

72 SG/12/CS1
Original: English
December 2003

**REPORT OF THE MEETING OF THE
OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION**

Paris, 1-12 December 2003

The OIE Terrestrial Animal Health Standards Commission (hereafter referred to as the Code Commission) met at the OIE Headquarters in Paris from 1-12 December 2003, and discussed some common issues with the Scientific Commission for Animal Diseases (hereafter referred to as the Scientific Commission) on 5 December 2003.

The members of the Code Commission are listed in [Appendix I](#). The agenda adopted is given in [Appendix II](#).

The Director General of the OIE, Dr B. Vallat, welcomed the members, noted that Prof A.M. Hassan was attending his first meeting, and thanked them all for their participation in this important OIE work. He discussed the following priorities:

- bluetongue - updating the chapter of the OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code*) as a result of the recent OIE Bluetongue Conference in Sicily;
- bovine spongiform encephalopathy - the resolution arising from the 2003 General Session to simplify the *Terrestrial Code* chapter while retaining its scientific base; Dr Vallat believed that another meeting of an *Ad hoc* Group would be necessary in early 2004 to draft a simplified approach to country/zone categorisation for bovine spongiform encephalopathy and that an indication should be given to the International Committee in May 2004 as to directions, with a detailed text available for adoption in 2005;
- bovine tuberculosis - to review the proposal from a Member Country to revise the *Terrestrial Code* chapter to explicitly distinguish animal health and public health measures and resulting certification;
- avian influenza - the need to improve transparency of notification of avian influenza while minimising unjustified trade restrictions arising from notification of strains of low pathogenicity; the Code Commission should propose in May 2004 a differential approach for trade in commodities based on the risks posed by the relevant two subtypes.

Dr Vallat encouraged the Code Commission to continue its move away from an emphasis only on free status of countries or zones towards an approach based on the risk posed by specific commodities.

The Code Commission examined draft revised *Terrestrial Code* texts circulated for Member Country comment by the Bureau of the Code Commission after its July 2003 meeting, and comments received on those texts. The outcome of the Code Commission's work is presented as appendices to this report. Amendments made to existing and previously circulated drafts are shown as double underlined text, with deleted text in ~~strikeout~~. A grey background is used to distinguish amendments and deletions made at this meeting from those made at the meeting of the Bureau in July 2003.

The Code Commission noted that only four Member Countries (Australia, India, New Zealand and Switzerland) had commented on the report of the Bureau of the Code Commission by the date requested. Other comments were received after that date, which made it difficult to prepare the working document for this meeting. The Code Commission strongly encourages Member Countries to participate in the development of the OIE's international standards by sending comments in sufficient time for them to be considered by the Commission.

Member Countries are invited to comment on all aspects of this report. Comments need to reach the OIE Headquarters by 7 May 2004 in order to be considered at the 72nd General Session. Comments requiring minor changes to the *Terrestrial Code* would be considered at a meeting of the Code Commission just prior to the General Session and a revised text presented for adoption. Comments requiring major changes would be deferred to the meeting of the Bureau of the Code Commission in July 2004.

As the next meeting of the *Ad hoc* Group on BSE has been proposed for March 2004, at which the experts will consider a modified country/zone categorisation system for BSE, Member Countries are strongly requested to submit to the Director General by 1 March 2004 comments on the proposed general criteria for that chapter (Appendix XXV).

The next meeting of the *Ad hoc* Group on animal disease notification has been proposed for mid-February 2004. Member Countries are requested to review the criteria proposed by the *Ad hoc* Group (Appendix XXVII) and to provide comments to the Director General by 10 February 2004.

A. TEXTS WHICH ARE SUBMITTED FOR ADOPTION BY THE INTERNATIONAL COMMITTEE AT THE 72nd GENERAL SESSION IN MAY 2004

1. General definitions (Chapter 1.1.1)

The Code Commission decided not to modify the term '*artificial insemination centre*' (as proposed by Australia) as that term was the one accepted worldwide by the industry.

The Code Commission decided not to modify the definition of '*Veterinary Administration*' (as proposed by New Zealand) as not all *Veterinary Administrations* in Member Countries currently have central control over animal health measures within the country.

Several other modifications to the list of definitions were made in accordance with comments received from Member Countries and after discussions with the Scientific Commission. The Code Commission decided to delete those definitions relating to 'products of animal origin' as it was considered that they were self-evident.

Suggested changes, shown in Appendix III, are presented for adoption

2. Obligations and ethics in international trade (Section 1.2)

The Code Commission modified Article 1.2.1.2 in line with comments received from the European Union (EU) and New Zealand. The Code Commission concluded that the existing article on electronic certification was satisfactory.

Suggested changes, shown in Appendix IV are presented for adoption.

3. Evaluation of Veterinary Services (Chapter 1.3.3) Guidelines for the evaluation of Veterinary Services (Chapter 1.3.4)

In revising the above chapters, the Code Commission examined the reports of the two meetings of the *Ad hoc* Group on the Role of Private Veterinarians and Veterinary Para-professionals in the Provision of Animal Health Services, and took into account comments received from Argentina, Australia, the EU, India, New Zealand, Switzerland and the United States of America (USA). The report of the second meeting is in Section C at [Appendix XXVIII](#).

The Code Commission also examined the definitions proposed by that *Ad hoc* Group on and, with minor amendments, added these to Chapter 1.1.1 (see [Appendix III](#)). The Code Commission believed that membership of the veterinary statutory body should be flexible to enable efficient addressing of issues relating to veterinary para-professionals as they arise. It recognised the need for the veterinary statutory body to be autonomous but noted that it could be state or provincial based (rather than being a single national authority). The Code Commission also recognised that each Member Country would decide whether or not to register veterinary para-professionals.

In addressing comments from New Zealand, Switzerland and the USA, the Code Commission noted that a licensing system for veterinary para-professionals may not be in place in all Member Countries, and appropriate changes have been proposed to the definition. The Code Commission also noted that a veterinary para-professional need not operate under the ‘supervision’ of a veterinarian but under their ‘direction’.

The Code Commission saw no need to change the title of Chapter 1.3.3 as the term ‘*Veterinary Services*’ is broader than ‘*Veterinary Administration*’. The Code Commission addressed the New Zealand comment regarding flexible responses. The chapeau to Article 1.3.3.2 was modified which in turn allowed for the deletion of the proposed paragraph j).

The Code Commission adopted the EU comment regarding the deletion of references to ‘export’. Reference in Article 1.3.4.13 to the WHO/FAO Directory of Veterinary Schools was deleted as no such directory could be found.

Suggested changes to Chapter 1.3.3 and Chapter 1.3.4 have been incorporated into a revised text ([Appendix V](#)) which is presented for adoption.

4. Guidelines for reaching a judgement of equivalence of sanitary measures (Chapter 1.3.7)

The Code Commission made minor amendments to Article 1.3.7.2 which have been incorporated into a revised text ([Appendix VI](#)) which is presented for adoption.

5. Animal disease notification (Chapter 1.1.3)

The Code Commission met with Drs Karim Benjebara and Julio Pinto, Head and Deputy-Head of the Animal Health Information Department, to discuss the report of the first meeting of the *Ad hoc* Group on animal disease notification.

The Code Commission endorsed the report and noted the following important points:

- The *Ad hoc* Group decided to avoid the use of ‘scoring’ as this was too subjective and thus open to controversy.
- Criteria were kept to a minimum of easily definable factors. It was reasoned that in considering criteria such as significant spread and zoonotic potential, economic and social issues were being adequately addressed, while the overriding concern would be the potential of a disease for international spread.

- The economic impact of a disease is linked directly to its morbidity and mortality. While various economic tools are available for the evaluation of disease impact, these have not been widely enough applied for accurate comparisons to be made between diseases. Mortality and morbidity have, however, been well measured over time.
- In terms of the social importance of diseases, their zoonotic effects were considered to be of prime importance. Where diseases disrupt social norms, this is once again due to morbidity and mortality.
- Further economic effects, such as trade restrictions and the imposition of control measures, are a function of various epidemiologic parameters, such as spread, morbidity, mortality and zoonotic potential.

The report of the first meeting of the *Ad hoc* Group on disease notification is in Section C at [Appendix XXVII](#). Member Countries are requested to review the criteria proposed by the *Ad hoc* Group and to provide comments to the Director General by 10 February 2004. A second meeting of the *Ad hoc* Group will be held in late February to review comments received, and the report of that meeting will be circulated to all Member Countries by the Director General in March. The proposed criteria arising from that meeting will be put to the International Committee for adoption in May 2004.

Changes recommended by the Code Commission, bringing the content of Chapter 1.1.2 and 1.1.3 ([Appendix VII](#)) in line with the decisions made on notification, are presented for adoption.

Once the new criteria for listing diseases are adopted by Member Countries, proposals for inclusion in the *Terrestrial Code* of new or emerging diseases such as chronic wasting disease, ovine pulmonary adenocarcinoma (the new name for ovine pulmonary adenomatosis), and porcine reproductive and respiratory syndrome can be considered during the following General Sessions.

6. Zoning and regionalisation (Chapter 1.3.5)

The Code Commission took into account the output of an OIE *Ad hoc* Group on epidemiology in modifying the chapter on zoning and regionalisation ([Appendix VIII](#)) which is presented for adoption. Existing definitions for zone and compartment were revised to clarify their relationship in distinguishing animal sub-populations with a distinct health status, based on geography or management ([Appendix III](#)).

The proposed changes were discussed with and agreed by the Scientific Commission.

7. Foot and mouth disease (Chapter 2.1.1 and Appendix 3.8.6)

Proposals received from the EU, Japan and the USA on paragraph 2) of Article 2.1.1.7, which would have required surveillance for infection, were not incorporated because the Code Commission considered that it was appropriate to retain the three sub-clauses in the expectation that a validated test will become available in the near future.

The Code Commission believed that concerns expressed by the EU, Japan and the USA regarding bone-in meat were addressed by the requirement that the country or zone be free from infection; the International Committee had adopted the modified chapter on the basis that exports would be permitted only after tools for the required surveillance were available.

The Code Commission did not adopt the EU's proposal to reinstate former Article 2.1.1.9 (listing commodities which should be considered a risk) as the International Committee has accepted the principle that lists of safe commodities will be systematically incorporated into the *Terrestrial Code* chapters.

The Japanese proposal regarding Article 2.1.1.11 to add testing for foot and mouth disease (FMD) virus infection within an infected country or zone was not adopted because it was considered to be unnecessarily restrictive given the other measures recommended to manage the risk. An administrative error was corrected in paragraph 3) of this article – the word 'quarantine' was replaced by the word 'shipment'. The EU proposal that the animals be required to spend the 30 days prior to shipment in a quarantine station was not adopted; the intention of the current text is to recognise that on-farm isolation could provide an equivalent level of protection under certain circumstances. Additional measures proposed by the EU regarding testing of all animals were incorporated.

The change proposed by the EU regarding Article 2.1.1.14 was not adopted in the absence of a technical justification.

The proposal by the EU regarding Article 2.1.1.17 (three months residence) was not considered warranted in a country or zone free from FMD without vaccination.

The proposal by the EU regarding Article 2.1.1.20 was not incorporated as the article had been adopted at the 71st General Session. The Code Commission decided to await a technically justified assessment of the risks before proceeding with any changes. Requests from the EU and USA that the requirement for deboning be re-introduced was not adopted as the Code Commission believed that the criteria for defining an FMD free zone have been strengthened sufficiently to make additional measures redundant.

The EU proposal regarding Article 2.1.1.22 (vaccines) was addressed through a proposed definition for vaccination (see [Appendix III](#)).

The New Zealand proposal to delete paragraph 1) a) of Article 2.1.1.25 was not adopted as the milking of infected cows was considered as a possible source of contamination for equipment, etc.

Issues relating to safe commodities had been referred to the Scientific Commission after the meeting of the Bureau in July 2003. The Scientific Commission decided to recommend that the OIE appoint an expert to review the relevant literature and report back to that Commission. Other issues including comments received from Uruguay and FMD vaccination are addressed in the report of the Scientific Commission.

Suggested changes to Chapter 2.1.1 have been incorporated into a revised text ([Appendix IX](#)) which is presented for adoption.

Appendix 3.8.6

The Scientific Commission took into account comments from the EU and New Zealand and proposals from several experts in modifying Appendix 3.8.6. Due to the extensive nature of the changes, it was considered preferable that the modified Appendix be circulated as clean text ([Appendix X](#)) which is presented for adoption.

New issues addressed in the document include:

- the complexities of vaccination in FMD control;
- an explanation of why a standardised approach to FMD surveillance has proven extremely difficult, bearing in mind the various epidemiological situations that prevail in different parts of the world;
- the importance of detecting and following up suspicious cases of FMD to show that an effective surveillance system is operational;
- strategies for active FMD surveillance were expanded, including the possible use of targeted surveillance. Furthermore, the effect of sensitivity and specificity of testing systems on surveillance strategy development was emphasized, particularly when the design prevalence is low;
- the issue of cluster analysis in the distribution of serological positives;
- more details relating to serological surveillance, including the use of nonstructural protein (NSP) tests, were included.

8. Bovine spongiform encephalopathy (Chapter 2.3.13)

The Code Commission agreed with the *Ad hoc* Group on bovine spongiform encephalopathy (BSE) that references to other transmissible spongiform encephalopathies (TSEs) in the chapter of the *Terrestrial Code* on BSE continued to be justified.

In the interest of clarity and in response to suggestions from the BSE *Ad hoc* Group and requests from Member Countries, recommendations on the safety of certain commodities were moved to the front of the chapter.

The Code Commission agreed with the *Ad hoc* Group on BSE and with several Member Countries in recognising the importance of a quality risk assessment. Accordingly, after examining a proposal from New Zealand, the Code Commission modified Article 2.3.13.2 to harmonise the risk assessment process with Section 1.3 of the *Terrestrial Code* and to clarify the most important risk factors which needed to be taken into account.

In paragraph 1)c) of Article 2.3.13.2, the reference to embryos and oocytes was deleted as, of genetic material, the importation of live animals was considered to be the only significant risk factor. The Japanese suggestion regarding fallen stock in paragraph 2) was adopted. A small wording change was made in paragraph 3) in line with the approach in the BSE Appendix. The Code Commission considered that the comment from Argentina regarding the usefulness of rapid tests was appropriately addressed in the BSE Appendix.

Wording in paragraphs 2)b) and 2)c)iii) of Article 2.3.13.3 was harmonised. The Code Commission recognised however the very low rate of vertical transmission and decided to refer to the next meeting of the BSE *Ad hoc* Group the question of whether references to progeny could be deleted from the chapter.

The Code Commission modified Articles 2.3.13.3, 2.3.13.4 and 2.3.13.5 to require that the surveillance and monitoring in place meets the requirements of Appendix 3.8.4.

In Articles 2.3.13.5 and 2.3.13.6, regarding the calculation of the BSE incidence rate, an increased level of surveillance which complies with the requirements of Appendix 3.8.4 was added to increase the reliability of the outcome. The cut-off limit was raised from one case per million to two cases per million, taking into account the implementation of both passive and active surveillance.

In the continuing pathogenesis studies, additional data accumulated over the 12 months since the previous meeting of the BSE *Ad hoc* Group had strengthened the case for reconsideration of the list of tissues that should be defined as specific risk materials (SRMs). Central nervous system (CNS) tissues collected at 18, 22 and 26 months post oral exposure, and inoculated intracerebrally into calves, had not transmitted BSE to the challenged calves. CNS collected at 32 months post infection had killed the group of challenged calves with a mean incubation of 24 months. Although impossible to precisely define the time of entry of infectivity to the CNS on the basis of such limited data, the results do indicate that entry is later than seen in sheep or murine scrapie where it is traditionally considered to appear at approximately 50% of the incubation period. Therefore changes were made to the recommendations on CNS tissues removal in Article 2.3.13.19. New scientific evidence was taken into account in adding tonsils and intestine to the list of SRMs for cattle of all ages.

Although requested by several countries, the *Ad hoc* Group was not in favour of reducing the required period of compliance with Article 2.3.13.3 from 7 to 5 years, or the minimum period after implementation of the ruminant-to-ruminant feed ban, as the 7 years represented the 95th percentile of the observed incubation periods for BSE. The Code Commission made no changes to this part of the chapter.

The Code Commission modified Appendix 3.8.4 in accordance with the recommendations of the *Ad hoc* Group on BSE to reinforce the importance of the risk assessment, to give more guidance on Table 1 and on surveillance of the three sub-populations.

Suggested changes have been incorporated into a revised text ([Appendix XI](#)) which is presented for adoption.

The Code Commission also examined comments from the EU, India, New Zealand and Switzerland on 'Factors to consider in conducting the risk assessment recommended in Chapter 2.3.13' which were supportive of the document. It took into account those comments and its own proposals regarding the risk assessment process in modifying the draft guidelines which are presented as clean text ([Appendix XII](#)) for adoption.

Proposed simplified BSE categorisation system

The Code Commission examined a request from the International Committee to simplify the current BSE categorisation system in the *Terrestrial Code*. The OIE also received detailed suggestions from two Member Countries on a three category approach. The issues were discussed at the recent meeting of an *Ad hoc* Group of BSE experts. A proposal from the EU for a four category approach was later received.

After considering the opinion of the experts, the Code Commission was of the view that a simplified categorisation system containing only three categories could be developed for Member Country examination. However, the Code Commission believed that it would be helpful, prior to drafting such a revision, to seek the opinion of Member Countries on proposed basic criteria.

The Code Commission was of the view that any new categorisation system was not likely to resolve the current level of unjustified trade restrictions, as these are more related to non-compliance with the commodity specific recommendations in the existing *Terrestrial Code* than to difficulties arising from the number of categories. Member Countries might also recall that the existing number of categories was the result of their requests over some years aimed at minimising the trade repercussions which might follow the reporting of an initial case of BSE. The five categories were also designed to address the demands of Member Countries that three categories reflect different incidence rates and that a category of 'provisionally free' be created for those countries claiming to be free but which had not met the time requirements for the feed ban and/or the time of compliance with Article 2.3.13.2.

The BSE *Ad hoc* Group recommended a revised categorisation system which grouped countries into the following three categories, solely based on the outcome of a risk assessment and when supported by a strong surveillance system (as described in Appendix 3.8.4):

- negligible risk of BSE
- controlled BSE risk
- unknown risk of BSE.

A country or zone in the negligible risk category would be one which, on the basis of a risk assessment and surveillance, had demonstrated that there has been no recent indigenous case of BSE, and that the relevant parts of Article 2.3.13.2 have been complied with.

A country or zone in the controlled risk category would be one which, on the basis of a risk assessment and surveillance, had demonstrated the presence of risk factors and/or cases, but could show that all risk factors were being addressed through appropriate measures to prevent the transmission of the BSE agent to animals or humans.

A country or zone which is unable to fulfil the requirements of the 'negligible risk' or 'controlled risk' categories would fall into the 'unknown risk' category.

As the next meeting of the *Ad hoc* Group reviewing the BSE chapter will be held in late March / early April 2004, Member Country comments on the above revised categorisation criteria are strongly requested by 12 March.

9. Rinderpest (Chapter 2.1.4)

The Code Commission noted the recommendation of the Scientific Commission that, of the changes to the rinderpest chapter it had discussed, only a definition for rinderpest infection should be submitted to the International Committee in May 2004. Other changes, which are more fundamental, will be taken up by experts forming part of the *Ad hoc* Group on rinderpest to be coordinated by that Commission.

A definition for rinderpest infection proposed by the Scientific Commission, has been harmonised with the definition for FMDV, and is presented for adoption ([Appendix XIII](#)).

10. Leptospirosis (Chapter 2.2.4)

Several Member Countries had proposed the deletion of this chapter due to the ubiquity of the causative organism, and the absence of meaningful official control programmes and effective treatments in the live animal. The Code Commission discussed the transmission of the organism via semen with an expert who was of the view that this pathogenic agent was appropriately addressed through the routine addition of antibiotics to semen.

The Code Commission therefore proposed that the chapter be removed from the *Terrestrial Code*.

11. Bovine tuberculosis (Chapter 2.3.3)

The Code Commission recalled a resolution adopted at a previous General Session concerning bovine tuberculosis, and a recommendation of the OIE Working Group on Animal Production Food Safety that the *Terrestrial Code* chapter address more explicitly the animal health and public health risks associated with the disease, and that the chapter be a model for the revision of other zoonotic diseases in the *Terrestrial Code*.

The Code Commission examined a revised chapter developed by New Zealand. The Code Commission draws the attention of Member Countries to the proposed approach which addresses animal health and public health risks in separate articles, including separate certification requirements.

The Code Commission noted the use of the terms ‘maintenance host species’ and ‘spill-over host species’ without a list of the relevant species; as a result, the Code Commission decided to confine its initial recommendations to cattle and products originating from cattle.

Member Countries are invited to examine closely the structure of the proposed revised chapter, as well as the detail of the recommendations ([Appendix XIV](#)). The revised chapter is presented as clean text.

12. Classical swine fever (Chapter 2.1.13)

The Code Commission examined further comments from Australia, the EU, Japan, India, New Zealand, Switzerland and the USA, regarding changes proposed in the report of the July 2003 meeting of the Bureau. Appropriate modifications have been incorporated into a revised text ([Appendix XV](#)) which is presented for adoption.

The Australian comment regarding inapparent clinical signs (Article 2.1.13.4) was not adopted as the Code Commission considered that clinical signs would be apparent on a herd basis when dealing with naïve populations; this could be contrasted with the situation concerning Aujeszky’s disease. Point 2)d) of Article 2.1.13.4 was deleted as the Code Commission considered that internal movement controls were not necessary in a free country or zone. The Australian proposal regarding serological monitoring (point 2)e) of Article 2.1.13.4) was not adopted as the Code Commission considered that such monitoring was not necessary in an unvaccinated and susceptible population. The New Zealand question regarding the necessary level of monitoring of the wild pig population would be addressed by the OIE *Ad hoc* Group on epidemiology.

Regarding a comment from New Zealand on Article 2.1.13.6, the Code Commission acknowledged the pragmatic nature of the zone radii but considered that the distances listed in the chapter were workable in practice.

The Australian proposal (Article 2.3.13.14) that all pigs at the centre be tested was not adopted as the requirement that all donors be tested 21 days after semen collection was considered adequate.

The Japanese proposal (Article 2.3.13.19) regarding an exclusion period of three months for domestic pigs from wild pig control areas was not adopted as the Code Commission was not aware of any evidence of cross-contamination from carcasses at abattoirs.

When a list of commodities which could be safely traded regardless of the classical swine fever (CSF) status of the exporting country was discussed with the Scientific Commission, this Commission indicated that the information it had received from some experts was inconclusive. It had therefore decided to recommend that the OIE appoint an expert to review the relevant literature and report back to that Commission. The Scientific Commission also decided to check the available information on the inactivation of CSF in various meat products.

The Code Commission was of the view that the recent development of a test able to discriminate between the vaccinated and infected pigs should be considered for inclusion in the *Terrestrial Manual*.

13. Contagious bovine pleuropneumonia (Chapter 2.1.6)

The Code Commission modified Articles 2.1.6.8 and 2.1.6.13 in accordance with recommendations from the Biological Standards Commission. Suggested modifications have been incorporated into a revised text ([Appendix XVI](#)) which is presented for adoption.

14. Equine influenza (Chapter 2.5.5)

The Code Commission modified paragraph 2)d) of Article 2.5.5.3 to harmonise it with other references in the *Terrestrial Code* to procedures in the *Terrestrial Manual*. Suggested modifications have been incorporated into a revised text ([Appendix XVII](#)) which is presented for adoption.

15. Rabies (Chapter 2.2.5)

The Code Commission modified paragraph 4) of Article 2.2.5.5 in accordance with a recommendation from the Biological Standards Commission, to harmonise it with other references in the *Terrestrial Code* to procedures in the *Terrestrial Manual*.

The Code Commission modified paragraph 2) of Article 2.2.5.6 in line with a comment from Australia ([Appendix XVIII](#)) which is presented for adoption.

16. Paratuberculosis (Chapter 2.2.6)

A revised draft chapter on paratuberculosis, developed by an expert in consultation with others, was discussed with the Scientific Commission. The Scientific Commission made no specific comments but recommended that the zoonotic potential of this disease be addressed through collaboration with the World Health Organization (WHO).

The Code Commission decided that it would circulate the revised draft for the comment of Member Countries when it has received appropriate technical review from the Scientific Commission.

The Code Commission was of the view that the current *Terrestrial Code* chapter is not in line with current scientific understanding and would not provide safe trade in domestic ruminants. For these reasons, Article 2.2.6.2 is proposed for deletion ([Appendix XIX](#)).

17. Diseases of bees (Section 2.9)

An OIE *Ad hoc* Group met in July 2003 to address comments from Member Countries in revising the chapters of the *Terrestrial Code* on the diseases of bees. The Code Commission examined the report of that meeting and noted that the *Ad hoc* Group was continuing its work out of session. It recalled the concerns which had been expressed that any revised or new chapters take into account the fact that few Member Countries were free of these diseases and do not unnecessarily restrict trade in bees and bee products. The report of the *Ad hoc* Group is circulated to Member Countries to provide information on the directions taken by the *Ad hoc* Group (Section C of [Appendix XXIX](#)).

The Code Commission examined the proposals of the *Ad hoc* Group for some chapters on bee diseases and an appendix on control programmes. It made some modifications to the chapters (principally the removal of articles describing control programmes as it felt that these needed better integration with the rest of the chapters). The Code Commission is proposing the following chapters for adoption (as clean text in Appendix XX):

- acarapisosis of honey bees (previously called ‘acariosis of bees’) (Chapter 2.9.1);
- American foulbrood of honey bees (Chapter 2.9.2);
- European foulbrood of honey bees (Chapter 2.9.3);
- varroosis of honey bees (Chapter 2.9.5); and
- a new chapter on *Tropilaelaps* mite infestation of honey bees.

The Code Commission is also proposing the deletion of the chapter on nosemosis of bees (Chapter 2.9.4) (in line with the recommendation of the *Ad hoc* Group).

18. Semen and embryo related matters

The Code Commission received comments on various issues relating to semen and embryos.

Comments from Australia and the USA regarding the transmissibility of enzootic bovine leukosis (EBL) via semen have been received. The USA asserts that published research shows that EBL virus is not transmitted by semen used for artificial insemination, regardless of the serologic status of the donor bull. The Code Commission recognizes that semen free from blood cells is unlikely to transmit the EBL virus. However, an expert has indicated that, in practice, the presence of blood cells in semen cannot be ruled out. For this reason, no changes to articles addressing semen in the EBL chapter have been made, but the Code Commission seeks comments from Member Countries on this issue.

Comments from Australia on the approach a ruminant semen chapter should take were noted and passed to an expert who indicated that he was updating the chapter on small ruminant semen to harmonise it with the current bovine semen chapter. The Code Commission would examine this work at its next meeting and circulate it for the comment of Member Countries. It would then work towards a single ruminant semen chapter. In doing so, it would take into account the view of the expert that Article 3.2.1.10 was out of date and should be deleted.

In reviewing comments from Member Countries, the Code Commission confined itself to addressing disease issues. Other comments will be taken up when the chapters are reorganised. Regarding bovine brucellosis, the expert agreed with the comment received that paragraph 2)d) of Article 2.3.1.7 did not offer a similar level of protection as the other paragraphs; as a result, this paragraph is proposed for deletion (Appendix XXI). The expert advised that the International Embryo Transfer Society was examining the information available on the ability of bovine embryos to transmit bovine tuberculosis and had not yet formed a view.

The Code Commission consulted with an expert and confirmed that there was no new information on enzootic bovine leucosis which could support a change to the articles addressing semen.

19. Antimicrobial resistance (Section 3.9)

The Code Commission revised the draft guidelines on risk analysis for antimicrobial resistance (which had been developed by the Biological Standards Commission), a companion appendix for the three adopted at the 71st General Session. The Code Commission is presenting this Appendix for adoption (Appendix XXII).

20. Animal welfare

The Code Commission commended the significant progress achieved by the four *Ad hoc* Groups on animal welfare and is circulating their reports for the information of Member Countries (Section C of [Appendix XXX](#)). While recognising that the reports are working documents (and are not in final form), the Code Commission seeks the views of Member Countries on the approaches taken, before each *Ad hoc* Group moves towards the drafting of more specific and detailed guidelines during 2004.

In the meantime, the Code Commission is proposing for adoption generic guiding principles on animal welfare which have been endorsed by the Working Group on Animal Welfare ([Appendix XXIII](#)).

The Code Commission expects the outcomes of the February 2004 Animal Welfare Conference to be relevant to the work of these *Ad hoc* Groups. The Working Group on Animal Welfare will review these outcomes at its next meeting immediately after the Conference, and report to the Director General and the Code Commission. Accordingly, the comments of Member Countries on the above are sought by 15 February 2004.

B. OTHER ISSUES CONSIDERED

21. Avian influenza (Chapter 2.1.15)

During the 71st General Session in May 2003, a revised chapter was discussed by the OIE International Committee. As a result of concerns expressed by several Delegates regarding implementation of the recommendations as written, the chapter was not adopted.

The Code Commission considered in depth the comments received shortly before the 71st General Session from Argentina, Australia, the EU, Japan and the USA, the outcome of the discussion held during the General Session, as well as further written comments. To address comments received, the Code Commission referred the following issues to an *Ad hoc* Group:

- the zoonotic aspects of avian influenza;
- the influence of different disease control strategies including vaccination;
- surveillance for avian influenza;
- the role of non-poultry species;
- the risks presented by different commodities from countries of different disease status; and
- the incubation period for avian influenza.

The *Ad hoc* Group discussed the definition of AI and the associated reporting obligations of Member Countries, and revised the definition. The *Ad hoc* Group recognised that fresh meat and table eggs probably present a much lower likelihood of transmission to animals of low pathogenic notifiable avian influenza (LPNAI) than highly pathogenic notifiable avian influenza (HPNAI) viruses, but, due to incomplete scientific data, the recommendations proposed for these commodities only partly reflected this difference. The *Ad hoc* Group addressed this difference as well through a proposed new definition for '*NAI-free establishment*' which distinguishes between the two regarding permitted distances from establishments infected with LPNAI or HPNAI.

The Code Commission reviewed the report of the November 2003 meeting of the *Ad hoc* Group (Section C of [Appendix XXVI](#)) and made further changes to its proposals with a view to accomplishing adoption once the following matters have been addressed:

- categories of notifiable avian influenza (NAI) status – free from NAI (i.e. both LPNAI and HPNAI), free from HPNAI (LPNAI probably present) and of unknown NAI status;

- encouragement of surveillance and notification of both LPNAI and HPNAI to maximise transparency and minimise unjustified trade restrictions as a result of the reporting of the presence of LPNAI; in this regard the Code Commission encouraged Member Countries to conduct further research on LPNAI virus to clarify its relationship with HPNAI virus and the risk it poses, if any, in international trade in specific poultry commodities;
- the Code Commission's revision of the measures proposed by the *Ad hoc* Group to better differentiate the risks associated with the different commodities traded; for each group of commodities, articles were drafted to address the different risk levels posed by the NAI status of the country/zone/compartment of origin;
- the revised chapter's taking into account the proposed revised definitions for zone and compartment, and the Code Commission's view that the correct use of these concepts is essential for the proper application of this chapter.

The revised chapter ([Appendix XXIV](#)) is submitted for Member Country comment by 18 June 2004, to enable consideration by the Bureau of the Code Commission.

Prior to this, progress in this chapter (and the chapter on Newcastle disease) is dependent on a productive discussion at the General Session on the concepts underlying the general approach.

22. Traceability

The Code Commission again reviewed the desirability of incorporating traceability into the *Terrestrial Code*. In this respect, the OIE encourages Member Countries to submit proposals and draft texts which could form the basis of guidelines.

23. General principles and surveillance systems (Section 3.8)

The Code Commission received from the Scientific Commission a proposed *Terrestrial Code* appendix on the general principles of surveillance. The proposed appendix ([Appendix XXXII](#)) is circulated unchanged for comment by Member Countries.

24. Bluetongue (Chapter 2.1.9)

The Code Commission discussed with the Scientific Commission Member Countries' comments on a draft appendix on surveillance and monitoring for bluetongue (developed by Australia). The Code Commission noted comments received from Member Countries on the bluetongue chapter. During its meeting, the Code Commission received a proposal for a revised chapter based on the outcomes of the recent OIE Conference on Bluetongue.

The Code Commission decided that, due to the significant nature of the proposal and Member Countries' comments, it would be inappropriate to make interim changes to the chapter. However, it would request that the Director General convene an *Ad hoc* Group with expertise in bluetongue to review the chapter prior to the 2004 General Session. The report of that meeting would be circulated to Member Countries for information and comment; these comments would be examined at the July meeting of the Bureau of the Code Commission.

The two Commissions agreed that the epidemiology *Ad hoc* Group would continue with the development of the appendix on surveillance, and report to the Scientific Commission.

25. Anthrax (Chapter 2.2.1)

The Code Commission proposed that no changes be made to the chapter as it was of the view that the risks associated with dairy products were adequately addressed. The Code Commission is awaiting information from experts regarding inactivation of the organism, preparatory to a revision of the Appendix on inactivation.

26. Bovine brucellosis (Chapter 2.3.1)

The Code Commission decided to await the finalisation of the revision of the chapter on bovine tuberculosis before proceeding with a revision of the chapter on brucellosis. The revision will be done in conjunction with the OIE Working Group on Animal Production Food Safety.

27. Maedi-visna (Chapter 2.4.5)

The chapter was discussed with the Scientific Commission which advised that it would request an expert to review the chapter on maedi-visna in conjunction with caprine arthritis/encephalitis, in light of the current understanding of the relationships among small ruminant lentiviruses.

28. Scrapie (Chapter 2.4.8)

The chapter was discussed with the Scientific Commission which advised that it would request the Director General to convene an *Ad hoc* Group on epidemiology to draft surveillance guidelines for scrapie.

29. Aujeszky's disease (Chapter 2.2.2)

The Scientific Commission advised that it would request the Director General to convene an *Ad hoc* Group on epidemiology to draft surveillance guidelines for Aujeszky's disease.

30. Newcastle disease (Chapter 2.1.15)

The Code Commission has asked the Scientific Commission to revise the current chapter on Newcastle disease to harmonise it with the concepts underpinning the revised avian influenza chapter, when the general approach has been endorsed by the International Committee.

31. Infectious bursal disease (Chapter 2.7.1)

In order to update the chapter of the *Terrestrial Code* on infectious bursal disease (IBD), the Code Commission is still seeking information from Member Countries on any research they may have conducted on the transmissibility of IBD virus by poultry meat.

32. Animal production food safety

The Code Commission endorsed the report of the July 2003 meeting of the Working Group on Animal Production Food Safety and is circulating the report for Member Country information and comment on the work programme (Section C of [Appendix XXXI](#)). The Code Commission also draws the attention of Member Countries to the Working Group paper entitled 'Role and functionality of veterinary services in food safety throughout the food chain' which is included in the report, and seeks feedback on that paper before the General Session.

The draft proposal on bovine tuberculosis submitted by New Zealand and modified by the Code Commission will be circulated to the Working Group for comment.

33. Export zone or compartment

The Code Commission discussed the concept of 'export zone or compartment' as proposed in a recent draft AU/IBAR document, with the aim of promoting trade from Eastern Africa to Middle East countries, through disease reduction strategies. The concept of 'export zone or compartment' is a particular application of the principles of zoning and compartmentalisation adapted to the conditions of that region. As such, the Code Commission considered that it can be a useful approach to facilitating the safe trade of specific commodities, as long as biosecurity is maintained through the rigorous application of sanitary measures as laid out in the *Terrestrial Code*, as appropriate to the size, location and organisation of the 'export zone or compartment'.

The Code Commission considered that the development of such an 'export zone or compartment' should not be an alternative to appropriate resourcing of, and certification by, Veterinary Services.

34. Training centre

The Biological Standards Commission submitted a request from the French National Training Centre for Veterinary Services at Lyon in France for consideration as an OIE Collaborating Centre for the training of official veterinarians. The Standards Commission was of the opinion that this request was more in line with regulatory activities, and therefore it should be dealt by the Code Commission.

The Code Commission examined the dossier submitted by the Training Centre and was of the view that such a Centre would provide the needed expertise in the area of capacity building for Veterinary Services. The OIE has already committed itself through the Central Bureau to participate in such capacity building activities with the World Bank, the WTO and other international and regional organisations. The Code Commission felt that this was a significant proposal, worthy of consideration by the OIE. It will therefore recommend to the Administrative Commission that the proposal be submitted for final approval by the International Committee.

C. REPORTS OF *AD HOC* GROUPS

These reports are for the information of Member Countries.

35. *Ad hoc* Group on BSE ([Appendix XXV](#))
36. *Ad hoc* Group on avian influenza ([Appendix XXVI](#))
37. *Ad hoc* Group on animal disease notification ([Appendix XXVII](#))
38. *Ad hoc* Group on veterinary paraprofessionals and private veterinarians ([Appendix XXVIII](#))
39. *Ad hoc* Group on diseases of bees ([Appendix XXIX](#))
40. Animal welfare *Ad hoc* Groups ([Appendix XXX](#))
41. Animal food Safety Working Group ([Appendix XXXI](#))

The list of chapters proposed for adoption is in Section A of this report.

.../Appendices

**MEETING OF THE OIE TERRESTRIAL ANIMAL
HEALTH STANDARDS COMMISSION**

Paris, 1-12 December 2003

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**MEETING OF THE OIE TERRESTRIAL ANIMAL
HEALTH STANDARDS COMMISSION**

Paris, 1-12 December 2003

Agenda adopted

**PART 1: MATTERS CONCERNING THE OIE
TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION**

- 1) **General definitions (Chapter 1.1.1)**
- 2) **General obligations (Chapter 1.2.1)**
- 3) **Evaluation of Veterinary Services (Chapters 1.3.3. and 1.3.4)**
- 4) **Veterinary paraprofessionals**
- 5) **Traceability**
- 6) **Equivalence (Chapter 1.3.7)**
- 7) **Animal disease notification (Chapter 1.1.3)**
- 8) **Zoning and regionalisation (Chapter 1.3.5)**
- 9) **Foot and mouth disease (Chapter 2.1.1)**
- 10) **Bovine spongiform encephalopathy (Chapter 2.3.13)**
- 11) **Bluetongue (Chapter 2.1.9)**
- 12) **Enzootic bovine leukosis (Chapter 2.3.4)**
- 13) **Chronic wasting disease**
- 14) **Leptospirosis (Chapter 2.2.4)**
- 15) **Anthrax (Chapter 2.2.1)**
- 16) **Paratuberculosis (Chapter 2.2.6)**
- 17) **Bovine brucellosis (Chapter 2.3.1)**
- 18) **Bovine tuberculosis (Chapter 2.3.3)**
- 19) **Peste des petits ruminants (Chapter 2.1.5)**
- 20) **Maedi-visna (Chapter 2.4.5)**
- 21) **Scrapie (Chapter 2.4.8)**
- 22) **Ovine pulmonary adenocarcinoma**
- 23) **Classical swine fever (Chapter 2.1.13)**
- 24) **Porcine reproductive and respiratory syndrome**
- 25) **Aujeszky's disease (Chapter 2.2.2)**
- 26) **Avian influenza (Chapter 2.1.14)**

Appendix II (contd)

- 27) Newcastle disease (Chapter 2.1.15)
- 28) Infectious bursal disease (2.7.1)
- 29) Rabies (Chapter 2.2.5)
- 30) Diseases of bees (Chapters 2.9.1 - 2.9.5)
- 31) Semen and embryo related matters (Sections 3.2 and 3.3)
- 32) Antimicrobial resistance (Section 3.9)
- 33) Animal welfare
- 34) Animal production food safety
- 35) Other matters
 - . export zones
 - . proposed training centre

**PART 2: MATTERS ALSO REFERRED TO THE OIE
SCIENTIFIC COMMISSION FOR ANIMAL DISEASES**

- 36) Traceability
 - 37) Animal disease notification (Chapter 1.1.3)
 - 38) Zoning and regionalisation (Chapter 1.3.5)
 - 39) Foot and mouth disease (Chapter 2.1.1)
 - 40) Bovine spongiform encephalopathy (Chapter 2.3.13)
 - 41) Bluetongue (Chapter 2.1.9)
 - 42) Chronic wasting disease
 - 43) Paratuberculosis (Chapter 2.2.6)
 - 44) Scrapie (Chapter 2.4.8)
 - 45) Ovine pulmonary adenocarcinoma
 - 46) Classical swine fever (Chapter 2.1.13)
 - 47) Porcine reproductive and respiratory syndrome
 - 48) Aujeszky's disease (Chapter 2.2.2)
 - 49) Avian influenza (Chapter 2.1.14)
 - 50) Newcastle disease (Chapter 2.1.15)
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CHAPTER 1.1.1. GENERAL DEFINITIONS

Article 1.1.1.1.

For the purposes of the *Terrestrial Code*:

...

Apiary

means a collection hive or group of hives whose management allows them to be considered as a single epidemiological unit situated in the same bee-keeping establishment.

Beehive

means a structure for the keeping of honey bee colonies that is being used for that purpose, including frameless hives, fixed frame hives and all designs of moveable frame hives (including nucleus hives), but not including packages or cages used to confine bees for the purpose of transport or isolation.

Approved

means formally officially approved, accredited or registered by the *Veterinary Administration* for export purposes.

Artificial insemination centre

means a facility for the production of semen approved by the *Veterinary Administration* and which meets the conditions set out in the *Terrestrial Code* for the collection, processing and/or storage of semen and used exclusively for don or animals which meet the conditions set out in the *Terrestrial Code*.

Official control programme

means a programme which is approved, and managed or supervised by the *Veterinary Administration* of a country for the purpose of controlling a vector, pathogen or *disease* by specific measures applied throughout that country, or within a zone or zones of that country.

Official Veterinarian

means a veterinarian authorised by the *Veterinary Administration* of the country to perform certain designated official tasks associated with animal health and/or public health and inspections of *commodities* and, when appropriate, to certify perform certification in conformity with the provisions of Section 1.2. of the *Terrestrial Code*.

Products of animal origin intended for human consumption

means fresh meat, meat products, gelatin, eggs, egg products, milk, milk products and honey when intended for human consumption.

Products of animal origin intended for agricultural or industrial use

means products of animal origin, except those intended for food for human consumption, pharmaceutical or surgical purposes and animal feeding.

Products of animal origin intended for pharmaceutical or surgical use

means animal organs, tissues and organic fluids to be used in the preparation of pharmaceutical products or of surgical devices.

Appendix III (contd)

Products of animal origin intended for use in animal feeding

means meat meal, liver meal, bone meal, blood meal, feather meal, pork fat, milk and milk products when intended for use in animal feeding.

Vaccination

means the successful immunisation of susceptible animals through the administration of vaccine comprising antigens appropriate to the *disease* to be prevented.

Veterinarian

means a person registered or licensed by the relevant *veterinary statutory body* of a country to practice veterinary medicine/science in that country.

Veterinary Services

the ~~Veterinary Services comprise~~ means the *Veterinary Administration*, and all the *Veterinary Authorities*, and all persons **authorised**, registered or licensed by the *veterinary statutory body*.

Veterinary statutory body

means **the an** autonomous **national** authority regulating *veterinarians* and **veterinary** *para-professionals*.

Veterinary para-professional

means a person who, for the purposes of the *Terrestrial Code*, is authorised **by the veterinary statutory body** to carry out certain **designated veterinary** tasks (dependent upon the category of **veterinary para-professional**) in a country **through a license from the veterinary statutory body**, and delegated to them under the responsibility and direction of a **registered or licensee** *veterinarian*. The **veterinary** tasks authorized for each category of **veterinary para-professional** should be defined by the *veterinary statutory body* depending on qualifications and training, and according to need.

Compartment

means an autonomous epidemiological entity defined on the basis of either geography (*zone*) or management (*enterprise*) for the purpose of *international trade*.

Enterprise

means one or more *establishments* with an integrated system of animal management forming an autonomous epidemiological entity.

Zone

is a clearly defined part of the territory of a country with a distinct animal health status. The following types of zones are recognised: *free zone*, *infected zone*, *surveillance zone* and *buffer zone*.

Compartment

means one or more *establishments* under a common biosecurity management system containing an animal *sub-population* with a distinct health status with respect to a specific disease for which required surveillance, control and biosecurity measures have been applied for the purpose of *international trade*.

Zone/Region

means a clearly defined part of a country containing an animal *sub-population* with a distinct health status with respect to a specific disease for which required surveillance, control and biosecurity measures have been applied for the purpose of *international trade*.

Population

means a group of *units* sharing a common defined characteristic.

Sub-population

means a distinct part of a *population* identifiable according to specific common animal health characteristics.

Unit

means an individually identifiable element used to describe, for example, the members of a *population* or the elements selected when sampling; examples of *units* include individual *animals*, herds, flocks and *apiaries*.

Surveillance

means the investigation of a given *population* or *sub-population* to detect the presence of a pathogenic agent or *disease*; the frequency and type of *surveillance* will be determined by the epidemiology of the pathogenic agent or *disease*, and the desired outputs.

Monitoring

means the continuous investigation of a given *population* or *sub-population*, and its environment, to detect changes in the *prevalence* of a *disease* or characteristics of a pathogenic agent.

Zoonosis

means a *disease* of humans that may be acquired from *animals*.

Emerging disease

means a new *infection* resulting from the evolution or change of an existing pathogenic agent, a known *infection* spreading to a new geographic area or *population*, or a previously unrecognized pathogenic agent or *disease* diagnosed for the first time.

List A

means the List of transmissible diseases which have the potential for very serious and rapid spread, irrespective of national borders, which are of serious socio-economic or public health consequence and which are of major importance in the international trade of animals and animal products. Reports are submitted to the OIE as often as necessary to comply with Articles 1.1.3.2. and 1.1.3.3. Diseases in List A are set out in Article 1.1.2.1. of the *Terrestrial Code*.

List B

means the List of transmissible diseases which are considered to be of socio-economic and/or public health importance within countries and which are significant in the international trade of animals and animal products. Reports are normally submitted once a year, although more frequent reporting may in some cases be necessary to comply with Articles 1.1.3.2. and 1.1.3.3. Diseases in List B are set out in Articles 1.1.2.2. to 1.1.2.10. of the *Terrestrial Code*.

Listed diseases

means the list of transmissible diseases agreed by the OIE International Committee and set out in Article 1.1.2.1. of the *Terrestrial Code*.

which have the potential for international spread or significant spread within naïve populations, or have significant zoonotic potential or could be described as emerging diseases, and which are of major importance in the *international trade of animals* and animal products. Reports should be submitted to the OIE as often as necessary to comply with Articles 1.1.3.2. and 1.1.3.3. Listed diseases are set out in Article 1.1.2.1. of the *Terrestrial Code*.

Appendix III (contd)***Outbreak of disease***

means ~~the an~~ occurrence of one of the diseases ~~in the OIE List in OIE List A or List B~~ in an ~~agricultural~~ establishment, breeding establishment or premises, including all buildings and all adjoining premises, where *animals* are present.

...

— text deleted

CHAPTER 1.2.1. GENERAL OBLIGATIONS

Article 1.2.1.1.

International trade in animals and animal products depends on a combination of factors which should be taken into account to ensure unimpeded trade, without incurring unacceptable risks to human and animal health.

Because of the likely variations in animal health situations, various options are offered by the *Terrestrial Code*. The animal health situation in the *exporting country*, in the *transit country* or *countries* and in the *importing country* should be considered before determining the requirements which have to be met for trade. To maximise harmonisation of the sanitary aspects of *international trade*, *Veterinary Administrations* of Member Countries should base their import requirements on the OIE standards, guidelines and recommendations.

These requirements should be included in the model certificates approved by the OIE which form Part 4 of this *Terrestrial Code*.

Certification requirements should be exact and concise, and should clearly convey the wishes of the *importing country*. For this purpose, prior consultation between *Veterinary Administrations* of *importing* and *exporting countries* is useful and may be necessary. It enables the setting out of the exact requirements so that the signing veterinarian can, if necessary, be given a note of guidance explaining the understanding between the *Veterinary Administrations* involved.

When Members of a *Veterinary Administration* wish to visit another country for matters of professional interest to the *Veterinary Administration* of the other country, the latter should be informed.

Article 1.2.1.2.

Responsibilities of the importing country

1. The import requirements included in the *international veterinary certificate* should assure that *commodities* introduced into the *importing country* comply with the national level of protection that it has chosen for animal and human health. *Importing countries* should restrict their requirements to those justified for such level of protection.
2. The *international veterinary certificate* should not include requirements for the exclusion of pathogens or animal diseases which are present within the territory of the *importing country* and are not subject to any *official control programme*. The requirements applying to pathogens or diseases subject to *official control programmes* in a country or zone should not provide a higher level of protection on imports than that provided for the same pathogens or diseases by the measures applied within that country or zone.
3. The *international veterinary certificate* should not include requirements for disease agents or diseases which are not OIE listed, unless the *importing country* has identified the disease agent as presenting a significant risk hazard for that country, after conducting a scientifically based import risk analysis according to the guidelines in Section 1.3.
4. The transmission by the *Veterinary Administration* of certificates or the communication of import requirements to persons other than the *Veterinary Administration* of another country, necessitates that copies of these documents are also sent to the *Veterinary Administration*. This important procedure avoids delays and difficulties which may arise between traders and *Veterinary Administrations* when the authenticity of the certificates or permits is not established.

Appendix IV (contd)

This information is usually the responsibility of *Veterinary Administrations*. However, it can be the responsibility of *Veterinary Authorities* at the place of origin of the *animals* when it is agreed that the issue of certificates does not require the approval of the *Veterinary Administration*.

Article 1.2.1.3.

Responsibilities of the exporting country

1. An *exporting country* should be prepared to supply the following information to *importing countries* on request:
 - a) information on the animal health situation and national animal health information systems to determine whether that country is free or has *free zones* of listed diseases, including the regulations and procedures in force to maintain its free status;
 - b) regular and prompt information on the occurrence of transmissible diseases;
 - c) details of the country's ability to apply measures to control and prevent the relevant listed diseases;
 - d) information on the structure of the *Veterinary Services* and the authority which they exercise;
 - e) technical information, particularly on biological tests and vaccines applied in all or part of the national territory.
2. *Veterinary Administrations* of *exporting countries* should:
 - a) have official procedures for authorisation of certifying veterinarians, defining their functions and duties as well as conditions covering possible suspension and termination of the appointment;
 - b) ensure that the relevant instructions and training are provided to certifying veterinarians;
 - c) monitor the activities of the certifying veterinarians to verify their integrity and impartiality.
3. The Head of the *Veterinary Service* of the *exporting country* is ultimately accountable for veterinary certification used in *international trade*.

Article 1.2.1.4.

Responsibilities in case of an incident occurring after importation

International trade involves a continuing ethical responsibility. Therefore, if within the recognised *incubation periods* of the various diseases subsequent to an export taking place, the *Veterinary Administration* becomes aware of the appearance or reappearance of a disease which has been specifically included in the *international veterinary certificate*, there is an obligation for the Administration to notify the *importing country*, so that the imported stock may be inspected or tested and appropriate action be taken to limit the spread of the disease should it have been inadvertently introduced.

Equally, if a disease condition appears in imported stock within a time period after importation consistent with the recognised *incubation period* of the disease, the *Veterinary Administration* of the *exporting country* should be informed so as to enable an investigation to be made, since this may be the first available information on the occurrence of the disease in a previously free herd. The *Veterinary Administration* of the *importing country* should be informed of the result of the investigation since the source of infection may not be in the *exporting country*.

— text deleted

CHAPTER 1.3.3.

EVALUATION OF VETERINARY SERVICES

Article 1.3.3.1.

The quality of the *Veterinary Services* depends on a set of factors, which include fundamental principles of an ethical, organisational and technical nature. The *Veterinary Services* shall conform to these fundamental principles, regardless of the political, economic or social situation of their country.

Compliance with these fundamental principles by the *Veterinary Services* of a Member Country is important to the establishment and maintenance of confidence in its *international veterinary certificates* by the *Veterinary Services* of other Member Countries.

The same fundamental principles should apply in countries where the responsibility for establishing or applying certain animal health measures, or issuing some *international veterinary certificates* is exercised by an organisation other than the *Veterinary Services*, or by an authority or agency on behalf of the *Veterinary Services*. In all cases, the *Veterinary Services* retain ultimate responsibility for the application of these principles.

These fundamental principles are presented in Article 1.3.3.2. The remaining factors of quality are described in Part 1 (notification, principles of certification, etc.) and the document entitled “Guidelines for the evaluation of Veterinary Services” included in Chapter 1.3.4.

The quality of *Veterinary Services* can be measured through an evaluation, whose general principles are described in Articles 1.3.3.3. and 1.3.3.4.

Article 1.3.3.2.

Fundamental principles of quality

The *Veterinary Services* shall comply with the following principles to ensure the quality of their activities:

1. Professional judgement

The **officials personnel** of *Veterinary Services* should have the relevant qualifications, scientific expertise and experience to give them the competence to make sound professional judgements.

2. Independence

Care shall be taken to ensure that *Veterinary Services'* **staff personnel** are free from any commercial, financial, hierarchical, political or other pressures which might affect their judgement or decisions.

3. Impartiality

The *Veterinary Services* shall be impartial. In particular, all the parties affected by their activities have a right to expect their services to be delivered under reasonable and non-discriminatory conditions.

4. Integrity

The *Veterinary Services* shall guarantee that the work of each of their **officials personnel** is of a consistently high level of integrity. Any fraud, corruption or falsification shall be identified and corrected.

5. Objectivity

The *Veterinary Services* shall at all times act in an objective, transparent and non-discriminatory manner.

Appendix V (contd)6. General organisation

The *Veterinary Services* must be able to demonstrate by means of an appropriate legislation, **sufficient financial resources** and **effective** organisation that they are in a position to have control of the establishment and application of animal health measures, and of international veterinary certification activities. Legislation should be suitably flexible to allow for judgements of equivalence and efficient responses to changing situations to be addressed efficiently, and the incorporation of animal welfare and food safety measures. In particular, they shall define and document the responsibilities and structure of the organisations in charge of the animal identification system, control of animal movements, animal disease control and reporting systems, epidemiological surveillance and communication of epidemiological information.

A similar demonstration should be made by *Veterinary Services* when they are in charge of veterinary public health activities.

The *Veterinary Services* shall have at their disposal effective systems for animal disease surveillance and for *notification* of disease problems wherever they occur, in accordance with the provisions of the *Terrestrial Code*. Adequate coverage of animal populations should also be demonstrated. They shall at all times endeavour to improve their performance in terms of animal health information systems and animal disease control.

The *Veterinary Services* shall define and document the responsibilities and structure of the organisation (in particular the chain of command) in charge of issuing *international veterinary certificates*.

Each position within the *Veterinary Services* which has an impact on their quality shall be described. These job descriptions shall include the requirements for education, training, technical knowledge and experience.

7. Quality policy

The *Veterinary Services* shall define and document their policy and objectives for, and commitment to, quality, and shall ensure that this policy is understood, implemented and maintained at all levels in the organisation. Where conditions allow, they may implement a quality system corresponding to their areas of activity and appropriate for the type, range and volume of work that they have to perform. The guidelines for the quality and evaluation of *Veterinary Services* propose a suitable reference system, which should be used if a Member Country chooses to adopt a quality system.

