal the presence of any disease or condition that might affect public or animal health, or compromise animal welfare. Currently this feedback of information to primary producers is not fully implemented in all MSs (EFSA BIOHAZ, CONTAM and AHAW Panels, 2011). The UK FSA carried out a study on the implementation of FCI in the United Kingdom since 2006 to explore ways of improving it (FSA, 2013b). This study

[54] 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

concludes that the effective and efficient flow of information provides valuable information to both the farmer and the FBO and allows more targeted and effective inspection procedures in the slaughterhouse and effective interventions on the farm that should contribute to a cycle of continuous improvement with positive implications for animal health and welfare. The effectiveness of this information cycle depends on a reliable animal identification and recording system at the slaughterhouse and an information transfer system to the primary producer. The collection and communication of slaughterhouse inspection results is an opportunity to collect and use data and knowledge applicable to disease control and the effectiveness of interventions, animal production systems, food safety and animal health/welfare (Garcia, 2012). At national and EU level such data can contribute to disease surveillance (for the detection of exotic diseases, monitoring of endemic diseases and identification of emerging diseases) and targeted animal health and welfare interventions. Therefore FCI, if consistently and effectively implemented as enshrined within the hygiene package, will form an integral part of a risk-based MI system.

Extended use of FCI has the potential to compensate for some, but not all, of the information on animal health and welfare that would be lost if visual only PMI is applied. For the FCI to be effective it should include species-specific indicators for the occurrence of disease and welfare conditions. FCI for public health purposes may not have an optimal design for the surveillance and monitoring of disease and welfare conditions; therefore, an integrated system should be developed whereby FCI for public health and for animal health and welfare can be used in parallel, more effective.

3. Implications for surveillance and monitoring for small ruminant 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 system for chemical substances of potential concern and its updating, the use of FCI to help facilitate risk-based sampling strategies; the inclusion of new hazards in control programmes for chemical residues and contaminants (see CONTAM Appendix B, for full details). None of these were considered to have an impact on animal health and welfare surveillance and monitoring.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

- As shown in the COMISURV assessment, a change to visual only inspection would cause a significant reduction in the probability of detection (i.e. non-overlapping 90 % probability intervals) of detectable cases of fasciolosis and of tuberculosis in goats.

- Clinical surveillance had a greater sensitivity for detecting FMD than slaughterhouse surveillance following the assessment by COMISURV, although the sensitivity of meat inspection increased with an increase in population size. A change to a visual only system would not have a negative impact on sensitivity of detection.

- As shown in the COMISURV assessment, the proposed changes to meat inspection would not greatly affect the probability of detection of any of the welfare conditions analysed.

- From the COMISURV assessment, for two welfare conditions (leg and foot disorders and sheep scab), a combination of the two surveillance components (clinical surveillance and meat inspection) were shown to be more effective (detecting a higher fraction of affected animals) than either one of the surveillance components on its own.

- According to Regulation (EC) 854/2004, current inspection in small ruminants includes visual inspection and palpation of the lungs and respiratory lymph nodes. A change to visual inspection would imply that palpation is abandoned.

- Small ruminants are usually not subjected to official tuberculosis eradication campaigns, and farm controls are only performed on premises where cattle and goats are kept together, or in flocks/herds that commercialise raw milk. Surveillance for small ruminant tuberculosis at present relies on meat inspection of sheep and goats slaughtered for human consumption, or other limited diagnostic surveillance activities.

- As is the case with tuberculosis in bovines, the contribution of meat inspection surveillance of tuberculosis in small ruminants is to support the detection of flocks/herds with tuberculosis. Detection of tuberculosis in individual animals is merely the first step in improving the effectiveness of flock/herd surveillance, and for any given flock/herd, the flock/herd sensitivity will increase with the number of animals slaughtered.

- Results of two recent risk assessments (COMISURV report; FSA, 2013a) show that a change from the current inspection to visual only will reduce the probability of detection of tuberculosis in small ruminants. However, the consequences for animal health were considered as negligible in the FSA assessment, due to the fact that current meat inspection does not prescribe routine incision of lymph nodes, and the only inspection task omitted will be palpation of lungs and respiratory lymph nodes.