8. Procedures and standards

The *Veterinary Services* shall develop and document appropriate procedures and standards for **all providers of relevant activities and associated facilities the implementation and management of animal health measures and international veterinary certification activities.** These procedures and standards may for example relate to:

- a) programming and management of activities, including international veterinary certification activities;
- b) prevention, control and **notification** of disease *outbreaks*;
- c) risk analysis, epidemiological surveillance and zoning;
- d) inspection and sampling techniques;
- e) diagnostic tests for animal diseases;

Appendix V (contd)

- f) preparation, production, registration and control of biological products for use in the diagnosis or prevention of diseases;
- g) border controls and import regulations;
- h) *disinfection* and *disinfestation*;
- i) treatments intended to destroy, if appropriate, pathogens in animal products,

standards for registration of slaughter establishments.

Inasmuch as the OIE has adopted standards on these matters, the *Veterinary Services* shall comply with these standards when applying animal health measures and when issuing *international veterinary certificates*.

9. Information, complaints and appeals

The *Veterinary Administration* shall undertake to reply to legitimate requests from *Veterinary Administrations* of other Member Countries or any other authority, in particular ensuring that any requests for information, complaints or appeals that they may present are dealt with in a timely manner.

A record shall be maintained of all complaints and appeals and of the relevant action taken by the *Veterinary Services*.

10. Documentation

The *Veterinary Services* shall have at their disposal a reliable and up-to-date documentation system suited to their activities.

11. Self-evaluation

The *Veterinary Services* should undertake periodical self-evaluation especially by documenting achievements against goals, and demonstrating the efficiency of their organisational components and resource adequacy.

A Member Country can request the Director General of the OIE to arrange for an expert or experts to assist in the process.

12. Communication

Veterinary Services should have effective internal and external systems of communication covering administrative and technical staff levels and parties affected by their activities.

13. Human and financial resources

Responsible authorities should ensure that adequate resources are made available to implement effectively the above activities.

Article 1.3.3.3.

For the purposes of this *Terrestrial Code*, every Member Country shall recognise the right of another Member Country to undertake, or request it to undertake, an evaluation of its *Veterinary Services* where the initiating Member Country is an actual or a prospective importer or exporter of *commodities* and where the evaluation is to be a component of a risk analysis process which is to be used to determine or review sanitary measures which apply to such trade.

Appendix V (contd)

Any evaluation of *Veterinary Services* should be conducted having regard to the OIE Guidelines for the evaluation of *Veterinary Services* presented in Chapter 1.3.4. of the *Terrestrial Code*.

A Member Country has the right to expect that the evaluation of its *Veterinary Services* will be conducted in an objective manner. A Member Country undertaking evaluation should be able to justify any measure taken as a consequence of its evaluation.

Article 1.3.3.4.

A Member Country which intends to conduct an evaluation of another Member Country's *Veterinary Services* shall give them notice in writing. This notice should define the purpose of the evaluation and details of the information required.

On receipt of a formal request for information to enable an evaluation of its *Veterinary Services* by another Member Country, and following bilateral agreement of the evaluation process and criteria, a Member Country should expeditiously provide the other country with meaningful and accurate information of the type requested.

The evaluation process should take into account the fundamental principles and other factors of quality laid down in Articles 1.3.3.1. and 1.3.3.2. It should also take into consideration the specific circumstances regarding quality, as described in Article 1.3.3.1., prevailing in the countries concerned.

The outcome of the evaluation conducted by a Member Country should be provided in writing as soon as possible, and in any case within 4 months of receipt of the relevant information, to the Member Country which has undergone the evaluation. The evaluation report should detail any findings which affect trade prospects. The Member Country which conducts the evaluation should clarify in detail any points of the evaluation on request.

In the event of a dispute between two Member Countries over the conduct or the conclusions of the evaluation of the *Veterinary Services*, the matter should be dealt with having regard to the procedures set out in Article 1.3.1.4.

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CHAPTER 1.3.4.

GUIDELINES FOR THE EVALUATION OF VETERINARY SERVICES

Article 1.3.4.1.

General considerations

1. Evaluation of *Veterinary Services* is an important element in the risk analysis process which countries may legitimately use in their policy formulations directly applying to animal health and sanitary controls of *international trade* in *animals*, animal-derived products, animal genetic material and animal feedstuffs.

Any evaluation should be carried out with due regard for Chapter 1.3.3. of the *Terrestrial Code*.

2. In order to ensure that objectivity is maximised in the evaluation process, it is essential for some standards of discipline to be applied. The OIE has developed these guidelines which can be practically applied to the evaluation of *Veterinary Services*. These are relevant for evaluation of the *Veterinary Services* of one country by those of another country for the purposes of risk analysis in *international trade*. The guidelines are also applicable for evaluation by a country of its own *Veterinary Services* – the process known as self-evaluation or self-assessment– and for periodic re-evaluation.

In carrying out a risk analysis prior to deciding the sanitary/zoosanitary conditions for the importation of a *commodity*, an *importing country* is justified in regarding its evaluation of the *Veterinary Services* of the *exporting country* as critical.

3. The purpose of evaluation may be either to assist a national authority in the decision-making process regarding priorities to be given to its own *Veterinary Services* (self-evaluation) or to assist the process of risk analysis in *international trade* in *animals* and animal-derived products to which official sanitary and/or zoosanitary controls apply.
4. In both situations, the evaluation should demonstrate that the *Veterinary Services* have the capability for effective control of the sanitary and zoosanitary status of *animals* and animal products. Key elements to be covered in this process include resource adequacy, management capability, legislative and administrative infrastructures, independence in the exercise of official functions and performance history, including disease reporting.
5. Competence and integrity are qualities on which others base their confidence in individuals or organisations. Mutual confidence between relevant official *Veterinary Services* of trading partner countries contributes fundamentally to stability in *international trade* in *animals* and animal-related products. In this situation, scrutiny is directed more at the *exporting country* than at the *importing country*.
6. Although quantitative data can be provided on *Veterinary Services*, the ultimate evaluation will be essentially qualitative. While it is appropriate to evaluate resources and infrastructure (organisational, administrative and legislative), it is also appropriate to place emphasis on the evaluation of the quality of outputs and performance of *Veterinary Services*. Evaluation should take into consideration any quality systems used by *Veterinary Services*.
7. An *importing country* has a right of assurance that information on sanitary/zoosanitary situations provided by the *Veterinary Services* of an *exporting country* is objective, meaningful and correct. Furthermore, the *Veterinary Services* of the *importing country* are entitled to expect validity in the veterinary certification of export.

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8. An *exporting country* is entitled to expect that its *animals* and animal products will receive reasonable and valid treatment when they are subjected to import inspection in the country of destination. The country should also be able to expect that any evaluation of its standards and performance will be conducted on a non-discriminatory basis. The *importing country* should be prepared and able to defend any position which it takes as a consequence of the evaluation.
9. While As the *veterinary statutory body* is not a part of the *Veterinary Services*, an evaluation of that body should be carried out to ensure that the registration/licensing of veterinarians and authorisation of veterinary para-professionals is included as an important element of the risk analysis process.

Article 1.3.4.2.

Scope

1. In the evaluation of *Veterinary Services*, the following items may be considered, depending on the purpose of the evaluation:
- organisation, structure and authority of the *Veterinary Services*
 - human resources
 - material (including financial) resources
 - functional capabilities and legislative support
 - animal health and veterinary public health controls
 - formal quality systems including quality policy
 - performance assessment and audit programmes
 - participation in OIE activities and compliance with OIE Member Countries' obligations.
2. To complement the evaluation of *Veterinary Services*, it is necessary to also consider the organisation structure and functioning of the *veterinary statutory body*.
3. Article 1.3.4.13. outlines appropriate information requirements for:
- self-evaluation by national *Veterinary Services* which perceive a need to prepare information for national or international purposes;
 - evaluation by a prospective or actual *importing country* of the *Veterinary Services* of a prospective or actual *exporting country*;
 - verification or re-verification of an evaluation in the course of a visit to the *exporting country* by the *importing country*.

Article 1.3.4.3.

Evaluation criteria for the organisational structure of the Veterinary Services

1. A key element in the evaluation is the study of the organisation and structure of the official *Veterinary Services*. The *Veterinary Services* should define and set out their policy, objectives and commitment to quality systems and standards. These organisational and policy statements should be described in detail. Organisational charts and details of functional responsibilities of staff should be available for evaluation. The role and responsibility of the Chief Veterinary Officer/Veterinary Director should be clearly defined. Lines of command should also be described.

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2. The organisational structure should also clearly set out the interface relationships of government Ministers and departmental Authorities with the Chief Veterinary Officer/Veterinary Director and the *Veterinary Services*. Formal relationships with statutory authorities and with industry organisations and associations should also be described. It is recognised that Services may be subject to changes in structure from time to time. Major changes should be notified to trading partners so that the effects of re-structuring may be assessed.
3. Organisational components of *Veterinary Services* which have responsibility for key functional capabilities should be identified. These capabilities include epidemiological surveillance, disease control, import controls, animal disease reporting systems, animal identification systems, traceability systems, animal movement control systems, communication of epidemiological information, training, inspection and certification. Laboratory and field systems and their organisational relationships should be described.
4. To reinforce the reliability and credibility of their services, the *Veterinary Services* may have set up quality systems that correspond with their fields of activity and to the nature and scale of activities that they carry out. Evaluation of such systems should be as objective as possible.
5. The *Veterinary Administration* alone speaks for the country as far as official international dialogue is concerned. This is also particularly important to cases where zoning and regionalisation are being applied. The responsibilities of the national *Veterinary Administration* and all *Veterinary Authorities* in that country should be made clear in the process of evaluation of *Veterinary Services*.
6. A *Veterinary Authority* is defined in Chapter 1.1.1. of the *Terrestrial Code*. As some countries have some official veterinary authority roles vested in autonomous sub-national (state/provincial, municipal) government bodies, there is an important need to assess the role and function of these Services. Details of their roles, relationship (legal and administrative) to each other and to the national *Veterinary Services* should be available for evaluation. Annual reports, review findings and access to other information pertinent to the animal health activities of such bodies should also be available.
7. Similarly, where the national *Veterinary Services* have arrangements with other providers of relevant services such as universities, laboratories, information services, etc., these arrangements should also be described. For the purposes of evaluation, it is appropriate to expect that the quality of organisational and functional standards which apply to *Veterinary Services* should also apply to the services of these other providers.

Article 1.3.4.4.

Evaluation criteria for quality systems

1. The *Veterinary Services* should demonstrate a commitment to the quality of the processes and outputs of their services. Where services or components of services are delivered under a formal quality systems programme which is based on OIE recommended standards or, especially in the case of laboratory components of *Veterinary Services* other internationally recognised quality standards, the *Veterinary Services* undergoing evaluation should make available evidence of accreditation, details of the documented quality processes and documented outcomes of all relevant audits undertaken.
2. Where the *Veterinary Services* undergoing evaluation make large use of formal quality systems in the delivery of their services, it is appropriate that greater emphasis be placed on the outcomes of evaluation of these quality systems than on the resource and infrastructural components of the services.

Appendix V (contd)

Article 1.3.4.5.

Evaluation criteria for human resources

1. The *Veterinary Services* should demonstrate that their human resource component includes an integral core of full-time civil service employees. This core must include ~~graduate~~ veterinarians. It should also ~~and should include other qualified professional officers, and~~ administrative officials and ~~veterinary para-professionals~~ technical support staff. The human resources ~~does not exclude~~ ~~should~~ ~~may~~ also include the possibility of employing, in addition, part-time and private sector veterinarians and ~~veterinary para-professionals~~ and para-veterinary staff, ~~and private sector veterinarians and para-professionals~~. It is essential that all the above categories of ~~personnel staff~~ be subject to legal disciplinary provisions. Data relating to the resource base of the *Veterinary Services* undergoing evaluation should be available.
2. In addition to raw quantitative data on this resource base, the functions of the various categories of ~~staff personnel~~ in the *Veterinary Services* should be described in detail. This is necessary for analysis and estimation of the appropriateness of the application of qualified skills to the tasks undertaken by the *Veterinary Services* and may be relevant, for example, to the roles of veterinarians and ~~animal technical assistants~~ health ~~health~~ ~~veterinary para-professionals~~ in field services. In this case, the evaluation should provide assurances that disease monitoring is being conducted by a sufficient number of qualified, experienced field veterinarians who are directly involved in farm visits; there should not be an over-reliance on ~~technical assistant staff~~ ~~veterinary para-professionals~~ for this task.
3. Analysis of these data can be used to estimate the potential of the *Veterinary Services* to have reliable knowledge of the state of animal health in the country and to support an optimal level of animal disease control programmes. A large population of private ~~veterinarians practitioners~~ would not provide the *Veterinary Services* with an effective epizootiological information base without legislative (e.g. compulsory reporting of notifiable diseases) and administrative (e.g. official animal health surveillance and reporting systems) mechanisms in place.
4. These data should be assessed in close conjunction with the other information described in this Chapter. For example, a large field staff (veterinarians and ~~veterinary para-professionals~~ ~~animal health technical assistants~~) need fixed, mobile and budgetary resources for animal health activities in the livestock farming territory of the country. If deficiencies are evident, there would be reason to challenge the validity of epizootiological information.

Article 1.3.4.6.

Evaluation criteria for material resources1. Financial

Actual yearly budgetary information regarding the *Veterinary Services* should be available and should include the details set out in the model questionnaire outlined in Article 1.3.4.13. Information is required on conditions of service for veterinary staff (including salaries and incentives) and should provide a comparison with the private sector and perhaps with other professionals. Information should also be available on non-government sources of revenue available to veterinarians in their official responsibilities.

2. Administrative

a) Accommodation

The *Veterinary Services* should be accommodated in premises suitable for efficient performance of their functions. The component parts of the *Veterinary Services* should be located as closely as possible to each other at the central level, and in the regions where they are represented, in order to facilitate efficient internal communication and function.

b) Communications

The *Veterinary Services* should be able to demonstrate that they have reliable access to effective communications systems, especially for animal health surveillance and control programmes. Inadequate communications systems within the field services components of these programmes or between outlying offices and headquarters, or between the *Veterinary Services* and other relevant administrative and professional services, signify an inherent weakness in these programmes. Adequate communications systems between laboratories and between field and laboratory components of the *Veterinary Services* should also be demonstrated.

Examples of types of communications which should be routinely available on an adequate country-wide basis are national postal, freight and telephone networks. Rapid courier services, facsimile and electronic data interchange systems (e.g. e-mail and Internet services) are examples of useful communication services which, if available, can supplement or replace the others. A means for rapid international communication should be available to the national *Veterinary Services*, to permit reporting of changes in national disease status consistent with OIE recommendations and to allow bilateral contact on urgent matters with counterpart *Veterinary Services* in trading-partner countries.

c) Transport systems

The availability of sufficient reliable transport facilities is essential for the performance of many functions of *Veterinary Services*. This applies particularly to the field services components of animal health activities (e.g. emergency response visits). Otherwise, the *Veterinary Services* cannot assure counterpart services in other countries that they are in control of the animal health situation within the country.

Appropriate means of transport are also vital for the satisfactory receipt of samples to be tested at veterinary laboratories, for inspection of imports and exports, and for the performance of *animal* and animal product inspection in outlying production or processing establishments.

3. Technical

Details available on laboratories should include resources data, programmes under way as well as those recently completed and review reports on the role or functions of the laboratory. Information as described in the model questionnaire should be used in the evaluation of laboratory services.

a) Cold chain for laboratory samples and veterinary medicines

Adequate refrigeration and freezing systems should be available and should be used throughout the country to provide suitable low temperature protection for laboratory samples in transit or awaiting analysis, as well as veterinary medical products (e.g. vaccines) when these are required for use in animal disease control programmes. If these assurances cannot be given, it may be valid to discount many types of test results, as well as the effectiveness of certain disease control programmes and the export inspection system in the country undergoing evaluation.

b) Diagnostic laboratories

Analysis of the laboratory service component of *Veterinary Services*, which would include official governmental laboratories and other laboratories accredited by the *Veterinary Services* for specified purposes, is an essential element of the evaluation process. The quality of the veterinary diagnostic laboratories of a country underpins the whole control and certification processes of the zoosanitary/sanitary status of exported *animals* and animal products, and therefore these laboratories should be subject to rigid quality assurance procedures and should use international quality assurance programmes (wherever available) for standardising test methodologies and testing proficiency. An example is the use of International Standard Sera for standardising reagents.

Appendix V (contd)

This emphasis is valid whether one relates it to the actual testing performed on individual export consignments or to the more broad and ongoing testing regimes which are used to determine the animal health and veterinary public health profiles of the country and to support its disease control programmes. For the purposes of evaluation, veterinary diagnostic laboratories include those which are concerned with either animal health or veterinary public health activities. The *Veterinary Services* must approve and designate these laboratories for such purposes and have them audited regularly.

c) Research

The scope of animal disease and veterinary public health problems in the country concerned, the stages reached in the controls which address those problems and their relative importance can be measured to some degree by analysis of information on government priorities and programmes for research in animal health. This information should be accessible for evaluation purposes.

Article 1.3.4.7.

Functional capabilities and legislative support1. Animal health and veterinary public health

The *Veterinary Services* should be able to demonstrate that they have the capacity, supported by appropriate legislation, to exercise control over all animal health matters. These controls should include, where appropriate, compulsory notification of prescribed animal diseases, inspection, movement controls **through systems which provide adequate traceability** ~~including registration of holdings and animal identification, registration of facilities,~~ quarantine of infected premises/areas, testing, treatment, destruction of infected *animals* or contaminated materials, controls over the use of veterinary medicines, etc. The scope of the legislative controls should include domestic animals and their reproductive material, animal products, wildlife as it relates to the transmission of diseases to **humans and** domestic animals, and other products subject to veterinary inspection. Arrangements should exist for co-operation with the veterinary authorities of the neighbouring countries for the control of animal diseases in border areas **and for establishing linkages to recognise and regulate trans-boundary activities.** ~~including the movements of veterinarians and para-professionals.~~ Information on the veterinary public health legislation covering the production of products of animal origin for national consumption may be also considered in the evaluation.

2. Export/import inspection

National *Veterinary Services* should have appropriate legislation and adequate capabilities to prescribe the methods for control and to exercise systematic control over the import and export processes of *animals* and animal products in so far as this control relates to sanitary and zoonotic matters. The evaluation should also involve the consideration of administrative instructions to ensure the enforcement of *importing country* requirements during the pre-export period.

In the context of production for export of foodstuffs of animal origin, the *Veterinary Services* should demonstrate that comprehensive legislative provisions are available for the oversight by the relevant authorities of the hygienic process and to support official inspection systems of these *commodities* which function to standards consistent with or equivalent to relevant Codex Alimentarius and OIE standards.

Control systems should be in place which permit the exporting *Veterinary Authorities* to approve export premises. The *Veterinary Services* should also be able to conduct testing and treatment as well as to exercise controls over the movement, handling and storage of exports and to make inspections at any stage of the export process. The product scope of this export legislation should include, *inter alia*, *animals* and animal products (including animal semen, ova and embryos), and animal feedstuffs.

Appendix V (contd)

The national *Veterinary Services* should be able to demonstrate that they have adequate capabilities and legislative support for zoosanitary control of imports and transit of *animals*, animal products and other materials which may introduce animal diseases. This could be necessary to support claims by the *Veterinary Services* that the animal health status of the country is suitably stable, and that cross-contamination of exports from imports of unknown or less favourable zoosanitary status is unlikely. The same considerations should apply in respect of veterinary control of public health. The *Veterinary Services* should be able to demonstrate that there is no conflict of interest when certifying veterinarians are performing official duties.

Legislation should also provide the right to deny and/or withdraw official certification. Penalty provisions applying to malpractice on the part of certifying officials should be included.

The *Veterinary Services* should demonstrate that they are capable of providing accurate and valid certification for exports of *animals* and animal products, based on Section 1.2. of the *Terrestrial Code*. They should have appropriately organised procedures which ensure that sanitary/animal health certificates are issued by efficient and secure methods. The documentation control system should be able to correlate reliably the certification details with the relevant export consignments and with any inspections to which the consignments were subjected.

Security in the export certification process, including electronic documentation transfer, is important. A system of independent compliance review is desirable, to safeguard against fraud in certification by officials and by private individuals or corporations. The certifying veterinarian should have no conflict of interest in the commercial aspects of the animal or product being certified and be independent from the commercial parties.

Article 1.3.4.8.

Animal health controls

1. Animal health status

An updated assessment of the present animal disease status of a country is an important and necessary procedure. For this undertaking, studies of the OIE publications such as *World Animal Health*, the *Bulletin* and *Disease Information* must be fundamental reference points. The evaluation should consider the recent history of the compliance of the country with its obligations regarding international notification of animal diseases. In the case of an OIE Member Country, failure to provide the necessary animal health reports consistent with OIE requirements will detract from the overall outcome of the evaluation of the country.

An *exporting country* should be able to provide further, detailed elaboration of any elements of its animal disease status as reported to the OIE. This additional information will have particular importance in the case of animal diseases which are foreign to or strictly controlled in the *importing country* or region. The ability of the *Veterinary Services* to substantiate elements of their animal disease status reports with surveillance data, results of monitoring programmes and details of disease history is highly relevant to the evaluation. In the case of evaluation of the *Veterinary Services* of an *exporting country* for *international trade* purposes, an *importing country* should be able to demonstrate the reasonableness of its request and expectations in this process.

2. Animal health control

Details of current animal disease control programmes should be considered in the evaluation. These programmes would include epidemiological surveillance, official government-administered or officially-endorsed, industry-administered control or eradication programmes for specific diseases or disease complexes, and animal disease emergency preparedness. Details should include enabling legislation, programme plans for epidemiological surveillance and animal disease emergency responses, quarantine arrangements for infected and exposed animals or herds, compensation provisions for animal owners affected by disease control measures, training programmes, physical and other barriers between the free country or zone and those infected, incidence and prevalence data, resource commitments, interim results and programme review reports.

Appendix V (contd)3. National animal disease reporting systems

The presence of a functional animal disease reporting system which covers all agricultural regions of the country and all veterinary administrative control areas should be demonstrated.

An acceptable variation would be the application of this principle to specific zones of the country. In this case also, the animal disease reporting system should cover each of these zones. Other factors should come to bear on this situation, e.g. the ability to satisfy trading partners that sound animal health controls exist to prevent the introduction of disease or export products from regions of lesser veterinary control.

Article 1.3.4.9.

Veterinary public health controls1. Food hygiene

The national *Veterinary Services* should be able to demonstrate effective responsibility for the veterinary public health programmes relating to the production and processing of animal products **especially for export**. If the national *Veterinary Services* do not exercise responsibility over these programmes, the evaluation should include a comprehensive review of the role and relationship of the organisations (national, state/provincial, and municipal) which are involved. In such a case, the evaluation should consider whether the national *Veterinary Services* can provide guarantees of responsibility for and effective control of the sanitary status of animal products **prior to export, especially meat and meat products** throughout the slaughter, processing, transport and storage periods.

2. Zoonoses

Within the structure of *Veterinary Services*, there should be appropriately qualified **personnel staff** whose responsibilities include the monitoring and control of zoonotic diseases and, where appropriate, liaison with medical authorities.

3. Chemical residue testing programmes

Adequacy of controls over chemical residues in exported *animals*, animal products and feedstuffs should be demonstrated. Statistically-based surveillance and monitoring programmes for environmental and other chemical contaminants in *animals*, in animal-derived foodstuffs and in animal feedstuffs should be favourably noted. These programmes should be coordinated nationwide. Correlated results should be freely available on request to existing and prospective trading partner countries. Analytical methods and result reporting should be consistent with internationally recognised standards. If official responsibility for these programmes does not rest with the *Veterinary Services*, there should be appropriate provision to ensure that the results of such programmes are made available to the *Veterinary Services* for assessment.

4. Veterinary medicines

It should be acknowledged that primary control over veterinary medicinal products may not rest with the veterinary authorities in some countries, owing to differences between governments in the division of legislative responsibilities. However, for the purpose of evaluation, the *Veterinary Services* should be able to demonstrate the existence of effective controls (including nationwide consistency of application) over the manufacture, ~~or~~ importation, export, registration, supply, **sale** and use of veterinary medicines, biologicals and diagnostic reagents, whatever their origin. The control of veterinary medicines has direct relevance to the areas of animal health and public health.

Appendix V (contd)

In the animal health sphere, this has particular application to biological products. Inadequate controls on the registration and use of biological products leave the *Veterinary Services* open to challenge over the quality of animal disease control programmes and over safeguards against animal disease introduction in imported veterinary biological products.

It is valid, for evaluation purposes, to seek assurances of effective government controls over veterinary medicines in so far as these relate to the public health risks associated with residues of these chemicals in *animals* and animal-derived foodstuffs. This process should be consistent with the standards set by the Codex Alimentarius or with alternative requirements set by the *importing country* where the latter are scientifically justified.

5. Integration between animal health controls and veterinary public health

The existence of any organised programme which incorporates a structured system of information feedback from inspection in fresh meat or dairy product establishments and applies this in animal health control should be favourably noted. Such programmes should be integrated within a national **epizootiological disease** surveillance scheme.

Veterinary Services which direct a significant element of their animal health programmes specifically towards minimising microbial and chemical contamination of animal-derived products in the human food chain should receive favourable recognition in the evaluation. There should be evident linkage between these programmes and the official control of veterinary medicines and relevant agricultural chemicals.

Article 1.3.4.10.

Performance assessment and audit programmes

1. Strategic plans

The objectives and priorities of the *Veterinary Services* can be well evaluated if there is a published official strategic plan which is regularly updated. Understanding of functional activities is enhanced if an operational plan is maintained within the context of the strategic plan. The strategic and operational plans, if these exist, should be included in the evaluation.

Veterinary Services which use strategic and operational plans may be better able to demonstrate effective management than countries without such plans.

2. Performance assessment

If a strategic plan is used, it is desirable to have a process which allows the organisation to assess its own performance against its objectives. Performance indicators and the outcomes of any review to measure achievements against pre-determined performance indicators should be available for evaluation. The results should be considered in the evaluation process.

3. Compliance

Matters which can compromise compliance and adversely affect a favourable evaluation include instances of inaccurate or misleading official certification, evidence of fraud, corruption, or interference by higher political levels in international veterinary certification, and lack of resources and poor infrastructure.

It is desirable that the *Veterinary Services* contain (or have a formal linkage with) an independent internal unit/section/commission the function of which is to critically scrutinise their operations. The aim of this unit should be to ensure consistent and high integrity in the work of the individual officials in the *Veterinary Services* and of the corporate body itself. The existence of such a body can be important to the establishment of international confidence in the *Veterinary Services*.

An important feature when demonstrating the integrity of the *Veterinary Services* is their ability to take corrective action when miscertification, fraud or corruption has occurred.

Appendix V (contd)

A supplementary or an alternative process for setting performance standards and application of monitoring and audit is the implementation of formal quality systems to some or all activities for which the *Veterinary Services* are responsible. Formal accreditation to international quality system standards should be utilised if recognition in the evaluation process is to be sought.

4. Veterinary Services administration

a) Annual reports

Official government annual reports should be published, which provide information on the organisation and structure, budget, activities and contemporary performance of the *Veterinary Services*. Current and retrospective copies of such reports should be available to counterpart Services in other countries, especially trade partners.

b) Reports of government review bodies

The reports of any periodic or ad hoc government reviews of *Veterinary Services* or of particular functions or roles of the *Veterinary Services* should be considered in the evaluation process. Details of action taken as a consequence of the review should also be accessible.

c) Reports of special committees of enquiry or independent review bodies

Recent reports on the *Veterinary Services* or elements of their role or function, and details of any subsequent implementation of recommendations contained in these reports should be available. The *Veterinary Services* concerned should recognise that the provision of such information need not be detrimental to the evaluation outcome; in fact, it may demonstrate evidence of an effective audit and response programme. The supplying of such information can reinforce a commitment to transparency.

d) In-service training and development programme for staff

In order to maintain a progressive approach to meeting the needs and challenges of the changing domestic and international role of *Veterinary Services*, the national administration should have in place an organised programme which provides appropriate training across a range of subjects for relevant staff. This programme should include participation in scientific meetings of animal health organisations. Such a programme should be used in assessing the effectiveness of the Services.

e) Publications

Veterinary Services can augment their reputation by demonstrating that their staff publish scientific articles in refereed veterinary journals or other publications.

f) Formal linkages with sources of independent scientific expertise

Details of formal consultation or advisory mechanisms in place and operating between the *Veterinary Services* and local and international universities, scientific institutions or recognised veterinary organisations should be taken into consideration. These could serve to enhance the international recognition of the *Veterinary Services*.

g) Trade performance history

In the evaluation of the *Veterinary Services* of a country, it is pertinent to examine the recent history of their performance and integrity in trade dealings with other countries. Sources of such historical data may include Customs Services.

Article 1.3.4.11.

Participation in OIE activities

Questions on a country's adherence to its obligations as a member of the OIE are relevant to an evaluation of the *Veterinary Services* of the country. Self-acknowledged inability or repeated failure of a Member Country to fulfil reporting obligations to the OIE will detract from the overall outcome of the evaluation. Such countries, as well as non-member countries, will need to provide extensive information regarding their *Veterinary Services* and sanitary/zoosanitary status for evaluation purposes.

Article 1.3.4.11.bis**Evaluation of veterinary statutory body**

In the evaluation of the *veterinary statutory body*, the following items may be considered, depending on the purpose of the evaluation:

- ≡ human resources, including the appropriateness composition and representation of the body's membership for veterinarians and para-professionals;
- ≡ institutional arrangements, accountability and transparency of decision-making procedures, including;
- ≡ sources and management of funding financial resources;
- ≡ functional capabilities, including the ability to enforce its decisions (for example regarding registration requirements, standards of conduct, deregistration and disciplinary procedures);
- ≡ administration of continuing professional development and education programmes for veterinarians and veterinary para-professionals;
- ≡ legislative basis, including autonomy.
- decision-making procedures, including transparency.

Article 1.3.4.12.

1. The *Veterinary Services* of a country may undertake self-evaluation against the above criteria for such purposes as national interest, improvement of internal efficiency or export trade facilitation. The way in which the results of self-evaluation are used or distributed is a matter for the country concerned.
2. A prospective *importing country* may undertake an evaluation of the *Veterinary Services* of an *exporting country* as part of a risk analysis process, which is necessary to determine the sanitary or zoosanitary measures which the country will use to protect human or animal life or health from disease or pest threats posed by imports. Periodic evaluation reviews are also valid following the commencement of trade.
3. In the case of evaluation for the purposes of *international trade*, the authorities of an *importing country* should use the principles elaborated above as the basis for the evaluation and should attempt to acquire information according to the model questionnaire outlined in Article 1.3.4.13. The *Veterinary Services* of the *importing country* are responsible for the analysis of details and for determining the outcome of the evaluation after taking into account all the relevant information. The relative ranking of importance ascribed, in the evaluation, to the criteria described in this document will necessarily vary according to case-by-case circumstances. This ranking should be established in an objective and justifiable way. Analysis of the information obtained in the course of an evaluation study must be performed in as objective a manner as possible. The validity of the information should be established and reasonableness should be employed in its application. The assessing country must be willing to defend any position taken on the basis of this type of information, if challenged by the other party.

Appendix V (contd)

Article 1.3.4.13.

This Article outlines appropriate information requirements for the self-evaluation or evaluation of the *Veterinary Services* of a country.

1. Organisation and structure of Veterinary Services

a) National Veterinary Services

Organisational chart including numbers, positions and numbers of vacancies.

b) Sub-national Veterinary Services

Organisational charts including numbers, positions and number of vacancies.

c) Other providers of Veterinary Services

Description of any linkage with other providers of *Veterinary Services*.

2. National information on human resources

a) Veterinarians

i) Total numbers of:

- veterinarians registered/licensed by the veterinary statutory body of ~~in~~ the country who are graduates from internationally recognised veterinary schools which are registered accordingly in the WHO/FAO World Directory of Veterinary Schools;
- ~~graduate veterinarians not included above.~~

ii) Numbers of:

- full time government veterinarians: national and sub-national;
- part time government veterinarians: national and sub-national;
- private veterinarians authorised by the *Veterinary Services* to perform official veterinary functions [*Describe accreditation standards, responsibilities and/or limitations applying to these private veterinarians*];
- = other veterinarians.

iii) Animal health:

Numbers associated with farm livestock sector on a majority time basis in a veterinary capacity, by geographical area [*Show categories and numbers to differentiate staff involved in field service, laboratory, administration, import/export and other functions, as applicable*]:

- full time government veterinarians: national and sub-national;
- part time government veterinarians: national and sub-national;
- ~~privately employed~~ other veterinarians.

Appendix V (contd)

iv) Veterinary public health:

Numbers employed in food inspection on a majority time basis, by commodity [*Show categories and numbers to differentiate staff involved in inspection, laboratory and other functions, as applicable*]:

- full time government veterinarians: national and sub-national;
- part time government veterinarians: national and sub-national;
- ~~privately employed~~ other veterinarians.

v) Numbers of veterinarians relative to certain national indices:

- per total human population;
- per farm livestock population, by geographical area;
- per livestock-farming unit, by geographical area.

vi) Veterinary education:

- number of veterinary schools;
- length of veterinary course (years);
- international recognition of veterinary degree.

vii) Veterinary professional associationsb) Graduate personnel staff (non-veterinary)

Details to be provided by category (including biologists, biometricians, economists, engineers, lawyers, other science graduates and others) on numbers within national *Veterinary Services* and available to national *Veterinary Services*.

c) ~~Technical assistants~~ Veterinary para-professionals employed by the *Veterinary Services*

i) Animal health:

- Categories and numbers involved with farm livestock on a majority time basis:
 - . by geographical area;
 - . proportional to numbers of field Veterinary Officers in the *Veterinary Services*, by geographical area.
- Education/training details.

ii) Veterinary public health:

- Categories and numbers involved in food inspection on a majority time basis:
 - . meat inspection: export meat establishments with an export function and domestic meat establishments (no export function);
 - . dairy inspection;
 - . other foods.
- Numbers in import/export inspection.
- Education/training details.

Appendix V (contd)

- d) Support **personnel staff**
Numbers directly available to *Veterinary Services* per sector (administration, communication, transport).
 - e) Descriptive summary of the functions of the various categories of staff mentioned above
 - f) Veterinary, veterinary para-professional, livestock owner, farmer and other relevant associations**
 - g) Additional information and/or comments.
3. Financial management information
- a) Total budgetary allocations to the *Veterinary Services* for the current and past two fiscal years:
 - i) for the national *Veterinary Services*;
 - ii) for each of any sub-national veterinary authorities;
 - iii) for other relevant government-funded institutions.
 - b) Sources of the budgetary allocations and amount:
 - i) government budget;
 - ii) sub-national authorities;
 - iii) taxes and fines;
 - iv) grants;
 - v) private services.
 - c) Proportional allocations of the amounts in a) above for operational activities and for the programme components of *Veterinary Services*.
 - d) Total allocation proportionate of national public sector budget (*This data may be necessary for comparative assessment with other countries which should take into account the contexts of the importance of the livestock sector to the national economy and of the animal health status of the country.*).
 - e) Actual and proportional contribution of animal production to gross domestic product.
4. Administration details
- a) Accommodation
Summary of the numbers and distribution of official administrative centres of the *Veterinary Services* (national and sub-national) in the country.
 - b) Communications
Summary of the forms of communication systems available to the *Veterinary Services* on a nation-wide and local area bases.
 - c) Transport
 - i) Itemised numbers of types of functional transport available on a full-time basis for the *Veterinary Services*. In addition provide details of transport means available part-time.
 - ii) Details of annual funds available for maintenance and replacement of motor vehicles.

5. Laboratory services

- a) Diagnostic laboratories (laboratories engaged primarily in diagnosis)
 - i) Descriptive summary of the organisational structure and role of the government veterinary laboratory service in particular its relevance to the field *Veterinary Services*.
 - ii) Numbers of veterinary diagnostic laboratories operating in the country:
 - government operated laboratories;
 - private laboratories accredited by government for the purposes of supporting official or officially–endorsed animal health control or public health testing and monitoring programmes and import/export testing.
 - iii) Descriptive summary of accreditation procedures and standards for private laboratories.
 - iv) Human and financial resources allocated to the government veterinary laboratories, including staff numbers, graduate and post–graduate qualifications and opportunities for further training.
 - v) List of diagnostic methodologies available against major diseases of farm livestock (including poultry).
 - vi) Details of collaboration with external laboratories including international reference laboratories and details on numbers of samples submitted.
 - vii) Details of quality control and assessment (or validation) programmes operating within the veterinary laboratory service.
 - viii) Recent published reports of the official veterinary laboratory service which should include details of specimens received and foreign animal disease investigations made.
 - ix) Details of procedures for storage and retrieval of information on specimen submission and results.
 - x) Reports of independent reviews of the laboratory service conducted by government or private organisations (if available).
 - xi) Strategic and operational plans for the official veterinary laboratory service (if available).
- b) Research laboratories (laboratories engaged primarily in research)
 - i) Numbers of veterinary research laboratories operating in the country:
 - government operated laboratories;
 - private laboratories involved in full time research directly related to animal health and veterinary public health matters involving production animal species.
 - ii) Summary of human and financial resources allocated by government to veterinary research.
 - iii) Published programmes of future government sponsored veterinary research.
 - iv) Annual reports of the government research laboratories.

Appendix V (contd)6. Functional capabilities and legislative support

- a) Animal health and veterinary public health
 - i) Assessment of the adequacy and implementation of relevant legislation (national or sub-national) concerning the following:
 - animal and veterinary public health controls at national frontiers;
 - control of endemic animal diseases, including zoonoses;
 - emergency powers for control of exotic disease outbreaks, including zoonoses;
 - inspection and registration of facilities;
 - veterinary public health controls of the production, processing, storage and marketing of meat for domestic consumption;
 - veterinary public health controls of the production, processing, storage and marketing of fish, dairy products and other foods of animal origin for domestic consumption;
 - registration and use of veterinary pharmaceutical products including vaccines.
 - ii) Assessment of ability of *Veterinary Services* to enforce legislation.
- b) Export/import inspection
 - i) Assessment of the adequacy and implementation of relevant national legislation concerning:
 - veterinary public health controls of the production, processing, storage and transportation of meat for export;
 - veterinary public health controls of production, processing, storage and marketing of fish, dairy products and other foods of animal origin for export;
 - animal health and veterinary public health controls of the export and import of *animals*, animal genetic material, animal products, animal feedstuffs and other products subject to veterinary inspection;
 - animal health controls of the importation, use and bio-containment of organisms which are aetiological agents of animal diseases, and of pathological material;
 - animal health controls of importation of veterinary biological products including vaccines;
 - administrative powers available to *Veterinary Services* for inspection and registration of facilities for veterinary control purposes (if not included under other legislation mentioned above);
 - documentation and compliance.
 - ii) Assessment of ability of *Veterinary Services* to enforce legislation.

7. Animal health and veterinary public health controls

- a) Animal health
- i) Description of and sample reference data from any national animal disease reporting system controlled and operated or coordinated by the *Veterinary Services*.
 - ii) Description of and sample reference data from other national animal disease reporting systems controlled and operated by other organisations which make data and results available to *Veterinary Services*.
 - iii) Description and relevant data of current official control programmes including:
 - epidemiological surveillance or monitoring programmes;
 - officially approved industry-administered control or eradication programmes for specific diseases.
 - iv) Description and relevant details of animal disease emergency preparedness and response plans.
 - v) Recent history of animal disease status:
 - animal diseases eradicated nationally or from defined sub-national zones in the last ten years;
 - animal diseases of which the prevalence has been controlled to a low level in the last ten years;
 - animal diseases introduced to the country or to previously free sub-national regions in the last ten years;
 - emerging diseases in the last ten years;
 - animal diseases of which the prevalence has increased in the last ten years.
- b) Veterinary public health
- i) Food hygiene
 - Annual national slaughter statistics for the past three years according to official data by species of animals (bovine, ovine, porcine, caprine, poultry, farmed game, wild game, equine and other).
 - Estimate of total annual slaughterings which occur but are not recorded under official statistics.
 - Proportion of total national slaughter which occurs in registered export establishments, by category of animal.
 - Proportion of total national slaughter which occurs under veterinary control, by category of animal.
 - Numbers of commercial fresh meat establishments in the country which are registered for export by national *Veterinary Services*:
 - . slaughterhouses (indicate species of *animals*);
 - . cutting/packing plants (indicate meat type);
 - . meat processing establishments (indicate meat type);
 - . cold stores.

Appendix V (contd)

- Numbers of commercial fresh meat establishments in the country approved by other *importing countries* which operate international assessment inspection programmes associated with approval procedures.
 - Numbers of commercial fresh meat establishments under direct public health control of the *Veterinary Services* (including details of category and numbers of inspection staff associated with these premises).
 - Description of the veterinary public health programme related to production and processing of animal products for human consumption (including fresh meat, poultry meat, meat products, game meat, dairy products, fish, fishery products, molluscs and crustaceans and other foods of animal origin) especially including details applying to exports of these *commodities*.
 - Descriptive summary of the roles and relationships of other official organisations in public health programmes for the products listed above if the national *Veterinary Services* do not have responsibility for those programmes which apply to national production destined to domestic consumption and/or exports of the *commodities* concerned.
- ii) Zoonoses
- Descriptive summary of the numbers and functions of staff of the *Veterinary Services* involved primarily with monitoring and control of zoonotic diseases.
 - Descriptive summary of the role and relationships of other official organisations involved in monitoring and control of zoonoses to be provided if the national *Veterinary Services* do not have these responsibilities.
- iii) Chemical residue testing programmes
- Descriptive summary of national surveillance and monitoring programmes for environmental and chemical residues and contaminants applied to animal-derived foodstuffs, *animals* and animal feedstuffs.
 - Role and function in these programmes of the national *Veterinary Services* and other *Veterinary Services* to be described in summary form.
 - Descriptive summary of the analytical methodologies used and their consistency with internationally recognised standards.
- iv) Veterinary medicines
- Descriptive summary of the administrative and technical controls involving registration, supply and use of veterinary pharmaceutical products especially including biological products. This summary should include a focus on veterinary public health considerations relating to the use of these products in food-producing *animals*.
 - Role and function in these programmes of the national *Veterinary Services* and other *Veterinary Services* to be described in summary form.
8. Quality Systems
- a) Accreditation
- Details and evidence of any current, formal accreditation by external agencies of the *Veterinary Services* of any components thereof.
- b) Quality manuals
- Documented details of the quality manuals and standards which describe the accredited quality systems of the *Veterinary Services*.

Appendix V (contd)

c) Audit

Details of independent (and internal) audit reports which have been undertaken of the *Veterinary Services* of components thereof.

9. Performance assessment and audit programmes

a) Strategic plans and review

i) Descriptive summary and copies of strategic and operational plans of the *Veterinary Services* organisation.

ii) Descriptive summary of corporate performance assessment programmes which relate to the strategic and operational plans – copies of recent review reports.

b) Compliance

Descriptive summary of any compliance unit which monitors the work of the *Veterinary Services* (or elements thereof).

c) Annual reports of the national Veterinary Services

Copies of official annual reports of the national (sub-national) *Veterinary Services*.

d) Other reports

i) Copies of reports of official reviews into the function or role of the *Veterinary Services* which have been conducted within the past three years.

ii) Descriptive summary (and copy of reports if available) of subsequent action taken on recommendations made in these reviews.

e) Training

i) Descriptive summary of in-service and development programmes provided by the *Veterinary Services* (or their parent Ministries) for relevant staff.

ii) Summary descriptions of training courses and duration.

iii) Details of staff numbers (and their function) who participated in these training courses in the last three years.

f) Publications

Bibliographical list of scientific publications by staff members of *Veterinary Services* in the past three years.

g) Sources of independent scientific expertise

List of local and international universities, scientific institutions and recognised veterinary organisations with which the *Veterinary Services* have consultation or advisory mechanisms in place.

Appendix V (contd)

10. Membership of the OIE

State if country is a member of the OIE and period of membership.

11. Other assessment criteria

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CHAPTER 1.3.7.
GUIDELINES FOR REACHING A
JUDGEMENT OF EQUIVALENCE OF
SANITARY MEASURES

Article 1.3.7.1.

Introduction

The importation of *animals* and animal products involves a degree of risk to the animal health status of an *importing country*. The estimation of that risk and the choice of the appropriate risk management option(s) are made more difficult by differences among the animal health and production systems in OIE Member Countries. It is now recognised that significantly different animal health and production systems can provide equivalent animal and human health protection for the purpose of *international trade*, with benefits to both the *importing* and *exporting country*.

These guidelines are to assist OIE Member Countries to determine whether sanitary measures arising from different animal health and production systems may provide the same level of animal and human health protection. They discuss principles which might be utilised in a judgement of equivalence, and outline a step-wise process for trading partners to follow in facilitating a judgement of equivalence. These guidelines are applicable whether equivalence applies at the level of specific measures or on a systems-wide basis, and whether equivalence applies to specific areas of trade or *commodities*, or generally.

Article 1.3.7.2.

General considerations

Before trade in *animals* or their products may occur, an *importing country* must be satisfied that its animal health status will be appropriately protected. In most cases, the risk management measures drawn up will rely in part on judgements made about the animal health and production system(s) in the *exporting country* and the effectiveness of sanitary procedures undertaken there. Systems operating in the *exporting country* may differ from those in the *importing country* and from those in other countries with which the *importing country* has traded. Differences may be with respect to infrastructure, policies and/or operating procedures, laboratory systems, approaches to the pests and diseases present, border security and internal movement controls.

International recognition of the legitimacy of different approaches to achieving the *importing country's* appropriate level of protection (ALOP) has led to the principle of equivalence being included in trade agreements, including the Agreement on Application of Sanitary and Phytosanitary Measures (the so-called SPS Agreement) of the World Trade Organization (WTO).

Benefits of applying equivalence may include:

- 1) minimising costs associated with *international trade* by tailoring animal health measures to local circumstances;
- 2) maximising animal health outcomes for a given level of resource input;
- 3) facilitating trade by achieving the required health protection through less trade restrictive sanitary measures; and
- 4) decreased reliance on relatively costly *commodity* testing and isolation procedures in bilateral or multilateral agreements.

Appendix VI (contd)

The *Terrestrial Code* recognises equivalence by recommending alternative sanitary measures for many diseases and pathogenic agents. Equivalence may be gained, for example, by enhanced surveillance and monitoring, by the use of alternative test, treatment or isolation procedures, or by combinations of the above. To facilitate the judgement of equivalence, Member Countries are encouraged to base their sanitary measures on OIE standards, guidelines and recommendations to the extent possible.

It is essential to apply **the discipline of risk assessment (the primary scientific component of a scientific risk analysis)** to the extent practicable in establishing the basis for a judgement of equivalence.

Article 1.3.7.3.

Definitions

For the purposes of these guidelines, the following definitions apply:

Appropriate level of protection (ALOP) (acceptable risk): The level of protection deemed appropriate by the country establishing a sanitary measure to protect human or animal life or health within its territory.

Equivalence of sanitary measures: The state wherein the sanitary measure(s) proposed by the *exporting country* as an alternative to those of the *importing country*, achieve(s) the same level of protection.

Hazard: A biological, chemical or physical agent in, or a condition of, an *animal* or animal product with the potential to cause an adverse health effect.

Risk: The likelihood of the occurrence and the likely magnitude of the consequences of an adverse event to animal or human health in the *importing country* during a specified time period, as a result of a hazard.

Risk analysis: The process composed of hazard identification, risk assessment, risk management and risk communication.

Risk assessment: The evaluation of the likelihood and the biological and economic consequences of entry, establishment, or spread of a pathogenic agent within the territory of an *importing country*.

Sanitary measure: Any measure applied to protect animal or human health or life within the territory of the Member Country from risks arising from the entry, establishment or spread of a hazard. [Note: A detailed definition of sanitary measure may be found in the WTO SPS Agreement.]

Article 1.3.7.4.

Prerequisite considerations in a judgement of equivalence

1. Application of risk assessment

Application of the discipline of risk assessment provides a structured basis for judging equivalence among different sanitary measures as it allows a close examination to be made of the effect of a measure(s) on a particular step(s) in the importation pathway, and the relative effects of proposed alternative measure(s) on the same or related steps.

A judgement of equivalence needs to assess the sanitary measure in terms of its effectiveness regarding the particular risk or group of risks against which the measure is designed to protect. Such an assessment may include the following elements: the purpose of the measure, the level of protection achieved by the measure and the contribution the measure makes to achieving the ALOP of the *importing country*.

2. Categorisation of sanitary measures

Proposals for equivalence may be in terms of a measure comprising a single component of a measure (e.g. an isolation procedure, a test or treatment requirement, a certification procedure) or multiple components (e.g. a production system for a commodity), or a combination of measures. Multiple components or combinations of measures may be applied consecutively or concurrently.

Sanitary measures are those described in each Chapter of the *Terrestrial Code* which are used for risk reduction and are appropriate for particular diseases. Sanitary measures may be applied either alone or in combination and include test requirements, processing requirements, inspection or certification procedures, quarantine confinements, and sampling procedures.

For the purposes of judging equivalence, sanitary measures can be broadly categorised as:

- a) infrastructure: including the legislative base (e.g. animal health law) and administrative systems (e.g. organisation of national and regional animal health authorities, emergency response organisations);
- b) programme design/implementation: including documentation of systems, performance and decision criteria, laboratory capability, and provisions for certification, audit and enforcement;
- c) specific technical requirement: including requirements applicable to the use of secure facilities, treatment (e.g. retorting of cans), specific test (e.g. ELISA) and procedures (e.g. pre-export inspection).

A sanitary measure(s) proposed for a judgement of equivalence may fall into one or more of these categories, which are not mutually exclusive.

In some cases a comparison of specific technical requirements may suffice. In many instances, however, a judgement as to whether the same level of protection is likely to be achieved may only be able to be determined through an evaluation of all relevant components of an *exporting country's* animal health and production system. For example, a judgement of equivalence for a specific sanitary measure at the programme design/implementation level may require a prior examination of infrastructure while a judgement of equivalence for a specific measure at the specific technical requirement level may require that the specific measure be judged in its context through examination of infrastructure and programmes.

Article 1.3.7.5.

Principles for judgement of equivalence

In conjunction with the above considerations, judgement of the equivalence of sanitary measures should be based on application of the following principles:

- 1) an *importing country* has the right to set the level of protection it deems appropriate (its ALOP) in relation to human and animal life and health in its territory; this ALOP may be expressed in qualitative or quantitative terms;
- 2) the *importing country* should be able to describe the reason for each sanitary measure i.e. the level of protection intended to be achieved by application of the identified measure against a hazard;
- 3) an *importing country* should recognise that sanitary measures different from the ones it has proposed may be capable of providing the same level of protection;
- 4) ~~there are benefits in applying the concept of equivalence to animal health and production systems;~~

Appendix VI (contd)

- 5) ~~countries~~ the importing country should, upon request, enter into consultations with the exporting country with the aim of facilitating a judgement of equivalence;
- 6) any sanitary measure or combination of sanitary measures can be proposed for judgement of equivalence;
- 7) an interactive process should be followed that applies a defined sequence of steps, and utilises an agreed process for exchange of information, so as to limit data collection to that which is necessary, minimise administrative burden, and facilitate resolution of claims;
- 8) the *exporting country* should be able to demonstrate objectively how the alternative sanitary measure(s) proposed as equivalent will provide the same level of protection;
- 9) the *exporting country* should present a submission for equivalence in a form that facilitates judgement by the *importing country*;
- 10) the *importing country* should evaluate submissions for equivalence in a timely, consistent, transparent and objective manner, and according to appropriate risk assessment principles;
- 11) the *importing country* should take into account any knowledge of and prior experience with the *Veterinary Administration* or other competent authority of the *exporting country*;
- 12) the *exporting country* should provide access to enable the procedures or systems which are the subject of the equivalence judgement to be examined and evaluated upon request of the *importing country*;
- 13) the *importing country* should be the sole determinant of equivalence, but should provide to the *exporting country* a full explanation for its judgement;
- 14) to facilitate a judgement of equivalence, Member Countries should base their sanitary measures on relevant OIE standards;
- 15) to allow the judgement of equivalence to be reassessed if necessary, the *importing* and *exporting countries* should keep each other informed of significant changes to infrastructure, health status or programmes which may bear on the judgement of equivalence; and
- 16) an *importing country* should give positive consideration to a request by an exporting developing country for appropriate technical assistance that would facilitate the successful completion of a judgement of equivalence.

Article 1.3.7.6.

Sequence of steps to be taken in judgement of equivalence

There is no single sequence of steps which must be followed in all judgements of equivalence. The steps that trading partners choose will generally depend on the circumstances and their trading experience. The interactive sequence of steps described below may be useful for all sanitary measures irrespective of their categorisation as infrastructure, programme design/implementation or specific technical requirement components of an animal health and production system.

This sequence assumes that the *importing country* is meeting its obligations under the WTO SPS Agreement and has in place a transparent measure based either on an international standard or a risk analysis.

Recommended steps are:

- 1) the *exporting country* identifies the measure(s) for which it wishes to propose an alternative measure(s), and requests from the *importing country* a reason for its sanitary measure in terms of the level of protection intended to be achieved against a hazard(s);

Appendix VI (contd)

- 2) the *importing country* explains the reason for the measure(s), in terms which would facilitate comparison with an alternative sanitary measure(s) and consistent with the principles set out in these guidelines;
- 3) the *exporting country* demonstrates the case for equivalence of an alternative sanitary measure(s) in a form which facilitates analysis by an *importing country*;
- 4) the *exporting country* responds to any technical concerns raised by the *importing country* by providing relevant further information;
- 5) judgement of equivalence by the *importing country* takes into account as appropriate:
 - a) the impact of biological variability and uncertainty;
 - b) the expected effect of the alternative sanitary measure(s) on all relevant hazards;
 - c) OIE standards;
 - d) application of solely qualitative frameworks where it is not possible or reasonable to conduct quantitative risk assessment;
- 6) the *importing country* notifies the *exporting country* of its judgement and the underlying reasons within a reasonable period of time:
 - a) recognition of the equivalence of the *exporting country's* alternative sanitary measure(s);
 - b) request for further information; or
 - c) rejection of the case for equivalence of the alternative sanitary measure(s);
- 7) an attempt should be made to resolve any differences of opinion over judgement of a case, either interim or final, by using an agreed mechanism to reach consensus (e.g. the OIE dispute settlement mechanism), or by referral to an agreed expert;
- 8) depending on the category of measures involved, the *importing* and *exporting countries* may enter into a formal equivalence agreement giving effect to the judgement or a less formal acknowledgement of the equivalence of a specific measure(s) may suffice.

An *importing country* recognising the equivalence of an *exporting country's* alternative sanitary measure(s) needs to ensure that it acts consistently with regard to applications from third countries for recognition of equivalence applying to the same or very similar measure(s). Consistent action does not mean however that a specific measure(s) proposed by several *exporting countries* should always be judged as equivalent as a measure(s) should not be considered in isolation but as part of a system of infrastructure, policies and procedures.

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CHAPTER 1.1.2.

~~OIE LIST A AND LIST B DISEASES~~OIE LISTED DISEASES

Article 1.1.2.1.