- In recent years tuberculosis has been reported in small ruminants in several EU countries and most information derives from recognition of tuberculosus lesions at the slaughterhouse and from laboratory reports. Although small ruminants are not considered to represent a significant reservoir of the disease for the persistence of bovine tuberculosis in cattle, it is still possible that infected sheep and goat herds could act as vectors of infection for other domestic and wild animals. Therefore, surveillance and control of tuberculosis in domestic small ruminants does have consequences for the overall surveillance and control of tuberculosis.

- Liver examination at slaughter is the most direct, reliable, and cost-effective technique for diagnosis of fasciolosis.

- Moving to a visual only meat inspection system would decrease the sensitivity of inspection at animal level for fasciolosis, however it would be sensitive enough to identify most, if not all, affected herds. Therefore the consequences of change are low (Charleston et al., 1990).

- The feedback to farmers regarding *Fasciola hepatica* detected at meat inspection is low at present and the real risk to animal health/welfare for this disease, caused by a change to a visual only meat inspection method, is probably low.

- Implementation of welfare assessment protocols using appropriate animal based indicators during clinical and slaughterhouse (AMI + PMI) surveillance systems would improve the welfare of small ruminants.

- Extended use of food chain information has the potential to compensate for some, but not all, of the information on animal health and welfare that would be lost if visual only *post-mortem* inspection is applied.

- Food chain information is a potentially effective tool to perform more targeted *ante-mortem* and *post-mortem* inspection tasks in the slaughterhouse which may increase the effectiveness of those tasks in detecting conditions of animal health and animal welfare significance.

- The existing ineffective flow of information from primary production to the slaughterhouses and vice versa reduces the ability of detection of animal diseases and animal welfare conditions at the slaughterhouse and as a result it limits possible improvements on animal

health and welfare standards at the farm as farmers will not be aware of the slaughterhouse findings.

- The conclusions and recommendations on chemical hazards were reviewed by the AHAW Working Group and none of them were considered to have impact on animal health and welfare surveillance and monitoring.

RECOMMENDATIONS

- Data collected during clinical and slaughterhouse (*ante-mortem* and *post mortem* inspection) surveillance systems should be utilised more effectively to improve animal welfare at farm level.

- Slaughterhouse surveillance of tuberculosis in small ruminants should be improved and encouraged, as this is in practice the only surveillance system available. The detection of tuberculosis in small ruminants should be adequately recorded and notified, followed by control measures at the farm level.

- Lack of feedback of *post-mortem* inspection results to the farmer prevents instigation of a fluke management programme, which could be detrimental to animal health and welfare. An improvement in this feedback of information is recommended.

- Welfare surveillance systems should become an integral part of the food chain information.

- An integrated system should be developed whereby food chain information for public health and for animal health and welfare can be used in parallel, more effectively

- Provide farmers with background information on the animal diseases and welfare conditions of key concern that may affect their livestock and why it is important to provide this information to the slaughterhouse through the use of food chain information.

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ANNEXES

Annex 1. Results from Stage 2 models

Table A: The probability of detection for all cases of diseases and welfare conditions combined at AMI, PMI (two proposed scenarios – current and visual) inspection scenarios with the most likely (ML), 5th and 95th percentiles