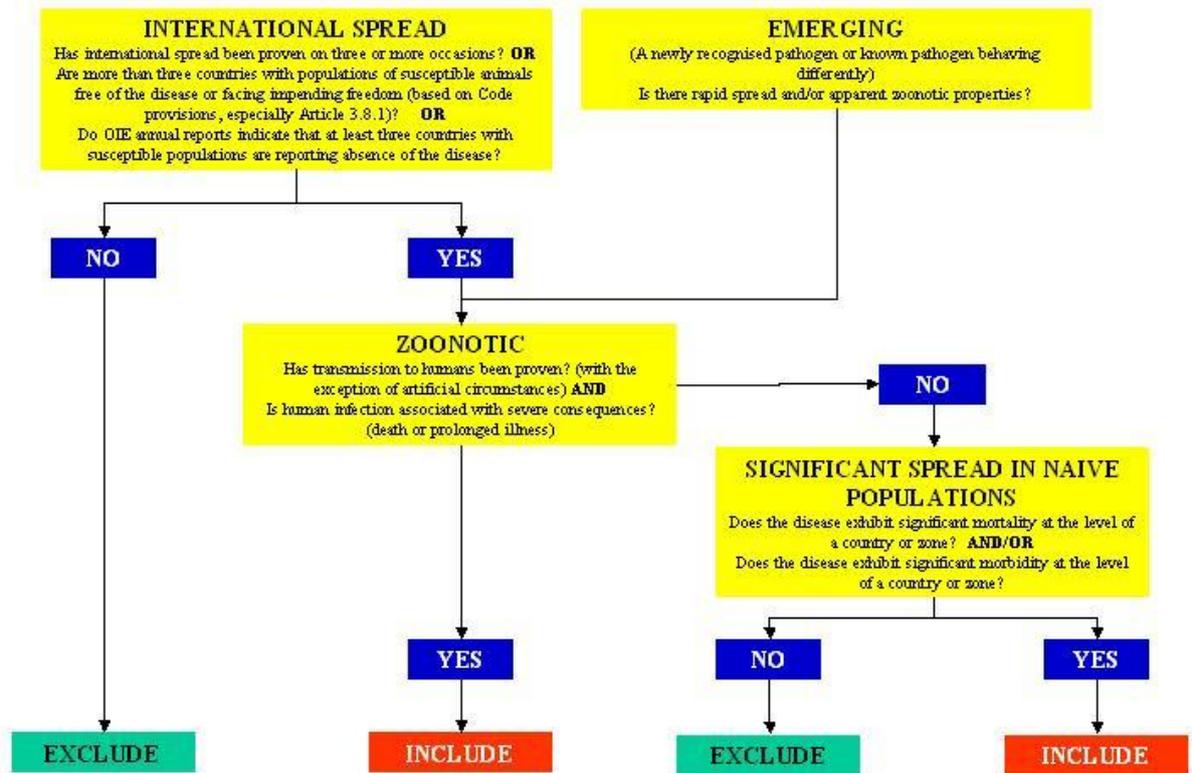
The criteria for the inclusion of a disease in the OIE List are as follows:

International Spread	Has international spread been proven on three or more occasions? OR Are more than three countries with populations of susceptible animals free of the disease or facing impending freedom (based on the <i>Terrestrial Code</i> provisions, especially Appendix 3.8.1)? OR Do OIE annual reports indicate that a significant number of countries with susceptible populations have reported absence of the disease for several consecutive years?
Significant Spread within Naïve Populations	Does the disease exhibit significant mortality at the level of a country or compartment? AND/OR Does the disease exhibit significant morbidity at the level of a country or compartment?
Zoonotic Potential	Has transmission to humans been proven? (with the exception of artificial circumstances) AND Is human infection associated with severe consequences? (death or prolonged illness)
Emerging Diseases (A newly recognised pathogen or known pathogen behaving differently)	Is there rapid spread and/or apparent zoonotic properties?

Article 1.1.2.2.

The criteria in Article 1.1.2.1 above are applied according to the decision-making model shown below:

Appendix VII (contd)



Article 1.1.2.3.

The following diseases are included in the *List A*

Article 1.1.2.1.

The following diseases are included in *List A*:

- Foot and mouth disease
- Vesicular stomatitis
- Swine vesicular disease
- Rinderpest
- Peste des petits ruminants
- Contagious bovine pleuropneumonia
- Lumpy skin disease
- Rift Valley fever
- Bluetongue
- Sheep pox and goat pox
- African horse sickness
- African swine fever
- Classical swine fever
- Highly pathogenic avian influenza
- Newcastle disease

Appendix VII (contd)

Article 1.1.2.2.

The following diseases are included in List B, within the category of multiple species diseases:

- Anthrax
- Aujeszky's disease
- Echinococcosis/hydatidosis
- Heartwater
- Leptospirosis
- Q fever
- Rabies
- Paratuberculosis
- New world screwworm (*Cochliomyia hominivorax*)
- Old world screwworm (*Chrysomya bezziana*)
- Trichinellosis

– Foot and mouth disease

– Vesicular stomatitis

– Lumpy skin disease

– Bluetongue

– Rift Valley fever.

Article 1.1.2.3.

The following diseases are included in List B, within the category of cattle diseases:

- Bovine anaplasmosis
- Bovine babesiosis
- Bovine brucellosis
- Bovine genital campylobacteriosis
- Bovine tuberculosis
- Bovine cysticercosis
- Dermatophilosis
- Enzootic bovine leukosis
- Haemorrhagic septicaemia
- Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
- Theileriosis
- Trichomonosis
- Trypanosomosis (tsetse-transmitted)
- Malignant catarrhal fever
- Bovine spongiform encephalopathy

– Rinderpest

– Contagious bovine pleuropneumonia.

Article 1.1.2.4.

The following diseases are included in List B, within the category of sheep and goat diseases:

- Ovine epididymitis (*Brucella ovis*)
- Caprine and ovine brucellosis (excluding *B. ovis*)
- Caprine arthritis/encephalitis
- Contagious agalactia
- Contagious caprine pleuropneumonia
- Enzootic abortion of ewes (ovine chlamydiosis)
- Ovine pulmonary adenomatosis

Appendix VII (contd)

- Nairobi sheep disease
- Salmonellosis (*S. abortusovis*)
- Scrapie
- Maedi–visna
- = Peste des petits ruminants
- = Sheep pox and goat pox.

Article 1.1.2.5.

The following diseases are included in List B within the category of equine diseases:

- Contagious equine metritis
- Dourine
- Epizootic lymphangitis
- Equine encephalomyelitis (Eastern and Western)
- Equine infectious anaemia
- Equine influenza
- Equine piroplasmiasis
- Equine rhinopneumonitis
- Glanders
- Horse pox
- Equine viral arteritis
- Japanese encephalitis
- Horse mange
- Surra (*Trypanosoma evansi*)
- Venezuelan equine encephalomyelitis
- = African horse sickness.

Article 1.1.2.6.

The following diseases are included in List B within the category of swine diseases:

- Atrophic rhinitis of swine
- Porcine cysticercosis
- Porcine brucellosis
- Transmissible gastroenteritis
- Enterovirus encephalomyelitis
- Porcine reproductive and respiratory syndrome
- = African swine fever
- = Classical swine fever.

Article 1.1.2.7.

The following diseases are included in List B within the category of avian diseases:

- Avian infectious bronchitis
- Avian infectious laryngotracheitis
- Avian tuberculosis
- Duck virus hepatitis
- Duck virus enteritis
- Fowl cholera
- Fowl pox
- Fowl typhoid
- Infectious bursal disease (Gumboro disease)

Appendix VII (contd)

- Marek's disease
- Avian mycoplasmosis (*M. gallisepticum*)
- Avian chlamydiosis
- Pullorum disease
- = Highly pathogenic avian influenza
- = Newcastle disease.

~~Article 1.1.2.8.~~

The following diseases are included ~~in List B,~~ within the category of lagomorph diseases:

- Myxomatosis
- Tularemia
- Rabbit haemorrhagic disease.

~~Article 1.1.2.9.~~

The following diseases are included ~~in List B,~~ within the category of bee diseases:

- Acariosis of bees
- American foulbrood
- European foulbrood
- Nosemosis of bees
- Varroosis.

~~Article 1.1.2.10.~~

The following disease is included ~~in List B,~~ within the category of other diseases:

- Leishmaniosis.

 — text deleted

CHAPTER 1.1.3.
NOTIFICATION AND
EPIDEMIOLOGICAL INFORMATION

Article 1.1.3.1.

For the purposes of this *Terrestrial Code* and in terms of Articles 5, 9 and 10 of the Statutes, every Member Country of the OIE shall recognise the right of the *Central Bureau* to communicate directly with the *Veterinary Administration* of its territory or territories.

All *notifications* and all information sent by the OIE to the *Veterinary Administration* shall be regarded as having been sent to the country concerned and all *notifications* and all information sent to the OIE by the *Veterinary Administration* shall be regarded as having been sent by the country concerned.

Article 1.1.3.2.

1. Countries shall make available to other countries, through the OIE, whatever information is necessary to minimise the spread of important animal diseases and to assist in achieving better worldwide control of these diseases.
2. To achieve this, countries shall comply with the *notification* requirements specified in Article 1.1.3.3.
3. To assist in the clear and concise exchange of information, reports shall conform as closely as possible to the official OIE disease reporting format.
4. Recognising that scientific knowledge concerning the relationship between disease agents and diseases is constantly developing and that the presence of an infectious agent does not necessarily imply the presence of a disease, countries shall ensure through their reports that they comply with the spirit and intention of paragraph 1 above.
5. In addition to notifying new findings in accordance with Article 1.1.3.3., countries shall also provide information on the measures taken to prevent the spread of diseases; including quarantine measures and restrictions on the movement of *animals*, animal products and biological products and other miscellaneous objects which could by their nature be responsible for transmission of disease. In the case of diseases transmitted by vectors, the measures taken against such vectors shall also be specified.

Article 1.1.3.3.

Veterinary Administrations shall send to the *Central Bureau*:

1. *notification* **from the Delegate of the country** by telegram, fax or e-mail, within 24 hours, of any of the following events:
 - a) **for diseases listed by the OIE, the suspected or (under study) confirmed first occurrence or re-occurrence of a disease, if the country or zone of the country was previously considered to be free from that particular disease;**
 - b) **for diseases listed by the OIE, evidence of changes in the epidemiology of a disease (including host range, pathogenicity, strain) if this represents important new information of epidemiological significance to other countries, in particular if a disease may have a zoonotic impact;**

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- e) for diseases not listed by the OIE, if there is information of exceptional epidemiological significance to other countries, for example if a disease may be a zoonosis;
- in deciding whether findings justify immediate *notification*, countries must ensure that they comply with the obligations of Section 1.2. (especially Article 1.2.1.3.) of the *Terrestrial Code*, to report developments which may have implications for *international trade*;
- a) first occurrence of a listed disease and/or infection in a country or zone/compartment;
- b) re-occurrence of a listed disease and/or infection in a country or zone/compartment following a report declaring the *outbreak* ended;
- c) first occurrence of a new strain of a pathogen in a country or zone/compartment;
- d) a sudden and unexpected increase in the morbidity or mortality of an existing disease;
- e) an emerging disease with significant morbidity or mortality, or zoonotic potential;
- f) evidence of change in the epidemiology of a listed disease (including host range, pathogenicity, strain) in particular if there is a zoonotic impact;
2. weekly reports by telegram, fax or e-mail subsequent to a *notification* under point 1 above, to provide further information on the evolution of an incident which justified urgent *notification*; these reports should continue until the disease has been eradicated or the situation has become sufficiently stable that monthly reporting under point 3 will satisfy the obligation of the country to the OIE;
 3. monthly reports on the absence or presence, and evolution of diseases listed by the OIE and information of epidemiological significance to other countries;
 4. annual reports on all diseases listed by the OIE and any other information of epidemiological significance to other countries.

Article 1.1.3.4.

1. The *Veterinary Administration* of a territory in which an *infected zone* was located shall inform the *Central Bureau* when this zone is free from the disease.
2. An *infected zone* for a particular disease shall be considered as such until a period exceeding the *infective period* specified in the *Terrestrial Code* has elapsed after the last reported *case*, and when full prophylactic and appropriate animal health measures have been applied to prevent possible reappearance or spread of the disease. These measures will be found in detail in the various chapters of Section 2.1. of the *Terrestrial Code*.
3. A country may be considered to regain freedom from a specific disease when all conditions given in the relevant chapters of the *Terrestrial Code* have been fulfilled.

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4. The *Veterinary Administration* of a country which sets up one or several *free zones* shall inform the OIE giving the necessary details, including the criteria on which the free status is based, the requirements for maintaining the status and indicating clearly the location of the zones on a map of the country.

Article 1.1.3.5.

1. The *Central Bureau* shall send by telegram, fax, e-mail or *Disease Information* to the *Veterinary Administrations* concerned, all *notifications* received as provided in Articles 1.1.3.2. to 1.1.3.4.
2. The *Central Bureau* shall dispatch to the Delegates information on new *outbreaks* of listed diseases.
3. The *Central Bureau*, on the basis of information received and of any official communication, shall prepare an annual report concerning the application of the *Terrestrial Code* and its effects on *international trade*.

Article 1.1.3.6.

All telegrams or faxes sent by *Veterinary Administrations* in pursuance of Articles 1.1.3.3. and 1.1.3.5. shall receive priority in accordance with the circumstances. Communications by telephone, telegram or fax, sent in the case of exceptional urgency when there is danger of spread of a notifiable epizootic disease, shall be given the highest priority accorded to these communications by the International Arrangements of Telecommunications.

— text deleted

CHAPTER 1.3.5.
ZONING, ~~AND~~ REGIONALISATION ~~AND~~
~~COMPARTMENTALISATION~~

Article 1.3.5.1.

~~For the purposes of this *Terrestrial Code*, ‘zoning’ and ‘regionalisation’ have the same meaning.~~

~~Compartmentalisation and~~ zoning ~~are is a~~ procedures implemented by a country under the provisions of this Chapter with a view to defining ~~geographical areas~~ ~~sub-populations~~ of different *animal health status* within its territory for the purpose of *international trade*, and in accordance with the recommendations stipulated in the relevant Chapters in the *Terrestrial Code*.

~~Compartmentalisation applies to a sub-population when management criteria are applied while zoning applies when a sub-population is defined on a geographical basis.~~

~~Separate requirements will be developed for each disease for which the application of zoning or compartmentalisation is considered appropriate.~~

Article 1.3.5.2.

The requirements necessary to preserve the distinct health status of a zone ~~or compartment~~ must be appropriate to the particular disease ~~The requirements will differ and size, location and delineation of a zone and~~ will depend on the epidemiology of the disease, environmental factors, control measures and surveillance.

The extent of ~~a~~ zone and ~~its these~~ limits should be established by the *Veterinary Administration* on the basis of natural, artificial or legal boundaries and made public through official channels. ~~The requirements regarding a compartment should be established by the *Veterinary Administration* on the basis of relevant criteria such as management and husbandry practices and made public through official channels.~~

~~Animals and herds belonging to sub-populations need to be clearly recognisable as such. The *Veterinary Administration* must document in detail the measures taken to ensure the identification of the sub-population and the recognition and maintenance of its health status.~~

Thus defined, the zones ~~and compartments~~ constitute the relevant ~~geographical units~~ ~~sub-populations~~ for the application of the recommendations in Part 2 of the *Terrestrial Code*.

Article 1.3.5.3.

When an *exporting country* has defined a zone ~~or compartment~~ within its territory in respect of one or more of the diseases covered by the *Terrestrial Code*, it needs to implement the measures stipulated in the *Terrestrial Code* for setting up and maintaining such a zone ~~or compartment~~.

An *importing country* should recognise the existence of this zone ~~or compartment~~ and accept the application of the appropriate measures recommended in the *Terrestrial Code* corresponding to the *animal health status* of the zone ~~or compartment~~ with regard to the importation, or transit through its territory, of *commodities* from the zone ~~or compartment~~.

— text deleted

CHAPTER 2.1.1. FOOT AND MOUTH DISEASE

Article 2.1.1.1.

For the purposes of this *Terrestrial Code*, the *incubation period* for foot and mouth disease (FMD) shall be 14 days.

For the purposes of this Chapter, ruminants include animals of the family of Camelidae.

For the purposes of this Chapter, a *case* includes an animal infected with FMD virus (FMDV).

For the purposes of *international trade*, this Chapter deals not only with the occurrence of clinical signs caused by FMDV, but also with the presence of infection with FMDV in the absence of clinical signs.

The following defines the occurrence of FMDV infection:

- 1) FMDV has been isolated and identified as such from an animal or a product derived from that animal, or
- 2) viral antigen or viral RNA specific to one or more of the serotypes of FMDV has been identified in samples from one or more animals showing clinical signs consistent with FMD, or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV, or
- 3) antibodies to structural or nonstructural proteins of FMDV that are not a consequence of vaccination, have been identified in one or more animals ~~with either epidemiological links to a confirmed or suspected *outbreak* of FMD, or showing clinical signs consistent with recent infection with FMDV~~ showing clinical signs consistent with FMD, or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 2.1.1.2.

FMD free country where vaccination is not practised

To qualify for inclusion in the existing list of FMD free countries where vaccination is not practised, a country should:

- 1) have a record of regular and prompt animal disease reporting;
- 2) send a declaration to the OIE stating that:
 - a) there has been no *outbreak* of FMD during the past 12 months;
 - b) no evidence of FMDV infection has been found during the past 12 months;
 - c) no vaccination against FMD has been carried out during the past 12 months,

and supply documented evidence that surveillance for both FMD and FMDV infection in accordance with Appendix 3.8.6. is in operation and that regulatory measures for the prevention and control of FMD have been implemented;

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- 3) not have imported since the cessation of vaccination any animals vaccinated against FMD.

The country will be included in the list only after the submitted evidence has been accepted by the OIE.

Article 2.1.1.3.

FMD free country where vaccination is practised

To qualify for inclusion in the list of FMD free countries where vaccination is practised, a country should:

- 1) have a record of regular and prompt animal disease reporting;
- 2) send a declaration to the OIE that there has been no *outbreak* of FMD for the past 2 years and no evidence of FMDV infection for the past 12 months, with documented evidence that:
 - a) surveillance for FMD and FMDV infection in accordance with Appendix 3.8.6. is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;
 - b) routine vaccination is carried out for the purpose of the prevention of FMD;
 - c) the vaccine used complies with the standards described in the *Terrestrial Manual*.

The country will be included in the list only after the submitted evidence has been accepted by the OIE.

If an FMD free country where vaccination is practised wishes to change its status to FMD free country where vaccination is not practised, the country should wait for 12 months after vaccination has ceased and provide evidence showing that FMDV infection has not occurred during that period.

Article 2.1.1.4.

FMD free zone where vaccination is not practised

An FMD free zone where vaccination is not practised can be established in either an FMD free country where vaccination is practised or in a country of which parts are still infected. The FMD free zone must be separated from the rest of the country and, if relevant, from neighbouring infected countries by a *surveillance zone*, or physical or geographical barriers, and animal health measures that effectively prevent the entry of the virus must be implemented. A country in which an FMD free zone where vaccination is not practised is to be established should:

- 1) have a record of regular and prompt animal disease reporting;
- 2) send a declaration to the OIE stating that it wishes to establish an FMD free zone where vaccination is not practised and that:
 - a) there has been no *outbreak* of FMD during the past 12 months;
 - b) no evidence of FMDV infection has been found during the past 12 months;
 - c) no vaccination against FMD has been carried out during the past 12 months;
 - d) no vaccinated animal has been introduced into the zone since the cessation of vaccination, except in accordance with Article 2.1.1.8.;
- 3) supply documented evidence that surveillance for both FMD and FMDV infection in accordance with Appendix 3.8.6. is in operation in the FMD free zone where vaccination is not practised;

Appendix IX (contd)

- 4) describe in detail:
- a) regulatory measures for the prevention and control of both FMD and FMDV infection,
 - b) the boundaries of the FMD free zone, and the *surveillance zone*,
 - c) the system for preventing the entry of the virus into the FMDV free zone (in particular if the procedure described in Article 2.1.1.8. is implemented),
- and supply documented evidence that these are properly implemented and supervised.

The free zone will be included in the list of FMD free zones where vaccination is not practised only after the submitted evidence has been accepted by the OIE.

Article 2.1.1.5.

FMD free zone where vaccination is practised

An FMD free zone where vaccination is practised can be established in an FMD free country where vaccination is not practised or in a country of which parts are still infected. Vaccination of zoo animals, animals belonging to rare species or breeds, or animals in research centres as a precaution for conservation purposes is an example of implementation of such a zone. The free zone where vaccination is practised is separated from the rest of the country and, if relevant, from neighbouring infected countries by a *buffer zone*, or physical or geographical barriers, and animal health measures that effectively prevent the entry of the virus must be implemented. A country in which an FMD free zone where vaccination is practised is to be established should:

- 1) have a record of regular and prompt animal disease reporting;
- 2) send a declaration to the OIE that it wishes to establish an FMD free zone where vaccination is practised, where there has been no *outbreak* of FMD for the past 2 years and no evidence of FMDV infection for the past 12 months, with documented evidence that surveillance for FMD and FMDV in accordance with Appendix 3.8.6. is in operation;
- 3) supply documented evidence that the vaccine used complies with the standards described in the *Terrestrial Manual*;
- 4) describe in detail:
 - a) regulatory measures for the prevention and control of both FMD and FMDV infection,
 - b) the boundaries of the FMD free zone where vaccination is practised and the *buffer zone* if applicable,
 - c) the system for preventing the entry of the virus into the FMD free zone (in particular if the procedure described in Article 2.1.1.8. is implemented),

and supply evidence that these are properly implemented and supervised;
- 5) supply documented evidence that it has a system of intensive and frequent surveillance for FMD in the FMD free zone where vaccination is practised.

The free zone will be included in the list of FMD free zones where vaccination is practised only after the submitted evidence has been accepted by the OIE.

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If a country that has an FMD free zone where vaccination is practised wishes to change the status of the zone to FMD free zone where vaccination is not practised, a waiting period of 12 months after vaccination has ceased or 12 months after the last *outbreak*, whichever is later, is required and evidence must be provided showing that FMDV infection has not occurred in the said zone during that period.

Article 2.1.1.6.

FMD infected country or zone

An FMD infected country is a country that does not fulfil the requirements to qualify as either an FMD free country where vaccination is not practised or an FMD free country where vaccination is practised.

An FMD infected zone is a zone that does not fulfil the requirements to qualify as either an FMD free zone where vaccination is not practised or an FMD free zone where vaccination is practised.

Article 2.1.1.7.

Recovery of free status

- 1) When an FMD *outbreak* or FMDV infection occurs in an FMD free country or zone where vaccination is not practised, one of the following waiting periods is required to regain the status of FMD free country or zone where vaccination is not practised:
 - a) 3 months after the last *case* where a *stamping-out policy* and serological surveillance are applied in accordance with Appendix 3.8.6., or
 - b) 3 months after the slaughter of all vaccinated animals where a *stamping-out policy*, emergency vaccination and serological surveillance are applied in accordance with Appendix 3.8.6., or
 - c) 6 months after the last *case* or the last vaccination (according to the event that occurs the latest), where a *stamping-out policy*, emergency vaccination not followed by the slaughtering of all vaccinated animals, and serological surveillance are applied in accordance with Appendix 3.8.6., provided that a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of infection in the remaining vaccinated population.

- 2) When an FMD *outbreak* or FMDV infection occurs in an FMD free country or zone where vaccination is practised, one of the following waiting periods is required to regain the status of FMD free country or zone where vaccination is practised:
 - a) 6 months after the last *case* where a *stamping-out policy*, emergency vaccination and serological surveillance in accordance with Appendix 3.8.6. are applied, provided that the serological surveillance based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of infection, or
 - b) 12 months after the last *case* where a *stamping-out policy* is applied provided that surveillance demonstrates the absence of clinical *cases*, or
 - c) 18 months after the last *case* where a *stamping-out policy* is not applied, but emergency vaccination and serological surveillance in accordance with Appendix 3.8.6. are applied, provided that the serological surveillance based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of infection.

Article 2.1.1.8.

Transfer of FMD susceptible animals from an infected zone to a free zone within a country

Live animals from FMD susceptible species can only leave the infected zone if moved by **mechanical** **mechanised** transport to the nearest designated abattoir located in the *buffer zone* or the *surveillance zone* for immediate slaughter. In the absence of an abattoir in the *buffer zone* or the *surveillance zone*, live FMD susceptible animals can be transported to the nearest abattoir in a free zone for immediate slaughter only under the following conditions:

- 1) no FMD susceptible animal has been introduced into the *establishment* of origin and no animal in the *establishment* of origin has shown clinical signs of FMD for at least 30 days prior to movement;
- 2) the animals were kept in the *establishment* of origin for at least 3 months prior to movement;
- 3) FMD has not occurred within a 10-kilometre radius of the *establishment* of origin for at least 3 months prior to movement;
- 4) the animals must be transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before loading, directly from the *establishment* of origin to the abattoir without coming into contact with other susceptible animals;
- 5) such an abattoir is not approved for the export of *fresh meat*;
- 6) all products obtained from the animals must be considered infected and treated in such a way as to destroy any residual virus in accordance with Appendix 3.6.2.;
- 7) *vehicles* and the abattoir must be subjected to thorough cleansing and *disinfection* immediately after use.

Animals moved into a free zone for other purposes must be moved under the supervision of the *Veterinary Authority* and comply with the conditions in Article 2.1.1.11.

Article 2.1.1.9.

When importing from FMD free countries or zones where vaccination is not practised, *Veterinary Administrations* should require:

for FMD susceptible animals

the presentation of an *international veterinary certificate* attesting that the animals:

- 1) showed no clinical sign of FMD on the day of shipment;
- 2) were kept in an FMD free country or zone where vaccination is not practised since birth or for at least the past 3 months.

Article 2.1.1.10.

When importing from FMD free countries or zones where vaccination is practised, *Veterinary Administrations* should require:

for domestic ruminants and pigs

the presentation of an *international veterinary certificate* attesting that the animals:

- 1) showed no clinical sign of FMD on the day of shipment;

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- 2) were kept in an FMD free country since birth or for at least the past 3 months; and
- 3) have not been vaccinated and were subjected, with negative results, to tests for antibodies against FMD virus, when destined to an FMD free country or zone where vaccination is not practised.

Article 2.1.1.11.

When importing from FMD infected countries or zones, *Veterinary Administrations* should require:

for domestic ruminants and pigs

the presentation of an *international veterinary certificate* attesting that the animals:

- 1) showed no clinical sign of FMD on the day of shipment;
- 2) were kept in the *establishment* of origin since birth or
 - a) for the past 30 days, if a *stamping-out policy* is in force in the *exporting country*, or
 - b) for the past 3 months, if a *stamping-out policy* is not in force in the *exporting country*,
 and that FMD has not occurred within a 10-kilometre radius of the *establishment* of origin for the relevant period as defined in points a) and b) above; and
- 3) were isolated in an *establishment* for the 30 days prior to **shipment quarantine, and all animals in isolation** were subjected to diagnostic tests (probang and serology) for evidence of FMDV infection with negative results at the end of that period, and that FMD did not occur within a 10-kilometre radius of the *establishment* during that period; or
- 4) were kept in a *quarantine station* for the 30 days prior to shipment, **all animals in quarantine** were subjected to diagnostic tests (probang and serology) for evidence of FMDV infection with negative results at the end of that period, and that FMD did not occur within a 10-kilometre radius of the *quarantine station* during that period;
- 5) were not exposed to any source of FMD infection during their transportation from the *quarantine station* to the *place of shipment*.

Article 2.1.1.12.

When importing from FMD free countries or zones where vaccination is not practised, *Veterinary Administrations* should require:

for fresh semen of domestic ruminants and pigs

the presentation of an *international veterinary certificate* attesting that:

- 1) the donor animals:
 - a) showed no clinical sign of FMD on the day of collection of the semen;
 - b) were kept in an FMD free country or zone where vaccination is not practised for at least 3 months prior to collection;
- 2) the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.1., Appendix 3.2.2. or Appendix 3.2.3., as relevant.

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Article 2.1.1.13.

When importing from FMD free countries or zones where vaccination is not practised, *Veterinary Administrations* should require:

for frozen semen of domestic ruminants and pigs

the presentation of an *international veterinary certificate* attesting that:

- 1) the donor animals:
 - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
 - b) were kept in an FMD free country or zone where vaccination is not practised for at least 3 months prior to collection;
- 2) the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.1., Appendix 3.2.2. or Appendix 3.2.3., as relevant.

Article 2.1.1.14.

When importing from FMD free countries or zones where vaccination is practised, *Veterinary Administrations* should require:

for semen of domestic ruminants and pigs

the presentation of an *international veterinary certificate* attesting that:

- 1) the donor animals:
 - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
 - b) were kept in a country or zone free from FMD for at least 3 months prior to collection;
 - c) if destined to an FMD free country or zone where vaccination is not practised:
 - i) have not been vaccinated and were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMD virus, with negative results; or
 - ii) had been vaccinated at least twice, with the last vaccination not more than 12 and not less than one month prior to collection;
- 2) no other animal present in the *artificial insemination centre* has been vaccinated within the month prior to collection;
- 3) the semen:
 - a) was collected, processed and stored in conformity with the provisions of Appendix 3.2.1., Appendix 3.2.2. or Appendix 3.2.3., as relevant;
 - b) was stored in ~~a country free from FMD~~ the country of origin for a period of at least one month following collection ~~before export~~, and during this period no animal on the *establishment* where the donor animals were kept showed any sign of FMD.

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Article 2.1.1.15.

When importing from FMD infected countries or zones, *Veterinary Administrations* should require:

for semen of domestic ruminants and pigs

the presentation of an *international veterinary certificate* attesting that:

- 1) the donor animals:
 - a) showed no clinical sign of FMD on the day of collection of the semen;
 - b) were kept in an *establishment* where no animal had been added in the 30 days before collection, and that FMD has not occurred within 10 kilometres for the 30 days before and after collection;
 - c) have not been vaccinated and were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMD virus, with negative results; or
 - d) had been vaccinated at least twice, with the last vaccination not more than 12 and not less than one month prior to collection;
- 2) no other animal present in the *artificial insemination centre* has been vaccinated within the month prior to collection;
- 3) the semen:
 - a) was collected, processed and stored in conformity with the provisions of Appendix 3.2.1., Appendix 3.2.2. or Appendix 3.2.3., as relevant;
 - b) was subjected, with negative results, to a test for FMDV infection if the donor animal has been vaccinated within the 12 months prior to collection;
 - c) was stored in the country of origin for a period of at least one month following collection ~~between collection and export~~, and during this period no animal on the *establishment* where the donor animals were kept showed any sign of FMD.

Article 2.1.1.16.

Irrespective of the FMD status of the *exporting country* or zone, *Veterinary Administrations* should authorise without restriction the import or transit through their territory of: ~~*Veterinary Administrations* should require:~~

for *in vivo* derived embryos of cattle

subject to the presentation of an *international veterinary certificate* attesting that:

- ~~1) the donor females showed no clinical sign of FMD at the time of collection of the embryos;~~
- 2) the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1. or Appendix 3.3.3., as relevant.

Article 2.1.1.17.

When importing from FMD free countries or zones where vaccination is not practised, *Veterinary Administrations* should require:

Appendix IX (contd)for *in vitro* produced embryos of cattle

the presentation of an *international veterinary certificate* attesting that:

- 1) the donor females:
 - a) showed no clinical sign of FMD at the time of collection of the **oocytes embryos**;
 - b) were kept in a country or zone free from FMD at the time of collection;
- 2) fertilisation was achieved with semen meeting the conditions referred to in Articles 2.1.1.12., 2.1.1.13., 2.1.1.14. or 2.1.1.15., as relevant;
- 3) the **oocytes embryos** were collected, **and the embryos were** processed and stored in conformity with the provisions of Appendix 3.3.2. or Appendix 3.3.3., as relevant.

Article 2.1.1.18.

When importing from FMD free countries or zones where vaccination is practised, *Veterinary Administrations* should require:

for *in vitro* produced embryos of cattle

the presentation of an *international veterinary certificate* attesting that:

- 1) the donor females:
 - a) showed no clinical sign of FMD at the time of collection of the **oocytes embryos**;
 - b) were kept in a country or zone free from FMD for at least 3 months prior to collection;
 - c) if destined for an FMD free country or zone where vaccination is not practised:
 - i) have not been vaccinated and were subjected, with negative results, to tests for antibodies against FMD virus, or
 - ii) had been vaccinated at least twice, with the last vaccination not less than one month and not more than 12 months prior to collection;
- 2) no other animal present in the *establishment* has been vaccinated within the month prior to collection;
- 3) fertilization was achieved with semen meeting the conditions referred to in Articles 2.1.1.12., 2.1.1.13., 2.1.1.14. or 2.1.1.15., as relevant;
- 4) the **oocytes embryos** were collected, **and the embryos** were processed and stored in conformity with the provisions of Appendix 3.3.2. or Appendix 3.3.3., as relevant.

Article 2.1.1.19.

When importing from FMD free countries or zones where vaccination is not practised, *Veterinary Administrations* should require:

for *fresh meat* of FMD susceptible animals

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from animals which:

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- 1) have been kept in the FMD free country or zone where vaccination is not practised since birth, or which have been imported in accordance with Article 2.1.1.9., Article 2.1.1.10. or Article 2.1.1.11.;
- 2) have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results.

Article 2.1.1.20.

When importing from FMD free countries or zones where vaccination is practised, *Veterinary Administrations* should require:

for fresh meat of bovines (excluding feet, head and viscera)

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from animals which:

- 1) have been kept in the FMD free country or zone where vaccination is practised since birth, or which have been imported in accordance with Article 2.1.1.9., Article 2.1.1.10. or Article 2.1.1.11.;
- 2) have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results.

Article 2.1.1.21.

When importing from FMD free countries or zones where vaccination is practised, *Veterinary Administrations* should require:

for fresh meat or meat products of pigs and ruminants other than bovines

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from animals which:

- 1) have been kept in the country or zone since birth, or have been imported in accordance with Article 2.1.1.9., Article 2.1.1.10. or Article 2.1.1.11.;
- 2) have not been vaccinated;
- 3) have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results.

Article 2.1.1.22.

When importing from FMD infected countries or zones, where an official control programme exists, involving compulsory systematic vaccination of cattle, *Veterinary Administrations* should require:

for fresh meat of bovines (excluding feet, head and viscera)

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat:

- 1) comes from animals which:
 - a) have remained in the *exporting country* for at least 3 months prior to slaughter;

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- b) have remained, during this period, in a part of the country where cattle are regularly vaccinated against FMD and where official controls are in operation;
 - c) have been vaccinated at least twice with the last vaccination not more than 12 months and not less than one month prior to slaughter;
 - d) were kept for the past 30 days in an *establishment*, and that FMD has not occurred within 10 kilometres a 10-kilometre radius of the establishment during that period;
 - e) have been transported, in a *vehicle* which was cleansed and disinfected before the cattle were loaded, directly from the *establishment* of origin to the *approved abattoir* without coming into contact with other animals which do not fulfil the required conditions for export;
 - f) have been slaughtered in an *approved abattoir*:
 - i) which is officially designated for export;
 - ii) in which no FMD has been detected during the period between the last *disinfection* carried out before slaughter and the shipment for export has been dispatched;
 - g) have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results within 24 hours before and after slaughter;
- 2) comes from deboned carcasses:
- a) from which the major lymphatic glands lymph nodes have been removed;
 - b) which, prior to deboning, have been submitted to maturation at a temperature above + 2°C for a minimum period of 24 hours following slaughter and in which the pH value was below 6.0 when tested in the middle of both the longissimus dorsi.

Article 2.1.1.23.

When importing from FMD infected countries or zones, *Veterinary Administrations* should require:

for meat products of domestic ruminants and pigs

the presentation of an *international veterinary certificate* attesting that:

- 1) the entire consignment of *meat* comes from animals which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results;
- 2) the *meat* has been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Article 3.6.2.1.;
- 3) the necessary precautions were taken after processing to avoid contact of the *meat products* with any potential source of FMD virus.

Article 2.1.1.24.

When importing from FMD free countries or zones (where vaccination either is or is not practised), *Veterinary Administrations* should require:

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for milk and milk products intended for human consumption and for products of animal origin (from FMD susceptible animals) intended for use in animal feeding or for agricultural or industrial use

the presentation of an *international veterinary certificate* attesting that these products come from animals which have been kept in the country or zone since birth, or which have been imported in accordance with Article 2.1.1.9., Article 2.1.1.10. or Article 2.1.1.11.

Article 2.1.1.25.

When importing from FMD infected countries or zones where an official control programme exists, *Veterinary Administrations* should require:

for milk, cream, milk powder and milk products

the presentation of an *international veterinary certificate* attesting that:

- 1) these products:
 - a) originate from herds or flocks which were not infected or suspected of being infected with ~~subjected to any restrictions due to~~ FMD at the time of *milk* collection;
 - b) have been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Article 3.6.2.5. and in Article 3.6.2.6.;
- 2) the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMD virus.

Article 2.1.1.26.

When importing from FMD infected countries, *Veterinary Administrations* should require:

for blood and meat-meals (from domestic or wild ruminants and pigs)

the presentation of an *international veterinary certificate* attesting that the manufacturing method for these products included heating to a minimum internal temperature of 70°C for at least 30 minutes.

Article 2.1.1.27.

When importing from FMD infected countries, *Veterinary Administrations* should require:

for wool, hair, bristles, raw hides and skins (from domestic or wild ruminants and pigs)

the presentation of an *international veterinary certificate* attesting that:

- 1) these products have been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Articles 3.6.2.2., 3.6.2.3. and 3.6.2.4.;
- 2) the necessary precautions were taken after collection or processing to avoid contact of the products with any potential source of FMD virus.

Veterinary Administrations can authorise, without restriction, the import or transit through their territory of semi-processed hides and skins (limed hides, pickled pelts, and semi-processed leather - e.g. wet blue and crust leather), provided that these products have been submitted to the usual chemical and mechanical processes in use in the tanning industry.

Appendix IX (contd)

Article 2.1.1.28.

When importing from FMD infected countries or zones, *Veterinary Administrations* should require:

for straw and forage

the presentation of an *international veterinary certificate* attesting that these commodities:

- 1) are free of grossly identifiable contamination with material of animal origin;
- 2) have been subjected to one of the following treatments, which, in the case of material sent in bales, has been shown to penetrate to the centre of the bale:
 - a) either to the action of steam in a closed chamber such that the centre of the bales has reached a minimum temperature of 80°C for at least 10 minutes,
 - b) or to the action of formalin fumes (formaldehyde gas) produced by its commercial solution at 35-40% in a chamber kept closed for at least 8 hours and at a minimum temperature of 19°C;

OR

- 3) have been kept in bond for at least 3 months (under study) before being released for export.

Article 2.1.1.29.

When importing from FMD free countries or zones (where vaccination either is or is not practised), *Veterinary Administrations* should require:

for skins and trophies derived from wild animals susceptible to FMD

the presentation of an *international veterinary certificate* attesting that these products are derived from animals that have been kept in such a country or zone since birth, or which have been imported from a country or zone free of FMD (where vaccination either is or is not practised).

Article 2.1.1.30.

When importing from FMD infected countries or zones, *Veterinary Administrations* should require:

for skins and trophies derived from wild animals susceptible to FMD

the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of the FMD virus in conformity with the procedures referred to in Article 3.6.2.7.

[Note: International veterinary certificates for animal products coming from infected countries or zones may not be required if the products are transported in an approved manner to premises controlled and approved by the Veterinary Administration of the importing country for processing to ensure the destruction of the FMD virus in conformity with the procedures referred to in Articles 3.6.2.2., 3.6.2.3. and 3.6.2.4.]

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APPENDIX 3.8.6

GUIDELINES FOR THE SURVEILLANCE REQUIRED TO
SUPPORT THE ESTABLISHMENT OR REGAINING OF
RECOGNITION FOR A FOOT AND MOUTH DISEASE
FREE COUNTRY OR ZONE

Article 3.8.6.1.

Introduction

This document defines the principles and provides a guide for the surveillance of foot and mouth disease (FMD) applicable to countries seeking recognition from the OIE for freedom from FMD, either with or without the use of vaccination. This may be for the entire country or a zone within the country. Guidance for countries seeking reestablishment of freedom from FMD for the whole country or a zone, either with or without vaccination, following an *outbreak* is also provided. These guidelines are intended to expand on and explain the requirements of Chapter 2.1.1. of this *Terrestrial Code*. Applications to the OIE for such recognition should follow the format and answer all the questions posed by the “Questionnaire on FMD” available from the OIE Central Bureau.

Reference to vaccination in this guide implies vaccination as part of an official disease control programme under the supervision of the *Veterinary Administration* aimed at interrupting the transmission of FMD virus (FMDV) in the zone or country concerned. The level of herd immunity required to achieve interruption of transmission will depend on the size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive in this matter but, in general, unless there are good reasons to employ a different target, the aim should be to vaccinate at least 80% of the susceptible population in the manner and at the frequency prescribed by the manufacturer of the vaccine concerned. The vaccine must also comply with the provisions stipulated for FMD vaccines in the *Terrestrial Manual*. It may be that a decision is reached to vaccinate only certain species or other subset of the total susceptible population. In that case the rationale should be contained within the dossier accompanying the application to the OIE for recognition of a free country or zone or recovery of such status.

The impact and epidemiology of FMD differs widely in different regions of the world and therefore it is impossible to provide specific guidelines for all potential situations. It is axiomatic that the surveillance strategies employed for demonstrating freedom from FMD at an acceptable level of confidence will need to be adapted to the local situation. For example, the approach to proving freedom from FMD following an outbreak caused by a pig-adapted strain of FMDV should differ significantly from an application designed to prove freedom from FMD for a country or zone where African buffaloes (*Syncerus caffer*) provide a potential reservoir of infection. It is incumbent upon the applicant country to submit a dossier to the OIE in support of its application that not only explains the epidemiology of FMD in the region concerned but also demonstrates how all the risk factors are managed. This should include provision of scientifically based supporting data. There is therefore considerable latitude available to Member Countries to provide a well-reasoned argument to prove that absence of FMDV infection is assured at an acceptable level of confidence.

Surveillance for FMD may be in the form of a continuing disease surveillance programme or it may be a specific programme designed to establish that the whole territory or part of it is free from FMDV infection.

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Article 3.8.6.2.

General conditions

- 1) A surveillance system should be supported by a *Veterinary Service* (Chapter 1.3.3. of this *Terrestrial Code*) with expertise in FMD. A procedure should be in place for the rapid collection and transport of samples from suspect cases of FMD to a laboratory suitably equipped and staffed to perform tests appropriate for FMD diagnoses.
- 2) The FMD surveillance programme should:
 - a) include an early warning system for reporting suspicious cases. Farmers and workers who have day-to-day contact with livestock should be encouraged to report promptly any clinical disease resembling FMD. They should be supported directly or indirectly (e.g. through private veterinarians or veterinary para-professionals) by government information programmes and the *Veterinary Administration*. All suspect cases of FMD should be investigated immediately and, if still considered suspect, samples should be taken and submitted to an approved laboratory. This requires that sampling kits and other equipment are available for those responsible for surveillance. Personnel responsible for surveillance should be able to call for assistance from a team with expertise in FMD diagnosis and control;
 - b) implement, when relevant, regular and frequent clinical inspection and serological testing of high-risk groups of animals, such as those adjacent to an FMD infected country or zone (for example, bordering a game park in which infected wildlife are present).

An effective surveillance system will periodically identify suspicious cases that require follow up and investigation to confirm or exclude that the cause of the condition is FMDV. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from FMD infection should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of laboratory testing and the control measures to which the animals concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

During investigation into suspect *outbreaks* of FMD it is necessary to apply measures that will contain the infection to its original locality until such time as the diagnosis is confirmed or refuted, e.g. through application of quarantine measures. The details of actions that need to be applied in such situations are not covered by this guide.

- 3) These general requirements apply in all Member Countries submitting their annual request for re-confirmation of FMD free status although active surveillance for FMD is not a requirement for countries that are recognised by the OIE as being free from FMD without vaccination. An active surveillance programme is required from Member Countries applying for the first time for recognition of freedom from FMD for the whole country or zone either with or without vaccination. It is also a requirement for countries seeking recognition for the recovery of their former status following an *outbreak*.

Article 3.8.6.3.

Countries applying for freedom from FMD for the whole country or a zone where vaccination is not practised1) Introduction

A Member Country applying for recognition of freedom for the country or a zone from FMD where vaccination is not practised should provide evidence for the existence of an effective surveillance programme. The strategy and design of the surveillance programme will depend on the prevailing epidemiological circumstances. Conventionally, a statistically significant proportion of the whole population should be subjected to clinical and serological surveillance to demonstrate absence of FMDV, i.e. circulation of virus, during the preceding 12 months. This requires the support of a national or other laboratory able to undertake identification of FMDV infection through virus/antigen/genome detection and antibody tests described in the *Terrestrial Manual*.

2) Survey design

The target population for surveillance aimed at identification of *disease* and *infection* should cover all the susceptible species within the country or zone to be recognised as free from infection. This would usually require stratification of different species.

Countries wishing to show freedom from FMDV infection in which a pig-adapted strain of virus had been prevalent should concentrate on sampling the national pig population. However, it would also be necessary to show that no spill-over into other susceptible species has occurred. In countries or zones in which an African buffalo population is present, the buffaloes should also be sampled if included in the proposed FMDV infection-free zone.

The strategy employed may be based either on randomised sampling requiring surveillance consistent with demonstrating the absence of *infection* at an acceptable level of statistical confidence. The frequency of sampling would be dependent on the epidemiological situation, but should occur at least once during the year preceding the application. Alternatively, targeted surveillance (e.g. based on the likelihood of infection in particular localities or species) may provide a more appropriate and cost-effective strategy. If the latter approach is used, it would be incumbent upon the applicant country to show that the surveillance conducted was at least as effective as randomised surveillance with stratification of different susceptible species. It may, for example, be appropriate to target clinical surveillance at particular species likely to exhibit clear clinical signs (e.g. cattle and pigs) while directing serological surveillance at species that tend to develop less obvious signs of infection such as sheep and, in some locations, goats and wildlife species.

If a Member Country wishes to apply for recognition of a specific zone/region within the country as being free from FMDV infection, the design of the survey and the basis for the sampling process would need to be aimed at the population within the zone/region.

For randomised surveillance, the design of the sampling strategy will need to incorporate an epidemiologically appropriate design prevalence because, obviously, the sample selected for testing will need to be large enough to detect infection if it were to occur at a predetermined minimum rate. The sample size and expected disease prevalence determine the level of confidence in the result of the survey. A typical random sampling strategy would be one that provides 95% probability of detecting evidence of FMD or FMDV infection if it were present in 1% of the primary sampling units. A minimum expected level of infection within sampling units also has to be set to ensure that a sufficient number of animals within each sampling unit is tested to detect the infection if it were present in the sampling unit. Typically this value is set somewhere between 5-20% with a confidence level of 95%. In many instances it could be safely assumed that within-sampling unit prevalence

Appendix X (contd)

would be greater than 5% bearing in mind the contagiousness of FMDV. Selection of the prevalence estimate clearly needs to be based on the prevailing or historical epidemiological situation. The reasoning used in the selection of prevalence parameters needs to be clearly spelt out in the dossier supplied to the OIE when applications are made for recognition of freedom from FMD.

The sensitivities and specificities of the testing methods employed also affect the design of sampling strategies. Clinical inspection, for example, typically has low sensitivity, especially in species that tend to suffer mild or indistinct signs of FMD (e.g. sheep). In other words, the probability of detecting FMD infection through identification of clinical cases is not particularly dependable and this therefore needs to be allowed for in the sampling design. For proving absence of infection through serology, it is usually desirable to have either a test with both high sensitivity (likely to detect a high proportion of seropositive individuals) and specificity (few false positive animals likely to be identified) or to use a combination of tests that together provide high net sensitivity and specificity. However, even if the net specificity is high, in cases where the design prevalence is low (e.g. in situations where proving absence of FMD is the objective), the positive predictive value (PV) of a test or testing system may be considerably lower than 100% (because PV is mainly a function of specificity and prevalence). This means that in such circumstances it needs to be anticipated that false positive results will occur. If the characteristics of the testing system are known, the rate at which these false positive are likely to occur can be calculated. In such circumstances detected prevalence rates significantly greater than the calculated rate would be suspicious of infection. More typically, the parameters of the testing system are imprecisely known and therefore an element of judgement in the interpretation of serological results will be necessary. Whatever the case, there needs to be an effective procedure for following up serological positives to determine ultimately, to a high level of probability, whether they are indicative of infection or not. This should involve both supplementary laboratory tests (see below) and further field follow-up to collect diagnostic material from the original sampling unit if possible as well as animals in the vicinity which may be epidemiologically linked to the suspect focus.

It is evident from the above that although the principles involved in surveillance for disease/infection are reasonably straight forward, design of large surveillance programmes to prove absence of FMD needs to be carefully done to avoid producing results that are either insufficiently reliable to be accepted by the OIE or international trading partners or excessively costly and logistically complicated. The design of any large surveillance programme therefore requires inputs from competent and experienced professionals in this field.

3) Clinical surveillance

Clinical surveillance aims at the detection of clinical signs of FMD by close inspection of susceptible animals. It is essential that all animals within the selected primary sampling unit are examined for signs of FMD. Any unit where suspicious animals are detected should be classified as infected until contrary evidence is produced.

There are a number of issues that need to be considered in clinical surveillance for FMD. Some of these (e.g. the general insensitivity of clinical surveillance and species differences) have been mentioned above. The practical difficulty, hard work and boredom involved in conducting repetitive clinical examinations are almost invariably underestimated (hence the low sensitivity). This therefore needs to be borne in mind in the surveillance design.

Furthermore, now that the emphasis of the chapter of this *Terrestrial Code* on FMD is on detection of infection rather than disease, it needs to be remembered that in practice detection of disease is only one of the ways in which infection can be identified. Other techniques, such as serology, may be more sensitive especially in situations where vaccination is not practised but, on the other hand, identification of clinical cases is still fundamental to FMD surveillance. Identification of such cases is also vital in providing sources of the causative virus that enable the molecular, antigenic and other biological characteristics of the virus to be established. It is essential that FMDV isolates are sent regularly to the regional reference laboratory for genetic and antigenic characterization.

4) Serological surveillance

Serological surveillance aims at the detection of antibodies against FMDV. Positive tests for FMDV antibody tests can have four possible causes:

- a) natural infection with FMDV;
- b) vaccination against FMD;
- c) maternal antibodies derived from an immune dam (maternal antibodies in cattle are usually found only up to 6 months of age, however, in some individuals and in buffalo calves, maternal antibody can be detected for considerably longer);
- d) heterophile (cross) reactions.

It is important that serological tests, where appropriate, contain antigens appropriate for detecting viral variants (types, subtypes, lineages, topotypes, etc.) that have recently occurred in the region concerned. Where the probable identity of FMDVs is unknown or where exotic viruses are suspected to be present, tests able to detect representatives of all serotypes should be employed (e.g. tests based on non-structural viral proteins – see below).

It may be possible to use serum collected for other survey purposes for FMD surveillance but the requirement for a statistically valid survey for the presence of FMDV should not be compromised.

General considerations in the design and conduct of sero-surveys have been addressed above (see Survey design). An important issue requiring planning is the procedure to be followed in the event that seropositives are detected. As already indicated, it is likely that where the design prevalence is low false positive results should be anticipated. When these occur, both laboratory and field follow-up are necessary to differentiate between true and false positives.

Infected animals are unlikely to be evenly dispersed within the population and a cross sectional analysis will usually detect clusters of infection. FMD is no exception to this general rule. Therefore, it is important to identify clusters of seropositive animals through simple mapping or more sophisticated cluster analysis.

If vaccination cannot be excluded as the cause of positive serological reactions, testing for the presence of antibodies to the nonstructural proteins (NSPs) of FMDVs (as described in the *Terrestrial Manual*) should be used.

The results of random sample or targeted surveys based on serology are important in providing reliable evidence that no FMDV infection is present in a country or zone. It is therefore essential that the survey be thoroughly documented.

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Article 3.8.6.4.

Countries or zones applying for freedom from FMD where vaccination is practised

In addition to the general conditions, a country or zone applying for recognition of freedom from FMD with vaccination should show evidence of an effective surveillance programme for clinical disease and demonstrate that FMD has not occurred in the country or zone for the past 2 years. Furthermore, surveillance for FMDV infection should show that FMDV has not been circulating in the vaccinated population within the past 12 months. This will require serological surveillance incorporating tests able to detect antibodies to NSPs as described in Article 3.8.6.6.

Evidence to show the effectiveness of the vaccination programme is recommended.

Article 3.8.6.5.

Countries or zones re-applying for freedom from FMD where vaccination is either practised or not practised, following an outbreak

In addition to the general conditions, a country re-applying for freedom from FMD where vaccination is practised should show evidence of an active surveillance programme for FMD as well as absence of FMDV infection. This will require serological surveillance incorporating tests able to detect antibodies to NSPs as described in the *Terrestrial Manual*. This is particularly important if a country intends for the whole of its territory or a zone to avail itself of the possibility of a reduced waiting period, i.e. less than 2 years after the last *outbreak*.

Four strategies are recognised by the OIE in a programme to eradicate FMDV infection following an *outbreak*:

- 1) slaughter of all clinically affected and in-contact susceptible animals;
- 2) slaughter of all clinically affected and in-contact susceptible animals and vaccination of at-risk animals, with subsequent slaughter of vaccinated animals;
- 3) slaughter of all clinically affected and in-contact susceptible animals and vaccination of at-risk animals, without subsequent slaughter of vaccinated animals;
- 4) vaccination used without slaughter of affected animals or subsequent slaughter of vaccinated animals.

The time periods before which an application can be made for re-instatement of freedom from FMD depending on which of these alternatives is followed. The time periods are indicated in Article 2.1.1.7. of this *Terrestrial Code*.

In all circumstances, a Member Country re-applying for freedom from FMD with vaccination in a country or zone should report the results of an active surveillance programme in which the FMD susceptible population undergoes regular clinical examination or where active surveillance has targeted a statistically significant sample of the susceptible population. In addition, a statistically significant sample, based on the susceptible population at risk during the *outbreak*, would need to be tested for absence of FMDV infection. In particular circumstances, targeted surveillance could be used to accomplish the task. The procedures are outlined above.

Article 3.8.6.6.

The use and interpretation of serological tests (see Fig 1)

The recommended serological tests for FMD surveillance are described in the *Terrestrial Manual*.

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ELISAs based on structural proteins are useful for screening sera for evidence of infection in animals that have not been vaccinated. However, although their sensitivity is generally high, their specificity, particularly in the case of the liquid-phase blocking ELISA (LPBE), is relatively low. This presents difficulties when it comes to proving freedom from infection. These tests are also effective for monitoring serological responses to vaccination where it is certain that the animals concerned have not been infected. The net specificity of serological screening with ELISAs can be improved by retesting positive sera using the virus neutralisation test (VNT). Precise values for sensitivity and specificity of these tests are not available and, in any case, are likely to vary slightly between laboratories.

Any animal whose serum is positive by the VNT should be tested additionally for evidence of infection using either serological tests for antibodies to NSPs and/or by collection of oesophageal-pharyngeal material (probang testing) for virus detection on cell cultures or by PCR. Ideally, fresh serum should be collected from the animal(s) concerned because repeated freezing and thawing of stored sera tends to damage immunoglobulins.