Disease or welfare condition		AMI			PMI						Combined AMI and PMI					
					Current			Visual			Current			Visual		
		0.05	ML	0.95	0.05	ML	0.95	0.05	ML	0.95	0.05	ML	0.95	0.05	ML	0.95
Exotic	BT	0.04	0.10	0.21	0.02	0.03	0.08	0.01	0.02	0.05	0.06	0.11	0.28	0.05	0.11	0.25
	FMD	0.01	0.01	0.03	0.00	0.00	0.00	0.00	0.00	0.00	0.01	0.02	0.03	0.01	0.01	0.03
	RVF	0.27	0.40	0.55	0.18	0.27	0.38	0.18	0.27	0.39	0.49	0.76	0.84	0.49	0.76	0.84
Endemic	TB in goats	0.10	0.15	0.22	0.28	0.40	0.52	0.19	0.26	0.36	0.40	0.57	0.69	0.31	0.40	0.54
	Caseous lymphadenitis	0.01	0.03	0.06	0.06	0.14	0.25	0.05	0.12	0.22	0.08	0.18	0.29	0.07	0.16	0.26
	Echinococcosis	0.00	0.00	0.00	0.18	0.24	0.36	0.16	0.24	0.33	0.18	0.25	0.36	0.16	0.24	0.33
	Fasciolosis	0.01	0.02	0.04	0.33	0.47	0.59	0.23	0.34	0.42	0.34	0.47	0.62	0.25	0.34	0.45
	Lower respiratory tract infection	0.14	0.22	0.35	0.16	0.22	0.41	0.16	0.22	0.41	0.32	0.50	0.72	0.32	0.50	0.72
	Lungworm	0.07	0.09	0.14	0.14	0.20	0.28	0.14	0.20	0.27	0.21	0.28	0.41	0.21	0.28	0.40
	Orf disease	0.19	0.27	0.34	0.04	0.06	0.08	0.00	0.00	0.00	0.25	0.33	0.40	0.19	0.27	0.34
	Pulmonary adenomatosis/ Maedi–Visna	0.14	0.24	0.34	0.07	0.13	0.20	0.06	0.10	0.17	0.23	0.39	0.50	0.22	0.33	0.48
Welfare conditions	Arthritis	0.23	0.34	0.48	0.14	0.21	0.32	0.11	0.15	0.23	0.41	0.58	0.74	0.37	0.53	0.66
	Broken bones	0.76	0.95	0.98	0.49	0.65	0.65	0.27	0.50	0.49	0.90	0.98	0.99	0.86	0.97	0.99
	Bruising	0.01	0.02	0.07	0.23	0.31	0.42	0.23	0.31	0.42	0.25	0.34	0.47	0.25	0.34	0.47
	Diarrhoea or soiling	0.49	0.66	0.71	0.07	0.10	0.13	0.06	0.09	0.13	0.58	0.74	0.80	0.57	0.75	0.80
	Leg and foot disorders	0.11	0.16	0.22	0.04	0.05	0.07	0.04	0.05	0.07	0.16	0.21	0.28	0.16	0.21	0.28
	Mastitis	0.03	0.05	0.10	0.12	0.18	0.27	0.12	0.18	0.27	0.16	0.26	0.34	0.16	0.26	0.34
	Partial vaginal prolapse/hernia	0.23	0.31	0.44	0.01	0.01	0.04	0.01	0.01	0.04	0.24	0.32	0.46	0.24	0.32	0.46
	Poor body condition	0.35	0.45	0.56	0.28	0.34	0.41	0.27	0.33	0.39	0.68	0.85	0.86	0.67	0.82	0.85
	Sheep scab	0.24	0.36	0.57	0.00	0.00	0.01	0.00	0.00	0.00	0.24	0.39	0.58	0.24	0.37	0.58

GLOSSARY AND ABBREVIATIONS

AHAW	Animal Health and Welfare (Panel)
AMI	*Ante-mortem* inspection
BIOHAZ	Biological Hazards (Panel)
BT	Bluetongue
bTB	Bovine tuberculosis
CONTAM	Contaminants in the Food Chain (Panel)
EFSA	European Food Safety Authority
EU	European Union
FAWC	Farm Animal Welfare Council
FBO	Food business operator
FCI	Food chain information
FMD	Foot and mouth disease
FSA	Food Standards Agency
HACCP	Hazard analysis and critical control point
I	Incision
MI	Meat inspection
ML	Most likely, which is equivalent to mode
MS	Member State
OIE	World Organisation for Animal Health
P	Palpation
PMI	*Post-mortem* inspection
RVF	Rift Valley fever
TB	Tuberculosis
V	Visual inspection
WG	Working group

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: 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, without pathological lesions detectable by meat inspection.

Non-overlapping probability intervals: indicates 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: 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 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.