Animals that have been vaccinated will have antibodies to the structural proteins of FMD virus, and some may have antibodies to the NSPs, depending on the number of times they have been vaccinated, and the amount of the NSPs present in the vaccine used. However, animals that have recovered from infection with FMD virus will have high levels of antibody to the NSPs. There are eight NSPs associated with the replication of FMD virus, namely L, 2A, 2B, 2C, 3A, 3B, 3C and 3D, and antibodies can be found to all of these in most recovered animals. Some do not persist for more than a few months, and some animals may fail to produce detectable levels to all NSPs. ELISAs have been developed to detect 2C, 3B or 3ABC antibodies, the former being detectable for up to one year after infection, and the latter for up to 2 years. A western blot technique (EITB) may also be used to detect the NSP antibodies to 2C, 3ABC, 3A, 3B and 3D; it is particularly specific and sensitive in identifying previously infected animals. All these tests have been extensively used in cattle. Similar testing in other species is on-going.

There is the option to use the NSP antibody test together with tests for detection of antibody to structural viral proteins, particularly in areas where vaccination has been used and virus activity is suspected. Titres higher than would be expected from vaccination alone may suggest FMDV infection and this can be confirmed by testing for the presence of antibodies to the NSPs.

As indicated above, the diagnostic sensitivity of tests used influences the numbers of animals that need to be sampled in a survey to provide evidence of absence of infection. The diagnostic specificity of the test influences the proportion and number of positive results to be expected in the absence or presence of infection, and therefore the selection and use of confirmatory tests. Results of surveys which indicate a significantly higher proportion of positive test results in comparison with that expected from the estimate of the false positive rate derived from the diagnostic specificity (i.e. 100 minus diagnostic specificity) may be interpreted as evidence of infection in the population. A confirmatory test of high specificity, and where appropriate other investigations, should be conducted to prove or refute the possibility of infection.

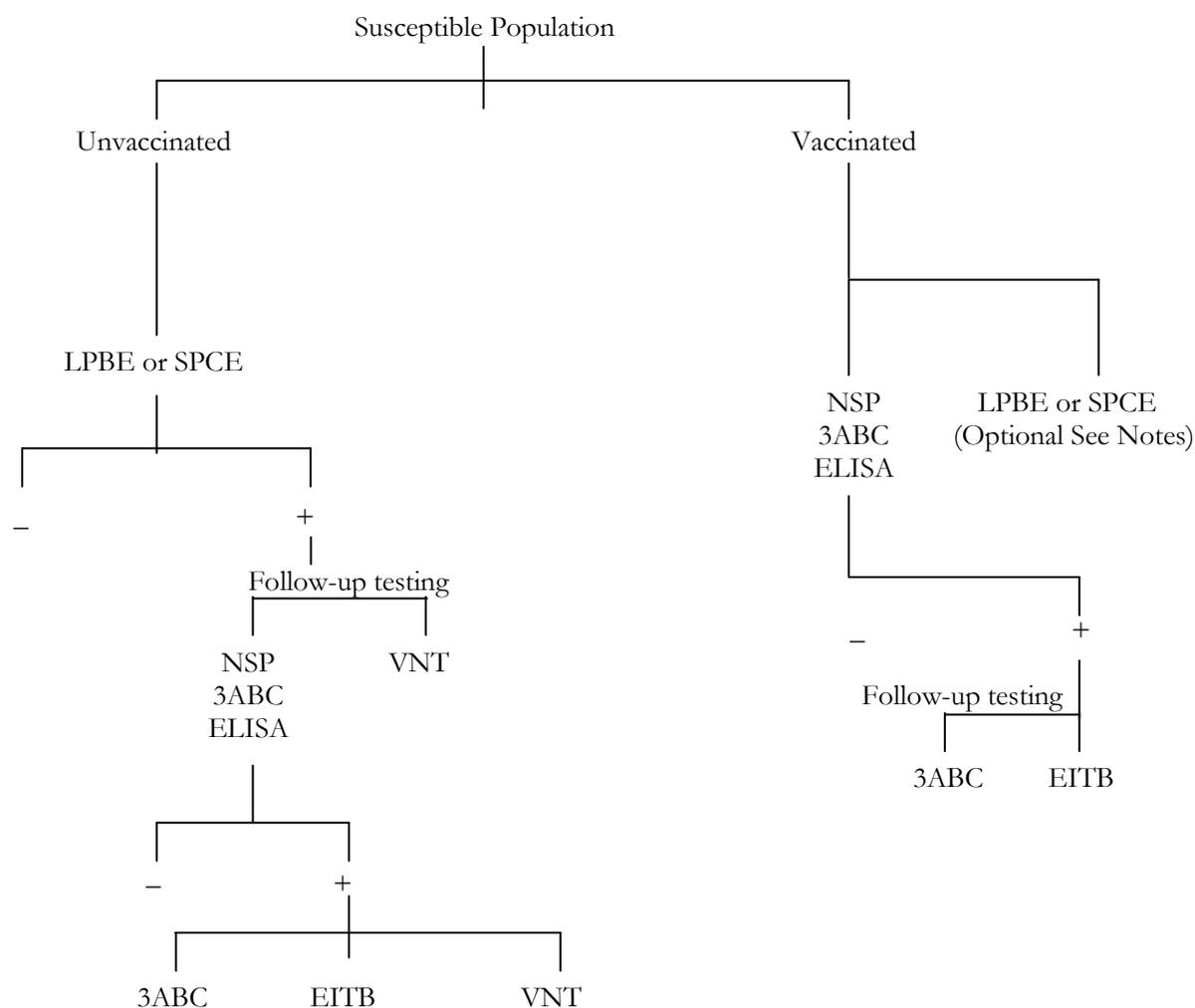
Figure 1 provides a flowchart of the test protocol that could be used to test the samples collected in a serological survey. If the population being tested has not been previously vaccinated against FMD, the serum samples can be tested using ELISAs based on structural proteins. Sera positive on the test used should be retested using the VNT, which increases the net specificity. In addition, or in place of the VNT

Appendix X (contd)

if the laboratory is not able to manipulate live FMDV, the positive sera may be retested using an NSP antibody test, such as the 3B, 3ABC or EITB. A positive VNT or NSP test would suggest that live virus had been circulating, and would require further investigation of the herd or flock to confirm or refute the possibility. Further investigation should include serum testing of the whole herd or flock from which the positive samples were obtained. NSP tests should be used for testing sera from vaccinated herds or flocks, as such sera will be positive by VNT. 3ABC or 3B positive samples may be repeat tested using the EITB for confirmation. All animals from the unit from which positive samples are obtained should be re-tested for antibodies to NSPs.

The sensitivity and specificity of the NSP tests currently available are not fully documented, in particular for species other than cattle. Member Countries submitting to the OIE data derived from commercial or other NSP tests should provide information on the characteristics of the test being used.

Figure 1 Schematic representation of laboratory tests for determining evidence of FMDV infection through or following serological surveys



The above diagram indicates the tests which are recommended for use in the investigation of sampling units in which a positive test result has been obtained.

When feasible, detection of virus in OP fluid can also be used as complementary test on units in which positive NSP test result has been obtained.

Key:

ELISA	Enzyme-linked immunosorbant assay
VNT	Virus neutralisation test
NSP	Nonstructural protein(s) of foot and mouth disease virus (FMDV)
3ABC	NSP antibody test
EITB	Western blot for NSP antibodies of FMDV
OP	Oesophageal-pharyngeal sample

CHAPTER 2.3.13.

BOVINE SPONGIFORM ENCEPHALOPATHY

Article 2.3.13.1.

The recommendations in this Chapter are intended to manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle (*Bos taurus* and *B. indicus*) only.

The following commodities can be safely traded:

1) without BSE related restrictions and regardless of the BSE status of the country:

a) milk and milk products;

b) semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;

c) hides and skins (excluding hides and skins from the head);

d) gelatin and collagen prepared exclusively from hides and skins (excluding hides and skins from the head);

2) subject to the prescribed conditions relating to the BSE status of the cattle population of the exporting country or zone:

a) cattle;

b) fresh meat and meat products;

c) gelatin and collagen prepared from bones;

d) tallow and tallow derivatives, and dicalcium phosphate.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 2.3.13.2.

The BSE risk status of the cattle population of a country or zone can only be determined on the basis of the following criteria:

1) the outcome of a risk assessment identifying all potential factors for BSE occurrence and their historic perspective, in particular:

a) the potential for introduction and recycling of the BSE agent through consumption by cattle of meat and bone meal or greaves of ruminant origin;

b) importation of meat and bone meal or greaves potentially contaminated with a transmissible spongiform encephalopathy (TSE) or feedstuffs containing either;

c) importation of animals or embryos/oocytes (other than cattle embryos described in Article 2.3.13.8.) potentially infected with a TSE;

d) epidemiological situation concerning all animal TSE in the country or zone;

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- e) extent of knowledge of the population structure of cattle, sheep and goats in the country or zone;
 - f) the origin and use of ruminant carcasses (including fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;
- 1) the outcome of a risk assessment (which is reviewed annually), based on Section 1.3 of this *Terrestrial Code*, identifying all potential factors for BSE occurrence and their historic perspective:
- a) Release assessment

Release assessment consists of assessing the likelihood that a transmissible spongiform encephalopathy (TSE) agent has been introduced via the importation of the following commodities potentially contaminated with a TSE agent:

 - i) meat-and-bone meal or greaves;
 - ii) live animals;
 - iii) animal feed and feed ingredients;
 - iv) products of animal origin for human consumption.
 - b) Exposure assessment

Exposure assessment consists of assessing the likelihood of exposure of the BSE agent to susceptible animal species, through a consideration of the following:

 - i) epidemiological situation concerning all animal TSE agents in the country or zone;
 - ii) recycling and amplification of the BSE agent through consumption by cattle of meat-and-bone meal or greaves of ruminant origin, or other feed or feed ingredients contaminated with these;
 - iii) the origin and use of ruminant carcasses (including fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;
 - iv) implementation and enforcement of feed bans, including measures to prevent cross-contamination of animal feed;
- 2) on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle to encourage reporting of all cases of neurological disease in adult cattle as well as fallen stock;
 - 3) compulsory notification and investigation of all cattle showing clinical signs consistent compatible with BSE;
 - 4) a BSE surveillance and monitoring system with emphasis on risks identified in point 1) above, taking into account the guidelines in Appendix 3.8.4.; records of the number and results of investigations should be maintained for at least 7 years;
 - 5) examination in an approved laboratory of brain or other tissues collected within the framework of the aforementioned surveillance and monitoring system.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 2.3.13.3.

BSE free country or zone

The cattle population of a country or zone may be considered free of BSE should the following conditions be met:

- 1) a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted and it has been demonstrated that appropriate measures have been taken for the relevant period of time to manage any risk identified;
- 2) a level of surveillance and monitoring which complies with the requirements of Appendix 3.8.4 is in place, and either:
 - a) there has been no *case* of BSE; and either:
 - i) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years; or
 - ii) the criteria in point 3) of Article 2.3.13.2. have been complied with for at least 7 years and it has been demonstrated that for at least 8 years no *meat-and-bone meal* or *greaves* have been fed to ruminants;

OR

- b) all *cases* of BSE have been clearly demonstrated to originate directly from the importation of live cattle, and the affected cattle as well as, if these are females, all their progeny born within 2 years prior to and after clinical onset of the disease, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed their last progeny born within 2 years prior to, or after, clinical onset of the disease, if alive in the country or zone, have been slaughtered and completely destroyed; and either:
 - i) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years; or
 - ii) the criteria in point 3) of Article 2.3.13.2. have been complied with for at least 7 years and it has been demonstrated that for at least 8 years no *meat-and-bone meal* or *greaves* have been fed to ruminants;

OR

- c) the last indigenous *case* of BSE was reported more than 7 years ago,
 - i) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years; and
 - ii) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced for at least 8 years; and
 - iii) the affected cattle as well as:
 - = if these are females, all their progeny born within 2 years prior to and after clinical onset of the disease, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed, and

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- ≡ all cattle which, during their first year of life, were reared with the affected cattle during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, if alive in the country or zone, are permanently identified and their movements controlled, and when slaughtered or at death, are completely destroyed, or
- ≡ where the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the affected cattle, if alive in the country or zone, are permanently identified and their movements controlled, and when slaughtered or at death, are completely destroyed.
and when slaughtered or at death, are completely destroyed.

Article 2.3.13.4.

BSE provisionally free country or zone

The cattle population of a country or zone may be considered as provisionally free of BSE should the following conditions be met:

- 1) a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted and it has been demonstrated that appropriate measures have been taken for the relevant period of time to manage any risk identified;
- 2) a level of surveillance and monitoring which complies with the requirements of Appendix 3.8.4 is in place, and either:
 - a) there has been no *case* of BSE; and either:
 - i) the criteria in points 2) to 5) of Article 2.3.13.2. are complied with, but have not been complied with for 7 years; or
 - ii) it has been demonstrated that for at least 8 years no *meat-and-bone meal* or *greaves* have been fed to ruminants, but the criteria in point 3) of Article 2.3.13.2. have not been complied with for 7 years;

OR

- b) all *cases* of BSE have been clearly demonstrated to originate directly from the importation of live cattle, and the affected cattle as well as, if these are females, all their progeny born within 2 years prior to and after clinical onset of the disease, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed, their last progeny born within 2 years prior to, or after, clinical onset of the disease, if alive in the country or zone, have been slaughtered and completely destroyed; and either:
 - i) the criteria in points 2) to 5) of Article 2.3.13.2. are complied with, but have not been complied with for 7 years; or
 - ii) it has been demonstrated that for at least 8 years no *meat-and-bone meal* or *greaves* have been fed to ruminants, but the criteria in point 3) of Article 2.3.13.2. have not been complied with for 7 years.

Article 2.3.13.5.

Country or zone with a minimal BSE risk

The cattle population of a country or zone may be considered as presenting a minimal BSE risk should the country or zone comply with the following requirements:

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- 1) a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted and it has been demonstrated that appropriate measures have been taken for the relevant period of time to manage any risk identified;
- 2) a level of surveillance and monitoring which complies with the requirements of Appendix 3.8.4 is in place, and

EITHER:

- a) the last indigenous *case* of BSE was reported more than 7 years ago, the criteria in points 2) to 5) of Article 2.3.13.2. are complied with and the ban on feeding ruminants with *meat-and-bone meal* and *greaves* derived from ruminants is effectively enforced, but:
 - i) the criteria in points 2) to 5) of Article 2.3.13.2. have not been complied with for 7 years; or
 - ii) the ban on feeding ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has not been effectively enforced for 8 years;

OR

- b) the last indigenous *case* of BSE has been reported less than 7 years ago, and the BSE incidence rate, calculated on the basis of indigenous *cases*, has been less than one two cases per million during each of the last four consecutive 12-month periods within the cattle population over 24 months of age in the country or zone (*Note: For countries with a population of less than one million adult cattle, the maximum allowed incidence should be expressed in cattle-years.*), and:
 - i) the ban on feeding ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been effectively enforced for at least 8 years;
 - ii) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years;
 - iii) the affected cattle as well as:
 - if these are females, all their progeny born within 2 years prior to and after clinical onset of the disease, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed, and
 - all cattle which, during their first year of life, were reared with the affected cattle during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed, or
 - where the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the affected cattle, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed.
- if alive in the country or zone, when slaughtered or at death, are completely destroyed.

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Article 2.3.13.6.

Country or zone with a moderate BSE risk

The cattle population of a country or zone may be considered as presenting a moderate BSE risk if:

- 1) a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted, and the other criteria listed in Article 2.3.13.2. are complied with;
- 2) the BSE incidence rate has been measured using a level of surveillance and monitoring which complies with the requirements of Appendix 3.8.4., and is:
 - a) if based only on surveillance in accordance with Article 3.8.4.2., greater than or equal to, one indigenous *case* per million and less than or equal to, one hundred indigenous *cases* per million within the cattle population over 24 months of age in the country or zone calculated over the past 12 months; or
 - b) if based on surveillance in accordance with Articles 3.8.4.2., 3.8.4.3. and 3.8.4.4., greater than, or equal to, one two indigenous *cases* per million and less than, or equal to, two hundred indigenous *cases* per million within the cattle population over 24 months of age in the country or zone calculated over the past 12 months; or
 - c) less than one two indigenous *cases* per million for less than four consecutive 12-month periods (*Note: For countries with a population of less than one million adult cattle, the maximum allowed incidence should be expressed in cattle-years.*);
- 3) the affected cattle as well as:
 - a) if these are females, all their progeny born within 2 years prior to and after clinical onset of the disease, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed, and
 - b) all cattle which, during their first year of life, were reared with the affected cattle during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed, or
 - c) where the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the affected cattle if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed.

if alive in the country or zone, when slaughtered or at death, are completely destroyed.

Countries and zones where the BSE incidence rate has been less than one indigenous *case* per million within the cattle population over 24 months of age during each of the last four consecutive 12-month periods, but where at least one of the other requirements to be considered as provisionally free from BSE or as presenting a minimal BSE risk is not complied with, shall be considered as countries or zones with a moderate BSE risk.

Article 2.3.13.7.

Country or zone with a high BSE risk

The cattle population of a country or zone may be considered as presenting a high BSE risk if it cannot demonstrate that it meets the requirements of another category.

Article 2.3.13.8.

Regardless of the BSE status of the *exporting country*, *Veterinary Administrations* should authorise without restriction the import or transit through their territory of the following *commodities*:

- 1) *milk and milk products*;
- 2) *semen and in vivo derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society*;
- 3) *protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow*;
- 4) *dicalcium phosphate (with no trace of protein or fat)*;
- 5) *hides and skins*;
- 6) *gelatin and collagen prepared exclusively from hides and skins*;

Article 2.3.13.9.

When importing from a BSE free country or zone, *Veterinary Administrations* should require:

for all *commodities* from cattle not listed in Article 2.3.13.8.

the presentation of an *international veterinary certificate* attesting that the country or zone complies with the conditions in Article 2.3.13.3. to be considered as free of BSE.

Article 2.3.13.10.

When importing from a BSE provisionally free country or zone, *Veterinary Administrations* should require:

for cattle

the presentation of an *international veterinary certificate* attesting that:

- 1) the country or zone complies with the conditions in Article 2.3.13.4. to be considered as provisionally free of BSE;
- 2) cattle selected for export are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspect or confirmed females.

Article 2.3.13.11.

When importing from a country or zone with a minimal BSE risk, *Veterinary Administrations* should require:

for cattle

the presentation of an *international veterinary certificate* attesting that:

- 1) the country or zone complies with the conditions in Article 2.3.13.5. to be considered as presenting a minimal BSE risk;
- 2) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;

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- 3) cattle selected for export:
- a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspect or confirmed females exposed cattle as described in point 2) b) iii) of Article 2.3.13.5.
 - b) were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been effectively enforced.

Article 2.3.13.12.

When importing from a country or zone with a moderate BSE risk, *Veterinary Administrations* should require:

for cattle

the presentation of an *international veterinary certificate* attesting that:

- 1) the country or zone complies with the conditions in Article 2.3.13.6. to be considered as presenting a moderate BSE risk;
- 2) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;
- 3) cattle selected for export:
 - a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspect or confirmed females exposed cattle as described in point 3) of Article 2.3.13.6.
 - b) were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been effectively enforced.

Article 2.3.13.13.

When importing from a country or zone with a high BSE risk, *Veterinary Administrations* should require:

for cattle

the presentation of an *international veterinary certificate* attesting that:

- 1) the country or zone complies with the conditions in Article 2.3.13.7. to be considered as presenting a high BSE risk;
- 2) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;
- 3) all affected cattle as well as:
 - a) if these are females, all their progeny born within 2 years prior to and after clinical onset of the disease, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed, and
 - b) all cattle which, during their first year of life, were reared with the affected cattle during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, or
 - c) where the results of an the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the affected cattle,

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if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed;

- 4) cattle selected for export:
 - a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspect or confirmed females;
 - b) were born at least 2 years after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants was effectively enforced.

Article 2.3.13.14.

When importing from a BSE provisionally free country or zone, *Veterinary Administrations* should require: for *fresh meat* (bone-in or deboned) and *meat products* from cattle

the presentation of an *international veterinary certificate* attesting that:

- 1) the country or zone complies with the conditions in Article 2.3.13.4. to be considered as provisionally free of BSE;
- 2) ante-mortem inspection is carried out on all cattle from which the meat or *meat products* destined for export originate.

Article 2.3.13.15.

When importing from a country or zone with a minimal BSE risk, *Veterinary Administrations* should require:

for *fresh meat* (bone-in or deboned) and *meat products* from cattle

the presentation of an *international veterinary certificate* attesting that:

- 1) the country or zone complies with the conditions in Article 2.3.13.5. to be considered as presenting a minimal BSE risk;
- 2) ante-mortem inspection is carried out on all cattle from which the meat or *meat products* destined for export originate;
- 3) cattle from which the meat or *meat products* destined for export originate were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process (laceration, after stunning, of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity);
- 4) the *fresh meat* and *meat products* destined for export do not contain brain, eyes, spinal cord or mechanically separated meat from skull and vertebral column from cattle over 30 months of age, all of which have been removed in a hygienic manner completely removed in a manner to avoid contamination with these tissues.

Article 2.3.13.16.

When importing from a country or zone with a moderate BSE risk, *Veterinary Administrations* should require:

for *fresh meat* (bone-in or deboned) and *meat products* from cattle

the presentation of an *international veterinary certificate* attesting that:

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- 1) the country or zone complies with the conditions in Article 2.3.13.6. to be considered as presenting a moderate BSE risk;
- 2) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;
- 3) ante-mortem inspection is carried out on all bovines;
- 4) cattle from which the meat or *meat products* destined for export originate were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process;
- 5) the *fresh meat* and *meat products* destined for export do not contain ~~brain, eyes, spinal cord, distal ileum~~ the tissues listed in point 1) of Article 2.3.13.19. nor mechanically separated meat from skull and vertebral column from cattle over 6 months of age, all of which have been ~~removed in a hygienic manner~~ completely removed in a manner to avoid contamination with these tissues.

Article 2.3.13.17.

When importing from a country or zone with a high BSE risk, *Veterinary Administrations* should require:
for *fresh meat* and *meat products* from cattle

the presentation of an *international veterinary certificate* attesting that:

- 1) the country or zone complies with the conditions in Article 2.3.13.7. to be considered as presenting a high BSE risk;
- 2) the meat destined for export does not contain the tissues listed in point 1) of Article 2.3.13.19., all of which have been ~~removed in a hygienic manner~~ completely removed in a manner to avoid contamination with these tissues;
- 3) the meat destined for export, if obtained from animals over 9 months of age, has been deboned and does not contain nervous and lymphatic tissues exposed during a deboning process, all of which have ~~been removed in a hygienic manner~~ completely removed in a manner to avoid contamination with these tissues;
- 4) the *meat products* destined for export are derived from deboned meat and do not contain the tissues listed in point 1) of Article 2.3.13.19. nor nervous and lymphatic tissues exposed during a deboning process, nor mechanically separated meat from skull and vertebral column of bovine animals, all of which have been ~~removed in a hygienic manner~~ completely removed in a manner to avoid contamination with these tissues;
- 5) a system is in operation enabling the *fresh meat* and *meat products* destined for export to be traced back to the *establishments* from which they are derived;
- 6) ante-mortem inspection is carried out on all bovines;
- 7) the cattle from which the *meat* or *meat products* destined for export originate:
 - a) were identified by a permanent identification system enabling them to be traced back to the dam and herd of origin;
 - b) are not the progeny of BSE suspect or confirmed females; and either:
 - i) were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been effectively enforced; or

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- ii) were born, raised and had remained in herds in which no *case* of BSE had been confirmed for at least 7 years;
 - c) were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process;
- 8) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;
- 9) all affected cattle as well as:
- a) if these are females, all their progeny born within 2 years prior to and after clinical onset of the disease, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed, and
 - b) all cattle which, during their first year of life, were reared with the affected cattle during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed, or
 - c) where the results of ~~an~~ the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the affected cattle, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed.

if alive in the country or zone, when slaughtered or at death, are completely destroyed.

Article 2.3.13.18.

Ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products, which originate from countries with a minimal, moderate or high BSE risk should not be traded between countries.

Article 2.3.13.19.

- 1) From cattle of any age originating from a country or zone with a moderate or a high BSE risk, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: tonsils and intestine, and protein products derived from them. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.
- 2) From cattle originating from a country or zone with a moderate or a high BSE risk, that were at the time of slaughter over 6 12 months of age, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, tonsils, thymus, spleen, intestines, dorsal root ganglia, trigeminal ganglia, skull and vertebral column and derived protein products derived from the preceding. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

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~~From cattle, originating from a country or zone with a moderate BSE risk, that were at the time of slaughter over 6 months of age, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, distal ileum, skull, vertebral column and derived protein products. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.~~

- 3) From cattle, originating from a country or zone with a minimal BSE risk, that were at the time of slaughter over 30 months of age, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes and spinal cord, skull, vertebral column and derived protein products. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

Article 2.3.13.20.

Veterinary Administrations of importing countries should require:

for gelatin and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that the bones came from:

- 1) a BSE free or provisionally free country or zone, or from a country or zone with a minimal BSE risk; or
- 2) a country or zone with a moderate BSE risk; and
 - a) skulls and vertebrae (excluding tail vertebrae) have been excluded;
 - b) the bones have been subjected to a process which includes all the following steps:
 - i) pressure washing (degreasing),
 - ii) acid demineralisation,
 - iii) prolonged alkaline treatment,
 - iv) filtration,
 - v) sterilisation at $\geq 138^{\circ}\text{C}$ for a minimum of 4 seconds,
 or to an equivalent process in terms of infectivity reduction.

Article 2.3.13.21.

Veterinary Administrations of importing countries should require:

for tallow ~~and dicalcium phosphate~~ other than protein-free tallow as defined in Article 2.3.13.8.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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the presentation of an *international veterinary certificate* attesting that it originates from:

- 1) a BSE free or provisionally free country or zone, or
- 2) a country or zone with a minimal BSE risk, and it originates from cattle which have been subjected to an ante-mortem inspection for BSE with favourable results and has not been prepared using the tissues listed in point 3 of Article 2.3.13.19., or
- 3) a country or zone with a moderate BSE risk, and it originates from cattle which have been subjected to an ante-mortem inspection for BSE with favourable results and has not been prepared using the tissues listed in point 2 of Article 2.3.13.19.

Article 2.3.13.22.

Veterinary Administrations of importing countries should require:

for tallow derivatives (other than those made from protein-free tallow as defined in Article 2.3.13.8.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that:

- 1) they originate from a BSE free or provisionally free country or zone, or from a country or zone with a minimal BSE risk;

OR

- 2) they have been produced by hydrolysis, saponification or transesterification using high temperature and pressure.

Article 2.3.13.23.

Careful selection of source materials is the best way to ensure maximum safety of ingredients or reagents of bovine origin used in the manufacture of medicinal products.

Countries wishing to import bovine materials for such purposes should therefore consider the following factors:

- 1) the BSE status of the country and herd(s) where the animals have been kept, as determined under the provisions of Articles 2.3.13.2. to 2.3.13.7.;
- 2) the age of the donor animals;
- 3) the tissues required and whether or not they will be pooled samples or derived from a single animal.

Additional factors may be considered in assessing the risk from BSE, including:

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- 4) precautions to avoid contamination during collection of tissues;
- 5) the process to which the material will be subjected during manufacture;
- 6) the amount of material to be administered;
- 7) the route of administration.

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APPENDIX 3.8.4.

SURVEILLANCE AND MONITORING SYSTEMS FOR
BOVINE SPONGIFORM ENCEPHALOPATHY

Article 3.8.4.1.

Introduction

Surveillance for bovine spongiform encephalopathy (BSE) has at least two goals: to determine whether BSE is present in the country, and, if present, to monitor the extent and evolution of the epizootic, thus aiding control measures and monitoring their effectiveness.

The cattle population of a country or zone not free from BSE, will comprise the following sub-populations in order of decreasing size:

- 1) cattle not exposed to the infective agent;
- 2) cattle exposed but not infected;
- 3) infected cattle, which may lie within one of three stages in the progress of BSE:
 - a) the majority will die or be killed before reaching a stage at which BSE is detectable by current methods;
 - b) some will progress to a stage at which BSE is detectable by testing before clinical signs of disease appear;
 - c) the smallest number will show clinical signs of disease.

A surveillance programme on its own cannot guarantee BSE status and should be determined by, and be commensurate with, the outcome of the risk assessment referred to in Article 2.3.13.2. and should take into account the diagnostic limitations associated with the above sub-populations and the relative distributions of infected animals among them.

Surveillance programmes developed before the advent of rapid diagnostic tests focused on the sub-population containing cattle displaying clinical signs compatible with BSE as described in Article 3.8.4.2. While surveillance should focus on the sub-population containing cattle displaying clinical signs consistent with BSE as described in Article 3.8.4.2, this sub-population where it is difficult to access all cattle displaying such clinical signs, investigation of other sub-populations using the new diagnostic techniques may provide a more accurate assessment picture of the BSE situation in the country or zone. A surveillance strategy programme may therefore need to combine several strategies. Recommended strategies for surveying the various sub-populations are described below.

Available data suggest the possibility that a gradient might be established to describe the relative value of surveillance applied to each sub-population. All countries should sample sub-populations identified in Articles 3.8.4.2. and 3.8.4.3. In countries where surveillance of cattle identified in Article 3.8.4.2. is unable to generate the numbers recommended in Table 1, surveillance should be enhanced by testing larger numbers of cattle identified in Article 3.8.4.3. Any shortfall in In addition, the first two sub-populations should be addressed by the surveillance can be complemented by sampling of normal cattle over 30 months of age at slaughter according to Article 3.8.4.4. Exclusive dependence on random sampling from normal cattle is not recommended, unless the number of samples examined annually is statistically sufficient to detect a disease prevalence of 1 in 1,000,000.

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Surveillance for BSE requires laboratory examination of samples in accordance with the methods described in the *Terrestrial Manual*.

For surveillance purposes, testing a part of the population is consistent with Chapter 1.3.6. on surveillance and monitoring of animal health.

Article 3.8.4.2.

Examination of cattle displaying clinical signs consistent with bovine spongiform encephalopathy

Cattle affected by illnesses that are refractory to treatment, and displaying progressive behavioural changes such as excitability, persistent kicking when milked, changes in herd hierarchical status, hesitation at doors, gates and barriers, as well as those displaying progressive neurological signs without signs of infectious illness are candidates for examination. Since BSE causes no pathognomonic clinical signs, all countries with cattle populations will observe individual animals displaying with compatible clinical signs consistent with BSE. It should be recognised that cases may display only some of these signs, which may also vary in severity, and such animals should still be investigated as potential BSE affected animals.

Table 1 indicates the minimum number of animals exhibiting one or more clinical signs of BSE that should be subjected to diagnostic tests according to the total cattle population over 30 months of age. The calculations assume a prevalence of one BSE clinically affected animal per one million adult cattle, a mortality rate not exceeding one percent per year in adult cattle, and a prevalence of central nervous system (CNS) signs not exceeding one percent within dying cattle.

As this sampling is not random, and as the mortality rate and prevalence of CNS signs within dying cattle may vary, the numbers indicated in this table are a subjective interpretation rather than a strict statistical deduction. This table should only be employed as a general guideline. Sampling in excess of the number indicated, ideally extending towards all cattle over 30 months of age showing clinical signs consistent with BSE, would give greater confidence in the outcome and is to be encouraged. In those cases where there is a shortfall in the number of samples required under this article, the difference may be made up by sampling in accordance with Article 3.8.4.3 and, in the event of a further shortfall, by sampling in accordance with Article 3.8.4.4.

Table 1. Minimum number of annual investigations of cattle showing clinical signs consistent with BSE required for effective surveillance according to the total cattle population over 30 months of age

Total cattle population over 30 months of age	Minimum number of samples to examine
500,000	50
700,000	69
1,000,000	99
2,500,000	195
5,000,000	300
7,000,000	336
10,000,000	367
20,000,000	409
30,000,000	425
40,000,000	433

Article 3.8.4.3.

Examination of targeted cattle displaying clinical signs not necessarily indicative of bovine spongiform encephalopathy

Cattle over 30 months of age that have died or have been killed for reasons other than routine slaughter should be examined. This population will include cattle which have died on farm or in transit, 'fallen stock', and stock sent for emergency slaughter.

Many of these cattle may have exhibited some of the clinical signs listed in Article 3.8.4.2. which were not recognised as being compatible consistent with BSE. Experience in countries where BSE has been identified indicates that this population is the second most appropriate population to target in order to detect BSE. Empirical evidence indicates that surveillance conducted on one clinical suspect from Article 3.8.4.2. is equivalent to that conducted on 100 or more animals in this category in terms of its ability to detect BSE within an infected cattle population.

This multiplication factor of 100 should be applied in calculating the minimum sample size to substitute for any shortfall in the sample numbers specified in Article 3.8.4.2.

Article 3.8.4.4.

Examination of cattle subject to normal slaughter

In countries not free from BSE, sampling at routine slaughter of cattle over 30 months of age is a means of monitoring the progress of the epizootic and the efficacy of control measures applied, because it offers continuous access to a cattle population of known class, age structure and geographical origin. Empirical evidence indicates that surveillance conducted on one clinical suspect from Article 3.8.4.2. is equivalent to that conducted on 5,000 to 10,000 animals in this category in terms of its ability to detect BSE within an infected cattle population.

This multiplication factor of 5,000 to 10,000 should be applied in calculating the minimum sample size to substitute for any shortfall in the sample numbers specified in Article 3.8.4.2 and a multiplication factor of 50 to 100 applied regarding any shortfall in the sample numbers specified in Article 3.8.4.3.

Within each of the above sub-populations, countries may wish to target cattle identifiable as imported from countries or zones not free from BSE, cattle which have consumed potentially contaminated feedstuffs from countries or zones not free from BSE, offspring of BSE affected cows and cattle which have consumed feedstuffs potentially contaminated with other TSE agents.

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APPENDIX X.X.X.

FACTORS TO CONSIDER IN CONDUCTING THE
BOVINE SPONGIFORM ENCEPHALOPATHY RISK
ASSESSMENT RECOMMENDED IN CHAPTER 2.3.13.

Article X.X.X.1.

Introduction

The first step in determining the bovine spongiform encephalopathy (BSE) risk status of the cattle population of a country or zone is to conduct a risk assessment (reviewed annually), based on Section 1.3 of this *Terrestrial Code*, identifying all potential factors for BSE occurrence and their historic perspective:

1) Release assessment

Release assessment consists of assessing the likelihood that a transmissible spongiform encephalopathy (TSE) agent has been introduced via the importation of the following commodities potentially contaminated with a TSE agent:

- a) *meat-and-bone meal* or *greaves*;
- b) live animals;
- c) animal feed and feed ingredients;
- d) products of animal origin for human consumption.

2) Exposure assessment

Exposure assessment consists of assessing the likelihood of exposure of the BSE agent to susceptible animal species, through a consideration of the following:

- a) epidemiological situation concerning all animal TSE agents in the country or zone;
- b) recycling and amplification of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;
- c) the origin and use of ruminant carcasses (including fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;
- d) implementation and enforcement of feed bans, including measures to prevent cross-contamination of animal feed.

The following guidelines are intended to assist *Veterinary Services* in conducting such a risk assessment.

Article X.X.X.2.

The potential for the release of the BSE agent through importation of meat-and-bone meal or greaves

This point is irrelevant if the exposure assessment outlined below in Article X.X.X.5. indicates that *meat-and-bone meal* or *greaves* has not been fed, either deliberately or accidentally, in the past 8 years. Nevertheless, documentation should be provided on the control systems (including relevant legislation) in place to ensure that *meat-and-bone meal* or *greaves* has not been fed to ruminants.

Appendix XII (contd)

Assumption: That *meat-and-bone meal* or *greaves* of ruminant origin plays the only significant role in BSE transmission.

Question to be answered: Has *meat-and-bone meal*, *greaves*, or feedstuffs containing either been imported within the past 8 years? If so, where from and in what quantities?

Rationale: Knowledge of the origin of *meat-and-bone meal*, *greaves* or feedstuffs containing either *meat-and-bone meal* or *greaves*, is necessary to assess the risk of release of BSE agent. *Meat-and-bone meal* and *greaves* originating in countries of high BSE risk pose a higher release risk than that from low risk countries. *Meat-and-bone meal* and *greaves* originating in countries of unknown BSE risk pose an unknown release risk.

Evidence required:

- Documentation to support claims that *meat-and-bone meal*, *greaves* or feedstuffs containing either *meat-and-bone meal* or *greaves* have not been imported, OR
- Where *meat-and-bone meal*, *greaves* or feedstuffs containing them have been imported, documentation of country of origin and, if different, the country of export.
- Documentation on annual volume, by country of origin, of *meat-and-bone meal*, *greaves* or feedstuffs containing them imported during the past 8 years.
- Documentation describing the composition (on a species and class of stock basis) of the imported *meat-and-bone meal*, *greaves* or feedstuffs containing them.
- Documentation, from the country of production, supporting why the rendering processes used to produce *meat-and-bone meal*, *greaves* or feedstuffs containing them would have inactivated, or significantly reduced the titre of TSE agent, should it be present.
- Documentation describing the fate of imported *meat-and-bone meal* and *greaves*.

Article X.X.X.3.

The potential for the release of the BSE agent through the importation of live animals potentially infected with a TSE

Assumptions:

- Countries which have imported ruminants from countries infected with animal TSEs are more likely to experience BSE.
- Cattle pose the only known risk although other species are under study.
- Animals imported for breeding may pose a greater risk than animals imported for slaughter because of the hypothetical risk of maternal transmission and because they are kept to a greater age than animals imported for slaughter.
- Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.
- Risk is proportional to volume of imports (Article 1.3.2.3).

Question to be answered: Have live animals been imported within the past 7 years?

Rationale: The release risks are dependent on:

- country of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical disease, or following active surveillance, or assessment of geographical BSE risk;

Appendix XII (contd)

- feeding and management of the animals in the country of origin;
- use to which the commodity has been put as apart from representing risk of developing clinical disease, the slaughter, rendering and recycling in *meat-and-bone meal* of imported animals represents a potential route of exposure of indigenous livestock even if *meat-and-bone meal* and *greaves*, or feedstuffs containing them, have not been imported;
- species;
- dairy versus meat breeds, where there are differences in exposure in the country of origin because feeding practices result in greater exposure of one category;
- age at slaughter.

Evidence required:

- Documentation on the country of origin of imports. This should identify the country of breeding of animals, the length of time they lived in that country and of any other country in which they have resided during their lifetime.
- Documentation describing origins, species and volume of imports.
- Documentation describing the fate of imported animals, including their age at slaughter.
- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article X.X.X.4.

The potential for the release of the BSE agent through the importation of products of animal origin potentially infected with a TSE*Assumptions:*

- Semen, embryos, hides and skins, milk or blood are not considered to play a role in the transmission of BSE.
- Countries which have imported products of animal origin from countries with animal TSEs are more likely to experience BSE.
- Risk is influenced by the date at which imports occurred, relative to the animal TSE status of the country of origin.
- Risk is proportional to volume of imports (Article 1.3.2.3).

Question to be answered: What products of animal origin have been imported within the past 7 years?

Rationale: The release risks are dependent on:

- the species of origin of the animal products and whether these products contain tissues known to contain BSE infectivity (Article 2.3.13.19);
- country of origin and its animal TSE status, which will change as more data become available; this may result from the detection of clinical disease, or following active surveillance, or assessment of geographical BSE risk;
- feeding and management of the animals in the country of origin;

Appendix XII (contd)

- use to which the commodity has been put as apart from representing risk of developing clinical disease, the slaughter, rendering and recycling in *meat-and-bone meal* of imported animals represents a potential route of exposure of indigenous livestock even if *meat-and-bone meal* and *greaves*, or feedstuffs containing them, have not been imported;
- species;
- dairy versus meat breeds, where there are differences in exposure in the country of origin because feeding practices result in greater exposure of one category:
- age at slaughter.

Evidence required:

- Documentation on the country of origin of imports. This should identify the country of breeding of animals, the length of time they lived in that country and of any other country in which they have resided during their lifetime.
- Documentation describing origins, species and volume of imports.
- Documentation describing the end use of imported animal products, and the disposal of waste.
- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article X.X.X.5.

The potential for the exposure of cattle to the BSE agent through consumption of meat-and-bone meal or greaves of ruminant origin*Assumptions:*

- That the consumption by bovines of *meat-and-bone meal* or *greaves* of ruminant origin plays the only significant role in BSE transmission.
- That commercially-available products of animal origin used in animal feeds may contain *meat-and-bone meal* or *greaves* of ruminant origin.
- Milk and blood are not considered to play a role in the transmission of BSE.

Question to be answered: Has *meat-and-bone meal* or *greaves* of ruminant origin been fed to cattle within the past 8 years (Articles 2.3.13.3. and 2.3.13.4. in the *Terrestrial Code*)?

Rationale: If cattle have not been fed products of animal origin (other than milk or blood) potentially containing *meat-and-bone meal* or *greaves* of ruminant origin within the past 8 years, *meat-and-bone meal* and *greaves* can be dismissed as a risk.

Article X.X.X.6.

Epidemiological situation concerning all animal TSE in the country or zone*Assumptions:*

- BSE may have originated from scrapie of sheep. Countries with scrapie may be at greater risk than those which have demonstrated scrapie freedom.

Appendix XII (contd)

- Theoretically, scrapie in small ruminants might mask the presence of BSE and no field methods are available to differentiate between different TSEs.
- Available evidence suggests there is no link between chronic wasting disease of cervids and BSE.
- It has been suggested that transmissible mink encephalopathy may be an indicator of a hitherto undefined and hypothetical TSE of cattle.
- If a hypothetical 'spontaneous' TSE of cattle is assumed to occur, it must also be assumed to occur in all countries at a similar rate.

Question to be answered: Have other animal TSEs been identified in the country? What surveillance is there for TSEs?

Rationale: Surveillance programmes generate a picture of the epidemiological situation of animal TSE. The greater the surveillance effort, the greater the power of the information. Adequately targeted surveillance for BSE, such as described in Appendix 3.8.4., provides more powerful information than generic animal disease surveillance.

Evidence required: Documentation on awareness and surveillance programmes targeting all TSEs of livestock, their legal basis, scale, duration, and data generated.

Article X.X.X.7.

The origin of animal waste, the parameters of the rendering processes and the methods of animal feed production

Assumptions:

- TSE of livestock have long incubation periods and insidious onset of signs, so cases may escape detection.
- Pre-clinical TSE cannot be detected by any method and may enter rendering, in particular if specified risk materials are not removed.
- Tissues most likely to contain high titres of TSE infectivity (brain, spinal cord, eyes) may not be harvested for human consumption and may be rendered.
- TSE of livestock may manifest in sudden death, chronic disease, or recumbency, and may be presented as fallen stock or materials condemned as unfit for human consumption.
- TSE agent survival in rendering is affected by the method of processing. Adequate rendering processes are described in Appendix 3.6.3.
- TSE agent is present at much higher titres in central nervous system and reticulo-endothelial tissues (so-called 'Specified Risk Materials', or SRM).

Question to be answered: How has animal waste been processed over the past 8 years?

Rationale: If potentially infected animals or contaminated materials are rendered, there is a risk that the resulting *meat-and-bone meal* could retain TSE infectivity.

Where *meat-and-bone meal* is utilized in the production of any animal feeds, the risk of cross-contamination exists.

Appendix XII (contd)*Evidence required:*

- Documentation describing the collection and disposal of fallen stock and materials condemned as unfit for human consumption.
- Documentation describing the definition and disposal of specified risk material, if any.
- Documentation describing the rendering process and parameters used to produce *meat-and-bone meal* and *greaves*.
- Documentation describing methods of animal feed production, including details of ingredients used, the extent of use of *meat-and-bone meal* in any livestock feed, and measures that prevent cross-contamination of cattle feed with ingredients used in monogastric feed.
- Documentation describing monitoring and enforcement of the above.

Article X.X.X.8.

The overall risk of BSE in the cattle population of a country or zone is proportional to the level of known or potential exposure to BSE infectivity and the potential for recycling and amplification of the infectivity through livestock feeding practices. For the risk assessment to conclude that the cattle population of a country or zone is free from BSE risk, it must have demonstrated that appropriate measures have been taken to manage any risks identified.

CHAPTER 2.1.4.

RINDERPEST

Article 2.1.4.1.

For the purposes of this *Terrestrial Code*, the *incubation period* for rinderpest shall be 21 days.

Ban on vaccination against rinderpest means a ban on administering a rinderpest vaccine to any susceptible species and a heterologous vaccine against rinderpest to any large ruminants or pigs.

- 1) Animal not vaccinated against rinderpest means:
- a) for large ruminants and pigs: an animal that has received neither a rinderpest vaccine nor a heterologous vaccine against rinderpest;
 - b) for small ruminants: an animal that has not received a rinderpest vaccine.

2) The following defines the occurrence of rinderpest virus infection:

- a) rinderpest virus has been isolated and identified as such from an animal or a product derived from that animal, or
- b) viral antigen or viral RNA specific to rinderpest has been identified in samples from one or more animals showing one or more clinical signs consistent with rinderpest, or epidemiologically linked to an outbreak of rinderpest, or giving cause for suspicion of association or contact with rinderpest, or
- c) antibodies to rinderpest virus antigens which are not the consequence of vaccination, have been identified in one or more animals with either epidemiological links to a confirmed or suspected outbreak of rinderpest in domestic or wild animals, or showing clinical signs consistent with recent infection with rinderpest.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 2.1.4.2.

Infection free country

To be considered free from infection, a country should meet the requirements contained in Appendix 3.8.2.

Should a localised rinderpest *outbreak* occur in an infection free country, the waiting period before infection free status can be regained shall be as follows:

- 1) 6 months after the last *case* where stamping-out without vaccination and serological surveillance are applied; or
- 2) 6 months after the slaughtering of the last vaccinated animal where stamping-out complemented by emergency vaccination (vaccinated animals should be clearly identified with a permanent mark) and serological surveillance are applied; or
- 3) 12 months after the last *case* or last vaccination (whichever occurs later) where emergency vaccination without slaughter (vaccinated animals should be clearly identified with a permanent mark) and serological surveillance are applied.

Appendix XIII (contd)

Article 2.1.4.3.

Disease free country or zone

To be considered free from the disease, a country or a zone should meet the requirements contained in Appendix 3.8.2.

Article 2.1.4.4.

Provisionally free country or zone

To be considered provisionally free from the disease, a country or a zone should meet the requirements contained in Appendix 3.8.2.

Article 2.1.4.5.

Infected country or zone

When the requirements for acceptance as an infection free country, a disease free country or zone, or a provisionally free country or zone are not fulfilled, a country or zone shall be considered as infected.

Article 2.1.4.6.

Veterinary Administrations of countries shall consider whether there is a risk with regard to rinderpest in accepting importation or transit through their territory, from other countries, of the following *commodities*:

- 1) ruminants and swine;
- 2) semen of ruminants and swine;
- 3) embryos/ova of ruminants and swine;
- 4) products of animal origin (from ruminants and swine);
- 5) *pathological material* and biological products (see Chapter 1.4.6. and Section 1.5.).

For the purposes of this Chapter, ruminants include animals of the family of Camelidae.

Article 2.1.4.7.

When importing from infection free countries, *Veterinary Administrations* should require:

for ruminants and swine

the presentation of an *international veterinary certificate* attesting that the animals:

- 1) showed no clinical sign of rinderpest on the day of shipment;
- 2) remained in an infection free country since birth or for at least 30 days prior to shipment.

Article 2.1.4.8.

When importing from disease free countries or zones, *Veterinary Administrations* should require:

for domestic ruminants and swine, and wild ruminants and swine reared under confined conditions

the presentation of an *international veterinary certificate* attesting that the animals:

Appendix XIII (contd)

- 1) showed no clinical sign of rinderpest on the day of shipment;
- 2) were kept in a disease free country or zone since birth or for at least the past 3 months;
- 3) have not been vaccinated against rinderpest;
- 4) were kept isolated in their *establishment* of origin for the 30 days prior to shipment and were subjected to a diagnostic test for rinderpest on two occasions with negative results, at an interval of not less than 21 days;
- 5) were not exposed to any source of infection during their transportation from the *establishment* of origin to the *place of shipment*.

Article 2.1.4.9.

When importing from disease free countries or zones, *Veterinary Administrations* should require:

for wild ruminants and swine not reared under confined conditions

the presentation of an *international veterinary certificate* attesting that the animals:

- 1) showed no clinical sign of rinderpest on the day of shipment;
- 2) come from a disease free country or zone;
- 3) have not been vaccinated against rinderpest;
- 4) were kept in a *quarantine station* for the 30 days prior to shipment and were subjected to a diagnostic test for rinderpest on two occasions with negative results, at an interval of not less than 21 days;
- 5) were not exposed to any source of infection during their transportation from the *quarantine station* to the *place of shipment*.

Article 2.1.4.10.

When importing from provisionally free countries or zones, *Veterinary Administrations* should require:

for domestic ruminants and swine, and wild ruminants and swine reared under confined conditions

the presentation of an *international veterinary certificate* attesting that the animals:

- 1) showed no clinical sign of rinderpest on the day of shipment;
- 2) were kept in the *establishment* of origin since birth or for at least 21 days before introduction into the *quarantine station* referred to in point 3) below;
- 3) have not been vaccinated against rinderpest, were isolated in a *quarantine station* for the 30 days prior to shipment, and were subjected to a diagnostic test for rinderpest on two occasions with negative results, at an interval of not less than 21 days.

Article 2.1.4.11.

When importing from infected countries or zones, *Veterinary Administrations* should require:

for domestic ruminants and swine, and wild ruminants and swine reared under confined conditions

the presentation of an *international veterinary certificate* attesting that:

Appendix XIII (contd)

- 1) in the country or zone, routine vaccination is carried out for the purpose of the prevention of rinderpest;
- 2) rinderpest has not occurred within a 10-kilometre radius of the *establishment* of origin of the animals destined for export for at least 21 days prior to their shipment to the *quarantine station* referred to in point 3)b) below;
- 3) the animals:
 - a) showed no clinical sign of rinderpest on the day of shipment;
 - b) were kept in the *establishment* of origin since birth or for at least 21 days before introduction into the *quarantine station* referred to in point c) below;
 - c) have not been vaccinated against rinderpest, were isolated in a *quarantine station* for the 30 days prior to shipment, and were subjected to a diagnostic test for rinderpest on two occasions with negative results, at an interval of not less than 21 days;
 - d) were not exposed to any source of infection during their transportation from the *quarantine station* to the *place of shipment*;
- 4) rinderpest has not occurred within a 10-kilometre radius of the *quarantine station* for 30 days prior to shipment.

Article 2.1.4.12.

When importing from disease or infection free countries, or from disease free zones, *Veterinary Administrations* should require:

for semen of domestic ruminants and swine

the presentation of an *international veterinary certificate* attesting that:

- 1) the donor animals:
 - a) showed no clinical sign of rinderpest on the day of collection of the semen;
 - b) were kept in a disease or infection free country, or disease free zone, for at least 3 months prior to collection;
- 2) the semen was collected, processed and stored in conformity with the provisions of either Appendix 3.2.1. or Appendix 3.2.2. or Appendix 3.2.3., as relevant.

Article 2.1.4.13.

When importing from provisionally free countries or zones, *Veterinary Administrations* should require:

for semen of domestic ruminants and swine

the presentation of an *international veterinary certificate* attesting that:

- 1) the donor animals:
 - a) showed no clinical sign of rinderpest on the day of collection of the semen;

Appendix XIII (contd)

- b) were vaccinated against rinderpest before the ban referred to in point 3)a) of Appendix 3.8.2.; or
 - c) have not been vaccinated against rinderpest, and were subjected to a diagnostic test for rinderpest on two occasions with negative results, at an interval of not less than 21 days within the 30 days prior to collection;
- 2) the semen was collected, processed and stored in conformity with the provisions of either Appendix 3.2.1. or Appendix 3.2.2. or Appendix 3.2.3., as relevant.

Article 2.1.4.14.

When importing from infected countries or zones, *Veterinary Administrations* should require:

for semen of domestic ruminants and swine

the presentation of an *international veterinary certificate* attesting that:

- 1) in the country or zone, routine vaccination is carried out for the purpose of the prevention of rinderpest;
- 2) the donor animals:
 - a) showed no clinical sign of rinderpest on the day of collection of the semen;
 - b) were kept in an *establishment* where no rinderpest susceptible animals had been added in the 21 days before collection, and that rinderpest has not occurred within 10 kilometres of the *establishment* for the 21 days before and after collection;
 - c) were vaccinated against rinderpest for at least 3 months prior to collection; or
 - d) have not been vaccinated against rinderpest, and were subjected to a diagnostic test for rinderpest on two occasions with negative results, at an interval of not less than 21 days within the 30 days prior to collection;
- 3) the semen was collected, processed and stored in conformity with the provisions of either Appendix 3.2.1. or Appendix 3.2.2. or Appendix 3.2.3., as relevant.

Article 2.1.4.15.

When importing from disease or infection free countries, or from disease free zones, *Veterinary Administrations* should require:

for *in vivo* derived embryos of domestic ruminants and swine

the presentation of an *international veterinary certificate* attesting that:

- 1) the donor females were kept in an *establishment* located in a disease or infection free country, or in a disease free zone, at the time of collection;
- 2) the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1. or Appendix 3.3.3., as relevant.

Article 2.1.4.16.

When importing from provisionally free countries or zones, *Veterinary Administrations* should require:

Appendix XIII (contd)for *in vivo* derived embryos of domestic ruminants and swine

the presentation of an *international veterinary certificate* attesting that:

- 1) the donor females:
 - a) showed no clinical sign of rinderpest at the time of collection and for the following 21 days;
 - b) were kept in an *establishment* where no rinderpest susceptible animals had been added in the 21 days before collection of the embryos;
 - c) were vaccinated against rinderpest before the ban referred to in point 3a) of Appendix 3.8.2.; or
 - d) have not been vaccinated against rinderpest, and were subjected to a diagnostic test for rinderpest on two occasions with negative results, at an interval of not less than 21 days within the 30 days prior to collection;
- 2) the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1. or Appendix 3.3.3., as relevant.

Article 2.1.4.17.

When importing from infected countries or zones, *Veterinary Administrations* should require:

for *in vivo* derived embryos of domestic ruminants and swine

the presentation of an *international veterinary certificate* attesting that:

- 1) in the country or zone, routine vaccination is carried out for the purpose of the prevention of rinderpest;
- 2) the donor females:
 - a) and all other animals in the *establishment* showed no clinical sign of rinderpest at the time of collection and for the following 21 days;
 - b) were kept in an *establishment* where no rinderpest susceptible animals had been added in the 21 days before collection of the embryos;
 - c) were vaccinated against rinderpest for at least 3 months prior to collection; or
 - d) have not been vaccinated against rinderpest, and were subjected to a diagnostic test for rinderpest on two occasions with negative results, at an interval of not less than 21 days within the 30 days prior to collection;
- 3) the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1. or Appendix 3.3.3., as relevant.

Article 2.1.4.18.

When importing from infection free countries, *Veterinary Administrations* should require:

for *fresh meat or meat products* of ruminants and swine

the presentation of an *international veterinary certificate* attesting that the entire consignment comes from animals which have been kept in the country since birth or for at least 3 months prior to slaughter.

Appendix XIII (contd)

Article 2.1.4.19.

When importing from disease free countries or zones, *Veterinary Administrations* should require:

for fresh meat or meat products of domestic ruminants and swine

the presentation of an *international veterinary certificate* attesting that:

- 1) the entire consignment comes from animals which have been kept in the country or zone since birth or for at least 3 months prior to slaughter;
- 2) the animals were slaughtered in an *approved abattoir* located in a disease free zone.

Article 2.1.4.20.

When importing from provisionally free countries or zones, *Veterinary Administrations* should require:

for fresh meat (excluding offal) of domestic ruminants and swine

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from:

- 1) animals which:
 - a) showed no clinical sign of rinderpest within 24 hours before slaughter;
 - b) have remained in the country or zone for at least 3 months prior to slaughter;
 - c) were kept in the *establishment* of origin since birth or for at least 30 days prior to shipment to the *approved abattoir*;
 - d) were vaccinated against rinderpest before the ban referred to in point 3a) of Appendix 3.8.2.; or
 - e) were not vaccinated against rinderpest, and were subjected to a diagnostic test for rinderpest with negative results during the 21 days prior to slaughter;
- 2) deboned carcasses from which the major lymphatic glands have been removed.

Article 2.1.4.21.

When importing from infected countries or zones, *Veterinary Administrations* should require:

for fresh meat (excluding offal) of domestic ruminants and swine

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat:

- 1) comes from a country or zone where routine vaccination is carried out for the purpose of the prevention of rinderpest;
- 2) comes from animals which:
 - a) showed no clinical sign of rinderpest within 24 hours before slaughter;
 - b) have remained in the country or zone for at least 3 months prior to slaughter;

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- c) were kept in the *establishment* of origin since birth or for at least 30 days prior to shipment to the *approved abattoir*, and that rinderpest has not occurred within a 10-kilometre radius of the *establishment* during that period;
 - d) were vaccinated against rinderpest at least 3 months prior to shipment to the *approved abattoir*;
 - e) had been transported, in a *vehicle* which was cleansed and disinfected before the animals were loaded, directly from the *establishment* of origin to the *approved abattoir* without coming into contact with other animals which do not fulfil the required conditions for export;
 - f) were slaughtered in an *approved abattoir* in which no rinderpest has been detected during the period between the last *disinfection* carried out before slaughter and the date on which the shipment has been dispatched;
- 3) comes from deboned carcasses from which the major lymphatic glands have been removed.

Article 2.1.4.22.

When importing from provisionally free countries or zones, or from infected countries or zones, *Veterinary Administrations* should require:

for *meat products* of domestic ruminants and swine

the presentation of an *international veterinary certificate* attesting that:

- 1) only *fresh meat* complying with the provisions of Article 2.1.4.20. or Article 2.1.4.21., as relevant, has been used in the preparation of the *meat products*; or
- 2) the *meat products* have been processed to ensure the destruction of the rinderpest virus in conformity with one of the procedures referred to in Article 3.6.2.1.;
- 3) the necessary precautions were taken after processing to avoid contact of the *meat products* with any possible source of rinderpest virus.

Article 2.1.4.23.

When importing from infection free countries, or from disease free countries or zones, *Veterinary Administrations* should require:

for *milk* and *milk products* intended for human consumption and for *products of animal origin* (from rinderpest susceptible animals) intended for use in animal feeding or for agricultural or industrial use

the presentation of an *international veterinary certificate* attesting that these products come from animals which have been kept in the country or zone since birth or for at least 3 months.

Article 2.1.4.24.

When importing from provisionally free countries or zones, or from infected countries or zones, *Veterinary Administrations* should require:

for *milk* and cream

the presentation of an *international veterinary certificate* attesting that:

- 1) these products:
 - a) originate from herds or flocks which were not subjected to any restrictions due to rinderpest at the time of *milk* collection;

Appendix XIII (contd)

- b) have been processed to ensure the destruction of the rinderpest virus in conformity with one of the procedures referred to in Article 3.6.2.5. and in Article 3.6.2.6.;
- 2) the necessary precautions were taken after processing to avoid contact of the products with any potential source of rinderpest virus.

Article 2.1.4.25.

When importing from provisionally free countries or zones, or from infected countries or zones, *Veterinary Administrations* should require:

for milk products

the presentation of an *international veterinary certificate* attesting that:

- 1) these products are derived from *milk* complying with the above requirements;
- 2) the necessary precautions were taken after processing to avoid contact of the *milk products* with a potential source of rinderpest virus.

Article 2.1.4.26.

When importing from provisionally free countries or zones, or from infected countries or zones, *Veterinary Administrations* should require:

for blood and meat-meals (from domestic or wild ruminants and swine)

the presentation of an *international veterinary certificate* attesting that the manufacturing method for these products included heating to a minimum internal temperature of 70°C for at least 30 minutes.

Article 2.1.4.27.

When importing from provisionally free countries or zones, or from infected countries or zones, *Veterinary Administrations* should require:

for wool, hair, bristles, raw hides and skins (from domestic or wild ruminants and swine)

the presentation of an *international veterinary certificate* attesting that:

- 1) these products have been processed to ensure the destruction of the rinderpest virus in conformity with one of the procedures referred to in Articles 3.6.2.2., 3.6.2.3. and 3.6.2.4.;
- 2) the necessary precautions were taken after processing to avoid contact of the products with any potential source of rinderpest virus.

Veterinary Administrations can authorise, without restriction, the import or transit through their territory of semi-processed hides and skins (limed hides, pickled pelts, and semi-processed leather – e.g. wet blue and crust leather), provided that these products have been submitted to the usual chemical and mechanical processes in use in the tanning industry.

Article 2.1.4.28.

When importing from provisionally free countries or zones, or from infected countries or zones, *Veterinary Administrations* should require:

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for hooves, claws, bones and horns, hunting trophies and preparations destined for museums (from domestic or wild ruminants and swine)

the presentation of an *international veterinary certificate* attesting that these products:

- 1) were completely dried and had no trace on them of skin, flesh or tendon; and/or
- 2) have been adequately disinfected.

[Note: International veterinary certificates for animal products coming from provisionally free countries or zones, or infected countries or zones, may not be required if the products are transported in an approved manner to premises controlled and approved by the Veterinary Administration of the importing country for processing to ensure the destruction of the rinderpest virus as described in Articles 3.6.2.2., 3.6.2.3. and 3.6.2.4.]

CHAPTER 2.3.3.

BOVINE TUBERCULOSIS

Article 2.3.3.1.

The recommendations in this Chapter are intended to manage the human and animal health risks associated with bovine tuberculosis, a zoonosis caused by the bacterium *Mycobacterium bovis*, which may infect some domestic and free-living animal species.

The recommendations in this Chapter apply to trade in cattle and products originating from cattle.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 2.3.3.2.

Criteria for determining animal health status

The animal health status of a country or zone/compartiment, with respect to bovine tuberculosis, can be determined on the basis of the following criteria, which may be applied within a country or zone/compartiment, either to all susceptible species, or to a single species or group of species*:

- 1) availability of adequate knowledge of all potential factors for occurrence of bovine tuberculosis, in particular:
 - a) the numbers and distribution of all susceptible domestic and free-living species including the numbers of herds or other groupings as appropriate;
 - b) the distribution of domestic and free-living species found to be infected with *M. bovis*;
 - c) evidence to establish whether the species found to be infected is a maintenance host or a spill-over host;
 - d) the epidemiological relationship between species in maintaining a reservoir of infection in the country or zone/compartiment;
 - e) the extent to which animal species can be treated as separate compartments;
 - f) the risk of introduction or re-introduction of infection through the importation of animals, semen or any other means;
- 2) the presence of a disease management, control or eradication programme based on the guidelines in Appendix 3.X.X.X. (under study);
- 3) continuing monitoring and surveillance based on the guidelines in Appendix 3.X.X.X. (under study), including compulsory notification and investigation of all suspected cases of *M. bovis* infection.

Article 2.3.3.3.

Country or zone/compartiment free from bovine tuberculosis

A country or zone/compartiment may be considered to be free from bovine tuberculosis when it is unable to detect *M. bovis* infection according to a specified surveillance and monitoring programme.

A country or zone/compartiment may be considered to be free from bovine tuberculosis when:

- 1) the criteria outlined in Article 2.3.3.2. are met; and

Appendix XIV (contd)

- 2) for a period of 6 years, no herd of a species recognised as a maintenance host has been found to be infected with *M. bovis* according to a surveillance and monitoring programme that is capable of detecting an annual period prevalence of more than one infected herd per 1,000 (0.1%) with 95% confidence (see Appendix 3.X.X.X. [under study]); and
- 3) appropriate surveys of spill-over host species and susceptible free-living species conducted over 6 years have not found infection; and
- 4) measures are in place to prevent the transfer of infection from countries or zones/compartments where *M. bovis* occurs; and
- 5) no vaccination of animal species has been undertaken for at least 6 years (this requirement excludes animals confined to a zoological park); and
- 6) any re-emergence or re-introduction of *M. bovis* is:
 - a) contained within and, within 12 months, eliminated from the herd or herds in which the infected animal(s) was found;
 - b) all in-contact animals have been traced and tested negative or eliminated, and
 - c) the source of the infection has been identified and appropriate actions are taken to prevent its recurrence;
- 7) failure to meet the conditions in point 6) above means the status shall revert to provisionally free.

Article 2.3.3.4.

Herd free from bovine tuberculosis

To qualify as free from bovine tuberculosis, a herd of cattle shall satisfy the following requirements:

- 1) the herd is in a country or zone/compartments free from bovine tuberculosis; or
- 2) all cattle in the herd:
 - a) show no clinical sign of bovine tuberculosis;
 - b) over 6 weeks of age, have shown a negative result to at least two tuberculin tests carried out at an interval of 6 months, the first test being performed at 6 months following the slaughter of the last affected animal;
 - c) showed a negative result to an annual tuberculin test to ensure the continuing absence of bovine tuberculosis;
- 3) cattle introduced into the herd:
 - a) must be accompanied by a certificate from an *Official Veterinarian* attesting that they were subjected to a tuberculin test during the 30 days prior to entry into the herd, with negative result; or
 - b) were kept in a herd free from bovine tuberculosis.

Article 2.3.3.5.

Country or zone/compartments provisionally free from bovine tuberculosis

Provisional freedom from bovine tuberculosis is a status in which it is recognised that tuberculosis is still likely to be present at a prevalence of not greater than five infected herds per 1,000 (0.5%).

A country or geographical compartment may be considered to be provisionally free from bovine tuberculosis where:

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- 1) the criteria outlined in Article 2.3.3.2. are met; and
- 2) for a period of 3 years, annual period prevalence amongst herds of maintenance host species has not exceeded five infected herds per 1,000 (0.5%), under a surveillance and monitoring programme capable of defining this with 95% confidence (see Appendix 3.X.X.X. [under study]); and
- 3) appropriate surveys of spill-over host species and susceptible free-living species conducted over 3 years have not found infection; and
- 4) measures are in place to prevent the transfer of infection from countries or zones/compartments where *M. bovis* occurs; and
- 5) no vaccination of animal species has been undertaken for at least 3 years (this requirement excludes animals confined to a zoological park); and
- 6) provisional freedom is lost if annual period herd prevalence exceeds 0.5%.

Article 2.3.3.6.

Conditions providing negligible animal health risk in international tradeFor live animals

Live animals are considered to constitute a negligible animal health risk of transmission of bovine tuberculosis when:

- 1) the criteria for country or zone/compartment freedom as specified in Article 2.3.3.3. have been met; and
- 2) the animals showed no clinical sign of bovine tuberculosis on the day of shipment; and
- 3) the animals come from a herd or herds not subject to movement restrictions or any other official control for bovine tuberculosis;

OR

- 4) the criteria for country or zone/compartment for provisional freedom as specified in Article 2.3.3.5. have been met; and
- 5) the animals are free from clinical sign of tuberculosis on the day of shipment; and
- 6) the animals come from a herd/herds free from bovine tuberculosis; and
- 7) within 30 days prior to shipment, the animals were subjected to a test for bovine tuberculosis with negative results;

OR

- 8) a disease management, control or eradication programme based on the guidelines in Appendix 3.X.X.X. (under study) has been in place in the *exporting country* for at least 3 years; and
- 9) the animals:
 - a) are free from clinical sign of tuberculosis on the day of shipment;
 - b) come from a herd/herds free from bovine tuberculosis; and
 - c) were subjected to a test for bovine tuberculosis with negative results on two occasions, with the second test conducted within 30 days prior to shipment.

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Article 2.3.3.7.

Conditions providing negligible animal health risk in international tradeFor bovine semen and embryos

Semen and embryos are considered to constitute a negligible animal health risk of transmission of bovine tuberculosis where:

- 1) each donor is resident in a country, geographical compartment or animal species compartment free from bovine tuberculosis as specified above;

OR

- 2) the donor is resident in a country, geographical compartment or animal species compartment provisionally free from bovine tuberculosis as specified above; and
- 3) the donor was subjected to a test for bovine tuberculosis with negative results during the 30 days prior to entering an *establishment* or *artificial insemination centre* where all animals are free from bovine tuberculosis;

OR

- 4) a disease management, control or eradication programme based on the guidelines in Appendix 3.X.X.X. (under study) is in place in the *exporting country*; and
- 5) each donor:
 - a) did not come from herds that have been subject to movement restrictions or any other official control within the previous 12 months; and
 - b) was subjected to a test for bovine tuberculosis with negative results on two occasions, with an interval between each test appropriate to the test used, prior to entering an *establishment* or *artificial insemination centre* where all animals are free from bovine tuberculosis.

Article 2.3.3.8.

Conditions providing negligible public health risk in international tradeFor animals intended for slaughter

Animals are considered to constitute a negligible public health risk of transmission of bovine tuberculosis when:

- 1) the *exporting country* has in place a tuberculosis control and/or surveillance programme based on the guidelines presented in Appendix 3.X.X.X. (under study); and
- 2) none of the animals is being killed as part of that programme; and
- 3) the animals are free from clinical sign of tuberculosis on the day of transport.

Article 2.3.3.9.

Conditions providing negligible public health risk in international tradeFor meat and meat products

Meat and *meat products* are considered to constitute a negligible public health risk of transmission of bovine tuberculosis when:

Appendix XIV (contd)

- 1) the *exporting country* has in place a tuberculosis control and/or surveillance programme based on the guidelines presented in Appendix 3.X.X.X. (under study); and
- 2) the animals are free from clinical sign of tuberculosis on the day of slaughter; and
- 3) the consignment of meat comes from animals which have been subjected to risk-based ante-mortem and post-mortem inspection as described in the Codex Alimentarius Code of Practice for Meat Hygiene.

Article 2.3.3.10.

Conditions providing negligible public health risk in international tradeFor milk and milk products

Milk and milk products are considered to constitute a negligible public health risk of transmission of bovine tuberculosis when the *exporting country* has in place a tuberculosis control and/or surveillance programme based on the guidelines presented in Appendix 3.X.X.X. (under study); and

EITHER

- 1) the consignment has been derived from animals in a country, zone/compartment or animal species compartment free from bovine tuberculosis as described in Article 2.3.3.3.;

OR

- 2) the consignment was subjected to pasteurisation or an equivalent process as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

Article 2.3.3.11.

Veterinary Administrations of importing countries should require for the purposes of animal health:

for animals for breeding or rearing

the presentation of an *international veterinary certificate* attesting that all the animals in the consignment meet the measures specified in Article 2.3.3.6. for live animals.

Article 2.3.3.12.

Veterinary Administrations of importing countries should require for purposes of animal health:

for animals destined for zoological gardens

the presentation of an *international veterinary certificate* attesting that the animals:

- 1) have not been in contact with any animal known to have been infected with *M. bovis*, and
- 2) during the 30 days prior to shipment, were subjected to a test for bovine tuberculosis, with negative results.

Article 2.3.3.13.

Veterinary Administrations of importing countries should require for purposes of animal health:

for semen and embryos

the presentation of an *international veterinary certificate* attesting that the consignment meets the measures specified in Article 2.3.3.7. for semen or embryos, and were collected, processed and stored in conformity with the provisions of the relevant Appendices.

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Article 2.3.3.14.

Veterinary Administrations should require for purposes of animal health:

for meat and meat products

the presentation of an *international veterinary certificate* attesting that the consignment meets the measures specified in Article 2.3.3.9. for *meat* and *meat products*.

Article 2.3.3.15.

Veterinary Administrations should require for purposes of animal health:

for milk and milk products

the presentation of an *international veterinary certificate* attesting that the consignment meets the measures specified in Article 2.3.3.10. for *milk* and *milk products*.

Article 2.3.3.16.

Veterinary Administrations or other competent authorities of *importing countries* having jurisdiction should require for purposes of public health:

for animals for slaughter

the presentation of an *international veterinary certificate* attesting that all the animals in the consignment meet the measures specified in Article 2.3.3.8. for animals intended for slaughter.

Article 2.3.3.17.

Veterinary Administrations or other competent authorities of *importing countries* having jurisdiction should require for purposes of public health:

for meat and meat products

the presentation of an *international veterinary certificate* attesting that the consignment meets the measures specified in Article 2.3.3.9. for *meat* and *meat products*.

Article 2.3.3.18.

Veterinary Administrations or other competent authorities of *importing countries* having jurisdiction should require for purposes of public health:

for milk and milk products

the presentation of an *international veterinary certificate* attesting that the consignment meets the measures specified in Article 2.3.3.10. for *milk* and *milk products*.

* Domestic and free-living animal species are classified according to the role that they play in the epidemiology of bovine tuberculosis. Maintenance host species are species that can sustain endemic infection of *M. bovis* in the long term through transmission of infection among members of the species without reinforcement through transmission of infection from another species. 'Spill-over' host species are species that acquire infection by exposure to infected animals but do not sustain the infection in the long term by transmission among members of the same species except that transmission among members of a spill-over species may occur at high population densities.

CHAPTER 2.1.13. CLASSICAL SWINE FEVER

Article 2.1.13.1.

The pig is the only natural host for classical swine fever (CSF) virus. The definition of pigs includes all varieties of *Sus scrofa*, both domestic breeds and wild boar. A distinction is made between farmed and permanently captive pigs, and free-living pigs. Farmed and permanently captive pigs of any breed will hereafter be referred to as domestic pigs. Free-living pigs of any breed will hereafter be referred to as wild pigs. Extensively kept pigs may fall into either of these categories or may alternate between the two.

Pigs exposed to CSF virus prenatally may be persistently infected throughout life and may have an *incubation period* of several months before showing signs of disease. Pigs exposed postnatally have an *incubation period* of 7-10 days, and are usually infective between post-infection days 5 and 14, but up to 3 months in cases of chronic infections.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 2.1.13.2.

The CSF status of a country or zone can only be determined after considering the following criteria both in domestic and wild pigs:

- 1) a risk assessment has been conducted, identifying all potential factors for CSF occurrence and their historic perspective;
- 2) CSF should be notifiable in the whole country and all clinical signs suggestive of CSF should be subjected to field and/or laboratory investigations;
- 3) an on-going awareness programme should be in place to encourage reporting of all *cases* suggestive of CSF;
- 4) the *Veterinary Administration* should have current knowledge of, and authority over, all *establishments* containing pigs in the whole country;
- 5) the *Veterinary Administration* should have current knowledge about the population and habitat of wild pigs in the whole country.

Article 2.1.13.3.

For the purposes of this *Terrestrial Code*:

'CSF infected establishment' means a domestic pig holding in which the presence of the infection has been confirmed by field and/or laboratory investigations.

'Country or zone with CSF infection in domestic pigs' means a country or zone containing a CSF infected *establishment*.

The size and limits of a CSF domestic pig control area must be based on the control measures used and the presence of natural and administrative boundaries, as well as an assessment of the risks for disease spread.

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Article 2.1.13.4.

Country or zone free of CSF in domestic and wild pigs1) Historically free status

A country or zone may be considered free from the disease in domestic and wild pigs after conducting a risk assessment as referred to in Article 2.1.13.2. but without formally applying a specific surveillance programme (historical freedom) if the country or zone complies with the provisions of Article 3.8.1.2.

2) Free status as a result of an eradication programme

A country or zone which does not meet the conditions of point 1) above may be considered free from CSF in domestic and wild pigs after conducting a risk assessment as referred to in Article 2.1.13.2. and when:

- a) it is a notifiable disease;
- b) ~~domestic pigs are properly identified when leaving their *establishment* of origin with an indelible mark giving the identification number of their herd of origin; a reliable tracing back procedure is in place for all pigs leaving their *establishment* of origin;~~
- e) ~~the feeding of swill is forbidden, unless the swill has been treated to destroy any CSF virus that may be present, in conformity with one of the procedures referred to in Article 3.6.4.1.;~~
- d) animal health regulations to control the movement of *commodities* covered in this Chapter in order to minimise the risk of introduction of the infection into the *establishments* of the country or zone have been in place for at least 2 years;

AND EITHER

- e) where a *stamping-out policy* without vaccination has been practised for CSF control, no *outbreak* has been observed in domestic pigs for at least 6 months; or
- f) ~~where a *stamping-out policy* combined with vaccination has been practised, vaccination against CSF should have been banned for all domestic pigs in the country or zone for at least one year, unless there are validated means of distinguishing between vaccinated and infected pigs; if vaccination has occurred in the past 5 years, a serological monitoring system should have been in place for at least 6 months to demonstrate absence of infection within the population of domestic pigs 6 months to one year old, and no *outbreak* has been observed in domestic pigs for at least 12 months; or~~
- g) where a vaccination strategy has been adopted, with or without a *stamping-out policy*, vaccination against CSF should have been banned for all domestic pigs in the country or zone for at least one year, unless there are validated means of distinguishing between vaccinated and infected pigs; if vaccination has occurred in the past 5 years, a serological monitoring system should have been in place for at least 6 months to demonstrate absence of infection within the population of domestic pigs 6 months to one year old, and no *outbreak* has been observed in domestic pigs for at least 12 months;

AND

- h) CSF infection is not known to occur in the wild pig population and monitoring of wild pigs indicates that there is no residual infection.

Article 2.1.13.5.

Country or zone free of CSF in domestic pigs but with infection in the wild pig population

Requirements in point 2) of Article 2.1.13.4., as relevant, are complied with, but CSF infection is known to occur in wild pigs. Additional conditions for the free status are that in the country or zone:

- 1) a programme for the management of CSF in wild pigs is in place, and CSF wild pig control areas are delineated around every CSF *case* reported in wild pigs, taking into account the measures in place to manage the disease in the wild pig population, the presence of natural boundaries, the ecology of the wild pig population, and an assessment of the risk of disease spread;
- 2) biosecurity measures are applied to prevent transmission from wild pigs to domestic pigs;
- 3) clinical and laboratory monitoring (under study) is carried out in the domestic pig population, with negative results.

Article 2.1.13.6.

Recovery of free status

Should a CSF *outbreak* occur in an *establishment* of a free country or zone (free in domestic and wild pigs, or free in domestic pigs only), the status of the country or zone may be restored at least 30 days after completion of a *stamping-out policy* which should include the following measures:

- 1) a CSF domestic pig control area (including an inner protection area of at least 3 kilometres radius and an outer surveillance area of at least 10 kilometres radius) should be delineated around the *outbreak*, taking into account the control measures applied, the presence of natural and administrative boundaries, and an assessment of the risk of disease spread;
- 2) all the pigs have been killed and their carcasses destroyed, and disinfection has been applied within the establishment;
- 3) in the protection area around a CSF *outbreak*:
 - a) a risk assessment should be carried out to determine the likelihood of CSF infection in neighbouring *establishments*; when a significant risk is indicated, a *stamping-out policy* of all domestic pigs within a radius of at least 0.5 kilometre may be applied;
 - b) an immediate clinical examination of all pigs in all pig *establishments* situated within the protection area has been carried out;
- 4) in the surveillance area around a CSF *outbreak*, all sick pigs should be subjected to laboratory tests for CSF;
- 5) an epidemiological examination including clinical examination, and/or serological and/or virological testing has been carried out in all pig *establishments* that have been directly or indirectly in contact with the infected *establishment* and in all pig *establishments* located within the CSF domestic pig control area, demonstrating that these *establishments* are not infected;
- 6) measures aimed at preventing any virus spread by live pigs, pig semen and pig embryos, contaminated material, *vehicles*, etc. have been implemented.

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If emergency vaccination has been practised within the CSF domestic pig control area, recovery of the free status can not occur before all the vaccinated pigs have been slaughtered, unless there are validated means of distinguishing between vaccinated and infected pigs.

Article 2.1.13.7.

Country or zone free of CSF in wild pigs

A country or zone may be considered free from CSF in wild pigs when:

- 1) the domestic pig population in the country or zone is free from CSF infection;
- 2) a monitoring system (under study) has been in place to determine the CSF status of the wild pig population in the country, and in the country or zone:
 - a) there has been no clinical or virological evidence of CSF in wild pigs during the past 12 months;
 - b) no seropositive wild pigs have been detected in the age class 6-12 months during the past 12 months;
- 3) there has been no vaccination in wild pigs for at least 12 months;
- 4) the feeding of swill to wild pigs is forbidden, unless the swill has been treated to destroy any CSF virus that may be present in conformity with one of the procedures referred to in Article 3.6.4.1.;
- 5) imported wild pigs comply with the relevant requirements set forth in the present Chapter.

A zoning approach can only be adopted if there is a wild pig population that is isolated from other wild pigs.

Article 2.1.13.8.

When importing from countries or zones free of CSF in domestic and wild pigs, *Veterinary Administrations* should require:

for domestic pigs

the presentation of an *international veterinary certificate* attesting that the animals:

- 1) showed no clinical sign of CSF on the day of shipment;
- 2) were kept in a country or zone free of CSF in domestic and wild pigs since birth or for at least the past 3 months;
- 3) have not been vaccinated against CSF, nor are they the progeny of vaccinated sows, unless there are validated means of distinguishing between vaccinated and infected pigs.

Article 2.1.13.9.

When importing from countries or zones free of CSF in domestic pigs but with infection in wild pigs, *Veterinary Administrations* should require:

Appendix XV (contd)for domestic pigs

the presentation of an *international veterinary certificate* attesting that the animals:

- 1) were kept in a country or zone free of CSF in domestic pigs since birth or for at least the past 3 months;
- 2) have not been vaccinated against CSF, nor are they the progeny of vaccinated sows, unless there are validated means of distinguishing between vaccinated and infected pigs;
- 3) come from an *establishment* which is not located in a CSF wild pig control area as defined in Article 2.1.13.5., and has been regularly monitored to verify absence of CSF;
- 4) have had no contact with pigs introduced into the *establishment* during the past 40 days;
- 5) showed no clinical sign of CSF on the day of shipment.

Article 2.1.13.10.

When importing from countries or zones with CSF infection in domestic pigs, *Veterinary Administrations* should require:

for domestic pigs

the presentation of an *international veterinary certificate* attesting that the animals:

- 1) have not been vaccinated against CSF nor are they the progeny of vaccinated sows, unless there are validated means of distinguishing between vaccinated and infected pigs;
- 2) were kept since birth, or for the past 3 months, in an *establishment* not situated in a CSF domestic or wild pig control area as defined in Articles 2.1.13.5. and 2.1.13.6.;
- 3) were isolated in a *quarantine station* for at least 40 days;
- 4) were subjected during that period of quarantine to a virological test, and a serological test performed at least 21 days after entry into the *quarantine station*, with negative results;
- 5) showed no clinical sign of CSF on the day of shipment.

Article 2.1.13.11.

When importing from countries or zones free of CSF in domestic and wild pigs, *Veterinary Administrations* should require:

for wild pigs

the presentation of an *international veterinary certificate* attesting that the animals:

- 1) showed no clinical sign of CSF on the day of shipment;
- 2) have been captured in a country or zone free from CSF in domestic and wild pigs;
- 3) have not been vaccinated against CSF, unless there are validated means of distinguishing between vaccinated and infected pigs;

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and, if the zone where the animal has been captured is adjacent to a zone with infection in wild pigs:

- 4) were kept in a *quarantine station* for 40 days prior to shipment, and were subjected to a virological test, and a serological test performed at least 21 days after entry into the *quarantine station*, with negative results.

Article 2.1.13.12.

When importing from countries or zones free of CSF in domestic and wild pigs, *Veterinary Administrations* should require:

for semen of domestic pigs

the presentation of an *international veterinary certificate* attesting that:

- 1) the donor animals:
 - a) were kept in a country or zone free of CSF in domestic and wild pigs since birth or for at least the past 3 months;
 - b) showed no clinical sign of CSF on the day of collection of the semen;
- 2) the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.3.

Article 2.1.13.13.

When importing from countries or zones free of CSF in domestic pigs but with infection in wild pigs, *Veterinary Administrations* should require:

for semen of domestic pigs

the presentation of an *international veterinary certificate* attesting that:

- 1) the donor animals:
 - a) have been kept in an *artificial insemination centre* which is not located in a CSF wild pig control area and is regularly monitored to verify absence of CSF;
 - b) were isolated in the *artificial insemination centre* for at least 40 days prior to collection;
 - c) showed no clinical sign of CSF on the day of collection of the semen and for the following 40 days;
- 2) the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.3.

Article 2.1.13.14.

When importing from countries or zones considered infected with CSF in domestic pigs, *Veterinary Administrations* should require:

for semen of domestic pigs

the presentation of an *international veterinary certificate* attesting that:

- 1) the donor animals:
 - a) showed no clinical sign of CSF on the day of collection of the semen and for the following 3 months;

Appendix XV (contd)

- b) have not been vaccinated against CSF, and were subjected to a serological test performed at least 21 days after collection, with negative results;
- 2) the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.3.

Article 2.1.13.15.

When importing from countries or zones free of CSF in domestic and wild pigs, *Veterinary Administrations* should require:

for *in vivo* derived embryos of pigs

the presentation of an *international veterinary certificate* attesting that:

- 1) the donor females showed no clinical sign of CSF on the day of collection of the embryos;
- 2) the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.1.13.16.

When importing from countries or zones free of CSF in domestic pigs but with infection in wild pigs, *Veterinary Administrations* should require:

for *in vivo* derived embryos of pigs

the presentation of an *international veterinary certificate* attesting that:

- 1) the donor females:
 - a) were kept for at least 40 days prior to collection in an *establishment* which is not located in a CSF domestic or wild pig control area and is regularly monitored to verify absence of CSF;
 - b) showed no clinical sign of CSF on the day of collection of the embryos;
- 2) the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.1.13.17.

When importing from countries considered infected with CSF in domestic pigs, *Veterinary Administrations* should require:

for *in vivo* derived embryos of pigs

the presentation of an *international veterinary certificate* attesting that:

- 1) the donor females:
 - a) were kept for at least 40 days prior to collection in an *establishment* which is not located in a CSF domestic or wild pig control area and is regularly monitored to verify absence of CSF;
 - b) showed no clinical sign of CSF on the day of collection of the embryos and for the following 21 days;
 - c) have not been vaccinated against CSF and were subjected, with negative results, to a serological test performed at least 21 days after collection;

Appendix XV (contd)

- 2) the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.1.13.18.

When importing from countries or zones free of CSF in domestic and wild pigs, *Veterinary Administrations* should require:

for fresh meat of domestic pigs

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from animals which:

- 1) have been kept in a country or zone free of CSF in domestic and wild pigs since birth or for at least the past 3 months;
- 2) have been slaughtered in an *approved abattoir*, have been subjected to ante-mortem and post-mortem inspections and have been found free of any sign suggestive of CSF.

Article 2.1.13.19.

When importing from countries or zones free of CSF in domestic pigs but with infection in wild pigs, *Veterinary Administrations* should require:

for fresh meat of domestic pigs

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from animals which:

- 1) were kept in a country or zone free of CSF in domestic pigs since birth or for at least the past 3 months;
- 2) were kept in an *establishment* which was not located in a CSF wild pig control area and had been regularly monitored to verify absence of CSF;
- 3) have been slaughtered in an *approved abattoir* not located in a CSF control area, have been subjected to ante-mortem and post-mortem inspections and have been found free of any sign suggestive of CSF.

Article 2.1.13.20.

When importing from countries or zones free of CSF in domestic and wild pigs, *Veterinary Administrations* should require:

for fresh meat of wild pigs

the presentation of an *international veterinary certificate* attesting that:

- 1) the entire consignment of meat comes from animals which:
 - a) have been killed in a country or zone free of CSF in domestic and wild pigs;
 - b) have been subjected to post-mortem inspection in an approved examination centre, and have been found free of any sign suggestive of CSF;

and, if the zone where the animal has been killed is adjacent to a zone with infection in wild pigs:

Appendix XV (contd)

- 2) a sample has been collected from every animal shot, and has been subjected to a virological test and a serological test for CSF, with negative results.

Article 2.1.13.21.

Veterinary Administrations of importing countries should require:

for meat products of pigs (either domestic or wild), or for products of animal origin (from fresh meat of pigs) intended for use in animal feeding, for agricultural or industrial use, or for pharmaceutical or surgical use, or for trophies derived from wild pigs

the presentation of an *international veterinary certificate* attesting that the products:

- 1) have been prepared:
 - a) exclusively from *fresh meat* meeting the conditions laid down in Articles 2.1.13.18., 2.1.13.19. or 2.1.13.20., as relevant;
 - b) in a processing establishment:
 - i) approved by the *Veterinary Administration* for export purposes;
 - ii) regularly inspected by the *Veterinary Authority*;
 - iii) not situated in a CSF control area;
 - iv) processing only meat meeting the conditions laid down in Articles 2.1.13.18., 2.1.13.19. or 2.1.13.20., as relevant;

OR

- 2) have been processed in an establishment approved by the *Veterinary Administration* for export purposes and regularly inspected by the *Veterinary Authority* so as to ensure the destruction of the CSF virus in conformity with one of the procedures referred to in Article 3.6.4.2.

Article 2.1.13.22.

Veterinary Administrations of importing countries should require:

for products of animal origin (from pigs, but not derived from fresh meat) intended for use in animal feeding and for agricultural or industrial use

the presentation of an *international veterinary certificate* attesting that the products:

- 1) have been prepared:
 - a) exclusively from products meeting the conditions laid down for *fresh meat* in Articles 2.1.13.18., 2.1.13.19. or 2.1.13.20., as relevant;
 - b) in a processing establishment:
 - i) approved by the *Veterinary Administration* for export purposes;
 - ii) regularly inspected by the *Veterinary Authority*;
 - iii) not situated in a CSF control area;
 - iv) processing only products meeting the conditions laid down in point a) above;

Appendix XV (contd)

OR

- 2) have been processed in an establishment approved by the *Veterinary Administration* for export purposes and regularly inspected by the *Veterinary Authority* so as to ensure the destruction of the CSF virus in conformity with one of the procedures referred to in Article 3.6.4.2.

Article 2.1.13.23.

Veterinary Administrations of importing countries should require:

for bristles (from pigs)

the presentation of an *international veterinary certificate* attesting that the products:

- 1) come from a country or zone free of CSF in domestic and wild pigs; or
- 2) have been processed in an establishment approved by the *Veterinary Administration* for export purposes and regularly inspected by the *Veterinary Authority* so as to ensure the destruction of the CSF virus.

Article 2.1.13.24.

Veterinary Administrations of importing countries should require:

for litter and manure (from pigs)

the presentation of an *international veterinary certificate* attesting that the products:

- 1) come from a country or zone free of CSF in domestic and wild pigs; or
- 2) come from *establishments* situated in a country or zone free of CSF in domestic pigs but with infection in wild pigs, but not located in a CSF control area; or
- 3) have been processed in an establishment approved by the *Veterinary Administration* for export purposes and regularly inspected by the *Veterinary Authority* so as to ensure the destruction of the CSF virus.

— text deleted

CHAPTER 2.1.6.

CONTAGIOUS BOVINE PLEUROPNEUMONIA

Article 2.1.6.1.

For the purposes of this *Terrestrial Code*, the *incubation period* for contagious bovine pleuropneumonia (CBPP) shall be 6 months.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 2.1.6.2.

CBPP free country

To be declared free from either disease or infection by the OIE, a country should meet the requirements contained in Appendix 3.8.3.

Article 2.1.6.3.

CBPP free zone

To be declared free from either disease or infection by the OIE, a zone defined according to the provisions of Chapter 1.3.5. should meet the requirements contained in Appendix 3.8.3.

Article 2.1.6.4.

CBPP infected country or zone

When the requirements for acceptance as a CBPP free country or zone are not fulfilled, a country or zone shall be considered as infected.

Article 2.1.6.5.

Veterinary Administrations of CBPP free countries may prohibit importation or transit through their territory, from countries considered infected with CBPP, of domestic and wild bovidae.

Article 2.1.6.6.

When importing from CBPP free countries, *Veterinary Administrations* should require:

for domestic bovidae

the presentation of an *international veterinary certificate* attesting that the animals:

- 1) showed no clinical sign of CBPP on the day of shipment;
- 2) were kept in a CBPP free country since birth or for at least the past 6 months.

Article 2.1.6.7.

When importing from CBPP free countries, *Veterinary Administrations* should require:

for wild bovidae

the presentation of an *international veterinary certificate* attesting that the animals:

Appendix XVI (contd)

- 1) showed no clinical sign of CBPP on the day of shipment;
- 2) come from a CBPP free country;

if the country of origin has a common border with a country considered infected with CBPP:

- 3) were kept in a *quarantine station* for the 6 months prior to shipment.

Article 2.1.6.8.

When importing from CBPP infected countries, *Veterinary Administrations* should require:

for bovidae for breeding

the presentation of an *international veterinary certificate* attesting that the animals:

- 1) showed no clinical sign of CBPP on the day of shipment;
- 2) were subjected to ~~a serological the complement fixation~~ test for CBPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between each test, the second test being performed within 14 days prior to shipment;
- 3) were isolated from other domestic bovidae from the day of the first ~~serological the complement fixation~~ test until shipment;
- 4) were kept since birth, or for the past 6 months, in an *establishment* ~~with no serologically positive bovidae, where no case of CBPP was officially reported during that period,~~ and that the *establishment* was not situated in a CBPP infected zone;
- 5) have not been vaccinated against CBPP; or
- 6) were vaccinated using a vaccine complying with the standards described in the *Terrestrial Manual* not more than 4 months prior to shipment. In this case, the condition laid down in point 2) above is not required.

Article 2.1.6.9.

When importing from CBPP infected countries, *Veterinary Administrations* should require:

for bovidae for slaughter

the presentation of an *international veterinary certificate* attesting that the animals:

- 1) showed no clinical sign of CBPP on the day of shipment;
- 2) were kept since birth, or for the past 6 months, in an *establishment* where no *case* of CBPP was officially reported during that period, and that the *establishment* was not situated in a CBPP infected zone.

Article 2.1.6.10.

When importing from CBPP infected countries, *Veterinary Administrations* should require:

for wild bovidae

the presentation of an *international veterinary certificate* attesting that the animals:

Appendix XVI (contd)

- 1) showed no clinical sign of CBPP on the day of shipment;
- 2) were kept, for the 180 days prior to shipment, in a *quarantine station* where no *case* of CBPP was officially reported during that period, and that the *quarantine station* was not situated in a CBPP infected zone;
- 3) have not been vaccinated against CBPP; or
- 4) were vaccinated using a vaccine complying with the standards described in the *Terrestrial Manual* not more than 4 months prior to shipment. In this case, the condition laid down in point 2) above is not required.

Article 2.1.6.11.

When importing from CBPP infected countries, *Veterinary Administrations* should require:

for fresh meat of bovidae

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from animals:

- 1) which showed no lesion of CBPP;
- 2) which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for CBPP with favourable results.

Article 2.1.6.12.

When importing from CBPP free countries, *Veterinary Administrations* should require:

for in vivo derived or in vitro produced embryos/oocytes of bovidae

the presentation of an *international veterinary certificate* attesting that:

- 1) the donor animals:
 - a) showed no clinical sign of CBPP on the day of collection of the embryos/oocytes;
 - b) were kept in a CBPP free country since birth or for at least the past 6 months;
- 2) the oocytes were fertilised with semen meeting the conditions referred to in points a) and b) above and in Appendix 3.2.1.;
- 3) the embryos/oocytes were collected, processed and stored in conformity with the provisions of Appendices 3.3.1., 3.3.2. or 3.3.3., as relevant.

Article 2.1.6.13.

When importing from CBPP infected countries, *Veterinary Administrations* should require:

for in vivo derived or in vitro produced embryos/oocytes of bovidae

the presentation of an *international veterinary certificate* attesting that:

- 1) the donor animals:
 - a) showed no clinical sign of CBPP on the day of collection of the embryos/oocytes;

Appendix XVI (contd)

- b) were subjected to ~~a serological the complement fixation~~ test for CBPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between each test, the second test being performed within 14 days prior to collection;
 - c) were isolated from other domestic bovidae from the day of the first ~~serological the complement fixation~~ test until collection;
 - d) were kept since birth, or for the past 6 months, in an *establishment* where no *case* of CBPP was reported during that period, and that the *establishment* was not situated in a CBPP infected zone;
 - e) have not been vaccinated against CBPP; or
 - f) were vaccinated using a vaccine complying with the standards described in the *Terrestrial Manual* not more than 4 months prior to collection; in this case, the condition laid down in point b) above is not required;
- 2) the oocytes were fertilised with semen meeting the conditions referred to in points a) to f) above and in Appendix 3.2.1.;
- 3) the embryos/oocytes were collected, processed and stored in conformity with the provisions of Appendices 3.3.1., 3.3.2. or 3.3.3., as relevant.

— text deleted

CHAPTER 2.5.5.

EQUINE INFLUENZA

Article 2.5.5.1.

For the purposes of this *Terrestrial Code*, the *infective period* for equine influenza shall be 14 days and the *incubation period* 5 days.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 2.5.5.2.

Equine influenza free country

1) Qualification

To qualify as free from equine influenza, a country must satisfy the following requirements:

- a) the disease is notifiable;
- b) vaccination against equine influenza is not authorised, except for equines intended for export;
- c) no clinical *case* of the disease has been reported for at least one year;
- d) a serological survey has been carried out on a representative sample of the equine population of the country (excluding imported vaccinated equines) sufficient to provide at least a 99% level of confidence of detecting the disease if it is present at a prevalence rate exceeding 5%.

2) Maintenance of free status

For a country to maintain its status as free from equine influenza:

- a) no clinical *case* of the disease has been reported since the achievement of the serological survey referred to in point 1)d) above;
- b) all imported equines comply with the provisions of Article 2.5.5.3.

Article 2.5.5.3.

Veterinary Administrations of equine influenza free *importing countries* should require:

for equines

the presentation of an *international veterinary certificate* attesting that the animals:

- 1) come from an equine influenza free country; or
- 2) meet the following conditions:
 - a) the animals were kept in isolation for 4 weeks prior to shipment and showed no clinical sign of equine influenza during this period;

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- b) no new animal has been introduced into the isolation facilities during this period;
- c) no animal in the isolation facilities showed clinical signs of equine influenza during the isolation period;
- d) the animals have been vaccinated in accordance with the recommendations in the *Terrestrial Manual*, against both subtypes of equine influenza virus and have received a booster dose of vaccine not less than 2 weeks and not more than 8 weeks prior to shipment.

— text deleted

CHAPTER 2.2.5.

RABIES

Article 2.2.5.1.

For the purposes of this *Terrestrial Code*, the *incubation period* for rabies shall be 6 months, and the *infective period* in domestic carnivores starts 15 days before the onset of the first clinical signs and ends when the animal dies.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 2.2.5.2.

Rabies free country

A country may be considered free from rabies when:

- 1) the disease is notifiable;
- 2) an effective system of disease surveillance is in operation;
- 3) all regulatory measures for the prevention and control of rabies have been implemented including effective importation procedures;
- 4) no case of indigenously acquired rabies infection has been confirmed in man or any animal species during the past 2 years; however, this status would not be affected by the isolation of a European Bat Lyssavirus (EBL1 or EBL2);
- 5) no imported case in carnivores has been confirmed outside a *quarantine station* for the past 6 months.

Article 2.2.5.3.

When importing from rabies free countries, *Veterinary Administrations* should require:

for domestic mammals, and wild mammals reared under confined conditions

the presentation of an *international veterinary certificate* attesting that the animals:

- 1) showed no clinical sign of rabies on the day of shipment;
- 2) were kept since birth or for the 6 months prior to shipment in a rabies free country or were imported in conformity with the regulations stipulated in Articles 2.2.5.5., 2.2.5.6. or 2.2.5.7.

Article 2.2.5.4.

When importing from rabies free countries, *Veterinary Administrations* should require:

for wild mammals not reared under confined conditions

the presentation of an *international veterinary certificate* attesting that the animals:

- 1) showed no clinical sign of rabies on the day of shipment;
- 2) have been captured in a rabies free country, at a sufficient distance from any infected country. The distance should be defined according to the species exported and the reservoir species in the infected country.

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Article 2.2.5.5.

When importing from countries considered infected with rabies, *Veterinary Administrations* should require:
for dogs and cats

the presentation of an *international veterinary certificate* attesting that the animals:

1) showed no clinical sign of rabies within 48 hours of shipment;

AND EITHER

2) were vaccinated against rabies:

- a) not less than 6 months and not more than one year prior to shipment in the case of a primary vaccination, which should have been carried out when the animals were at least 3 months old;
- b) not more than one year prior to shipment in the case of a booster vaccination;
- c) with an inactivated virus vaccine;

3) were identified by a permanent mark (including a microchip) before the vaccination (their identification number shall be stated in the certificate);

4) were subjected not less than 3 months and not more than 24 months prior to shipment to an antibody test as described in the *Terrestrial Manual* with a positive result equivalent to a neutralising antibody titration test, and that their serum contained at least 0,5 IU/ml;

OR

5) have not been vaccinated against rabies or do not meet all the conditions set out in points 1), 2), 3) and 4) above; in such cases, the *importing country* may require the placing of the animals in a *quarantine station* located on its territory, in conformity with the conditions stipulated in its animal health legislation.

Article 2.2.5.6.

When importing from countries considered infected with rabies, *Veterinary Administrations* should require:
for domestic ruminants, equines and pigs

the presentation of an *international veterinary certificate* attesting that the animals:

1) showed no clinical sign of rabies on the day of shipment;

2) were kept for the 6 months prior to shipment in an *establishment* where separation from wild and feral animals was maintained and where no *case* of rabies was reported for at least 12 months prior to shipment.

Article 2.2.5.7.

When importing from countries considered infected with rabies, *Veterinary Administrations* should require:
for laboratory reared rodents and lagomorphs, and lagomorphs or wild mammals (other than non-human primates) reared under confined conditions

Appendix XVIII (contd)

the presentation of an *international veterinary certificate* attesting that the animals:

- 1) showed no clinical sign of rabies on the day of shipment;
- 2) were kept since birth, or for the 12 months prior to shipment, in an *establishment* where no *case* of rabies was reported for at least 12 months prior to shipment.

Article 2.2.5.8.

When importing from countries considered infected with rabies, *Veterinary Administrations* should require:
for wild mammals not belonging to the orders of primates or carnivores and not reared under confined conditions

the presentation of an *international veterinary certificate* attesting that the animals:

- 1) showed no clinical sign of rabies on the day of shipment;
- 2) were kept in a *quarantine station* for the 6 months prior to shipment.

Article 2.2.5.9.

When importing from countries considered infected with rabies, *Veterinary Administrations* should require:
for frozen semen of dogs

the presentation of an *international veterinary certificate* attesting that the donor animals showed no clinical sign of rabies during the 15 days following collection of the semen.

[Note: For non-human primates, reference should be made to Chapter 2.10.1.]

— text deleted

CHAPTER 2.2.6.
PARATUBERCULOSIS

Article 2.2.6.1.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 2.2.6.2.

Veterinary Administrations of importing countries should require:

for domestic ruminants for breeding or rearing

the presentation of an *international veterinary certificate* attesting that the animals:

- 1) showed no clinical sign of paratuberculosis on the day of shipment;
- 2) were kept in a herd in which no clinical sign of paratuberculosis was officially reported during the 5 years prior to shipment;
- 3) were subjected to diagnostic tests for paratuberculosis with negative results during the 30 days prior to shipment.

— text deleted

CHAPTER 2.9.1.

ACARAPISOSIS OF HONEY BEES

Article 2.9.1.1.

For the purposes of this chapter, acarapisosis, acarine disease or tracheal mite infestation is a disease of the adult honey bee *Apis mellifera* L., and possibly of other *Apis* species (such as *Apis cerana*). It is caused by the Tarsonemid mite *Acarapis woodi* (Rennie). The mite is an internal obligate parasite of the respiratory system, living and reproducing mainly in the large prothoracic trachea of the bee. Early signs of infection normally go unnoticed, and only when infection is heavy does it become apparent; this is generally in the early spring. The infection spreads by direct contact from adult bee to adult bee, with newly emerged bees under 10 days old being the most susceptible. The mortality rate may range from moderate to high.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 2.9.1.2.

The acarapisosis status of a country or zone/compartiment can only be determined after considering the following criteria:

- 1) a risk assessment has been conducted, identifying all potential factors for acarapisosis occurrence and their historic perspective;
- 2) acarapisosis should be notifiable in the whole country or zone/compartiment and all clinical signs suggestive of acarapisosis should be subjected to field and laboratory investigations;
- 3) an on-going awareness programme should be in place to encourage reporting of all *cases* suggestive of acarapisosis;
- 4) the *Veterinary Administration* or other competent authority with responsibility for the health of honey bees should have current knowledge of, and authority over, all domesticated apiaries in the whole country.

Article 2.9.1.3.

Country or zone/compartiment free from acarapisosis

- 1) Historically free status

A country or zone/compartiment may be considered free from acarapisosis after conducting a risk assessment as referred to in Article 2.9.1.2. but without formally applying a specific surveillance programme if the country or zone/compartiment complies with the provisions of Article 3.8.1.2.

- 2) Free status as a result of an eradication programme

A country or zone/compartiment which does not meet the conditions of point 1) above may be considered free from acarapisosis after conducting a risk assessment as referred to in Article 2.9.1.2. and when:

- a) the *Veterinary Administration* or other competent authority with responsibility for the health of honey bees has current knowledge of, and authority over, all domesticated apiaries existing in the country or zone/compartiment;
- b) acarapisosis is notifiable in the whole country or zone/compartiment, and any clinical cases suggestive of acarapisosis are subjected to field and laboratory investigations;

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- c) for the 3 years following the last reported *case* of acarapisosis, annual surveys supervised by the *Veterinary Administration*, with negative results, have been carried out on a representative sample of apiaries in the country or zone/compartiment to provide a confidence level of at least 95% of detecting acarapisosis if at least 1% of the apiaries were infected at a within-apiary prevalence rate of at least 5% of the hives; such surveys may be targeted towards apiaries, areas and seasons with a higher likelihood of disease;
- d) to maintain free status, an annual survey supervised by the *Veterinary Administration*, with negative results, is carried out on a representative sample of apiaries in the country or zone/compartiment to indicate that there has been no new *cases*; such surveys may be targeted towards areas with a higher likelihood of disease;
- e) there is no self-sustaining feral population of *A. mellifera* or other possible host species in the country or zone/compartiment;
- f) the importation of the *commodities* listed in this Chapter into the country or zone/compartiment is carried out in conformity with the recommendations of this Chapter.

Article 2.9.1.4.

Regardless of the acarapisosis status of the *exporting country*, *Veterinary Administrations* should authorise without restriction the import or transit through their territory of the following commodities:

- 1) honey bee semen and honey bee venom;
- 2) used equipment associated with beekeeping;
- 3) honey, beeswax, honey bee-collected pollen, propolis and royal jelly.

Article 2.9.1.5.

Veterinary Administrations of *importing countries* should require:

for live queen honey bees, worker bees and drones with or without associated brood combs

the presentation of an *international veterinary certificate* attesting that the bees come from a country or zone/compartiment free from acarapisosis.

Article 2.9.1.6.

Veterinary Administrations of *importing countries* should require:

for eggs, larvae and pupae of honey bees

the presentation of an *international veterinary certificate* attesting that the products:

- 1) were sourced from an officially free country or zone/compartiment; or
- 2) were examined by an official laboratory and declared free of all life stages of *A. woodi*; or
- 3) have originated from queens in a *quarantine station* and were examined microscopically and found free of all life stages of *A. woodi*.

CHAPTER 2.9.2.

AMERICAN FOULBROOD OF HONEY BEES

Article 2.9.2.1.

For the purposes of this chapter, American foulbrood is a disease of the larval and pupal stages of the honey bee *Apis mellifera* and other *Apis* spp., and occurs in most countries where such bees are kept. *Paenibacillus larvae subsp. larvae*, the causative organism, is a bacterium that can produce over one billion spores in each infected larva. The spores are very long-living and extremely resistant to heat and chemical agents, and only the spores are capable of inducing the disease.

Combs of infected apiaries may show distinctive clinical signs which can allow the disease to be diagnosed in the field. However, subclinical infections are common and require laboratory diagnosis.

For the purposes of this *Terrestrial Code*, the *incubation period* for American foulbrood shall be 15 days (not including the wintering period which may vary according to country).

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 2.9.2.2.

The American foulbrood status of a country or zone/compartiment can only be determined after considering the following criteria:

- 1) a risk assessment has been conducted, identifying all potential factors for American foulbrood occurrence and their historic perspective;
- 2) American foulbrood should be notifiable in the whole country or zone/compartiment and all clinical signs suggestive of American foulbrood should be subjected to field and/or laboratory investigations;
- 3) an on-going awareness programme should be in place to encourage reporting of all cases suggestive of American foulbrood;
- 4) the *Veterinary Administration* or other competent authority with responsibility for the health of honey bees should have current knowledge of, and authority over, all domesticated apiaries in the country.

Article 2.9.2.3.

Country or zone/compartiment free from American foulbrood1) Historically free status

A country or zone/compartiment may be considered free from the disease after conducting a risk assessment as referred to in Article 2.9.2.2. but without formally applying a specific surveillance programme (historical freedom) if the country or zone/compartiment complies with the provisions of Article 3.8.1.2.

2) Free status as a result of an eradication programme

A country or zone/compartiment which does not meet the conditions of point 1) above may be considered free from American foulbrood after conducting a risk assessment as referred to in Article 2.9.2.2. and when:

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- a) the *Veterinary Administration* or other competent authority with responsibility for the health of honey bees has current knowledge of, and authority over, all domesticated apiaries existing in the country or zone/compartment;
- b) American foulbrood is notifiable in the whole country or zone/compartment, and any clinical cases suggestive of American foulbrood are subjected to field and/or laboratory investigations;
- c) for the 5 years following the last reported isolation of the American foulbrood agent, an annual survey supervised by the *Veterinary Administration*, with negative results, have been carried out on a representative sample of apiaries in the country or zone/compartment to provide a confidence level of at least 95% of detecting American foulbrood if at least 1% of the apiaries were infected at a within-apiary prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with the last reported isolation of the American foulbrood agent;
- d) to maintain free status, an annual survey supervised by the *Veterinary Administration*, with negative results, is carried out on a representative sample of hives in the country or zone/compartment to indicate that there has been no new isolations; such surveys may be targeted towards areas with a higher likelihood of isolation;
- e) there is no self-sustaining feral population of *A. mellifera* or other possible host species in the country or zone/compartment;
- f) all equipment associated with previously infected apiaries has been sterilised or destroyed;
- g) the importation of the *commodities* listed in this Chapter into the country or zone/compartment is carried out in conformity with the recommendations of this Chapter.

Article 2.9.2.4.

Regardless of the American foulbrood status of the *exporting country*, *Veterinary Administrations* should authorise without restriction the import or transit through their territory of honey bee semen and honey bee venom.

Article 2.9.2.5.

Veterinary Administrations of *importing countries* should require:

for live queen honey bees, worker bees and drones with or without associated brood combs

the presentation of an *international veterinary certificate* attesting that the bees come from a country or zone/compartment officially free from American foulbrood.

Article 2.9.2.6.

Veterinary Administrations of *importing countries* should require:

for eggs, larvae and pupae of honey bees

the presentation of an *international veterinary certificate* attesting that the products:

- 1) were sourced from a free country or zone/compartment; or
- 2) have been isolated from queens in a *quarantine station*.

Article 2.9.2.7.

Veterinary Administrations of importing countries should require:

for used equipment associated with beekeeping

the presentation of an *international veterinary certificate* attesting that the equipment was sterilised under the supervision of the *Veterinary Authority* by either immersion in 1% sodium hypochlorite for at least 30 minutes (suitable only for non-porous materials such as plastic and metal), gamma irradiation using a cobalt-60 source at a dose rate of 10 kGy, or processing to ensure the destruction of both bacillary and spore forms of *P. larvae larvae*, in conformity with one of the procedures referred to in Appendix XXX (under study).

Article 2.9.2.8.

Veterinary Administrations of importing countries officially free from American foulbrood should require:

for honey, honey bee-collected pollen, beeswax, propolis and royal jelly

the presentation of an *international veterinary certificate* attesting that the products:

- 1) were collected in a country or zone/compartment free from American foulbrood; or
 - 2) have been processed to ensure the destruction of both bacillary and spore forms of *P. larvae larvae*, in conformity with one of the procedures referred to in Appendix XXX (under study).
-

CHAPTER 2.9.3. EUROPEAN FOULBROOD OF HONEY BEES

Article 2.9.3.1.

For the purposes of this chapter, European foulbrood is a disease of the larval and pupal stages of the honey bee *Apis mellifera* and other *Apis* spp., and occurs in most countries where such bees are kept. The causative agent is the non-sporulating bacterium *Melissococcus pluton*. Subclinical infections are common and require laboratory diagnosis. Infection remains enzootic because of mechanical contamination of the honeycombs. Recurrences of disease can therefore be expected in subsequent years.

For the purposes of this *Terrestrial Code*, the *incubation period* for European foulbrood shall be 15 days (not including the wintering period which may vary according to country).

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 2.9.3.2.

The American foulbrood status of a country or zone/compartiment can only be determined after considering the following criteria:

- 1) a risk assessment has been conducted, identifying all potential factors for American foulbrood occurrence and their historic perspective;
- 2) American foulbrood should be notifiable in the whole country or zone/compartiment and all clinical signs suggestive of American foulbrood should be subjected to field and laboratory investigations;
- 3) an on-going awareness programme should be in place to encourage reporting of all cases suggestive of American foulbrood;
- 4) the *Veterinary Administration* or other competent authority with responsibility for the health of honey bees should have current knowledge of, and authority over, all apiaries in the whole country.

Article 2.9.3.3.

Country or zone/compartiment free from European foulbrood

1) Historically free status

A country or zone/compartiment may be considered free from the disease after conducting a risk assessment as referred to in Article 2.9.3.2. but without formally applying a specific surveillance programme if the country or zone/compartiment complies with the provisions of Article 3.8.1.2.

2) Free status as a result of an eradication programme

A country or zone/compartiment which does not meet the conditions of point 1) above may be considered free from European foulbrood after conducting a risk assessment as referred to in Article 2.9.3.2. and when:

- a) the *Veterinary Administration* or other competent authority with responsibility for the health of honey bees has current knowledge of, and authority over, all domesticated apiaries existing in the country or zone/compartiment;

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- b) European foulbrood is notifiable in the whole country or zone/compartiment, and any clinical cases suggestive of European foulbrood are subjected to field and laboratory investigations;
- c) for the 3 years following the last reported isolation of the European foulbrood agent, an annual survey supervised by the *Veterinary Administration*, with negative results, have been carried out on a representative sample of apiaries in the country or zone/compartiment to provide a confidence level of at least 95% of detecting European foulbrood if at least 1% of the apiaries were infected at a within-apiary prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with the last reported isolation of the European foulbrood agent;
- d) to maintain free status, an annual survey supervised by the *Veterinary Administration*, with negative results, is carried out on a representative sample of hives in the country or zone/compartiment to indicate that there has been no new isolations; such surveys may be targeted towards areas with a higher likelihood of isolation;
- e) there is no self-sustaining feral population of *A. mellifera* or other possible host species in the country or zone/compartiment;
- f) the importation of the *commodities* listed in this Chapter into the country or zone/compartiment is carried out in conformity with the recommendations of this Chapter.

Article 2.9.3.4.

Regardless of the European foulbrood status of the exporting country, *Veterinary Administrations* should authorise without restriction the import or transit through their territory of honey bee semen and honey bee venom.

Article 2.9.3.5.

Veterinary Administrations of *importing countries* should require:

for live queen honey bees, worker bees and drones with or without associated brood combs

the presentation of an *international veterinary certificate* attesting that the bees come from a country or zone/compartiment free from European foulbrood.

Article 2.9.3.6.

Veterinary Administrations of *importing countries* should require:

for eggs, larvae and pupae of honey bees

the presentation of an *international veterinary certificate* attesting that the products:

- 1) were sourced from an free country or zone/compartiment; or
- 2) have been isolated from queens in a *quarantine station*, and all workers which accompanied the queen or a representative sample of eggs or larvae were examined for the presence of *Melissococcus pluton* by bacterial culture or PCR.

Article 2.9.3.7.

Veterinary Administrations of *importing countries* should require:

for used equipment associated with beekeeping

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the presentation of an *international veterinary certificate* attesting that the equipment was sterilised under the supervision of the *Veterinary Authority* by either immersion in 0.5% sodium hypochlorite for at least 20 minutes (suitable only for non-porous materials such as plastic and metal), gamma irradiation using a cobalt-60 source at a dose rate of 10 kGy, or processing to ensure the destruction of *Melissococcus pluton*, in conformity with one of the procedures referred to in Appendix XXX (under study).

Article 2.9.3.8.

Veterinary Administrations of *importing countries* should require:

for honey, honey bee-collected pollen, beeswax, propolis and royal jelly

the presentation of an *international veterinary certificate* attesting that the products:

- 1) were collected in a country or zone/compartment free from European foulbrood; or
 - 2) have been processed to ensure the destruction of *Melissococcus pluton*, in conformity with one of the procedures referred to in Appendix XXX (under study).
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~~CHAPTER 2.9.4.~~~~NOSEMOSES OF BEES~~~~Article 2.9.4.1.~~

~~For the purposes of the *Terrestrial Code*, the *incubation period* for nosemosis of bees shall be 60 days (not including the wintering period which may vary according to country).~~

~~Standards for diagnostic tests are described in the *Terrestrial Manual*.~~

~~Article 2.9.4.2.~~

~~*Veterinary Administrations of importing countries* should require:~~

~~for bees (worker bees, queen bees and drones)~~

~~the presentation of an *international veterinary certificate* attesting that the bees:~~

- ~~1) showed no clinical sign of nosemosis on the day of shipment;~~
- ~~2) were raised in and come from an apiary controlled and approved for at least the past 2 years by the *Veterinary Authority* responsible for the application of the sanitary measures and special breeding techniques referred to in Appendix 3.4.2.;~~
- ~~3) come from an apiary which satisfies the requirements for sanitary surveillance referred to in Appendix 3.4.2.~~

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CHAPTER 2.9.5.

VARROOSIS OF HONEY BEES

Article 2.9.5.1.

For the purposes of this chapter, varroosis is a disease of the honey bee *Apis mellifera* L. It is caused by the Korea and Japan haplotypes of the mite *Varroa destructor*, the original hosts of which are the Korea and Japan haplotypes of *Apis cerana*. The mite is an ectoparasite of adults and brood of *Apis mellifera* L. Early signs of infection normally go unnoticed, and only when infection is heavy does it become apparent. The infection spreads by direct contact from adult bee to adult bee, and by the movement of infested bees and bee brood. The mite can also act as a vector for viruses of the honey bee.

The number of parasites steadily increases with increasing brood activity and the growth of the bee population, especially late in the season when clinical signs of infestation can first be recognised. The life span of the mite depends on temperature and humidity but, in practice, it can be said to last from some days to a few months.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 2.9.5.2.

The varroosis status of a country or zone/compartiment can only be determined after considering the following criteria:

- 1) a risk assessment has been conducted, identifying all potential factors for varroosis occurrence and their historic perspective;
- 2) varroosis should be notifiable in the whole country or zone/compartiment and all clinical signs suggestive of varroosis should be subjected to field and laboratory investigations;
- 3) an on-going awareness programme should be in place to encourage reporting of all cases suggestive of varroosis;
- 4) the *Veterinary Administration* or other competent authority with responsibility for the health of honey bees should have current knowledge of, and authority over, all domesticated apiaries in the whole country.

Article 2.9.5.3.

Country or zone/compartiment free from varroosis

- 1) Historically free status

A country or zone/compartiment may be considered free from the disease after conducting a risk assessment as referred to in Article 2.9.5.2. but without formally applying a specific surveillance programme (historical freedom) if the country or zone/compartiment complies with the provisions of Article 3.8.1.2.

- 2) Free status as a result of an eradication programme

A country or zone/compartiment which does not meet the conditions of point 1) above may be considered free from varroosis after conducting a risk assessment as referred to in Article 2.9.5.2. and when:

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- a) the *Veterinary Administration* or other competent authority with responsibility for the health of honey bees has current knowledge of, and authority over, all domesticated apiaries existing in the country or zone/compartments;
- b) varroosis is notifiable in the whole country or zone/compartments, and any clinical cases suggestive of varroosis are subjected to field and laboratory investigations;
- c) for the 3 years following the last reported case of varroosis, annual surveys supervised by the *Veterinary Administration*, with negative results, have been carried out on a representative sample of apiaries in the country or zone/compartments to provide a confidence level of at least 95% of detecting varroosis if at least 1% of the apiaries were infected at a within-apiary prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with a higher likelihood of disease;
- d) to maintain free status, an annual survey supervised by the *Veterinary Administration*, with negative results, is carried out on a representative sample of apiaries in the country or zone/compartments to indicate that there has been no new cases; such surveys may be targeted towards areas with a higher likelihood of disease;
- e) there is no self-sustaining feral population of *A. mellifera*, the Korea and Japan haplotypes of *Apis cerana* or other possible host species in the country or zone/compartments;
- f) the importation of the commodities listed in this Chapter into the country or zone/compartments is carried out in conformity with the recommendations of this Chapter.

Article 2.9.5.4.

Regardless of the varroosis status of the *exporting country*, *Veterinary Administrations* should authorise without restriction the import or transit through their territory of the following commodities:

- 1) honey bee semen, honey bee eggs and honey bee venom;
- 2) extracted honey and beeswax (not in the form of honeycomb).

Article 2.9.5.5.

Veterinary Administrations of *importing countries* should require:

for live queen honey bees, worker bees and drones with or without associated brood combs

the presentation of an *international veterinary certificate* attesting that the bees come from a country or zone/compartments officially free from varroosis.

Article 2.9.5.6.

Veterinary Administrations of *importing countries* should require:

for larvae and pupae of honey bees

the presentation of an *international veterinary certificate* attesting that the products:

- 1) were sourced from a free country or zone/compartments; or
- 2) have originated from queens in a *quarantine station* and were inspected and found free of *Varroa destructor*.

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Article 2.9.5.7.

Veterinary Administrations of importing countries should require:

for used equipment associated with beekeeping

the presentation of an *international veterinary certificate* attesting that the equipment:

- 1) comes from a country or zone/compartment free from varroosis; or
- 2) contains no live honey bees or bee brood and has been held away from contact with live honey bees for at least 7 days prior to shipment; or
- 3) has been treated to ensure the destruction of *Varroa destructor*, in conformity with one of the procedures referred to in Appendix XXX (under study).

Article 2.9.5.8.

Veterinary Administrations of importing countries should require:

for honey-bee collected pollen, beeswax (in the form of honeycomb), comb honey and propolis

the presentation of an *international veterinary certificate* attesting that the products:

- 1) come from a country or zone/compartment free from varroosis; or
 - 2) contain no live honey bees or bee brood and has been held away from contact with live honey bees for at least 7 days prior to shipment; or
 - 3) have been treated to ensure the destruction of *Varroa destructor*, in conformity with one of the procedures referred to in Appendix XXX (under study).
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CHAPTER 2.9.X.

TROPILAEELAPS INFESTATION OF HONEY BEES

Article 2.9.X.1.

For the purposes of this chapter, *Tropilaelaps* infestation of the honey bee *Apis mellifera* L. is caused by the mite *Tropilaelaps clareae* and *T. koenigerum*. The mite is an ectoparasite of brood of *Apis mellifera* L., *Apis laboriosa* and *Apis dorsata*, and cannot survive for periods of more than 7 days away from bee brood.

Early signs of infection normally go unnoticed, but the growth in the mite population is rapid leading to high hive mortality. The infection spreads by direct contact from adult bee to adult bee, and by the movement of infested bees and bee brood. The mite can also act as a vector for viruses of the honey bee.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 2.9.X.2.

The *Tropilaelaps* status of a country or zone/compartiment can only be determined after considering the following criteria:

- 1) a risk assessment has been conducted, identifying all potential factors for *Tropilaelaps* occurrence and their historic perspective;
- 2) *Tropilaelaps* infestation should be notifiable in the whole country or zone/compartiment and all clinical signs suggestive of *Tropilaelaps* infestation should be subjected to field and laboratory investigations;
- 3) an on-going awareness programme should be in place to encourage reporting of all cases suggestive of *Tropilaelaps* infestation;
- 4) the *Veterinary Administration* or other competent authority with responsibility for the health of honey bees should have current knowledge of, and authority over, all domesticated apiaries in the country.

Article 2.9.X.3.

Country or zone/compartiment free from *Tropilaelaps* spp1) Historically free status

A country or zone/compartiment may be considered free from the disease after conducting a risk assessment as referred to in Article 2.9.X.2. but without formally applying a specific surveillance programme if the country or zone/compartiment complies with the provisions of Article 3.8.1.2.

2) Free status as a result of an eradication programme

A country or zone/compartiment which does not meet the conditions of point 1) above may be considered free from *Tropilaelaps* infestation after conducting a risk assessment as referred to in Article 2.9.X.2. and when:

- a) the *Veterinary Administration* or other competent authority with responsibility for the health of honey bees has current knowledge of, and authority over, all domesticated apiaries existing in the country or zone/compartiment;

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- b) *Tropilaelaps* infestation is notifiable in the whole country or zone/compartment, and any clinical cases suggestive of *Tropilaelaps* infestation are subjected to field and laboratory investigations;
- c) for the 3 years following the last reported case of *Tropilaelaps* infestation, an annual survey supervised by the *Veterinary Administration*, with negative results, have been carried out on a representative sample of apiaries in the country or zone/compartment to provide a confidence level of at least 95% of detecting *Tropilaelaps* infestation if at least 1% of the apiaries were infected at a within-apiary prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with a higher likelihood of infestation;
- d) to maintain free status, an annual survey supervised by the *Veterinary Administration*, with negative results, is carried out on a representative sample of apiaries in the country or zone/compartment to indicate that there has been no new cases; such surveys may be targeted towards areas with a higher likelihood of disease;
- e) there is no self-sustaining feral population of *A. mellifera*, *A. dorsata* or *A. laboriosa*, or other possible host species in the country or zone/compartment;
- f) the importation of the *commodities* listed in this Chapter into the country or zone/compartment is carried out, in conformity with the recommendations of this Chapter.

Article 2.9.X.4.

Regardless of the status of the *exporting country* with regard to *Tropilaelaps* infestation, *Veterinary Administrations* should authorise without restriction the import or transit through their territory of the following commodities:

- 1) honey bee semen, honey bee eggs and honey bee venom;
- 2) extracted honey and beeswax (not in the form of honeycomb).

Article 2.9.X.5.

Veterinary Administrations of *importing countries* should require:

for live queen honey bees, worker bees and drones with associated brood combs

the presentation of an *international veterinary certificate* attesting that the bees come from a country or zone/compartment officially free from *Tropilaelaps* infestation.

Article 2.9.X.6.

Veterinary Administrations of *importing countries* should require:

for live queen honey bees, worker bees and drones without associated brood combs

the presentation of an *international veterinary certificate* attesting that the bees have been held in isolation from brood and bees with access to brood, for a period of at least 7 days.

Article 2.9.X.7.

Veterinary Administrations of *importing countries* should require:

for used equipment associated with beekeeping

the presentation of an *international veterinary certificate* attesting that the equipment:

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- 1) comes from a country or zone/compartment free from *Tropilaelaps* infestation; or
- 2) contains no live honey bees or bee brood and has been held away from contact with live honey bees for at least 7 days prior to shipment; or
- 3) has been treated to ensure the destruction of *Tropilaelaps* spp., in conformity with one of the procedures referred to in Appendix XXX (under study).

Article 2.9.X.8.

Veterinary Administrations of importing countries should require:

for honey-bee collected pollen, beeswax (in the form of honeycomb), comb honey and propolis

the presentation of an *international veterinary certificate* attesting that the products:

- 1) come from a country or zone/compartment free from *Tropilaelaps* infestation; or
 - 2) contain no live honey bees or bee brood and has been held away from contact with live honey bees for at least 7 days prior to shipment; or
 - 3) have been treated to ensure the destruction of *Tropilaelaps* spp., in conformity with one of the procedures referred to in Appendix XXX (under study).
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CHAPTER 2.3.1.

BOVINE BRUCELLOSIS

Article 2.3.1.1.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 2.3.1.2.

Country or zone free from bovine brucellosis

To qualify as free from bovine brucellosis, a country or zone shall satisfy the following requirements:

- 1) bovine brucellosis or any suspicion thereof is notifiable in the country;
- 2) the entire cattle population of a country or zone is under *official veterinary control* and it has been ascertained that the rate of brucellosis infection does not exceed 0.2% of the cattle herds in the country or zone under consideration;
- 3) the serological tests for bovine brucellosis are periodically conducted in each herd, with or without the ring test;
- 4) no animal has been vaccinated against bovine brucellosis for at least the past 3 years;
- 5) all reactors are slaughtered;
- 6) animals introduced into a free country or zone shall only come from herds officially free from bovine brucellosis or from herds free from bovine brucellosis. This condition may be waived for animals which have not been vaccinated and which, prior to entry into the herd, were isolated and were subjected to the serological tests for bovine brucellosis with negative results on two occasions, with an interval of 30 days between each test. These tests are not considered valid in female animals which have calved during the past 14 days.

In a country where all herds of cattle have qualified as officially free from bovine brucellosis and where no reactor has been found for the past 5 years, the system for further control may be decided by the country concerned.

Article 2.3.1.3.

Herd officially free from bovine brucellosis

To qualify as officially free from bovine brucellosis, a herd of cattle shall satisfy the following requirements:

- 1) it is under *official veterinary control*;
- 2) it contains no animal which has been vaccinated against bovine brucellosis during at least the past 3 years;
- 3) it only contains animals which have not showed evidence of bovine brucellosis infection during the past 6 months, all suspect cases (such as animals which have prematurely calved) having been subjected to the necessary laboratory investigations;

Appendix XXI (contd)

- 4) all cattle over the age of one year (except castrated males) were subjected to serological tests with negative results on two occasions, at an interval of 12 months between each test; this requirement is maintained even if the entire herd is normally tested every year or testing is conducted in conformity with other requirements established by the *Veterinary Administration* of the country concerned;
- 5) additions to the herd shall only come from herds officially free from bovine brucellosis. This condition may be waived for animals which have not been vaccinated, come from a herd free from bovine brucellosis, provided that negative results were shown following a buffered *Brucella* antigen test and the complement fixation test during the 30 days prior to entry into the herd. Any recently calved or calving animal should be retested after 14 days, as tests are not considered valid in female animals which have calved during the past 14 days.

Article 2.3.1.4.

Herd free from bovine brucellosis

To qualify as free from bovine brucellosis, a herd of cattle shall satisfy the following requirements:

- 1) it is under *official veterinary control*;
- 2) it is subjected to either a vaccination or a non-vaccination regime;
- 3) if a live vaccine is used in female cattle, vaccination must be carried out between 3 and 6 months of age, in which case these female cattle must be identified with a permanent mark;
- 4) all cattle over the age of one year are controlled as provided in paragraph 4) of the definition of a herd of cattle officially free from bovine brucellosis; however, cattle under 30 months of age which have been vaccinated using a live vaccine before reaching 6 months of age, may be subjected to a buffered *Brucella* antigen test with a positive result, with the complement fixation test giving a negative result;
- 5) all cattle introduced into the herd come from a herd officially free from bovine brucellosis or from a herd free from bovine brucellosis, or from a country or zone free from bovine brucellosis. This condition may be waived for animals which have been isolated and which, prior to entry into the herd, were subjected to the serological tests for bovine brucellosis with negative results on two occasions, with an interval of 30 days between each test. These tests are not considered valid in female animals which have calved during the past 14 days.

Article 2.3.1.5.

Veterinary Administrations of importing countries should require:

for cattle for breeding or rearing (except castrated males)

the presentation of an *international veterinary certificate* attesting that the animals:

- 1) showed no clinical sign of bovine brucellosis on the day of shipment;
- 2) were kept in a herd in which no clinical sign of bovine brucellosis was officially reported during the 6 months prior to shipment;
- 3) were kept in a country or zone free from bovine brucellosis, or were from a herd officially free from bovine brucellosis and were subjected to a serological test for bovine brucellosis with negative results during the 30 days prior to shipment; or

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- 4) were kept in a herd free from bovine brucellosis and were subjected to buffered *Brucella* antigen and complement fixation tests with negative results during the 30 days prior to shipment;

if the cattle come from a herd other than those mentioned above:

- 5) were isolated prior to shipment and were subjected to a serological test for bovine brucellosis with negative results on two occasions, with an interval of not less than 30 days between each test, the second test being performed during the 15 days prior to shipment. These tests are not considered valid in female animals which have calved during the past 14 days.

Article 2.3.1.6.

Veterinary Administrations of importing countries should require:

for cattle for slaughter (except castrated males)

the presentation of an *international veterinary certificate* attesting that the animals:

- 1) showed no clinical sign of bovine brucellosis on the day of shipment;
- 2) are not being eliminated as part of an eradication programme against bovine brucellosis;
- 3) were kept in a country or zone free from bovine brucellosis; or
- 4) were kept in a herd officially free from bovine brucellosis; or
- 5) were kept in a herd free from bovine brucellosis; or
- 6) were subjected to a serological test for bovine brucellosis with negative results during the 30 days prior to shipment.

Article 2.3.1.7.

Veterinary Administrations of importing countries should require:

for bovine semen

the presentation of an *international veterinary certificate* attesting that:

- 1) when the semen is from an *artificial insemination centre*, the testing programme includes the buffered *Brucella* antigen and complement fixation tests;
- 2) when the semen is not from an *artificial insemination centre*, the donor animals:
 - a) were kept in a country or zone free from bovine brucellosis; or
 - b) were kept in a herd officially free from bovine brucellosis, showed no clinical sign of bovine brucellosis on the day of collection of the semen and were subjected to a buffered *Brucella* antigen test with negative results during the 30 days prior to collection; or
 - c) were kept in a herd free from bovine brucellosis, showed no clinical sign of bovine brucellosis on the day of collection and were subjected to the buffered *Brucella* antigen and complement fixation tests with negative results during the 30 days prior to collection; or

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- d) showed no clinical sign of bovine brucellosis on the day of collection, were subjected to the buffered *Brucella* antigen and complement fixation tests with negative results during the 30 days prior to collection and no *Brucella* agglutinin was detected in the semen;
- 3) the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.1.

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APPENDIX 3.9.4.

RISK ANALYSIS FOR ANTIMICROBIAL RESISTANCE

Article 3.9.4.1.

Guidelines for analysing the risks to animal and public health from antimicrobial resistant bacteria of animal origin1) Introduction

The incorrect use of antimicrobials for therapy, prophylaxis and growth promotion in animals can reduce their efficacy in animal and human medicine, through the development of antimicrobial resistant strains of pathogenic bacteria. This risk may be represented by the loss of therapeutic efficacy of one or several antimicrobial drugs and includes the emergence of multi-resistant bacteria.

2) Objective

The principal aim of risk analysis for antimicrobial resistance in bacteria from animals is to provide Member Countries with a transparent, objective and defensible method of assessing and managing the human and animal health risks associated with the development of resistance arising from the use of antimicrobials in animals.

3) The risk analysis process

A generic risk analysis process is described in Section 1.3. of the *Terrestrial Code*.

A qualitative risk assessment should always be undertaken. Its outcome will determine whether progression to a quantitative risk assessment is feasible and/or necessary.

4) Hazard identification

For the purposes of this appendix, the hazard is the resistance determinant that emerges as a result of the use of a specific antimicrobial in animals. This definition reflects the development of resistance in a species of pathogenic bacteria, as well as the development of a resistance determinant that may be passed from one species of bacteria to another. The conditions under which the hazard might produce adverse consequences include any feasible scenarios through which humans or animals could become exposed to a pathogen which contains that resistance determinant, fall ill and then be treated with an antimicrobial that is no longer effective because of the resistance.

5) Risk assessment

The assessment of the risk to human and animal health from antimicrobial-resistant bacteria resulting from the use of antimicrobials in food-producing animals should examine:

- a) the likelihood of emergence of resistant bacteria arising from the use of antimicrobial(s), or more particularly, production of the resistant determinants if transmission is possible between bacteria;
- b) consideration of all pathways and their importance, by which humans could be exposed to these resistant bacteria or resistance determinants, together with the possible range of bacterial load ingested at the moment of exposure;
- c) the consequences of exposure and the estimated probability of its occurrence.

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Article 3.9.4.2.

Analysis of risks to human health1) Definition of the risk

The infection of humans with bacteria that have acquired resistance to a specific antimicrobial used in animals, and resulting in the loss of benefit of antimicrobial therapy used to manage the human infection.

2) Hazard identification

- Bacteria that have acquired resistance, (including multiple resistance) arising from the use of an antimicrobial(s) in animals
- Bacteria having obtained a resistance determinant(s) from another bacteria which have acquired resistance arising from the use of an antimicrobial(s) in animals.

The identification of the hazard must include consideration of the class or subclass of the antimicrobial(s).

3) Release assessment

A release assessment describes the biological pathways necessary for the use of a specific antimicrobial in animals to lead to the release of resistant bacteria or resistance determinants into a particular environment, and estimating either qualitatively or quantitatively the probability of that complete process occurring. The release assessment describes the probability of the release of each of the potential hazards under each specified set of conditions with respect to amounts and timing, and how these might change as a result of various actions, events or measures.

The following factors should be considered in the release assessment:

- species of animal treated with the antimicrobial(s) in question
- number of animals treated, geographical distribution of those animals
- variation in methods of administration of the antimicrobial(s)
- bacteria developing resistance as a result of the antimicrobial(s) use
- mechanism of direct or indirect transfer of resistance
- cross-resistance and/or co-resistance with other antimicrobials
- surveillance of animals, animal products and waste products for the existence of resistant bacteria.

4) Exposure assessment

An exposure assessment describes the biological pathways necessary for exposure of humans to the resistant bacteria or resistance determinants released from a given antimicrobial use in animals, and estimating the probability of the exposures occurring. The probability of exposure to the identified hazards is estimated for specified exposure conditions with respect to amounts, timing, frequency, duration of exposure, routes of exposure and the number, species and other characteristics of the human populations exposed.

Appendix XXII (contd)

The following factors should be considered in the exposure assessment:

- human demographics and food consumption patterns, including traditions and cultural practices
- prevalence of food and/or the animal environment contaminated with resistant bacteria
- prevalence of animal feed contaminated with resistant bacteria
- cycling of resistant bacteria between humans, animals and the environment
- steps of microbial decontamination of food
- microbial load in contaminated food at the point of consumption
- survival capacity and redistribution of resistant bacteria during the food production process (including slaughtering, processing, storage, transportation and retailing)
- disposal practices for waste products and the opportunity for human exposure to resistant bacteria or resistance determinants in those waste products
- point of consumption of food (professional catering, home cooking)
- variation in consumption and food-handling methods of exposed populations and subgroups of the population
- capacity of resistant bacteria to become established in human intestinal flora
- human-to-human transmission of the bacteria under consideration
- capacity of resistant bacteria to transfer resistance to human commensal bacteria
- amount and type of antimicrobials used in response to human illness
- dose, route of administration (oral, parenteral) and duration of human treatment
- pharmacokinetics (metabolism, bioavailability, access to intestinal flora).

5) Consequence assessment

A consequence assessment describes the relationship between specified exposures to resistant bacteria or resistance determinants and the consequences of those exposures. A causal process must exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences. The consequence assessment describes the potential consequences of a given exposure and estimates the probability of them occurring.

The following factors should be considered in the consequence assessment:

- dose-response relationships
- variation in susceptibility of exposed populations or subgroups of the population
- variation and frequency of human health effects resulting from loss of efficacy of antimicrobials
- changes in human medicinal practices resulting from reduced confidence in antimicrobials
- changes in food consumption patterns due to loss of confidence in the safety of food products and any associated secondary risks

Appendix XXII (contd)

- associated costs
- interference with a classical first line of antimicrobial therapy in humans
- perceived future usefulness of the drug (time reference).

6) Risk estimation

A risk estimation integrates the results from the release assessment, exposure assessment and consequence assessment to produce overall estimates of risks associated with the hazards. Thus, risk estimation takes into account the whole of the risk pathway from hazard identification to the unwanted consequences.

The following factors should be considered in the risk estimation:

- number of people falling ill
- increased severity or duration of disease
- number of person/days of illness per year
- deaths (total per year; probability per year or lifetime for a random member of the population or a member of a specific more exposed sub-population)
- importance of the pathology caused by the bacteria
- absence of alternate antimicrobial therapy
- incidence of resistance observed in humans
- some arbitrary scale of consequences to allow weighted summation of different risk impacts (e.g. illness and hospitalisation).

7) Risk management options

Risk management options have to be continuously monitored and reviewed in order to ensure that the objectives are being achieved.

Article 3.9.4.3.

Analysis of risks to animal health1) Definition of the risk

The infection of animals with bacteria that have acquired resistance from the use of a specific antimicrobial(s) in animals, and resulting in the loss of benefit of antimicrobial therapy used to manage the animal infection.

2) Hazard identification

- Bacteria that have acquired resistance, (including multiple resistance) arising from the use of an antimicrobial(s) in animals
- Bacteria having obtained a resistance determinant(s) from another bacteria which have acquired resistance arising from the use of an antimicrobial(s) in animals.

The identification of the hazard must include considerations of the class or subclass of the antimicrobial(s).

3) Release assessment

The following factors should be considered in the release assessment:

- animal species treated
- number of animals treated and their geographical distribution
- site and type of infection
- variation in routes of administration
- development of resistant bacteria
- mechanisms and pathways of resistance transfer
- cross-resistance and/or co-resistance
- surveillance of animals, animal products and waste products for resistant bacteria.

4) Exposure assessment

The following factors should be considered in the exposure assessment:

- prevalence and trends of resistant bacteria in clinically ill and clinically unaffected animals
- prevalence of resistant bacteria in feed /the animal environment
- animal-to-animal transmission of the resistant bacteria
- number/percentage of animals treated
- dissemination of resistant bacteria from animals (animal husbandry methods, movement of animals)
- quantity of antimicrobial(s) used in animals
- treatment regimens (dose, route of administration, duration)
- survival capacity of resistant bacteria
- exposure of wild life to resistant bacteria
- disposal practices for waste products and the opportunity for human exposure to resistant bacteria or resistance determinants in those products
- capacity of resistant bacteria to become established in animal intestinal flora
- exposure to resistance determinants from other sources
- dose, route of administration and duration of treatment
- pharmacokinetics (metabolism, bioavailability, access to intestinal flora)
- cycling of resistant bacteria between humans, animals and the environment.

Appendix XXII (contd)5) Consequence assessment

The following factors should be considered in the consequence assessment:

- dose-response relationships
- variation in susceptibility of exposed populations and subgroups of the populations
- variation and frequency of animal health effects resulting from loss of efficacy of antimicrobials
- changes in veterinary medicine practices resulting from reduced confidence in antimicrobials
- associated cost
- perceived future usefulness of the drug (time reference).

6) Risk estimation

The following factors should be considered in the risk estimation:

- number of therapeutic failures due to resistant bacteria
- animal welfare
- economic cost
- deaths (total per year; probability per year or lifetime for a random member of the population or a member of a specific more exposed sub-population)
- incidence of resistance observed in animals.

7) Risk management options

The recommendations in this *Terrestrial Code* apply.

SECTION X.X.X.
ANIMAL WELFARE
CHAPTER X.X.1.
INTRODUCTION TO THE GUIDELINES FOR
ANIMAL WELFARE

Article x.x.x.1.

Guiding principles for animal welfare

- 1) That there is a critical relationship between animal health and animal welfare.
- 2) That the internationally recognised ‘five freedoms’ (freedom from hunger, thirst and malnutrition; freedom from fear and distress; freedom from physical and thermal discomfort; freedom from pain, injury and disease; and freedom to express normal patterns of behaviour) provide valuable guidance in animal welfare.
- 3) That the internationally recognised ‘three Rs’ (reduction in numbers of animals, refinement of experimental methods and replacement of animals with non-animal techniques) provide valuable guidance for the use of animals in science.
- 4) That the scientific assessment of animal welfare involves diverse elements which need to be considered together, and that selecting and weighing these elements often involves value-based assumptions which should be made as explicit as possible.
- 5) That the use of animals in agriculture and science, and for companionship, recreation and entertainment, makes a major contribution to the wellbeing of people.
- 6) That the use of animals carries with it a duty to ensure the welfare of such animals to the greatest extent practicable.
- 7) That improvements in farm animal welfare can often improve productivity and food safety, and hence lead to economic benefits.
- 8) That equivalent outcomes (performance criteria), rather than identical systems (design criteria), be the basis for comparison of animal welfare standards and guidelines.

Article x.x.x.2.

Scientific basis for guidelines

- 1) Welfare is a broad term which describes how well individuals are coping with their environment, and includes their health, their feelings and other good and bad effects on brain and body mechanisms for dealing with problems.
- 2) Welfare can be scientifically evaluated and can be shown to range from very good to very poor. The study of how to assess animal welfare has progressed rapidly in recent years and evidence from such studies has been used in the formulation of these guidelines.

Appendix XXIII (contd)

- 3) Some studies of animal welfare involve assessing the extent of stress, which occurs when individuals are not able to cope with the consequences of treatment by humans or other impacts on the animal's environment. Other indicators of poor welfare reveal how much the individual is having to do in order to cope with problems.
- 4) Other areas of animal welfare research provide further information about the needs of animals by measuring the strengths of their positive and negative preferences. Once the needs of animals are known, conditions and treatment methods which fulfil these needs can be devised and used.
- 5) Some measures of poor welfare involve assessing the extent of pain or impaired functioning associated with injury or disease. Many of the problems can be revealed by an inspection of the animal.
- 6) Many measurements of animal welfare can be used as performance indicators in the evaluation of general methods for the keeping and treatment of animals and the actions of individuals who have an impact on those animals. Using such evidence, the acceptability of systems and of human performance can be decided.

Article x.x.x.3.

Ethical basis for guidelines

Those who use animals have obligations concerning the welfare of those animals. Actions should be taken to minimise pain, anxiety and stress experienced by animals during their lives, and to maximise good welfare through the use of adequate housing and ethically accepted methods of treatment, inspection, training and management.

CHAPTER X.X.2

GUIDELINES FOR THE WELFARE OF ANIMALS
DURING TRANSPORT BY LAND

CHAPTER X.X.3

GUIDELINES FOR THE WELFARE OF ANIMALS
DURING TRANSPORT BY SEA

CHAPTER X.X.4

GUIDELINES FOR THE WELFARE OF ANIMALS
DURING SLAUGHTER FOR HUMAN CONSUMPTION

CHAPTER X.X.5

GUIDELINES FOR THE WELFARE OF ANIMALS
DURING KILLING FOR DISEASE CONTROL PURPOSES

CHAPTER 2.1.14.

AVIAN INFLUENZA

Article 2.1.14.1.

For the purposes of this *Code*, avian influenza (AI) is defined as ‘an infection of poultry caused either by any influenza A virus which has an IVPI in 6-week-old chickens greater than 1.2 or by an influenza A virus of H5 or H7 subtype’.

For the purposes of this *Terrestrial Code*, notifiable avian influenza (NAI) is defined as an infection of poultry caused by any influenza A virus of the H5 or H7 subtypes or by any AI virus with an intravenous pathogenicity index (IVPI) greater than 1.2 (or as an alternative at least 75% mortality) as described below. NAI viruses can be divided into highly pathogenic notifiable avian influenza (HPNAI) and low pathogenicity notifiable avian influenza (LPNAI).

1) HPNAI viruses have an IVPI in 6-week-old chickens greater than 1.2 or, as an alternative, cause at least 75% mortality in 4-to 8-week-old chickens infected intravenously. H5 and H7 viruses which do not have an IVPI of greater than 1.2 or cause less than 75% mortality in an intravenous lethality test should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0); if the amino acid motif is similar to that observed for other HPNAI isolates, the isolate being tested should be considered as HPNAI.

2) LPNAI are all influenza A viruses of H5 and H7 subtype that are not HPNAI viruses.

Poultry is defined as ‘all birds reared or kept in captivity for the production of meat or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds’.

For the purpose of *international trade*, this chapter deals not only with the occurrence of clinical signs caused by NAI virus, but also with the presence of infection with NAI virus in the absence of clinical signs. Articles dealing with trade in commodities recommend different sanitary measures, depending on the presence or absence of clinical signs.

The following defines the occurrence of AI virus infection:

- 1) AI virus has been isolated and identified as such from poultry or a product derived from poultry, or
- 2) viral antigen or viral RNA specific to H5 or H7 subtype of AI virus has been identified in samples from poultry or a product derived from poultry, or
- 3) antibodies to H5 or H7 subtype of AI virus that are not a consequence of vaccination have been detected in poultry.

The following defines the occurrence of NAI virus infection:

- 1) HPNAI virus has been isolated and identified as such or specific viral RNA has been detected in poultry or a product derived from poultry, or
- 2) LPNAI virus has been isolated and identified as such or specific viral RNA has been detected in poultry or a product derived from poultry, or

Appendix XXIV (contd)

3) antibodies to H5 or H7 subtype of NAI virus that are not a consequence of vaccination, nor indicative of a non-specific reaction, have been detected in poultry; in such cases, virus isolation should be attempted to establish whether the serological positivity is due to LPNAI or HPNAI. If appropriate samples are not available or if results are negative, a thorough epidemiological investigation including further sampling and testing should be carried out to identify the type or exclude the presence of NAI infection.

For the purposes of this *Terrestrial Code*, 'NAI-free establishment' means an establishment in which there has been no clinical sign of NAI for the past 21 days, and which is not situated within 3 km of an establishment infected with HPNAI and within one km of an establishment infected with LPNAI.

For the purposes of this *Terrestrial Code*, the incubation period for NAI shall be 28 21 days.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Any vaccine used should comply with the standards described in the *Terrestrial Manual*.

Article 2.1.14.1bis.

The NAI status of a country, a zone or compartment can be determined on the basis of the following criteria:

- 1) the outcome of a risk assessment identifying all potential factors for NAI occurrence and their historic perspective;
- 2) NAI is notifiable in the whole country, an on-going NAI awareness programme is in place, and all notified suspect occurrences of NAI are subjected to field and, where applicable, laboratory investigations;
- 3) appropriate surveillance is in place to demonstrate the presence of infection in the absence of clinical signs in poultry, and the risk posed by birds other than poultry; this may be achieved through an NAI surveillance programme in accordance with this chapter and Chapter 1.3.6.

Article 2.1.14.2.

NAI free country or zone/compartment

A country or zone/compartment may be considered free from NAI when it has been shown that NAI infection has not been present for the past 12 months. If a stamping out policy is applied infected poultry are slaughtered, this period shall be 6 3 months after the slaughter of the last infected poultry and disinfection of all affected establishments.

The NAI status should be determined by an ongoing surveillance and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) based on virus isolation, virus detection or serology. The programme may need to be adapted to target parts of the country or zone/compartment at a higher risk due to historical or geographical factors, population data, or proximity to recent outbreaks.

Appendix XXIV (contd)

Freedom of infection in a country or zone can be demonstrated with random and/or targeted serological surveillance at a minimum interval of 6 months designed to provide at least a 95% level of confidence of detecting a prevalence of NAI infected enterprises of 1%. Freedom of infection in an enterprise compartment can be demonstrated with an ongoing surveillance programme designed to provide at least a 95% level of confidence of detecting a prevalence of NAI infection of 10%. Each *establishment* should be sampled to provide a 95% level of confidence of detecting a prevalence of NAI of 20-25%. For commercial ducks the surveillance programme should be based on virus isolation or detection in the absence of validated serological methods.

In the case of a country or zone in which vaccination is being conducted, the ongoing surveillance and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) based on virus isolation, virus detection or serology should be carried out on all vaccinated flocks at a minimum interval of 6 months. In each vaccinated flock, the number of birds to be tested should provide at least a 95% level of confidence of detecting a prevalence of NAI infection of 20-25%. In the case of a compartment enterprise in which vaccination is being conducted, the ongoing surveillance and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) based on virus isolation, virus detection or serology should be carried out to provide at least a 95% level of confidence of detecting a prevalence of NAI infection of 10%. If a serological test is used, it should be able to distinguish vaccinated birds from infected birds. Additional security should be provided by the use of relevant serological tests in identifiable sentinel birds which can be clinically inspected or tested to help identify field infections in vaccinated flocks.

Article 2.1.14.3.

When importing from an NAI free country or zone/compartment, *Veterinary Administrations* should require:

for live poultry (other than day-old poultry)

the presentation of an *international veterinary certificate* attesting that the poultry:

- 1) showed no clinical sign of NAI on the day of shipment;
- 2) were kept in an NAI free country or zone/compartment since they were hatched or for the past 28-21 days;
- 3) either have not been vaccinated against NAI, or have been vaccinated and the date of vaccination and the details of the vaccine are stated.

[Note: If the poultry were vaccinated against NAI, the nature of the vaccine used and the date of vaccination should be stated in the certificate.]

Article 2.1.14.4.

Regardless of the NAI status of the country of origin, *Veterinary Administrations* should require:

for the importation of live birds other than poultry

the presentation of an *international veterinary certificate* attesting that the birds:

- 1) showed no clinical sign of NAI on the day of shipment;
- 2) were kept in isolation approved by the Veterinary Services ~~a quarantine station~~ since they were hatched or for the 28-21 days prior to shipment and showed no clinical sign of NAI during the isolation quarantine period;

Appendix XXIV (contd)

3) were subjected to a diagnostic test 7 to 14 days prior to shipment to demonstrate freedom from NAI.

Article 2.1.14.5.

When importing from an NAI free country or zone/compartment, *Veterinary Administrations* should require:

for day-old live poultry

the presentation of an *international veterinary certificate* attesting that the poultry:

- 1) showed no clinical sign of NAI on the day of shipment;
- 2) were kept in an NAI free country or zone/compartment since they were hatched;
- 3) were derived from parent flocks which had been kept in an NAI free country or zone/compartment for 21 days prior to the collection of the eggs;
- 4) and/or the parent flock had/had not been vaccinated and, if vaccinated, the date of vaccination and the details of the vaccine are stated.

Note: If the day-old poultry or the parents of the poultry were vaccinated against NAI, the details of the vaccine and the date of vaccination should be provided.

Article 2.1.14.5bis.

When importing from an NAI free country or zone/compartment, *Veterinary Administrations* should require:

for hatching eggs

the presentation of an *international veterinary certificate* attesting that the eggs:

- 1) came from an NAI free country or zone/compartment;
- 2) were derived from parent flocks which had been kept in an NAI free country or zone/compartment for 21 days prior to the collection of the eggs;
- 3) were derived from parent flocks which had not been vaccinated against NAI, or which had been vaccinated against NAI and the date of vaccination and the details of the vaccine are stated.

Article 2.1.14.6.

When importing from an NAI free country or zone/compartment, *Veterinary Administrations* should require:

for ~~hatching eggs or~~ eggs for consumption

the presentation of an *international veterinary certificate* attesting that the eggs come from an NAI free country or zone/compartment.

Article 2.1.14.6bis.

When importing from a country or zone/compartment free from HPNAI infection, *Veterinary Administrations* should require:

for eggs for consumption

the presentation of an *international veterinary certificate* attesting that the eggs:

- 1) come from a country or zone/compartment free from HPNAI infection, and
- 2) are transported in new disposable packing material.

Article 2.1.14.6ter.

When importing from a country or zone/compartment not known to be free from HPNAI, *Veterinary Administrations* should require:

for eggs for consumption

the presentation of an *international veterinary certificate* attesting that the entire consignment of eggs comes from birds:

- 1) which have been kept in an NAI free *establishment*;
- 2) which have been tested serologically or by virus detection to give a 95% probability of detecting a 5% prevalence of NAI infection, every 21 days, with negative results.

Article 2.1.14.7.

When importing from an NAI free country or zone/compartment, *Veterinary Administrations* should require:

for egg products

the presentation of an *international veterinary certificate* attesting that the egg products come from, and were processed in, an NAI free country or zone/compartment.

Article 2.1.14.7bis.

When importing from a country or zone/compartment free from HPNAI infection, *Veterinary Administrations* should require:

for egg products

the presentation of an *international veterinary certificate* attesting that the egg products come from, and were processed in a country or zone/compartment free from HPNAI infection.

Article 2.1.14.7ter.

When importing from a country or zone/compartment not known to be free from HPNAI, *Veterinary Administrations* should require:

for egg products

the presentation of an *international veterinary certificate* attesting that the egg products:

- 1) are derived from eggs for consumption which meet the requirements of Articles 2.1.14.6., 2.1.14.6bis. or 2.1.14.6ter.; or
- 2) were processed to ensure the destruction of the NAI virus, and the necessary precautions were taken after processing to avoid contact of the commodity with any source of NAI virus.

Appendix XXIV (contd)

Article 2.1.14.8.

When importing from an NAI free country or zone/compartment, *Veterinary Administrations* should require:

for poultry semen

the presentation of an *international veterinary certificate* attesting that the donor birds:

- 1) showed no clinical sign of NAI on the day of semen collection;
- 2) were kept in an NAI free country or zone/compartment for the 28 21 days prior to semen collection.

Article 2.1.14.9.

Regardless of the NAI status of the country of origin, *Veterinary Administrations* should require:

for the importation of semen of birds other than poultry

the presentation of an *international veterinary certificate* attesting that the donor birds:

- 1) were kept in isolation approved by the Veterinary Services ~~quarantine~~ for the 28 21 days prior to semen collection;
- 2) showed no clinical sign of NAI during the isolation ~~quarantine~~ period;
- 3) were tested between 7 and 14 days prior to semen collection and shown to be free of NAI.

Article 2.1.14.10.

When importing from NAI free country or zone/compartment, *Veterinary Administrations* should require:

for fresh meat and meat products of poultry, and poultry viscera

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from birds:

- 1) which have been kept in an NAI free country or zone/compartment since they were hatched or for the past 28 21 days;
- 2) which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for NAI with favourable results.

Article 2.1.14.10bis.

When importing from a country or zone/compartment free from HPNAI infection, Veterinary Administrations should require:

for fresh meat and meat products of poultry (other than turkey)

the presentation of an international veterinary certificate attesting that the entire consignment of meat or meat product comes from birds:

- 1) which have been kept in an establishment since they were hatched or for the past 21 days in which there has been no clinical sign of NAI in the past 21 days;
- 2) which have been slaughtered in an approved abattoir and have been subjected to ante-mortem and post-mortem inspections for NAI with favourable results.

Article 2.1.14.10ter

When importing from a country or zone/compartiment not known to be free from HPNAI, *Veterinary Administrations* should require:

for *fresh meat* and *meat products* of poultry and poultry viscera (other than turkey)

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from birds:

- 1) which have been kept in a *free establishment*.
- 2) which have been tested to give a 95% probability of detecting a 5% prevalence of NAI infection not more than 7 days prior to slaughter using virus detection or virus isolation tests, and serological tests, with negative results in all cases;
- 3) which have been slaughtered in an *approved abattoir* which has not processed poultry infected with NAI since last cleaned and disinfected, and have been subjected to ante-mortem and post-mortem inspections for NAI with favourable results.

Article 2.1.14.11.

~~When importing from NAI free country or compartment, *Veterinary Administrations* should require:~~

~~for poultry viscera~~

~~the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from birds:~~

- ~~1) which have been kept in an NAI free country or compartment since they were hatched or for the past 28 days;~~
- ~~2) which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for NAI with favourable results.~~

Article 2.1.14.12.

When importing from a country or zone/compartment not known to be ~~considered~~ free from NAI, *Veterinary Administrations* should require:

for *fresh meat* and *viscera* of poultry turkey

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from birds:

- 1) which have been kept in a free establishment for at least 28 days and regularly inspected by the official veterinarian;
- 2) which have been tested to give a 95% probability of detecting a 5% prevalence of NAI infection not more than 7 days prior to slaughter using virus detection or virus isolation tests, and serological tests, with negative results in all cases;

Appendix XXIV (contd)

- 3) which have been slaughtered in an *approved abattoir* which has not processed poultry infected with NAI since last cleaned and disinfected, and have been subjected to ante-mortem and post-mortem inspections for NAI with favourable results.

Article 2.1.14.12 bis

~~When importing from a country or compartment free from clinical signs of NAI but not considered free from NAI infection, Veterinary Administrations should require:~~

~~for fresh meat of poultry~~

~~the presentation of an international veterinary certificate attesting that the entire consignment of meat comes from birds:~~

- ~~1) which have been kept in an country or compartment free from clinical signs of NAI but not considered free from NAI infection since they were hatched or for the past 28 days;~~
- ~~2) which have been slaughtered in an approved abattoir and have been subjected to ante-mortem and post-mortem inspections for NAI with favourable results.~~

Article 2.1.14.13.

When importing from country or zone/compartment not known to be considered free from NAI, *Veterinary Administrations* should require:

for ~~processed meat products~~ and processed viscera ~~and egg products~~ of poultry

the presentation of an *international veterinary certificate* attesting that:

- 1) the commodity is derived from fresh meat, meat products and/or viscera which meet the requirements of Articles 2.1.14.10., 2.1.14.10bis. or 2.1.14.10ter.; or
- 2) the commodity has been processed to ensure the destruction of the NAI virus, and the necessary precautions were taken after processing to avoid contact of the commodity with any source of NAI virus.

Article 2.1.14.14.

When importing from NAI free country or zone/compartment, *Veterinary Administrations* should require:

for products of poultry origin intended for use in animal feeding, or for agricultural or industrial use

the presentation of an *international veterinary certificate* attesting that these products come from birds which have been kept in an NAI free country or zone/compartment since they were hatched or for the past 28 21 days.

Article 2.1.14.15.

When importing from a country or zone/compartment not considered free from NAI, *Veterinary Administrations* should require:

for meal containing meat and/or feathers and/or bones (from poultry)

the presentation of an *international veterinary certificate* attesting that:

- 1) the commodity has been processed to ensure the destruction of the NAI virus;
- 2) the necessary precautions were taken after processing to avoid contact of the *commodity* with any source of NAI virus.

Appendix XXIV (contd)

Article 2.1.14.16.

When importing from a NAI free country or compartment, *Veterinary Administrations* should require:

for feathers and down (from poultry)

the presentation of an *international veterinary certificate* attesting that the entire consignment of feathers or down comes from birds which have been kept in an NAI free country or compartment since they were hatched or for the **past 21 28** days.

Article 2.1.14.17.

When importing from a country or compartment not **considered known to be** free from NAI, *Veterinary Administrations* should require:

for feathers and down (from poultry)

the presentation of an *international veterinary certificate* attesting that:

- 1) the commodity has been processed to ensure the destruction of the NAI virus;
- 2) the necessary precautions were taken after processing to avoid contact of the *commodity* with any source of NAI virus.

Article 2.1.14.18.

Regardless of the NAI status of the country of origin, *Veterinary Administrations* should require for the importation of:

meat or other products from birds other than poultry

the presentation of an *international veterinary certificate* attesting that:

- 1) the commodity has been processed to ensure the destruction of the NAI virus;
- 2) the necessary precautions were taken after processing to avoid contact of the *commodity* with any source of NAI virus.

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Original: English
September 2003

**REPORT OF THE MEETING OF THE OIE AD HOC GROUP
TO REVIEW THE BOVINE SPONGIFORM ENCEPHALOPATHY CHAPTER IN THE
OIE TERRESTRIAL ANIMAL HEALTH CODE**

Paris, 22-24 September 2003

The OIE *Ad hoc* Group to review the bovine spongiform encephalopathy (BSE) chapter in the OIE *Terrestrial Animal Health Code* (referred to in brief as “the *Ad hoc* Group”) met at the OIE Headquarters from 22 to 24 September 2003.

The members of the *Ad hoc* Group and other participants are listed in [Appendix I](#). The Agenda adopted is given in [Appendix II](#).

On behalf of Dr B. Vallat, Director General of the OIE, Dr A. Thiermann, President of the OIE Terrestrial Animal Health Standards Commission, welcomed the participants and thanked them for their willingness to work on some essential issues. He brought to the attention of participants the discussions on bovine spongiform encephalopathy (BSE) at the 2003 General Session, including the requests by Member Countries for a simplification of the BSE country categorisation system.

The *Ad hoc* Group noted that the OIE needed to continue to work closely with other international organisations such as the World Health Organization (WHO) to address animal and human health matters in the BSE chapter. Dr Thiermann described the collaborative work the OIE was engaged in with Codex in the OIE’s new mandate on animal production food safety, to address gaps and avoid duplicating international standards in this area. He also explained that the OIE is working with the WHO on the human health issues. The *Ad hoc* Group proposed to the Director General to maintain this cooperation in order to retain a well-balanced *Terrestrial Animal Health Code* (referred to in brief as the “*Terrestrial Code*”).

Some recent advances in the understanding of the infectivity of BSE were provided by Dr D. Matthews (see [Appendix III](#)) and they were used as a reference to revise the current *Terrestrial Code*.

The *Ad hoc* Group reiterated its position regarding references to other transmissible spongiform encephalopathies (TSEs) in the BSE chapter. It believed that it was necessary to retain these references to other TSEs, which remained relevant to theories of the origin of the BSE and concerns that sheep may have become infected with BSE. It emphasised that other TSEs should only be considered in the context of the risk they posed to BSE in cattle.

Appendix XXV (contd)

The *Ad hoc* Group discussed the issue of simplifying the BSE categorisation. First of all, the Group examined options for reduction of country status categories in the BSE chapter from five to three. Options for naming the categories were discussed, and included “negligible risk”, “controlled risk” (where a BSE risk had been identified or BSE cases had been detected and control measures were clearly in place) and “unclassified” (where control measures were not clearly in place, or where there were insufficient data to categorise the country). In the context of simplification of the *Terrestrial Code*, especially with respect to assisting countries in the current “provisionally free” category to enter a category of “negligible risk”, the *Ad hoc* Group believed that it was appropriate to emphasise the use of surveillance as specified in Appendix 3.8.4. to supplement data provided by risk assessments. This would enable surveillance data to be taken into account by any group tasked with evaluating categorisation as “negligible risk”, in addition to data available from the risk assessment, together with dates of implementation of control measures. The *Ad hoc* Group considered that additional targeted surveillance may allow a judgement on whether entry to a “negligible risk” category was possible in a period of time shorter than that specified in the *Terrestrial Code*. In addition, should some countries have insufficient data for an appropriate risk assessment, or should a country identify cases before there has been any implementation of statutory controls, the surveillance could again assist in either categorisation or defining a timetable for re-categorisation.

The *Ad hoc* Group revised some articles in the *Terrestrial Code* including the Appendix on surveillance, on the basis of the latest scientific information and comments from Argentina, Australia, Canada and the United States of America (USA), which had been examined in the Terrestrial Animal Health Standards Commission (referred to in brief as the “Code Commission”) meeting in July 2003.

Amendments proposed by the *Ad hoc* Group were as follows:

- 1) In Article 2.3.13.2, the terms “reviewed annually” were introduced as any risk assessment should take into account the current or revised conditions, and the latest scientific information. Regarding potential factors to be identified for risk assessment, reference to importation of embryos/oocytes was deleted because *in vivo* derived bovine embryos are regarded as a safe commodity and embryos from other species do not pose a direct risk of BSE in cattle.
- 2) Articles 2.3.13.3 and 2.3.13.5, regarding the treatment of affected cattle and their progeny, were revised to improve their consistency with other articles and to include more appropriate management procedures such as permanent identification and movement controls.
- 3) In Articles 2.3.13.5 and 2.3.13.6, regarding the calculation of the BSE incidence rate, an increased level of surveillance which complies with the combined requirements of Articles 3.8.4.2 and 3.8.4.3 was added to increase the reliability of the outcome. The cut-off limit was raised from one case per million to two cases per million taking into account the implementation of passive and active surveillance.
- 4) Article 2.3.13.8 was repositioned to follow Article 2.3.13.1 (to emphasise the need for risk-based decision-making) and modified to delete references to tallow and dicalcium phosphate, and to add a reference to restricted commodities. The *Ad hoc* Group recommended that tallow and dicalcium phosphate be deleted from the list of safe commodities after considering recent scientific evidence from the Scientific Steering Committee of the European Union (EU) and comments from the USA and the EU.
- 5) In Article 2.3.13.19 the lists of specific risk materials (SRMs) relating to moderate risk and high risk countries were combined; references to dorsal root ganglia and trigeminal ganglia were deleted as they were considered to fall within the term ‘skull and vertebral column’; thymus and spleen were considered safe while tonsils and intestine from cattle of all ages were considered to be unsafe for trade.
- 6) Appendix 3.8.4.
 - a) In “Introduction”, text was added to reinforce the importance of the risk assessment in determining country status and that surveillance should focus on the sub-population containing cattle displaying clinical signs consistent with BSE.

Appendix XXV (contd)

- b) The text was revised to give more guidance in understanding Table 1. The *Ad hoc* Group stressed that the requirements under Article 3.8.4.2 should be met first and, in the case of a shortfall, those of Article 3.8.4.3 should be met.
- c) In considering the scale of surveillance required in accordance with Article 3.8.4.3, empirical evidence suggested that many more animals would need to be tested in order to detect BSE in this sub-population in comparison with the effectiveness of surveillance of clinically affected animals (Article 3.8.4.2). Nevertheless, this population may be easier to target, and would serve as an appropriate reinforcement of surveillance of clinical cases.

Joint meeting

On the third day of the meeting, participants attended a joint meeting with the OIE *Ad hoc* Group for evaluation of country status for BSE in accordance with the *Terrestrial Code*. The joint meeting discussed ways of dealing with other TSEs in the risk assessment and with the requirement for a 7 year surveillance period for provisionally free status recognition.

The following issues were discussed:

- . the requests of Member Countries for a simplified BSE categorisation system;
- . clarification of the consideration of other TSEs in the risk assessment; and
- . strengthening the Appendix on surveillance.

Both *Ad hoc* Groups agreed that, regarding the evaluation of provisionally free countries, the required surveillance period of 7 years had a sound scientific basis and any shortening of that period needed to be balanced by appropriate surveillance for the period of implementation, to provide an equivalent level of assurance.

.../Appendices

**MEETING OF THE OIE AD HOC GROUP
TO REVIEW THE BOVINE SPONGIFORM ENCEPHALOPATHY CHAPTER IN THE
OIE TERRESTRIAL ANIMAL HEALTH CODE**

Paris, 22-24 September 2003

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**MEETING OF THE OIE AD HOC GROUP
TO REVIEW THE BOVINE SPONGIFORM ENCEPHALOPATHY CHAPTER IN THE
OIE TERRESTRIAL ANIMAL HEALTH CODE**

Paris, 22-24 September 2003

Adopted Agenda

1. Update on significant scientific advances on BSE and its relationship with other TSE's
 2. Discussion on the 2003 *Terrestrial Animal Health Code* Chapter and Appendix on BSE
 3. Any other issues
-

UPDATE ON SIGNIFICANT SCIENTIFIC ADVANCES ON BOVINE SPONGIFORM ENCEPHALOPATHY BY DR D. MATTHEWS

Dr D. Matthews provided an update on two key experiments that were of relevance to the chapter on bovine spongiform encephalopathy (BSE).

The attack rate studies at the Veterinary Laboratories Agency were intended to determine the minimum infectious dose (LD_{50}) following oral challenge. The first study had exposed four month old calves to doses ranging from 300g to 1g of BSE infected bovine brain. As this study had not reached an end point, with 7/10 calves dying of BSE in the 10g and 1g challenge groups, a further study had exposed calves to doses as low as 0.001g by mouth. Although still in progress, it was clear that doses as low as 0.01g had successfully infected calves. The additional data suggested that the ID_{50} could still be around 0.35g. Cross contamination of feed with such small amounts of mammalian meat-and-bone meal (MBM) were clearly difficult to prevent or detect.

In the continuing pathogenesis studies, an additional 12 months of data since the last BSE *Ad hoc* Group had strengthened the case for reconsideration of the list of tissues that should be defined as specific risk materials (SRMs). Central nervous system (CNS) tissues collected at 18, 22 and 26 months post oral exposure, and inoculated intracerebrally into calves, had not transmitted BSE to the challenged calves. CNS collected at 32 months post infection had killed the group of challenged calves with a mean incubation of 24 months. Although impossible to precisely define the time of entry of infectivity to the CNS on the basis of such limited data, the results do indicate that entry is later than seen in sheep or murine scrapie where it is traditionally considered to appear at approximately 50% of the incubation period.

No further cattle inoculated with tonsillar tissue had succumbed to BSE (1/5 collected at 10 months post-inoculation), and the remaining animals had now survived 12 months beyond the expected incubation period of 45 months. It remained possible that this result was due to residual oral inoculum lodged in the palatine tonsil used as inoculum. No infectivity had been detected in thymus collected during the pathogenesis study.

Nictitating membrane from naturally infected cattle, collected at the point of clinical disease, had also transmitted following intracerebral challenge of cattle, but once again the results were contradictory. The single calf to die had succumbed with an incubation of 31 months, but the remaining 4 cattle remained alive at 42 months post-inoculation.

There was still no evidence of infectivity in pooled muscle collected at 32 months post-inoculation (at a time when the CNS was both infectious and positive by immunohistochemistry). That assay had now been in progress 81 months. Similarly spleen was negative at 57, 62, 55, 54 months post challenge for tissues collected at 6, 10, 18, 26 months post-inoculation. This result reinforced earlier results where either pooled spleen or pooled peripheral lymph nodes from naturally infected cattle had failed to transmit to following intracerebral challenge of calves after a study lasting 110 months. Although the presence of infectivity could not be excluded, if present, it had to be at a titre of $<10^{-1}$ i.c. LD_{50}/g .

A summary of BSE in sheep pathogenesis studies indicated that in susceptible sheep, of genotype ARQ/ARQ, there was widespread distribution of infectivity within the gastrointestinal tract and lymphoid tissues, especially by the clinical phase of disease. In partially or fully resistant sheep (ARQ/ARR or ARR/ARR), there was no evidence of infectivity or immunostaining in the same range of tissues at 22 months post infection. Remaining animals were clinically healthy at 71 months post challenge.

CHAPTER 2.3.13.
BOVINE SPONGIFORM ENCEPHALOPATHY

Article 2.3.13.1.

The recommendations in this Chapter are intended to manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle (*Bos taurus* and *B. indicus*) only.

Article 2.3.13.1(bis)

The following commodities may be safely traded:

1) without BSE related restrictions and regardless of the BSE status of the country:

a) milk and milk products;

b) semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;

c) hides and skins (excluding hides and skins from the head);

d) gelatin and collagen prepared exclusively from hides and skins (excluding hides and skins from the head);

2) subject to the prescribed conditions relating to the BSE status of the cattle population of the exporting country or zone:

a) cattle;

b) fresh meat and meat products;

c) gelatin and collagen prepared from bones;

d) tallow and tallow derivatives, and dicalcium phosphate.

Article 2.3.13.2.

The BSE status of the cattle population of a country or zone can only be determined on the basis of the following criteria:

- 1) the outcome of a risk assessment reviewed annually identifying all potential factors for BSE occurrence and their historic perspective, in particular:
 - a) the potential for introduction and recycling of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin;
 - b) importation of *meat-and-bone meal* or *greaves* potentially contaminated with a transmissible spongiform encephalopathy (TSE) or feedstuffs containing either;
 - c) importation of animals ~~or embryos/oocytes (other than cattle embryos described in Article 2.3.13.8.)~~ potentially infected with a TSE;

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- d) epidemiological situation concerning all animal TSE in the country or zone;
 - e) extent of knowledge of the population structure of cattle, sheep and goats in the country or zone;
 - f) the origin and use of ruminant carcasses (including fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;
- 2) on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle to encourage reporting of all cases of neurological disease in adult cattle;
 - 3) compulsory notification and investigation of all cattle showing clinical signs compatible with BSE;
 - 4) a BSE surveillance and monitoring system with emphasis on risks identified in point 1) above, taking into account the guidelines in Appendix 3.8.4.; records of the number and results of investigations should be maintained for at least 7 years;
 - 5) examination in an approved laboratory of brain or other tissues collected within the framework of the aforementioned surveillance system.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 2.3.13.3.

BSE free country or zone

The cattle population of a country or zone may be considered free of BSE should the following conditions be met:

- 1) a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted and it has been demonstrated that appropriate measures have been taken for the relevant period of time to manage any risk identified;
- 2) either:
 - a) there has been no *case* of BSE; and either:
 - i) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years; or
 - ii) the criteria in point 3) of Article 2.3.13.2. have been complied with for at least 7 years and it has been demonstrated that for at least 8 years no *meat-and-bone meal* or *greaves* have been fed to ruminants;

OR

- b) all *cases* of BSE have been clearly demonstrated to originate directly from the importation of live cattle, and the affected cattle as well as, if these are females, all their progeny born within 2 years prior to and after clinical onset of the disease, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed ~~their last progeny born within 2 years prior to, or after, clinical onset of the disease, if alive in the country or zone, have been slaughtered and completely destroyed~~; and either:
 - i) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years; or

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- ii) the criteria in point 3) of Article 2.3.13.2. have been complied with for at least 7 years and it has been demonstrated that for at least 8 years no *meat-and-bone meal* or *greaves* have been fed to ruminants;

OR

- c) the last indigenous *case* of BSE was reported more than 7 years ago,
 - i) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years; and
 - ii) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced for at least 8 years; and
 - iii) the affected cattle as well as:
 - = if these are females, all their progeny born within 2 years prior to and after clinical onset of the disease, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed, and
 - = all cattle which, during their first year of life, were reared with the affected cattle during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or
 - = where the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the affected cattle
- if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed.

Article 2.3.13.4.

BSE provisionally free country or zone

The cattle population of a country or zone may be considered as provisionally free of BSE should the following conditions be met:

- 1) a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted and it has been demonstrated that appropriate measures have been taken for the relevant period of time to manage any risk identified;
- 2) either:
 - a) there has been no *case* of BSE; and either:
 - i) the criteria in points 2) to 5) of Article 2.3.13.2. are complied with, but have not been complied with for 7 years; or
 - ii) it has been demonstrated that for at least 8 years no *meat-and-bone meal* or *greaves* have been fed to ruminants, but the criteria in point 3) of Article 2.3.13.2. have not been complied with for 7 years;

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OR

- b) all *cases* of BSE have been clearly demonstrated to originate directly from the importation of live cattle, and the affected cattle as well as, if these are females, all their progeny born within 2 years prior to and after clinical onset of the disease, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed, ~~their last progeny born within 2 years prior to, or after, clinical onset of the disease, if alive in the country or zone, have been slaughtered and completely destroyed;~~ and either:
- i) the criteria in points 2) to 5) of Article 2.3.13.2. are complied with, but have not been complied with for 7 years; or
 - ii) it has been demonstrated that for at least 8 years no *meat-and-bone meal* or *greaves* have been fed to ruminants, but the criteria in point 3) of Article 2.3.13.2. have not been complied with for 7 years.

Article 2.3.13.5.

Country or zone with a minimal BSE risk

The cattle population of a country or zone may be considered as presenting a minimal BSE risk should the country or zone comply with the following requirements:

- 1) a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted and it has been demonstrated that appropriate measures have been taken for the relevant period of time to manage any risk identified;
- 2) EITHER:
 - a) the last indigenous *case* of BSE was reported more than 7 years ago, the criteria in points 2) to 5) of Article 2.3.13.2. are complied with and the ban on feeding ruminants with *meat-and-bone meal* and *greaves* derived from ruminants is effectively enforced, but:
 - i) the criteria in points 2) to 5) of Article 2.3.13.2. have not been complied with for 7 years; or
 - ii) the ban on feeding ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has not been effectively enforced for 8 years;

OR

- b) the last indigenous *case* of BSE has been reported less than 7 years ago, and the BSE incidence rate, measured using a level of surveillance which complies with the combined requirements of Articles 3.8.4.2. and 3.8.4.3., and calculated on the basis of indigenous cases, has been less than one two cases per million during each of the last four consecutive 12-month periods within the cattle population over 24 months of age in the country or zone (*Note: For countries with a population of less than one million adult cattle, the maximum allowed incidence should be expressed in cattle-years.*), and:
- i) the ban on feeding ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been effectively enforced for at least 8 years;
 - ii) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years;

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- iii) the affected cattle as well as:
- if these are females, all their progeny born within 2 years prior to and after clinical onset of the disease, if alive in the country or zone, **are permanently identified, and their movements controlled, and** when slaughtered or at death, are completely destroyed, and
 - all cattle which, during their first year of life, were reared with the affected cattle during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, or
 - where the results of **the** investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the affected cattle if alive in the country or zone, **are permanently identified, and their movements controlled, and** when slaughtered or at death, are completely destroyed.

Article 2.3.13.6.

Country or zone with a moderate BSE risk

The cattle population of a country or zone may be considered as presenting a moderate BSE risk if:

- 1) a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted, and the other criteria listed in Article 2.3.13.2. are complied with;
- 2) the BSE incidence rate has been **measured using a level of surveillance which complies with the requirements of Appendix 3.8.4., and is:**
 - a) if based only on surveillance in accordance with Article 3.8.4.2., greater than or equal to, one indigenous *case* per million and less than or equal to, one hundred indigenous *cases* per million within the cattle population over 24 months of age in the country or zone calculated over the past 12 months; or
 - b) if based on surveillance in accordance with Articles 3.8.4.2., 3.8.4.3. and 3.8.4.4., greater than, or equal to, **one two** indigenous *cases* per million and less than, or equal to, two hundred indigenous cases per million within the cattle population over 24 months of age in the country or zone calculated over the past 12 months; or
 - c) less than **one two** indigenous *cases* per million for less than four consecutive 12-month periods (*Note: For countries with a population of less than one million adult cattle, the maximum allowed incidence should be expressed in cattle-years.*);
- 3) the affected cattle as well as:
 - a) if these are females, all their progeny born within 2 years prior to and after clinical onset of the disease, if alive in the country or zone, **are permanently identified, and their movements controlled, and** when slaughtered or at death, are completely destroyed, and
 - b) all cattle which, during their first year of life, were reared with the affected cattle during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, or
 - c) where the results of **the** investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the affected cattle, if alive in the country or zone, **are permanently identified, and their movements controlled, and** when slaughtered or at death, are completely destroyed.

Appendix XXV (contd)Appendix IV (contd)

Countries and zones where the BSE incidence rate has been less than one indigenous *case* per million within the cattle population over 24 months of age during each of the last four consecutive 12-month periods, but where at least one of the other requirements to be considered as provisionally free from BSE or as presenting a minimal BSE risk is not complied with, shall be considered as countries or zones with a moderate BSE risk.

Article 2.3.13.7.

Country or zone with a high BSE risk

The cattle population of a country or zone may be considered as presenting a high BSE risk if it cannot demonstrate that it meets the requirements of another category.

~~Article 2.3.13.8.~~

~~Regardless of the BSE status of the *exporting country*, *Veterinary Administrations* should authorise without restriction the import or transit through their territory of the following *commodities*:~~

- ~~1) *milk and milk products*;~~
- ~~2) *semen and in vivo derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society*;~~
- ~~3) *protein free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow*;~~
- ~~4) *dicalcium phosphate (with no trace of protein or fat)*;~~
- ~~5) *hides and skins*;~~
- ~~6) *gelatin and collagen prepared exclusively from hides and skins*;~~

Article 2.3.13.9.

When importing from a BSE free country or zone, *Veterinary Administrations* should require:

for all *commodities* from cattle not listed in Article 2.3.13.8.

the presentation of an *international veterinary certificate* attesting that the country or zone complies with the conditions in Article 2.3.13.3. to be considered as free of BSE.

Article 2.3.13.10.

When importing from a BSE provisionally free country or zone, *Veterinary Administrations* should require:

for *cattle*

the presentation of an *international veterinary certificate* attesting that:

- 1) the country or zone complies with the conditions in Article 2.3.13.4. to be considered as provisionally free of BSE;
- 2) cattle selected for export are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspect or confirmed females.

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Article 2.3.13.11.

When importing from a country or zone with a minimal BSE risk, *Veterinary Administrations* should require:

for cattle

the presentation of an *international veterinary certificate* attesting that:

- 1) the country or zone complies with the conditions in Article 2.3.13.5. to be considered as presenting a minimal BSE risk;
- 2) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;
- 3) cattle selected for export:
 - a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspect or confirmed females exposed cattle as described in point 2) b) iii) of Article 2.3.13.5.
 - b) were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been effectively enforced.

Article 2.3.13.12.

When importing from a country or zone with a moderate BSE risk, *Veterinary Administrations* should require:

for cattle

the presentation of an *international veterinary certificate* attesting that:

- 1) the country or zone complies with the conditions in Article 2.3.13.6. to be considered as presenting a moderate BSE risk;
- 2) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;
- 3) cattle selected for export:
 - a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspect or confirmed females exposed cattle as described in point 3) of Article 2.3.13.6.
 - b) were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been effectively enforced.

Article 2.3.13.13.

When importing from a country or zone with a high BSE risk, *Veterinary Administrations* should require:

for cattle

the presentation of an *international veterinary certificate* attesting that:

- 1) the country or zone complies with the conditions in Article 2.3.13.7. to be considered as presenting a high BSE risk;

Appendix XXV (contd)Appendix IV (contd)

- 2) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;
- 3) all affected cattle as well as:
 - a) if these are females, all their progeny born within 2 years prior to and after clinical onset of the disease, if alive in the country or zone, **are permanently identified, and their movements controlled, and** when slaughtered or at death, are completely destroyed, and
 - b) all cattle which, during their first year of life, were reared with the affected cattle during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, or
 - c) where the results of **an the** investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the affected cattle, if alive in the country or zone, **are permanently identified, and their movements controlled, and** when slaughtered or at death, are completely destroyed;
- 4) cattle selected for export:
 - a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspect or confirmed females;
 - b) were born at least 2 years after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants was effectively enforced.

Article 2.3.13.14.

When importing from a BSE provisionally free country or zone, *Veterinary Administrations* should require:

for fresh meat (bone-in or deboned) and meat products from cattle

the presentation of an *international veterinary certificate* attesting that:

- 1) the country or zone complies with the conditions in Article 2.3.13.4. to be considered as provisionally free of BSE;
- 2) ante-mortem inspection is carried out on all cattle from which the meat or *meat products* destined for export originate.

Article 2.3.13.15.

When importing from a country or zone with a minimal BSE risk, *Veterinary Administrations* should require:

for fresh meat (bone-in or deboned) and meat products from cattle

the presentation of an *international veterinary certificate* attesting that:

- 1) the country or zone complies with the conditions in Article 2.3.13.5. to be considered as presenting a minimal BSE risk;
- 2) ante-mortem inspection is carried out on all cattle from which the meat or *meat products* destined for export originate;

Appendix XXV (contd)Appendix IV (contd)

- 3) cattle from which the meat or *meat products* destined for export originate were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process (laceration, after stunning, of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity);
- 4) the *fresh meat* and *meat products* destined for export do not contain brain, eyes, spinal cord or mechanically separated meat from skull and vertebral column from cattle over 30 months of age, all of which have been removed in a hygienic manner.

Article 2.3.13.16.

When importing from a country or zone with a moderate BSE risk, *Veterinary Administrations* should require:

for *fresh meat* (bone-in or deboned) and *meat products* from cattle

the presentation of an *international veterinary certificate* attesting that:

- 1) the country or zone complies with the conditions in Article 2.3.13.6. to be considered as presenting a moderate BSE risk;
- 2) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;
- 3) ante-mortem inspection is carried out on all bovines;
- 4) cattle from which the meat or *meat products* destined for export originate were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process;
- 5) the *fresh meat* and *meat products* destined for export do not contain **brain, eyes, spinal cord, distal ileum** **the tissues listed in point 1) of Article 2.3.13.19.** nor mechanically separated meat from skull and vertebral column from cattle over 6 months of age, all of which have been removed in a hygienic manner.

Article 2.3.13.17.

When importing from a country or zone with a high BSE risk, *Veterinary Administrations* should require:

for *fresh meat* and *meat products* from cattle

the presentation of an *international veterinary certificate* attesting that:

- 1) the country or zone complies with the conditions in Article 2.3.13.7. to be considered as presenting a high BSE risk;
- 2) the meat destined for export does not contain the tissues listed in point 1) of Article 2.3.13.19., all of which have been removed in a hygienic manner;
- 3) the meat destined for export, if obtained from animals over 9 months of age, has been deboned and does not contain nervous and lymphatic tissues exposed during a deboning process, all of which have been removed in a hygienic manner;
- 4) the *meat products* destined for export are derived from deboned meat and do not contain the tissues listed in point 1) of Article 2.3.13.19. nor nervous and lymphatic tissues exposed during a deboning process, nor mechanically separated meat from skull and vertebral column of bovine animals, all of which have been removed in a hygienic manner;

Appendix XXV (contd)Appendix IV (contd)

- 5) a system is in operation enabling the *fresh meat* and *meat products* destined for export to be traced back to the *establishments* from which they are derived;
- 6) ante-mortem inspection is carried out on all bovines;
- 7) the cattle from which the *meat* or *meat products* destined for export originate:
 - a) were identified by a permanent identification system enabling them to be traced back to the dam and herd of origin;
 - b) are not the progeny of BSE suspect or confirmed females; and either:
 - i) were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been effectively enforced; or
 - ii) were born, raised and had remained in herds in which no *case* of BSE had been confirmed for at least 7 years;
 - c) were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process;
- 8) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;
- 9) all affected cattle as well as:
 - a) if these are females, all their progeny born within 2 years prior to and after clinical onset of the disease, if alive in the country or zone, **are permanently identified, and their movements controlled, and** when slaughtered or at death, are completely destroyed, and
 - b) all cattle which, during their first year of life, were reared with the affected cattle during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, or
 - c) where the results of **an the** investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the affected cattle, if alive in the country or zone, **are permanently identified, and their movements controlled, and** when slaughtered or at death, are completely destroyed.

Article 2.3.13.18.

Ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products, which originate from countries with a minimal, moderate or high BSE risk should not be traded between countries.

Article 2.3.13.19.

- 1) From cattle originating from a country or zone with **a moderate or** a high BSE risk, that were at the time of slaughter over **6 12** months of age, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, **tonsils, thymus, spleen, intestines, dorsal root ganglia, trigeminal ganglia,** skull and vertebral column, and **derived protein products derived from the preceding.** Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

Appendix XXV (contd)Appendix IV (contd)

- 2) From cattle of all ages originating from a country or zone with a moderate or a high BSE risk, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: tonsils and intestine, and protein products derived from them.

From cattle, originating from a country or zone with a moderate BSE risk, that were at the time of slaughter over 6 months of age, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, distal ileum, skull, vertebral column and derived protein products. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

- 3) From cattle, originating from a country or zone with a minimal BSE risk, that were at the time of slaughter over 30 months of age, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes and spinal cord, skull, vertebral column and derived protein products. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

Article 2.3.13.20.

Veterinary Administrations of importing countries should require:

for gelatin and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that the bones came from:

- 1) a BSE free or provisionally free country or zone, or from a country or zone with a minimal BSE risk; or
 - 2) a country or zone with a moderate BSE risk; and
 - a) skulls and vertebrae (excluding tail vertebrae) have been excluded;
 - b) the bones have been subjected to a process which includes all the following steps:
 - i) pressure washing (degreasing),
 - ii) acid demineralisation,
 - iii) prolonged alkaline treatment,
 - iv) filtration,
 - v) sterilisation at $\geq 138^{\circ}\text{C}$ for a minimum of 4 seconds,
- or to an equivalent process in terms of infectivity reduction.

Article 2.3.13.21.

Veterinary Administrations of importing countries should require:

for tallow and dicalcium phosphate (other than protein free tallow as defined in Article 2.3.13.8.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

Appendix XXV (contd)Appendix IV (contd)

the presentation of an *international veterinary certificate* attesting that it originates from:

- 1) a BSE free or provisionally free country or zone, or
- 2) a country or zone with a minimal BSE risk, and it originates from cattle which have been subjected to an ante-mortem inspection for BSE with favourable results and has not been prepared using the tissues listed in point 3 of Article 2.3.13.19., or
- 3) a country or zone with a moderate BSE risk, and it originates from cattle which have been subjected to an ante-mortem inspection for BSE with favourable results and has not been prepared using the tissues listed in point 2 of Article 2.3.13.19.

Article 2.3.13.22.

Veterinary Administrations of importing countries should require:

for tallow derivatives (other than those made from protein free tallow as defined in Article 2.3.13.8.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that:

- 1) they originate from a BSE free or provisionally free country or zone, or from a country or zone with a minimal BSE risk;

OR

- 2) they have been produced by hydrolysis, saponification or transesterification using high temperature and pressure.

Article 2.3.13.23.

Careful selection of source materials is the best way to ensure maximum safety of ingredients or reagents of bovine origin used in the manufacture of medicinal products.

Countries wishing to import bovine materials for such purposes should therefore consider the following factors:

- 1) the BSE status of the country and herd(s) where the animals have been kept, as determined under the provisions of Articles 2.3.13.2. to 2.3.13.7.;
- 2) the age of the donor animals;
- 3) the tissues required and whether or not they will be pooled samples or derived from a single animal.

Additional factors may be considered in assessing the risk from BSE, including:

- 4) precautions to avoid contamination during collection of tissues;
- 5) the process to which the material will be subjected during manufacture;
- 6) the amount of material to be administered;
- 7) the route of administration.

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APPENDIX 3.8.4.

SURVEILLANCE AND MONITORING SYSTEMS FOR
BOVINE SPONGIFORM ENCEPHALOPATHY

Article 3.8.4.1.

Introduction

Surveillance for bovine spongiform encephalopathy (BSE) has at least two goals: to determine whether BSE is present in the country, and, if present, to monitor the extent and evolution of the epizootic, thus aiding control measures and monitoring their effectiveness.

The cattle population of a country or zone not free from BSE, will comprise the following sub-populations in order of decreasing size:

1. cattle not exposed to the infective agent;
2. cattle exposed but not infected;
3. infected cattle, which may lie within one of three stages in the progress of BSE:
 - a) the majority will die or be killed before reaching a stage at which BSE is detectable by current methods;
 - b) some will progress to a stage at which BSE is detectable by testing before clinical signs of disease appear;
 - c) the smallest number will show clinical signs of disease.

A surveillance programme on its own cannot guarantee BSE status and should be determined by, and commensurate with the outcome of the risk assessment referred to in Article 2.3.13.2. and should take into account the diagnostic limitations associated with the above sub-populations and the relative distributions of infected animals among them.

Surveillance programmes developed before the advent of rapid diagnostic tests focused on the sub-population containing cattle displaying clinical signs compatible with BSE as described in Article 3.8.4.2. While surveillance should focus on the sub-population containing cattle displaying clinical signs consistent with BSE as described in Article 3.8.4.2, this sub-population Where it is difficult to access all cattle displaying such clinical signs, investigation of other sub-populations using the new diagnostic techniques may provide a more accurate picture of the BSE situation in the country or zone. A surveillance strategy programme may therefore need to combine several strategies. Recommended strategies for surveying the various sub-populations are described below.

Available data suggest the possibility that a gradient might be established to describe the relative value of surveillance applied to each sub-population. All countries should sample sub-populations identified in Articles 3.8.4.2. and 3.8.4.3. In countries where surveillance of cattle identified in Article 3.8.4.2. is unable to generate the numbers recommended in Table 1, surveillance should be enhanced by testing larger numbers of cattle identified in Article 3.8.4.3. Any shortfall in In addition, the first two sub-populations should be addressed by the surveillance can be complemented by sampling of normal cattle over 30 months of age at slaughter according to Article 3.8.4.4. Exclusive dependence on random sampling from normal cattle is not recommended, unless the number of samples examined annually is statistically sufficient to detect a disease prevalence of 1 in 1,000,000.

Appendix XXV (contd)Appendix V (contd)

Surveillance for BSE requires laboratory examination of samples in accordance with the methods described in the *Terrestrial Manual*.

For surveillance purposes, testing a part of the population is consistent with Chapter 1.3.6. on surveillance and monitoring of animal health.

Article 3.8.4.2.

Examination of cattle displaying clinical signs consistent with bovine spongiform encephalopathy

Cattle affected by illnesses that are refractory to treatment, and displaying progressive behavioural changes such as excitability, persistent kicking when milked, changes in herd hierarchical status, hesitation at doors, gates and barriers, as well as those displaying progressive neurological signs without signs of infectious illness are candidates for examination. Since BSE causes no pathognomonic clinical signs, all countries with cattle populations will observe individual animals displaying with compatible clinical signs consistent with BSE. It should be recognised that cases may display only some of these signs, which may also vary in severity, and such animals should still be investigated as potential BSE affected animals.

Table 1 indicates the minimum number of animals exhibiting one or more clinical signs of BSE that should be subjected to diagnostic tests according to the total cattle population over 30 months of age. The calculations assume a prevalence of one BSE clinically affected animal per one million adult cattle; a mortality rate not exceeding one percent per year in adult cattle; and a prevalence of central nervous system (CNS) signs not exceeding one percent within dying cattle.

As this sampling is not random, and as the mortality rate and prevalence of CNS signs within dying cattle may vary, the numbers indicated in this table are a subjective interpretation rather than a strict statistical deduction. This table should only be employed as a general guideline. Sampling in excess of the number indicated, ideally extending towards all cattle over 30 months of age showing clinical signs consistent with BSE, would give greater confidence in the outcome and is to be encouraged. In those cases, where there is a shortfall in the number of samples required under this article, the difference may be made up by any combination of samples defined under Articles 3.8.4.3 and 3.8.4.4.

Table 1. Minimum number of annual investigations of cattle showing clinical signs consistent with BSE required for effective surveillance according to the total cattle population over 30 months of age

Total cattle population over 30 months of age	Minimum number of samples to examine
500,000	50
700,000	69
1,000,000	99
2,500,000	195
5,000,000	300
7,000,000	336
10,000,000	367
20,000,000	409
30,000,000	425
40,000,000	433

* Need to develop numbers for populations lower than 500,000

Appendix XXV (contd)

Appendix V (contd)

Article 3.8.4.3.

Examination of targeted cattle displaying clinical signs not necessarily indicative of bovine spongiform encephalopathy

Cattle **over 30 months of age** that have died or have been killed for reasons other than routine slaughter should be examined. This population will include cattle which have died on farm or in transit, 'fallen stock', and stock sent for emergency slaughter.

Many of these cattle may have exhibited some of the clinical signs listed in Article 3.8.4.2. which were not recognised as being **compatible consistent** with BSE. Experience in countries where BSE has been identified indicates that this population is the second most appropriate population to target in order to detect BSE. **Empirical evidence indicates that surveillance conducted on one clinical suspect from Article 3.8.4.2. is equivalent to that conducted on 100 or more animals in this category in terms of its ability to detect BSE within an infected cattle population. This factor should be applied in calculating the minimum sample size in this category to substitute for any shortfall in the sample numbers specified in Article 3.8.4.2.**

Article 3.8.4.4.

Examination of cattle subject to normal slaughter

In countries not free from BSE, sampling at routine slaughter **of cattle over 30 months of age** is a means of monitoring the progress of the epizootic and the efficacy of control measures applied, because it offers continuous access to a cattle population of known class, age structure and geographical origin. **Empirical evidence indicates that surveillance conducted on one clinical suspect from Article 3.8.4.2. is equivalent to that conducted on 5,000 to 10,000 animals in this category in terms of its ability to detect BSE within an infected cattle population. This factor should be applied in calculating the minimum sample size in this category to substitute for any shortfall in the sample numbers specified in Articles 3.8.4.2 and 3.8.4.3.**

Within each of the above sub-populations, countries may wish to target cattle identifiable as imported from countries or zones not free from BSE, cattle which have consumed potentially contaminated feedstuffs from countries or zones not free from BSE, offspring of BSE affected cows and cattle which have consumed feedstuffs potentially contaminated with other TSE agents.

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Original: English
November 2003

REPORT OF THE MEETING OF THE OIE AD HOC GROUP ON AVIAN INFLUENZA

Paris, 12-14 November 2003

The OIE *Ad hoc* Group on avian influenza met at the OIE Headquarters from 12 to 14 November 2003.

The members of the OIE *Ad hoc* Group and other participants are listed in [Appendix I](#). The Agenda adopted is given in [Appendix II](#).

On behalf of the Director General of the OIE, Dr D. Wilson welcomed the experts and thanked them for their willingness to address the requests from Member Countries to work further on revising the chapter of the OIE *Terrestrial Animal Health Code* (hereafter referred to as the “*Terrestrial Code*”) on avian influenza (AI).

An updated document outlining the latest information on avian influenza, drawn up by several members of the *Ad hoc* Group, is at [Appendix III](#).

Based on the epidemiology of the disease, avian commodities usually traded and the comments received from Member Countries, the *Ad hoc* Group revised the proposals made at its previous meeting ([Appendix IV](#)).

The *Ad hoc* Group discussed the definition of AI and the consequent reporting obligations of Member Countries, and revised the definition taking into account the essential link with the concept of compartmentalisation in assessing the risks associated with trade. The *Ad hoc* Group noted that a geographical approach to an outbreak of AI was still relevant but that an approach based on management was an additional option for Member Countries.

In addressing different disease control strategies, the *Ad hoc* Group recognised vaccination as a useful tool to support eradication and set guidelines for trade in commodities from vaccinated poultry.

The *Ad hoc* Group revised the commodity articles, taking into account the biological differences between low pathogenic notifiable avian influenza (LPNAI) and highly pathogenic notifiable avian influenza (HPNAI) regarding the likelihood of transmission of virus via various commodities and the likely consequences.

The *Ad hoc* Group reviewed Article 2.1.14.2, recognising the need for targeted surveillance. It considered that targeted surveillance should focus on areas of high poultry density (especially turkeys), free-range poultry and establishments lying along wild bird migration pathways. The *Ad hoc* Group felt, however, that it did not have the expertise to define detailed surveillance guidelines and strongly encouraged Member Countries to propose such guidelines to the OIE for examination by appropriate experts.

Appendix XXVI (contd)

The *Ad hoc* Group recognised that fresh meat and table eggs probably present a much lower likelihood of transmitting LPNAI than HPNAI viruses, but, due to incomplete scientific data, the recommendations proposed for these commodities only partly reflect this difference. The *Ad hoc* Group addressed this difference through a proposed new definition for ‘*NAI-free establishment*’ which distinguishes between the two regarding permitted distances from establishments infected with LPNAI or HPNAI.

Articles 2.1.14.5 and 2.1.14.6 were combined as the *Ad hoc* Group believed that the focus in both should be on the health status of the parent flock.

Regarding destruction of the NAI virus, the *Ad hoc* Group recognised that parameters for destruction were dependent on virus strain, virus concentration and commodity characteristics, and noted that sufficient up-to-date scientific data were unavailable for most virus strains and the majority of commodities.

The *Ad hoc* Group considered that recent developments in knowledge of the virus necessitated the text in the *Terrestrial Manual* on virus detection / isolation being reviewed.

Measures for commodities for human consumption address both the likelihood of transmission to other birds and the public health aspects. Birds with previous or current infections are not permitted to be traded, nor are meat nor eggs from such birds. The *Ad hoc* Group noted that only two episodes of H9N2 virus infection had been reported in humans (consisting of two and five cases), despite the widespread occurrence of this subtype in poultry, especially in Asia; as a result, it did not take that subtype into account in its recommendations.

.../Appendices

MEETING OF THE OIE *AD HOC* GROUP ON AVIAN INFLUENZA

Paris, 12-14 November 2003

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MEETING OF THE OIE *AD HOC* GROUP ON AVIAN INFLUENZA

Paris, 12-14 November 2003

Agenda adopted

- 1) Update on scientific and epidemiological information on avian influenza
 - 2) Examination of comments from OIE Member Countries
 - 3) Examination of revisions proposed by the Bureau of the OIE Terrestrial Animal Health Standards Commission
 - 4) Other issues
-

AVIAN INFLUENZA – Brief Review

Introduction

The severe form of avian influenza [AI] termed highly pathogenic [HPAI], at one time known as "fowl plague", is throughout the world one of the two most feared diseases of poultry and other birds. This is not only because of the devastation it may cause, with flock mortality of up to 100%, but also the economic impact that may ensue due to trading restrictions and embargoes placed on infected areas. Many countries, including all those in the European Union, enforce statutory control measures in the event of outbreaks of either disease [CEC 1992] and it is recognised as an OIE list A disease.

Aetiology

Influenza viruses are segmented, negative strand RNA viruses that are placed in the family Orthomyxoviridae and are divided into three types of influenza virus, A, B and C, which now have genus status. Only influenza A viruses have been reported to cause natural infections of birds. Type A influenza viruses are further divided into subtypes based on the antigenic relationships in the surface glycoproteins haemagglutinin (HA) and neuraminidase (NA). At present 15 HA subtypes (H1-H15) and nine neuraminidase subtypes (N1-N9) have been recognised. Each virus has one H and one N antigen, apparently in any combination. Although the range of subtypes and combinations occurring naturally in mammals appears to be restricted, all subtypes and the majority of possible combinations have been isolated from avian species.

Host Range

Although influenza viruses have been isolated from a large number of species covering 12 of the 50 Orders of birds (Stallknecht, 1998), the number, variety and widespread distribution of influenza viruses has been far greater in waterfowl, Order Anseriformes, than in other birds. In the surveys listed by Stallknecht and Shane (1988) a total of 21,318 samples from all species resulted in the isolation of 2,317 (10.9%) viruses. Of these samples 14,303 were from birds of the Order Anseriformes and yielded 2,173 (15.2%) isolates. The next highest isolation rates were 2.9% and 2.2% from the Passeriformes and Charadriiformes respectively and the overall isolation rate from all birds other than ducks and geese was 2.1%. However, in shorebirds and gulls, the predominant influenza viruses are of subtypes different to those in waterfowl. Each year waterfowl congregate in huge flocks, usually on lakes, before migratory flights are undertaken. Data from the 3-year study by Hinshaw et al., (1980) on ducks congregating on lakes in Alberta, Canada prior to their southern migration showed that influenza virus isolation rates from juvenile ducks may exceed 60%. The perpetuation of influenza viruses in free-living waterfowl is probably related to the passage of virus from adult to juvenile birds on lakes where the birds congregated before migration. Considerable quantities of the virus are excreted with the faeces, estimated up to $10^{8.7}$ mean egg infectious doses per g of faeces from infected ducks (Webster et al., 1978). This contaminates lake or pond water, to the extent that virus may be isolated from untreated lake water where large numbers of waterfowl are found.

Phylogenetic studies (Rohm et al., 1995; Banks et al., 2000a,b) of AI viruses show that lineages and clades of isolates are more related to geographical and temporal parameters than the host from which they were isolated and there is no distinction between wild and domestic bird isolates.

HPAI viruses have been isolated rarely from free-living birds and, apart from tern/S.Africa/61, when they have been isolated it has usually been close to known outbreaks in poultry.

Appendix XXVI (contd)Appendix III (contd)**Disease**

Influenza A viruses infecting poultry can be divided into two distinct groups on the basis of their ability to cause disease. The very virulent viruses HPAI in which mortality may be as high as 100%. These viruses have been restricted to subtypes H5 and H7, although not all viruses of these subtypes cause HPAI. There have been 19 reported primary isolates of such viruses from domestic poultry since 1959 (Table 1). All other viruses cause a much milder disease consisting primarily of mild respiratory disease, depression and egg production problems in laying birds. Sometimes other infections or environmental conditions may cause exacerbation of influenza infections leading to much more serious disease. For example, in outbreaks of LPAI in Italy in 1999, high mortality was often recorded in young turkeys, reaching 97% in one flock (Capua et al., 2000).

Molecular basis of virulence

The haemagglutinin (HA) glycoprotein for influenza viruses has two important functions that are imperative for the infectivity of the virus. First it brings about attachment to host cell and then fusion between the host cell membrane and the virus membrane so that the viral genetic material is introduced into the host cell. This glycoprotein is produced as a precursor, HA0, which requires post translational cleavage by host proteases before it is able to induce membrane fusion and virus particles become infectious (Rott, 1992). The HA0 precursor proteins of avian influenza viruses of low virulence for poultry have a single arginine at the cleavage site and another at position -3 or -4. These viruses are limited to cleavage by host proteases such as trypsin-like enzymes and thus restricted to replication at sites in the host where such enzymes are found, i.e. the respiratory and intestinal tracts. HPAI viruses possess multiple basic amino acids [arginine and lysine] at their HA0 cleavage sites either as a result of apparent insertion or apparent substitution (Vey et al, 1992, Wood et al, 1993, Senne et al, 1996) and appear to be cleavable by a ubiquitous protease[s], probably one or more proprotein-processing subtilisin-related endoproteases of which furin is the leading candidate (Stieneke-Grober et al., 1992). These viruses are able to replicate throughout the bird, damaging vital organs and tissues which results in disease and death (Rott, 1992). For example, all H7 subtype viruses of low virulence have had the amino acid motif at the HA0 cleavage site of either -PEIPKGR*GLF- or -PENPKGR*GLF-, whereas examples of cleavage site amino acid motifs for HPAI H7 viruses are: -PEIPKKKKR*GLF-, -PETPKRKRKR*GLF-, -PEIPKKREKR*GLF-, -PETPKRRRR*GLF-, -PEIPKGSRVRR*GLF-. The last example, from the Italian 1999-2000 outbreaks had what was considered the minimum requirement of two basic amino acids at position -1 and -2 plus a basic amino acid a -4.

Although the first 18 HPAI viruses in Table 1 have multiple basic amino acid motifs as do all HPAI viruses sequenced that were isolated prior to 1959, this is not true of the viruses isolated from the HPAI outbreaks in Chile in 2002. The H7N3 viruses isolated in these outbreaks had motifs with insertion of 11 amino acids but without the apparent minimum requirement of basic amino acids, as their sequences were either PEKPKTCSPLSRCRETR*GLF (4372) or PEKPKTCSPLSRCRKTR*GLF (4957).

Current theories suggest that AI subtype H5 and H7 viruses of high virulence emerge from viruses of low virulence by mutation (Garcia et al, 1996, Perdue et al., 1998) although there must be more than one mechanism by which this occurs. This is supported by phylogenetic studies of H7 subtype viruses, which indicate that HPAI viruses do not constitute a separate phylogenetic lineage or lineages, but appear to arise from non-pathogenic strains (Rohm et al., 1995; Banks et al., 2000a) and the *in vitro* selection of mutants virulent for chickens from an avirulent H7 virus (Li et al., 1990). It appears that such mutations occur only after the viruses have moved from their natural host to poultry.

Spread

Spread of AI viruses is related chiefly to the excretion of high concentrations of virus in the faeces of infected birds. All the indications for HPAI are that the viruses of H5 or H7 subtype are introduced initially from feral birds as viruses of low virulence and then they subsequently mutate to virulence. It follows that important control measures that can be taken are to prevent the introduction of LPAI viruses, prevent their spread and, if mutation to HPAI does take place, to prevent the spread of HPAI viruses.

Primary Introduction

All available evidence suggests that primary introduction of AI viruses into an area is by wild birds, usually waterfowl, but gulls and shorebirds have also been implicated. This may not necessarily involve direct contact as infected waterfowl may take the viruses to an area and these may then be introduced to poultry by a variety of mechanisms that may transfer the virus mechanically in infective faeces and respiratory secretions. Surface water used for drinking water may also be contaminated with influenza viruses and a source of infection. The occurrence of AI outbreaks in poultry is consistent with this: (1) there is a higher prevalence of infection of poultry on migratory waterfowl routes, e.g. Minnesota in USA, Norfolk in England; (2) there is a higher prevalence of infection of poultry kept in exposed conditions, e.g. turkeys on range, ducks on fattening fields; (3) surveillance studies in areas such as Minnesota have shown the same variation in virus subtypes in sampled waterfowl and turkey outbreaks; (4) influenza outbreaks show a seasonal occurrence in high-risk areas, which coincides with migratory activity; (5) in most documented specific outbreaks evidence has been obtained of probable waterfowl contact at the initial site.

Although waterfowl and other wild birds appear to be responsible, albeit indirectly, for most influenza introductions to domestic poultry, other possibilities should not be ruled out. For example, it seems highly likely that H1N1 viruses may pass readily between pigs, humans and turkeys and the introduction of viruses of this subtype to turkey flocks from infected pigs has been well documented.

Since wild birds are a source for primary introduction of AI viruses, it is preferable to design farms practices to minimise direct or indirect contact with wild birds. Since one of the major reservoirs of influenza viruses is in migratory waterfowl, ideally commercial farms should be located away from migratory routes. However, in many countries, particularly USA, Italy and other European countries at least part of the poultry industry has evolved, possibly from hunting origins, so that the greatest concentrations correspond precisely to these flyways. Similarly, poultry may be less likely to become infected with AI viruses if kept indoors (Lang, 1982), but there are strong pressures to rear them on range and for some species, e.g. ostriches, this is a necessity. Rearing of several species on the same farm, especially with one or more reared outdoors, is also a practice likely to attract infected wild birds and result in transfer of infective faeces inside. Use of surface drinking water and the presence of lakes that attracted waterfowl close to the farms were associated with the HPAI outbreaks in Australia (Westbury, 1998). On what was the index farm in the catastrophic outbreaks in Pennsylvania in 1983/4 the farmer had created an artificial pond to keep ducks and attract wild waterfowl (Webster and Kawaoka, 1988).

Appendix XXVI (contd)Appendix III (contd)*Secondary spread*

Secondary spread of AI viruses is mainly by mechanical transfer of infective faeces, in which virus may be present at high concentrations and may survive for considerable periods (Utterback, 1984). Birds or other animals that are not themselves susceptible to infection may become contaminated and spread the virus. Shared water or food may also become contaminated. However, for domestic poultry the main source of secondary spread is man. In several specific accounts of HPAI infections strong evidence has implicated the movements of caretakers, farm owners and staff, trucks and drivers moving birds or delivering food, and artificial inseminators in the spread of virus both on to and through a farm (Wells 1963; Homme et al., 1970; Halvorson et al., 1980; Alexander and Spackman, 1981; Glass et al., 1981).

Vaccination

In some countries, vaccines designed to contain or prevent HPAI are specifically banned or discouraged by government agencies because they may interfere with stamping out control policies. However, most HPAI control regulations reserve the right to use vaccines in emergencies.

There is little doubt, both in experiments and in the field, that if birds are sufficiently well immunised against the HA subtype corresponding to that of the challenge virus they will be protected from the worst effects of HPAI and the clinical disease and mortalities associated with LPAI. There is therefore economic pressure to invest in vaccination to insure against a potential short term but significant economic loss whenever there is a perceived threat from AI. However, conversely the high cost of vaccination, since it is necessary to inject inactivated avian influenza virus or live recombinant fowlpox-avian influenza vaccines, means there is economic pressure to stop once the threat has lessened.

The existence of a large number of virus subtypes together with the known variation of different strains within a subtype pose serious problems when selecting strains to produce influenza vaccines. In addition, some isolates do not grow to a sufficiently high titre to produce adequately potent vaccines without costly prior concentration. The vaccines produced have either been autogenous, i.e. prepared from isolates specifically involved in an epizootic, or have been prepared from viruses possessing the same haemagglutinin subtype that yield high concentrations of antigen. In the USA, some standardisation of the latter has been carried out in that the National Veterinary Services Laboratories have propagated and hold influenza viruses of each subtype for use as seed virus in the preparation of inactivated vaccines (Bankowski, 1985). The vaccines used extensively in the USA (Halvorson, 1998) and in Italy (D'Aprile, 1986) against viruses of low pathogenicity, and against HPAI in Mexico (Garcia et al., 1998) and Pakistan (Naeem, 1998) have been prepared from infective allantoic fluid inactivated by betapropiolactone or formalin and emulsified with mineral oil.

Recently vaccines have been developed employing new technologies such as baculovirus derived H5 and H7 haemagglutinins (Crawford et al., 1999) and fowl poxvirus recombinants expressing H7 haemagglutinin (Boyle et al., 2000).

In the USA since the 1970s there has been widespread use of inactivated vaccines produced under special licence on a commercial basis (Halvorson, 1998; McCapes & Bankowski, 1987; Price, 1982). These vaccines have been used primarily in turkeys against viruses that are not highly pathogenic but which may cause serious problems, especially in exacerbating circumstances. Significant quantities of vaccine have been used in Minnesota to protect turkeys against LPAI (Halvorson, 1998) This involves prediction and/or early detection of

Appendix XXVI (contd)Appendix III (contd)

the subtype likely to cause problems each year for incorporation into the vaccine. Vaccine uptake has varied considerably and generally reflected the number of outbreaks of LPAI or the cost of LPAI to the industry. The 178 outbreaks of LPAI caused primarily by virus of H9N2 subtype occurring in turkeys in Minnesota 1995 resulted in the highest loss recorded of over US\$ 6,000,000 (Halvorson et al., 1998).

Since July 1995, the use of vaccines of H5 or H7 subtype had been restricted in the USA, but they have been used within a control programme under federal, state and industry control (Myers & Morgan, 1998). Inactivated vaccine was prepared from the LPAI virus of H7N3 responsible for a series of outbreaks in turkeys in Utah in 1995 and used, with other measures, to bring the outbreaks under control (Halvorson et al., 1998).

Outside the USA, vaccination against AI has not been used widely or consistently. Zanella et al., (1981) described the production and testing of inactivated vaccines intended to combat the respiratory problems seen in turkeys in NE Italy and associated with LPAI influenza infections. Papparella et al., (1995,1996) reported that while vaccination against AI was only allowed officially in Italy in certain specific circumstances (i.e. as a ring vaccine), inactivated vaccines against H6N2 and H9N2, strains considered enzootic in Italian turkeys, were in common use in breeder birds. Werner (1999) reported use in turkeys of an inactivated vaccine to protect against H9N2 virus.

An inactivated H5N2 vaccine was used in Mexico as a result of the widespread HPAI outbreaks caused by H5N2 virus that began in December 1994 (Villareal & Flores 1997). Between the beginning of 1995 and May 1997 847 million doses of vaccine were licensed for use. Beginning in 1998, recombinant fowlpox vectored vaccine with avian influenza H5 gene insert has been used in Mexico, El Salvador and Guatemala. Inactivated H7N3 vaccine was also used extensively in Pakistan following the widespread HPAI outbreaks in 1995 (Naeem, 1998).

Recently in Italy an inactivated vaccine containing an H7N3 virus was used to vaccinate against a LPAI virus of H7N1 subtype. This enabled infected birds to be distinguished from vaccinated birds using a test to detect antibodies to N1 (Capua et al, 2002).

Zoonotic potential

Influenza is a highly contagious, acute illness in humans for which there are recognisable accounts of epidemics dating back to ancient times. In the 20th century the sudden emergence of antigenically different strains in humans, termed *antigenic shift*, occurred on 4 occasions, 1918 (H1N1), 1957 (H2N2), 1968 (H3N2) and 1977 (H1N1), resulting in pandemics. Frequent epidemics have occurred between the pandemics as a result of accumulated point mutations in the prevalent virus leading to gradual antigenic change, termed *antigenic drift*, which in turn results in infections in a proportion of the population that has become immunologically susceptible. The intra-pandemic influenza epidemics may have a considerable impact on a given population as a result of significant mortality, especially amongst the elderly and other vulnerable groups, and the severe economic cost associated with debilitating illness in a large portion of the population. However, the true influenza pandemics are unmistakable and by far the worst influenza pandemic was the one beginning in 1918. It has been estimated that during the pandemic between 20 to 40 million people died.

Appendix XXVI (contd)Appendix III (contd)

The RNA of influenza A viruses consists of 8 distinct segments that code for 10 proteins. Because the viral RNA is segmented, genetic reassortment can occur in mixed infections with different strains of influenza A viruses. This means that when two viruses infect the same cell, progeny viruses may inherit sets of RNA segments made up of combinations of segments identical to those of either of the parent viruses. This gives a theoretical possible number of 2^8 (=256) different combinations that can form a complete set of RNA segments from a dual infection, although in practice only a few progeny virions possess the correct gene constellation required for viability. Demonstration that the H3N2 1968 pandemic virus differed from the 1957-1968 H2N2 virus in the substitution of two genes, PB1 and the important surface glycoprotein HA gene, with genes almost certainly from an influenza virus of avian origin, led to the suggestion that antigenic shift occurred as a result of reassortment of genes in dual infections with viruses of human and avian origin (Fang et al., 1981; Kawaoka et al., 1989). However, although volunteer experiments had shown that transitory infections resulted when humans were infected with viruses of avian origin (Beare & Webster, 1991), no natural infections of humans with avian viruses had been reported. It was clear that there was some barrier to the establishment of avian influenza viruses in the human population that was related to one or more of the genome segments. Both human and avian viruses are known to infect pigs readily. It was, therefore, suggested that pigs acted as "mixing vessels" in which reassortment between human and avian influenza viruses could take place with the emergence of viruses with the necessary genome segments(s) from the virus of human origin to allow replication and spread in the human population, but with a different haemagglutinin surface glycoprotein, so that the human population could be regarded as immunologically naïve (Scholtissek, et al., 1985). This theory was also thought to account for the apparent emergence of pandemics in the 20th century in the Far East where agricultural practices mean high concentrations of people, pigs and waterfowl live closely together (Shortridge & Stuart-Harris, 1982).

However, in the last 6 years avian influenza virus infections of humans have been detected on four occasions, with three different subtypes.

In 1996 an H7N7 virus was isolated in England from the eye of a woman with conjunctivitis who kept ducks. This virus was shown to be genetically closest in all 8 genes to viruses of avian origin and to have >98% nucleotide homology in the HA gene with a virus of H7N7 subtype isolated from turkeys in Ireland in 1995 (Banks et al., 1998).

In May 1997 a virus of H5N1 subtype was isolated from a young child who died in Hong Kong and by December 1997 the same virus was confirmed by isolation to have infected 18 people, six of whom died (Shortridge et al., 2000). There was evidence of very limited human to human spread of this virus (Buxton Bridges et al., 2000), but clearly the efficiency of transmission must have been extremely low. There have been no new cases since December 1997. The viruses isolated from the human cases appeared to be identical to viruses first isolated from chickens in Hong Kong in March 1997 following an outbreak of highly pathogenic disease. Both human and avian isolates possess multiple basic amino acids at the HA0 cleavage site (Suarez et al., 1998).

In recent years outbreaks in poultry due to viruses of H9 subtype, usually H9N2, have been widespread. During the second half of the 1990s outbreaks, due to H9N2 subtype have been reported in Germany, Italy, Ireland, South Africa, USA, Korea, China, the Middle East, Iran and Pakistan (Banks et al., 2000b). These have often been associated with widespread and serious disease problems in commercial chickens. In March 1999 two independent isolations of influenza virus subtype H9N2 were made from girls aged one and 4 who recovered from flu-like illnesses in Hong Kong (Peiris et al., 1999a; 1999b). Subsequently, 5 isolations of H9N2 virus from humans on mainland China in August 1998 were reported.

Appendix XXVI (contd)Appendix III (contd)

The obvious inference is that the very high mortality, 6/18, amongst the people infected with the H5N1 virus in Hong Kong was because the virus was capable of systemic infection due to the presence of multiple basic amino acids at the HA0 cleavage site. This would allow cleavage to be mediated by a furin-like protease(s) and the virus to spread systemically. However, evidence that this was the case is lacking. Generally, the 18 patients presented with severe respiratory symptoms. For those that died, several of whom were vulnerable due to complicating medical conditions present prior to infection, pneumonia appeared to be the main cause as it often is in deaths occurring as a result of infections with influenza viruses “normally” in the human population. A serological survey after the outbreak identified 17% seroprevalence in poultry workers in Hong Kong but without any known occurrence of clinical disease.

The isolation of the H7 virus from the woman with conjunctivitis was fortuitous, the first isolation of H5N1 in Hong Kong as a result of the death of the patient and all other isolates of avian viruses from humans resulted from enhanced awareness and surveillance exercises. In all these cases there was no evidence of human to human spread except with the H5N1 infections where there was evidence of very limited spread. This is in keeping with the finding that all these viruses possessed all eight genes of avian origin. It may well be that infection of humans with avian influenza viruses occurs much more frequently than originally assumed, but due to their limited effect go unrecognised. For the human population as a whole the main danger appears to be if people infected with an “avian” virus are infected simultaneously with a “human” influenza virus. In such circumstances reassortment could occur with the potential emergence of a virus fully capable of spread in the human population, but with an HA for which the human population was immunologically naive. Presumably this represents a very rare coincidence, but one which could result in a true influenza pandemic.

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Appendix XXVI (contd)

Appendix III (contd)

Table 1: Primary HPAI virus isolates from poultry* since 1959

1.	A/chicken/Scotland/59 (H5N1)
2.	A/turkey/England/63 (H7N3)
3.	A/turkey/Ontario/7732/66 (H5N9)
4.	A/chicken/Victoria/76 (H7N7)
5.	A/chicken/Germany/79 (H7N7)
6.	A/turkey/England/199/79 (H7N7)
7.	A/chicken/Pennsylvania/1370/83 (H5N2)
8.	A/turkey/Ireland/1378/83 (H5N8)
9.	A/chicken/Victoria/85 (H7N7)
10.	A/turkey/England/50-92/91 (H5N1)
11.	A/chicken/Victoria/1/92 (H7N3)
12.	A/chicken/Queensland/667-6/94 (H7N3)
13.	A/chicken/Mexico/8623-607/94 (H5N2)
14.	A/chicken/Pakistan/447/94 (H7N3)
15.	A/chicken/NSW/97 (H7N4)
16.	A/chicken/Hong Kong/97 (H5N1)
17.	A/chicken/Italy/330/97 (H5N2)
18.	A/turkey/Italy/99 (H7N1)
19.	A/chicken/Chile/2002 (H7N3)
20.	A/chicken/The Netherlands/2003 (H7N7)

* Where outbreaks were widespread and affecting more than one species, the isolate from the first outbreak identified is listed.

CHAPTER 2.1.14. AVIAN INFLUENZA

Article 2.1.14.1.

For the purposes of this *Code*, avian influenza (AI) is defined as ‘an infection of poultry caused either by any influenza A virus which has an IVPI in 6-week-old chickens greater than 1.2 or by an influenza A virus of H5 or H7 subtype’.

For the purposes of this *Terrestrial Code*, notifiable avian influenza (NAI) is defined as an infection of poultry caused by any influenza A virus of the H5 or H7 subtypes or by any AI virus with an intravenous pathogenicity index (IVPI) greater than 1.2 (or as an alternative at least 75% mortality) as described below. NAI viruses can be divided into highly pathogenic notifiable avian influenza (HPNAI) and low pathogenicity notifiable avian influenza (LPNAI):

- 1) HPNAI viruses have an IVPI in 6-week-old chickens greater than 1.2 or, as an alternative, cause at least 75% mortality in 4 to 8 week-old chickens infected intravenously. H5 and H7 viruses which do not have an IVPI of greater than 1.2 or cause less than 75% mortality in an intravenous lethality test should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0); if the amino acid motif is similar to that observed for other HPNAI isolates, the isolate being tested should be considered as HPNAI.
- 2) LPNAI are all Influenza A viruses of H5 and H7 subtype that are not HPNAI viruses.

Poultry is defined as ‘all birds reared or kept in captivity for the production of meat or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds’.

For the purpose of *international trade*, this chapter deals not only with the occurrence of clinical signs caused by NAI virus, but also with the presence of infection with NAI virus in the absence of clinical signs. Articles dealing with trade in *commodities* recommend different sanitary measures, depending on the presence or absence of clinical signs.

The following defines the occurrence of AI virus infection:

- 1) ~~AI virus has been isolated and identified as such from poultry or a product derived from poultry, or~~
- 2) ~~viral antigen or viral RNA specific to H5 or H7 subtype of AI virus has been identified in samples from poultry or a product derived from poultry, or~~
- 3) ~~antibodies to H5 or H7 subtype of AI virus that are not a consequence of vaccination have been detected in poultry.~~

The following defines the occurrence of NAI virus infection:

- 1) HPNAI virus has been isolated and identified as such or specific viral RNA has been detected in poultry or a product derived from poultry, or
- 2) LPNAI virus has been isolated and identified as such or specific viral RNA has been detected in poultry or a product derived from poultry, or

Appendix XXVI (contd)Appendix IV (contd)

- 3) antibodies to H5 or H7 subtype of NAI virus that are not a consequence of vaccination, nor indicative of a non-specific reaction, have been detected in poultry; in such cases, virus isolation should be attempted to establish whether the serological positivity is due to LPNAI or HPNAI; if appropriate samples are not available or if results are negative, this should be regarded as LPNAI.

NAI free establishment means an establishment in which there has been no clinical sign of NAI for the past 21 days; and which is not situated within 3 kilometres of an establishment infected with HPNAI and within one kilometre of an establishment infected with LPNAI.

For the purposes of this *Terrestrial Code*, the *incubation period* for NAI shall be ~~28~~ 21 days.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Any vaccine used should comply with the standards described in the *Terrestrial Manual*.

Article 2.1.14.1.bis

The NAI status of a country or compartment can be determined on the basis of the following criteria:

- 1) the outcome of a risk assessment identifying all potential factors for NAI occurrence and their historic perspective;
- 2) NAI is notifiable in the whole country, an on-going NAI awareness programme is in place, and all notified suspect occurrences of NAI are subjected to field and, where applicable, laboratory investigations;
- 3) appropriate surveillance is in place to demonstrate the presence of infection in the absence of clinical signs in poultry, and the risk posed by birds other than poultry; this may be achieved through an NAI surveillance programme in accordance with this chapter and Chapter 1.3.6.

Article 2.1.14.2.

NAI free country or compartment

A country or compartment may be considered free from NAI when it has been shown that NAI infection has not been present for the past 12 months. If ~~a stamping out policy is applied~~ infected poultry are slaughtered, this period shall be ~~6~~ 3 months after the slaughter of the last infected poultry.

The NAI status should be determined by an ongoing surveillance and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) based on virus isolation, virus detection or serology. The programme may need to be adapted to target parts of the country or compartment at a higher risk due to historical or geographical factors, population data, or proximity to recent outbreaks.

Appendix XXVI (contd)

Appendix IV (contd)

Freedom of infection in a country or zone can be demonstrated with random and/or targeted serological surveillance at a minimum interval of 6 months designed to provide at least a 95% level of confidence of detecting a prevalence of NAI infected enterprises of 1%. Freedom of infection in an enterprise can be demonstrated with an ongoing surveillance programme designed to provide at least a 95% level of confidence of detecting a prevalence of NAI infection of 10%. Each establishment should be sampled to provide a 95% level of confidence of detecting a prevalence of NAI of 20%. For commercial ducks the surveillance programme should be based on virus isolation or detection in the absence of validated serological methods.

In the case of a country or zone in which vaccination is being conducted, the ongoing surveillance and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) based on virus isolation, virus detection or serology should be carried out on all vaccinated flocks at a minimum interval of 6 months. In each vaccinated flock, the number of birds to be tested should provide at least a 95% level of confidence of detecting a prevalence of NAI infection of 20%. In the case of an enterprise in which vaccination is being conducted, the ongoing surveillance and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) based on virus isolation, virus detection or serology should be carried out to provide at least a 95% level of confidence of detecting a prevalence of NAI infection of 10%. If a serological test is used, it should be able to distinguish vaccinated birds from infected birds. Additional security should be provided by the use of relevant serological tests in identifiable sentinel birds which can be tested to help identify field infections in vaccinated flocks.

Article 2.1.14.3.

When importing from an NAI free country or compartment, *Veterinary Administrations* should require:

for live poultry (other than day-old poultry)

the presentation of an *international veterinary certificate* attesting that the poultry:

- 1) showed no clinical sign of NAI on the day of shipment;
- 2) were kept in an NAI free country or compartment since they were hatched or for the past ~~28~~ 21 days;
- 3) either have not been vaccinated against NAI, or have been vaccinated and the date of vaccination and the details of the vaccine are stated.

~~[Note: If the poultry were vaccinated against NAI, the nature of the vaccine used and the date of vaccination should be stated in the certificate.]~~

Article 2.1.14.4.

Regardless of the NAI status of the country of origin, *Veterinary Administrations* should require:

for the importation of live birds other than poultry

the presentation of an *international veterinary certificate* attesting that the birds:

- 1) showed no clinical sign of NAI on the day of shipment;
- 2) were kept in isolation approved by the Veterinary Services ~~a quarantine station~~ since they were hatched or for the ~~28~~ 21 days prior to shipment and showed no clinical sign of NAI during the isolation ~~quarantine~~ period;

Appendix XXVI (contd)Appendix IV (contd)

3) were subjected to a diagnostic test 7 to 14 days prior to shipment to demonstrate freedom from NAI.

Article 2.1.14.5.

When importing from an NAI free country or compartment, *Veterinary Administrations* should require:

for day-old live poultry

the presentation of an *international veterinary certificate* attesting that the poultry:

- 1) ~~showed no clinical sign of NAI on the day of shipment;~~
- 2) were kept in an NAI free country or compartment since they were hatched;
- 3) were derived from parent flocks which had been kept in an NAI free country or compartment for 21 days prior to the collection of the eggs;
- 4) and/or the parent flock had/had not been vaccinated.

(Note: If the day-old poultry or the parents of the poultry were vaccinated against NAI, the details of the vaccine and the date of vaccination should be provided.)

Article 2.1.14.5.bis.

When importing from an NAI free country or compartment, *Veterinary Administrations* should require:

for hatching eggs

the presentation of an *international veterinary certificate* attesting that the eggs:

- 1) came from an NAI free country or compartment;
- 2) were derived from parent flocks which had been kept in an NAI free country or compartment for 21 days prior to the collection of the eggs;
- 3) were derived from parent flocks which had not been vaccinated against NAI, or had been vaccinated against NAI and the date of vaccination and the details of the vaccine are stated.

Article 2.1.14.6.

When importing from an NAI free country or compartment, *Veterinary Administrations* should require:

for hatching eggs or eggs for consumption

the presentation of an *international veterinary certificate* attesting that the eggs come from an NAI free country or compartment.

Article 2.1.14.6.bis.

When importing from a country or compartment not considered free from NAI, *Veterinary Administrations* should require:

for eggs for consumption

the presentation of an *international veterinary certificate* attesting that the entire consignment of eggs comes from birds:

Appendix XXVI (contd)Appendix IV (contd)

- 1) which have been kept in an NAI free establishment;
- 2) which have been tested serologically or by virus detection to give a 95% probability of detecting a 5% prevalence of NAI infection, every 21 days, with negative results.

Article 2.1.14.7.

When importing from an NAI free country or compartment, *Veterinary Administrations* should require:

for egg products

the presentation of an *international veterinary certificate* attesting that the egg products come from, and were processed in, an NAI free country or compartment.

Article 2.1.14.8.

When importing from an NAI free country or compartment, *Veterinary Administrations* should require:

for poultry semen

the presentation of an *international veterinary certificate* attesting that the donor birds:

- 1) showed no clinical sign of NAI on the day of semen collection;
- 2) were kept in an NAI free country or compartment for the ~~28~~ 21 days prior to semen collection.

Article 2.1.14.9.

Regardless of the NAI status of the country of origin, *Veterinary Administrations* should require:

for the importation of semen of birds other than poultry

the presentation of an *international veterinary certificate* attesting that the donor birds:

- 1) were kept in isolation approved by the *Veterinary Services* quarantine for the ~~28~~ 21 days prior to semen collection;
- 2) showed no clinical sign of NAI during the isolation quarantine period;
- 3) were tested between 7 and 14 days prior to semen collection and shown to be free of NAI.

Article 2.1.14.10.

When importing from NAI free country or compartment, *Veterinary Administrations* should require:

for fresh meat and processed meat of poultry, and poultry viscera

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from birds:

- 1) which have been kept in an NAI free country or compartment since they were hatched or for the past ~~28~~ 21 days;
- 2) which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for NAI with favourable results.

Appendix XXVI (contd)Appendix IV (contd)

Article 2.1.14.11.

When importing from NAI free country or compartment, *Veterinary Administrations* should require:

for poultry viscera

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from birds:

- 1) which have been kept in an NAI free country or compartment since they were hatched or for the past 28 days;
- 2) which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for NAI with favourable results.

Article 2.1.14.12.

When importing from a country or compartment not considered free from NAI, *Veterinary Administrations* should require:

for fresh meat and viscera of poultry

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from birds:

- 1) which have been kept in a *free establishment* for at least 28 days and regularly inspected by the official veterinarian;
- 2) which have been tested to give a 95% probability of detecting a 5% prevalence of NAI infection not more than 7 days prior to slaughter using virus detection or virus isolation tests, and serological tests, with negative results in all cases;
- 3) which have been slaughtered in an *approved abattoir* which has not processed poultry infected with NAI since last cleaned and disinfected, and have been subjected to ante-mortem and post-mortem inspections for NAI with favourable results.

Article 2.1.14.12 bis

When importing from a country or compartment free from clinical signs of NAI but not considered free from NAI infection, *Veterinary Administrations* should require:

for fresh meat of poultry

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from birds:

- 1) which have been kept in an country or compartment free from clinical signs of NAI but not considered free from NAI infection since they were hatched or for the past 28 days;
- 2) which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for NAI with favourable results.

Appendix XXVI (contd)

Appendix IV (contd)

Article 2.1.14.13.

When importing from country or compartment not considered free from NAI, *Veterinary Administrations* should require:

for processed meat, viscera and egg products of poultry

the presentation of an *international veterinary certificate* attesting that:

- 1) the commodity is derived from fresh meat and/or viscera which meets the requirements of Article 2.1.14.12.; or
- 2) the commodity is derived from eggs for consumption which meet the requirements of Article 2.1.14.6.bis; or
- 3) the commodity has been processed to ensure the destruction of the NAI virus, and the necessary precautions were taken after processing to avoid contact of the commodity with any source of NAI virus.

Article 2.1.14.14.

When importing from NAI free country or compartment, *Veterinary Administrations* should require:

for products of animal origin (from poultry) intended for use in animal feeding, or for agricultural or industrial use

the presentation of an *international veterinary certificate* attesting that these products come from birds which have been kept in an NAI free country or compartment since they were hatched or for the past ~~28~~ 21 days.

Article 2.1.14.15.

When importing from a country or compartment not considered free from NAI, *Veterinary Administrations* should require:

for meal containing meat and/or feathers and/or bones (from poultry)

the presentation of an *international veterinary certificate* attesting that:

- 1) the commodity has been processed to ensure the destruction of the NAI virus;
- 2) the necessary precautions were taken after processing to avoid contact of the commodity with any source of NAI virus.

Article 2.1.14.16.

When importing from an NAI free country or compartment, *Veterinary Administrations* should require:

for feathers and down (from poultry)

the presentation of an *international veterinary certificate* attesting that the entire consignment of feathers or down comes from birds which have been kept in an NAI free country or compartment since they were hatched or for the past ~~21~~ 28 days.

Article 2.1.14.17.

When importing from a country or compartment not considered free from NAI, *Veterinary Administrations* should require:

for feathers and down (from poultry)

the presentation of an *international veterinary certificate* attesting that that:

- 1) the commodity has been processed to ensure the destruction of the NAI virus;

Appendix XXVI (contd)

Appendix IV (contd)

- 2) the necessary precautions were taken after processing to avoid contact of the commodity with any source of NAI virus.

Article 2.1.14.18.

Regardless of the NAI status of the country of origin, *Veterinary Administrations* should require for the importation of meat or other products from birds other than poultry

the presentation of an *international veterinary certificate* attesting that:

- 1) the commodity has been processed to ensure the destruction of the NAI virus;
- 2) the necessary precautions were taken after processing to avoid contact of the commodity with any source of NAI virus.

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Original: English
September 2003

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON TERRESTRIAL ANIMAL DISEASE / PATHOGENIC AGENT NOTIFICATION

Paris, 10-12 September 2003

The OIE *Ad hoc* Group on terrestrial animal disease/ pathogenic agent notification (“the *Ad hoc* Group”) met at the OIE Headquarters from 10-12 September 2003.

The members of the *Ad hoc* Group and other participants are listed in [Appendix I](#). The terms of reference are given in [Appendix II](#).

Dr Vallat, Director-General of the OIE, welcomed the participants and thanked them for accepting his invitation to be members of the group. He explained that resolutions adopted by the Regional Commissions and by the International Committee instructed the OIE Central Bureau to work on establishing a single list of animal diseases after proposing criteria for inclusion or exclusion of a disease from the list. He asked the Group to propose some modifications to the Code Chapter on animal disease notification and epidemiological information.

The *Ad hoc Group* considered that there were two main tasks at hand for its first meeting:

- 1) Firstly, the defining of list of specific criteria according to which terrestrial animal diseases would be classified as ‘specific hazards’ in line with WTO SPS terminology and entered in the OIE disease list; and
- 2) Secondly, the definition of a set of criteria according to which the ‘urgency’ of reporting of diseases on the list would be applied. In tandem with this, there would also need to be some re-design of the current reporting system to accommodate the new criteria – this would be handled at a later meeting.

The *Ad hoc Group* decided to begin with the first task, i.e. that of defining the properties of diseases/pathogens for inclusion in the list and that urgency of reporting would be dealt with separately.

The *Ad hoc Group* drew on existing proposals submitted by member countries and on the work of the Aquatic Diseases Group in determining the criteria. It was decided to avoid the use of “scoring” as this was too subjective and thus open to controversy.

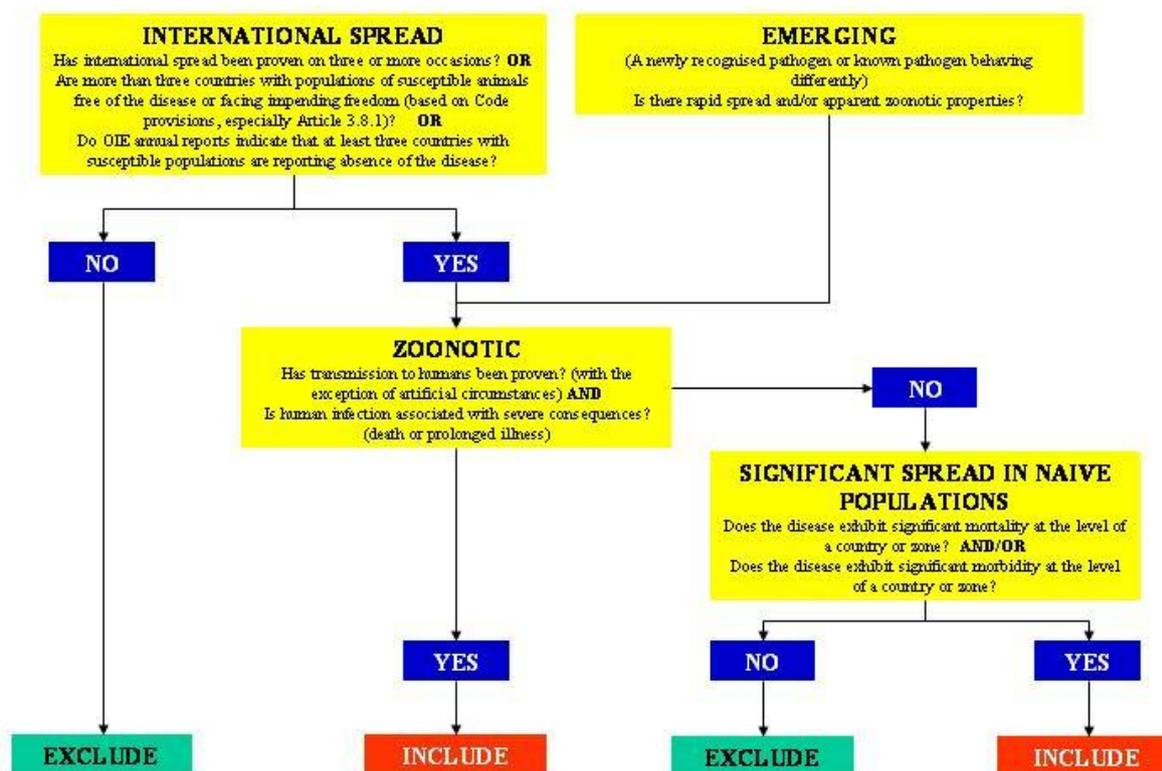
Appendix XXVII (contd)

1. Criteria

- a) Criteria were kept to a minimum of easily definable factors. It was reasoned that in considering criteria such as significant spread and zoonotic potential, economic and social issues were being adequately addressed, while the overriding concern would be the potential of a disease for international spread.
- b) The economic impact of a disease is linked directly to its morbidity and mortality. While various economic tools are available for the evaluation of disease impact, these have not been widely enough applied for accurate comparisons to be made between diseases. Mortality and morbidity have, however, been well measured over time.
- c) In terms of the social importance of diseases, their zoonotic effects were considered to be of prime importance. Where diseases disrupt social norms this is once again due to morbidity and mortality.
- d) Further economic effects, such as trade restrictions and the imposition of control measures, are a function of various epidemiologic parameters, such as spread, morbidity, mortality and zoonotic potential.
- e) One or more parameters were connected to each criterion; if a disease was in agreement with at least one of the given parameters, then the criterion was considered to be fulfilled. In cases where the ability of a disease to meet a criterion was considered dependent on a variety of circumstances not always directly connected to the properties of the pathogen, the “worst case” scenario was used.
- f) The criteria proposed are tabulated below.

Basic Criteria (always considering “worst case” scenario)	Parameters (at least one “yes” answer means that the criterion has been met)
International Spread	Has international spread been proven on three or more occasions? OR Are more than three countries with populations of susceptible animals free of the disease or facing impending freedom (based on Code provisions, especially Article 3.8.1)? OR Do OIE annual reports indicate that a significant number of countries with susceptible populations have reported absence of the disease for several consecutive years?
Significant Spread within Naïve Populations	Does the disease exhibit significant mortality at the level of a country or compartment? AND/OR Does the disease exhibit significant morbidity at the level of a country or compartment?
Zoonotic Potential	Has transmission to humans been proven? (with the exception of artificial circumstances) AND Is human infection associated with severe consequences? (death or prolonged illness)
Emerging Diseases (A newly recognised pathogen or known pathogen behaving differently)	Is there rapid spread with morbidity/mortality and/or apparent zoonotic properties?

- g) These criteria are plotted on a “decision tree” as shown below. A disease fulfilling each of the criteria in order from top downward on the tree is included in the list; a disease that does not meet certain key criteria is excluded.



- h) Following the setting of the criteria for the establishment of a new list of OIE diseases, the *Ad hoc Group* gave some thought (see tables below) to examples of diseases that may be included. The drawing-up of a final list awaits review by OIE Member Countries of the abovementioned criteria.

Testing the Criteria for List Inclusion

A number of diseases were tested against the proposed criteria and their parameters, following the decision tree. Examples are as follows (shaded cells indicate diseases that would qualify for listing on the basis of their international spread and zoonotic potential alone):

Appendix XXVII (contd)

Current List A diseases

Criterion	Parameter	FMD	RVF	NCD	VS	SVD
International spread	Proven spread, or	+	+	+		+
	Three countries free / impending free, or	+	+	+	+	+
	Three countries with disease absence in OIE reports	+	+	+	+	+
Zoonotic potential	Proven transmission to humans and severe consequences		+		-	
Significant spread in naïve populations	Significant mortality, or	-		+		
	Significant morbidity	+		+	+	+
Outcome		Listed	Listed	Listed	Listed	Listed

Criterion	Parameter	Rinderpest	PRP	CBPP	LSD	Bluetongue
International spread	Proven spread, or	+	+	+	+	+
	Three countries free / impending free, or	+	+	+	+	+
	Three countries with disease absence in OIE reports	+	+	+	+	+
Zoonotic potential	Proven transmission to humans and severe consequences	-	-	-	-	-
Significant spread in naïve populations	Significant mortality, or	+	+	+	-	+
	Significant morbidity	+	+	+	+	+
Outcome		Listed	Listed	Listed	Listed	Listed

Appendix XXVII (contd)

Criterion	Parameter	Sheep + goat pox	AHS	ASF	CSF	HPAI
International spread	Proven spread, or	+	+	+	+	+
	Three countries free /impending free, or	+	+	+	+	+
	Three countries with disease absence in OIE reports	+	+	+	+	+
Zoonotic potential	Proven transmission to humans and severe consequences	-	-	-	-	+
Significant spread in naïve populations	Significant mortality, or	+	+	+	+	
	Significant morbidity	+	+	+	+	
Outcome		Listed	Listed	Listed	Listed	Listed

Some examples of current List B diseases

Criterion	Parameter	Aujeszky's	Anthrax	BSE	Pullorum	Campylobact.	Hydatidosis	Horse mange	CEM	Varroasis	Scrapie
International spread	Proven spread, or	+	+	+	+	+		+	+	+	+
	Three countries free /impending free, or	+	-	+	+	+	+		+	+	+
	Three countries with disease absence in OIE reports	+	+	+	+	+	+	+	+	+	+
Zoonotic potential	Proven transmission to humans and severe consequences	-	+	+	-	-	+	-	-	-	-
Significant Spread in naïve populations	Significant mortality, or	+			+	-		-	-	+	+
	Significant morbidity	+			+	+		+	+	+	+
Outcome		Listed	Listed	Listed	Listed	Listed	Listed	Listed	Listed	Listed	Listed

Appendix XXVII (contd)**Some currently unlisted diseases**

Criterion	Parameter	Hendra/ Nipah	West Nile	BVD	Strangles	Small beehive beetle	Footrot	Listeriosis
International spread	Proven spread, or	-	+	+	-	+	-	+
	Three countries free/impending free, or	+	+	-	-	+	-	
	Three countries with disease absence in OIE reports	+	+	+	-	+	+	
Zoonotic potential	Proven transmission to humans and severe consequences	+	+	-	-	-	-	+
Significant spread in naïve populations	Significant mortality, or			-	-	+	-	
	Significant morbidity			+	-	+	-	
Outcome		Listed	Listed	Listed	Not Listed	Listed	Not Listed	Listed

Other pathogens, in particular food borne, will be taken into consideration after consultation with other Working Groups within the OIE.

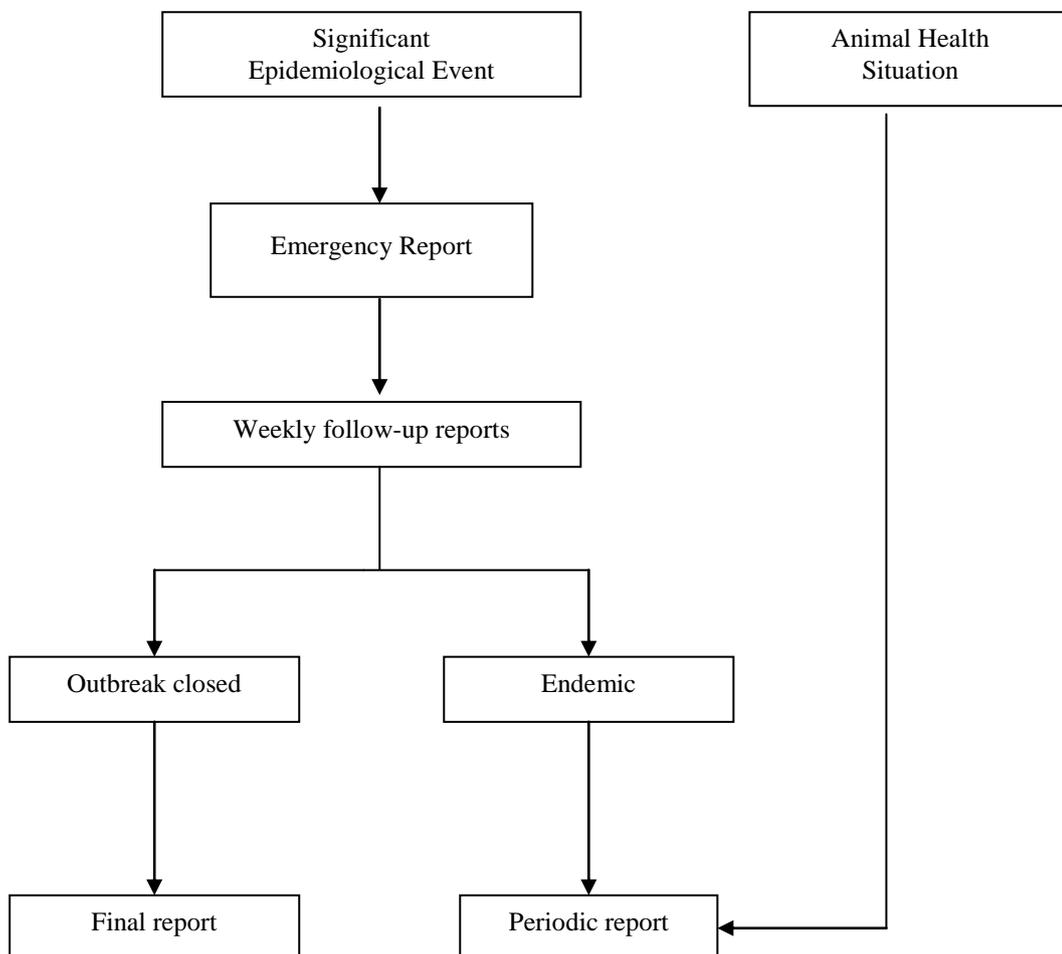
The *Ad hoc* Group then proceeded to consider the basic requirements for emergency reporting.

2. Emergency reporting

- a) All events regarded as having an epidemiological significance must be notified immediately to the OIE as laid down in Article 1.1.3.3. of the *Terrestrial Code*. The Group proposed six alternative scenarios for an event with epidemiological significance.
- b) These are:
 - i) First occurrence of a listed disease and/or infection in a country or compartment.
 - ii) Re-occurrence of a listed disease and/or infection in a country or compartment following a report by the delegate of the country declaring the outbreak closed.
 - iii) First occurrence of a new strain of a pathogen in a country or compartment.
 - iv) A sudden and unexpected increase in the morbidity or mortality caused by an existing disease.
 - v) Emerging diseases with significant morbidity/mortality or zoonotic potential.
 - vi) Evidence of change in the epidemiology of a listed disease (including host range, pathogenicity, strain of causative pathogen) in particular if there is a zoonotic impact.

3. Periodic reporting

Periodic reports are to include information on the situation with respect to all listed diseases, (including events of epidemiological significance as notified in emergency reports) in the relevant country. A flow chart of the disease notification, including both emergency and periodic reports, is presented in page 7. The Group will give further consideration to the frequency of periodic reports at its next meeting.

DISEASE NOTIFICATION TO THE OIE

.../Appendices

**OIE AD HOC GROUP ON
TERRESTRIAL ANIMAL DISEASE / PATHOGENIC AGENTS NOTIFICATION**

Paris, 10 - 12 September 2003

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**TERMS OF REFERENCE OF THE AD HOC GROUP ON
TERRESTRIAL ANIMAL DISEASE / PATHOGENIC AGENTS NOTIFICATION**

Paris, 10-12 September 2003

Objectives of the *Ad hoc* Group

The *Ad Hoc* Group is kindly requested to help the OIE Central Bureau in developing proposals following Resolutions of the International Committee on a new OIE disease information system. The main expected outputs are the following:

1. Criteria for notification of diseases or pathogenic agents

Establish new criteria for notification terrestrial animal diseases or pathogenic agents by Member Countries. The criteria should be scientifically based taking into account the following suggested factors:

- a) The potential for international spread; and
- b) The significant “socio-economic” implications internationally and /or within a country,
 - i) The significant impact in international trade irrespective of impact within a country, or
 - ii) The significant impact on animal production (morbidity/mortality) or the environment, within a country or a group of countries; or
- c) The zoonotic potential (including pathogens which may not always show clinical signs in animals); or
- d) An emerging disease with insufficient information available to address the above criteria but of potentially significant international concern; and
- e) Freedom or impending freedom from the disease or pathogenic agent is recognised for several countries.

2. Based on these criteria, establish a list of new OIE notifiable diseases/ pathogenic agents, to be considered for publication in the *Terrestrial Code*

3. New OIE information system

- a) *Immediate disease or pathogenic agent notification (basis for the OIE future early warning system)*
 - i) Describe criteria for disease/pathogens or epidemiological events to be notified on immediate basis that take into account specific epidemiological situations to be defined. Here below are few examples of suggested criteria:
 - The potential for fast and widespread dissemination, irrespective of national borders, either directly or through vectors; and
 - The first occurrence of a listed disease / pathogenic agent in a country or zone, or re-occurrence in a country or zone considered free (interval of time to be defined); or
 - The occurrence of emerging disease / pathogenic agent listed under 1 d); or

Appendix XXVII (contd)Appendix II (contd)

- The expected difficulty in diagnosing/controlling/eradicating occurrence of the disease/pathogenic agent; or
 - Any new findings which are of exceptional epidemiological significance to other countries or are of veterinary public health concern.
- ii) Following these criteria, determine diseases /pathogens and/or epidemiological events that should be reported on immediate basis and eventually describe criteria for each disease/group of diseases that necessitate such urgent notification.
- b) *Regular disease or pathogenic agent notification (basis for the future OIE monitoring system)*
- Propose a new system for regular disease or pathogenic agent notification to the OIE that complements A. and define a time frame for such regular notification.
4. Review and adapt the current OIE reporting forms of Member Countries used for A. and B. above.
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Original: English
October 2003

**REPORT OF THE SECOND MEETING OF THE
OIE AD HOC GROUP ON THE ROLE OF
PRIVATE VETERINARIANS AND VETERINARY PARA-PROFESSIONALS
IN THE PROVISION OF ANIMAL HEALTH SERVICES**

Paris, 23-24 October 2003

The OIE *Ad hoc* Group on the role of private veterinarians and veterinary para-professionals in the provision of animal health services held its second meeting at the OIE Headquarters from 23 to 24 October 2003.

The members of the OIE *Ad hoc* Group and other participants are listed in [Appendix I](#). The agenda adopted is given in [Appendix II](#). Dr H. Schneider chaired the meeting.

The Director General of the OIE, Dr B. Vallat, welcomed the members of the *Ad hoc* Group and thanked them for continuing the OIE's work on this very important area of improving Member Countries' Veterinary Services. He noted that the objectives of the *Ad hoc* Group fell under two of the OIE missions:

- 1) improving transparency in the world animal health situation through setting minimum requirements for effective surveillance systems (incorporating both competence in the field and an efficient chain of command); and
- 2) improving the safety of international trade of animals and their products through setting minimum standards underpinning export certification.

Dr Vallat recalled the commitment made by the various international organisations at the Doha Ministerial meeting regarding capacity building in developing countries to enhance their participation in international trade.

The *Ad hoc* Group recognised that its proposals needed to be balanced to ensure that animal health standards for exports were maintained and confidence in countries' ability to trade in safe commodities was not lost.

Building on the outcomes of its first meeting, the *Ad hoc* Group examined the proposals of the OIE Terrestrial Animal Health Standards Commission (hereafter referred to as the "Code Commission") and comments from Member Countries to the report of that meeting, and the chapters of the OIE *Terrestrial Animal Health Code* (hereafter referred to as the "*Terrestrial Code*") relevant to its work.

Recommendations

1) Definitions

The *Ad hoc* Group worked through the list of modified definitions and proposed a change to the title of one definition (now called veterinary para-professional) to better define the limits of the role of these persons.

Appendix XXVIII (contd)

The *Ad hoc* Group noted that the proposed definition of Veterinary Services included all persons registered or licensed by the veterinary statutory body and noted the importance of this broader definition to the evaluation of Veterinary Services. The modified definition emphasised the important role of the private sector in the provision of these services, especially regarding animal disease surveillance and reporting, and the implementation of animal disease control measures.

The definitions proposed are in Appendix III.

2) Evaluation of Veterinary Services

The *Ad hoc* Group endorsed the changes proposed to Chapter 1.3.3. proposed by the Code Commission.

The *Ad hoc* Group questioned the relevance of the reference to the WHO/FAO World Directory (paragraph 2a)i) of Article 1.3.4.13.) and suggested its deletion. The *Ad hoc* Group recognised the need for an international body to coordinate the harmonisation of standards among veterinary schools worldwide, and recommended that the OIE undertake this responsibility.

The *Ad hoc* Group considered that the veterinary statutory body was essential to the efficient operations of Veterinary Services and discussed the composition of the body, as well as the need to provide the body with the required level of credibility for its tasks. The *Ad hoc* Group recommended certain changes to Article 1.3.4.11bis, which deals with the evaluation of the veterinary statutory body.

The proposed changes are given in Appendix IV and Appendix V.

The *Ad hoc* Group viewed the following as being crucial components for the credibility of this body and recommended that these be incorporated in due course in the *Terrestrial Code*:

- a) Composition
 - i) a majority of members should be veterinarians;
 - ii) appropriate representation of government and non-government veterinarians; and
 - iii) representation of veterinary para-professionals in all decision-making procedures affecting them.
- b) Transparent and democratic election/nomination procedures for members of the veterinary statutory body.
- c) Autonomy of administrative (including financial) and regulatory procedures, and decision-making, contained in the body's enabling legislation.

The *Ad hoc* Group recommended that each Member Country investigate optimal structure and functions for a veterinary statutory body in their country, and its links with relevant stakeholders.

3) Maintaining quality

The *Ad hoc* Group also recommended, in view of current developments in respect of continuous professional development (CPD) programmes, that veterinary statutory bodies prescribe and implement such CPD for the maintenance of quality of service for all veterinarians and veterinary para-professionals.

4) Linkages

In order to enhance the cost effectiveness and efficiency of Veterinary Services, the *Ad hoc* Group stressed the necessity to create and formalize linkages between the Veterinary Administration and stakeholders. The *Ad hoc* Group believed that it was essential for the Veterinary Administration to find appropriate mechanisms for a transfer of authority to the private veterinarians required for them to fulfil official veterinary activities.

Appendix XXVIII (contd)

The role of private veterinarians and veterinary para-professionals in the provision of animal health service involves a close relationship with all stakeholders with interests in animal health, animal welfare, veterinary public health and food safety. This requires a structure whereby there is effective communication between the livestock owner/farmer and the direct provider of veterinary services whether a veterinary para-professional or private veterinarian. At the same time, the epidemiology and surveillance of animal diseases and zoonoses is a national and international issue and therefore there must be close linkages between the above groups in the field and government veterinary resources.

As Veterinary Services move from curative to preventive medicine, the *Ad hoc* Group considered that it was even more critical that Veterinary Administrations develop and implement strategic programmes, such as vaccination programmes, and monitoring and surveillance programmes, utilising the resources of private veterinarians and veterinary para-professionals.

The *Ad hoc* Group was of the view that veterinary bodies such as private/voluntary veterinary associations/organisations should be consulted regarding the involvement of private veterinarians in the provision of animal health services.

5) Surveillance and monitoring

The *Ad hoc* Group reviewed the chapter of the *Terrestrial Code* on surveillance and monitoring of animal health, but made no changes.

As early field reports of disease outbreaks are a key component of disease surveillance, the *Ad hoc* Group believed that livestock owners/farmers, veterinary para-professionals and private veterinarians have a vital role to play and that this role should be further recognized and developed by Veterinary Administrations. In countries where there is a limited availability of veterinarians and resources, the effective use of veterinary para-professionals is crucial to effective surveillance. The *Ad hoc* Group considered that this may require the use of innovative approaches to epidemiology to complement the formal science-based surveys described in Article 1.3.6.2.

Next meeting

The *Ad hoc* Group considered that the need for another meeting was dependent on the outcome of discussions at the 2004 General Session.

.../Appendices

**SECOND MEETING OF THE OIE AD HOC GROUP ON THE ROLE OF
PRIVATE VETERINARIANS AND VETERINARY PARA-PROFESSIONALS
IN THE PROVISION OF ANIMAL HEALTH SERVICES**

Paris, 23-24 October 2003

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**SECOND MEETING OF THE OIE AD HOC GROUP ON THE ROLE OF
PRIVATE VETERINARIANS AND VETERINARY PARA-PROFESSIONALS
IN THE PROVISION OF ANIMAL HEALTH SERVICES**

Paris, 23-24 October 2003

Agenda adopted

- 1) Introduction
 - 2) Update on relevant activities
 - 3) Examination of the revisions to the OIE *Terrestrial Animal Health Code* proposed by the Bureau of the OIE Terrestrial Animal Health Standards Commission in July 2003 and other relevant *Terrestrial Animal Health Code* chapters
 - 4) Other issues
-

CHAPTER 1.1.1. GENERAL DEFINITIONS

Article 1.1.1.1.

For the purposes of the *Terrestrial Code*:

...

Approved

means formally approved, accredited or registered by the *Veterinary Administration* for export purposes.

Official Veterinarian

means a *veterinarian* authorised by the *Veterinary Administration* of the country to perform certain official tasks associated with animal health and/or public health and inspections of *commodities* and, when appropriate, to certify ~~perform certification~~ in conformity with the provisions of Section 1.2. of the *Terrestrial Code*.

Veterinary para-professional

means a person who, for the purposes of the *Terrestrial Code*, is authorised to carry out certain *veterinary* tasks (dependent upon the category of *veterinary para-professional*) in a country through a license from the *veterinary statutory body*, and delegated to them under the responsibility and direction of a registered or licensed veterinarian. The *veterinary* tasks authorized for each category of *veterinary para-professional* should be defined by the *veterinary statutory body* depending on qualifications and training, and according to need.

Veterinarian

means a person registered or licensed to practice veterinary medicine/science in a country by the relevant *veterinary statutory body* of that country.

Veterinary Services

~~the *Veterinary Services* comprise~~ means the *Veterinary Administration*, ~~and~~ all the *Veterinary Authorities*, and all persons registered or licensed by the *veterinary statutory body*.

Veterinary statutory body

means the autonomous national authority regulating *veterinarians* and *veterinary para-professionals*.

— text deleted

CHAPTER 1.3.3. EVALUATION OF VETERINARY SERVICES

Article 1.3.3.1.

The quality of the *Veterinary Services* depends on a set of factors, which include fundamental principles of an ethical, organisational and technical nature. The *Veterinary Services* shall conform to these fundamental principles, regardless of the political, economic or social situation of their country.

Compliance with these fundamental principles by the *Veterinary Services* of a Member Country is important to the establishment and maintenance of confidence in its *international veterinary certificates* by the *Veterinary Services* of other Member Countries.

The same fundamental principles should apply in countries where the responsibility for establishing or applying certain animal health measures, or issuing some *international veterinary certificates* is exercised by an organisation other than the *Veterinary Services*, or by an authority or agency on behalf of the *Veterinary Services*. In all cases, the *Veterinary Services* retain ultimate responsibility for the application of these principles.

These fundamental principles are presented in Article 1.3.3.2. The remaining factors of quality are described in Part 1 (notification, principles of certification, etc.) and the document entitled “Guidelines for the evaluation of Veterinary Services” included in Chapter 1.3.4.

The quality of *Veterinary Services* can be measured through an evaluation, whose general principles are described in Articles 1.3.3.3. and 1.3.3.4.

Article 1.3.3.2.

Fundamental principles of quality

The *Veterinary Services* shall comply with the following principles to ensure the quality of their activities:

1. Professional judgement

The **officials personnel** of *Veterinary Services* should have the relevant qualifications, scientific expertise and experience to give them the competence to make sound professional judgements.

2. Independence

Care shall be taken to ensure that *Veterinary Services*' **staff personnel** are free from any commercial, financial, hierarchical, political or other pressures which might affect their judgement or decisions.

3. Impartiality

The *Veterinary Services* shall be impartial. In particular, all the parties affected by their activities have a right to expect their services to be delivered under reasonable and non-discriminatory conditions.

4. Integrity

The *Veterinary Services* shall guarantee that the work of each of their **officials personnel** is of a consistently high level of integrity. Any fraud, corruption or falsification shall be identified and corrected.

5. Objectivity

The *Veterinary Services* shall at all times act in an objective, transparent and non-discriminatory manner.

Appendix XXVIII (contd)Appendix IV (contd)6. General organisation

The *Veterinary Services* must be able to demonstrate by means of an appropriate legislation, **sufficient financial resources** and **effective** organisation that they are in a position to have control of the establishment and application of animal health measures, and of international veterinary certification activities. Legislation should be suitably flexible to allow changing situations to be addressed efficiently, including the incorporation of animal welfare and food safety measures. In particular, they shall define and document the responsibilities and structure of the organisations in charge of the animal identification system, control of animal movements, animal disease control and reporting systems, epidemiological surveillance and communication of epidemiological information.

A similar demonstration should be made by *Veterinary Services* when they are in charge of veterinary public health activities.

The *Veterinary Services* shall have at their disposal effective systems for animal disease surveillance and for *notification* of disease problems wherever they occur, in accordance with the provisions of the *Terrestrial Code*. Adequate coverage of animal populations should also be demonstrated. They shall at all times endeavour to improve their performance in terms of animal health information systems and animal disease control.

The *Veterinary Services* shall define and document the responsibilities and structure of the organisation (in particular the chain of command) in charge of issuing *international veterinary certificates*.

Each position within the *Veterinary Services* which has an impact on their quality shall be described. These job descriptions shall include the requirements for education, training, technical knowledge and experience.

7. Quality policy

The *Veterinary Services* shall define and document their policy and objectives for, and commitment to, quality, and shall ensure that this policy is understood, implemented and maintained at all levels in the organisation. Where conditions allow, they may implement a quality system corresponding to their areas of activity and appropriate for the type, range and volume of work that they have to perform. The guidelines for the quality and evaluation of *Veterinary Services* propose a suitable reference system, which should be used if a Member Country choose to adopt a quality system.

8. Procedures and standards

The *Veterinary Services* shall develop and document appropriate procedures and standards for the implementation and management of animal health measures and international veterinary certification activities. These procedures and standards may for example relate to:

- a) programming and management of activities, including international veterinary certification activities;
- b) prevention and control of disease *outbreaks*;
- c) risk analysis, epidemiological surveillance and zoning;
- d) inspection and sampling techniques;
- e) diagnostic tests for animal diseases;
- f) preparation, production, registration and control of biological products for use in the diagnosis or prevention of diseases;

Appendix XXVIII (contd)Appendix IV (contd)

- g) border controls and import regulations;
- h) *disinfection* and *disinfestation*;
- i) treatments intended to destroy, if appropriate, pathogens in animal products,
- j) standards for registration of slaughter establishments.

Inasmuch as the OIE has adopted standards on these matters, the *Veterinary Services* shall comply with these standards when applying animal health measures and when issuing *international veterinary certificates*.

9. Information, complaints and appeals

The *Veterinary Administration* shall undertake to reply to legitimate requests from *Veterinary Administrations* of other Member Countries or any other authority, in particular ensuring that any requests for information, complaints or appeals that they may present are dealt with in a timely manner.

A record shall be maintained of all complaints and appeals and of the relevant action taken by the *Veterinary Services*.

10. Documentation

The *Veterinary Services* shall have at their disposal a reliable and up to date documentation system suited to their activities.

11. Self-evaluation

The *Veterinary Services* should undertake periodical self-evaluation especially by documenting achievements against goals, and demonstrating the efficiency of their organisational components and resource adequacy.

A Member Country can request the Director General of the OIE to arrange for an expert or experts to assist in the process.

12. Communication

Veterinary Services should have effective internal and external systems of communication (particularly with/between private veterinarians and veterinary para-professionals) covering administrative and technical staff levels and parties affected by their activities.

13. Human and financial resources

Responsible authorities should ensure that adequate resources are made available to implement effectively the above activities.

Article 1.3.3.3.

For the purposes of the *Terrestrial Code*, every Member Country shall recognise the right of another Member Country to undertake, or request it to undertake, an evaluation of its *Veterinary Services* where the initiating Member Country is an actual or a prospective importer or exporter of *commodities* and where the evaluation is to be a component of a risk analysis process which is to be used to determine or review sanitary measures which apply to such trade.

Any evaluation of *Veterinary Services* should be conducted having regard to the OIE Guidelines for the evaluation of *Veterinary Services* presented in Chapter 1.3.4. of the *Terrestrial Code*.

Appendix XXVIII (contd)Appendix IV (contd)

A Member Country has the right to expect that the evaluation of its *Veterinary Services* will be conducted in an objective manner. A Member Country undertaking evaluation should be able to justify any measure taken as a consequence of its evaluation.

Article 1.3.3.4.

A Member Country which intends to conduct an evaluation of another Member Country's *Veterinary Services* shall give them notice in writing. This notice should define the purpose of the evaluation and details of the information required.

On receipt of a formal request for information to enable an evaluation of its *Veterinary Services* by another Member Country, and following bilateral agreement of the evaluation process and criteria, a Member Country should expeditiously provide the other country with meaningful and accurate information of the type requested.

The evaluation process should take into account the fundamental principles and other factors of quality laid down in Articles 1.3.3.1. and 1.3.3.2. It should also take into consideration the specific circumstances regarding quality, as described in Article 1.3.3.1., prevailing in the countries concerned.

The outcome of the evaluation conducted by a Member Country should be provided in writing as soon as possible, and in any case within 4 months of receipt of the relevant information, to the Member Country which has undergone the evaluation. The evaluation report should detail any findings which affect trade prospects. The Member Country which conducts the evaluation should clarify in detail any points of the evaluation on request.

In the event of a dispute between two Member Countries over the conduct or the conclusions of the evaluation of the *Veterinary Services*, the matter should be dealt with having regard to the procedures set out in Article 1.3.1.4.

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CHAPTER 1.3.4.
GUIDELINES FOR THE EVALUATION OF
VETERINARY SERVICES

Article 1.3.4.1.

General considerations

1. Evaluation of *Veterinary Services* is an important element in the risk analysis process which countries may legitimately use in their policy formulations directly applying to animal health and sanitary controls of *international trade in animals*, animal-derived products, animal genetic material and animal feedstuffs.

Any evaluation should be carried out with due regard for Chapter 1.3.3. of the *Terrestrial Code*.

2. In order to ensure that objectivity is maximised in the evaluation process, it is essential for some standards of discipline to be applied. The OIE has developed these guidelines which can be practically applied to the evaluation of *Veterinary Services*. These are relevant for evaluation of the *Veterinary Services* of one country by those of another country for the purposes of risk analysis in *international trade*. The guidelines are also applicable for evaluation by a country of its own *Veterinary Services* – the process known as self-evaluation or self-assessment– and for periodic re-evaluation.

In carrying out a risk analysis prior to deciding the sanitary/zoosanitary conditions for the importation of a *commodity*, an *importing country* is justified in regarding its evaluation of the *Veterinary Services* of the *exporting country* as critical.

3. The purpose of evaluation may be either to assist a national authority in the decision-making process regarding priorities to be given to its own *Veterinary Services* (self-evaluation) or to assist the process of risk analysis in *international trade in animals* and animal-derived products to which official sanitary and/or zoosanitary controls apply.
4. In both situations, the evaluation should demonstrate that the *Veterinary Services* have the capability for effective control of the sanitary and zoosanitary status of *animals* and animal products. Key elements to be covered in this process include resource adequacy, management capability, legislative and administrative infrastructures, independence in the exercise of official functions and performance history, including disease reporting.
5. Competence and integrity are qualities on which others base their confidence in individuals or organisations. Mutual confidence between relevant official *Veterinary Services* of trading partner countries contributes fundamentally to stability in *international trade in animals* and animal-related products. In this situation, scrutiny is directed more at the *exporting country* than at the *importing country*.
6. Although quantitative data can be provided on *Veterinary Services*, the ultimate evaluation will be essentially qualitative. While it is appropriate to evaluate resources and infrastructure (organisational, administrative and legislative), it is also appropriate to place emphasis on the evaluation of the quality of outputs and performance of *Veterinary Services*. Evaluation should take into consideration any quality systems used by *Veterinary Services*.
7. An *importing country* has a right of assurance that information on sanitary/zoosanitary situations provided by the *Veterinary Services* of an *exporting country* is objective, meaningful and correct. Furthermore, the *Veterinary Services* of the *importing country* are entitled to expect validity in the veterinary certification of export.

Appendix XXVIII (contd)Appendix V (contd)

8. An *exporting country* is entitled to expect that its *animals* and animal products will receive reasonable and valid treatment when they are subjected to import inspection in the country of destination. The country should also be able to expect that any evaluation of its standards and performance will be conducted on a non-discriminatory basis. The *importing country* should be prepared and able to defend any position which it takes as a consequence of the evaluation.
9. While the *veterinary statutory body* is not a part of the *Veterinary Services*, an evaluation of that body should be carried out to ensure that the registration/licensing of *veterinarians* and *veterinary para-professionals* is included as an important element of the risk analysis process.

Article 1.3.4.2.

Scope

1. In the evaluation of *Veterinary Services*, the following items may be considered, depending on the purpose of the evaluation:
 - organisation, structure and authority of the *Veterinary Services*
 - human resources
 - material (including financial) resources
 - functional capabilities and legislative support
 - animal health and veterinary public health controls
 - formal quality systems including quality policy
 - performance assessment and audit programmes
 - participation in OIE activities and compliance with OIE Member Countries' obligations.
2. To complement the evaluation of *Veterinary Services*, it is necessary to also consider the organisation structure and functioning of the *veterinary statutory body*.
3. Article 1.3.4.13. outlines appropriate information requirements for:
 - self-evaluation by national *Veterinary Services* which perceive a need to prepare information for national or international purposes;
 - evaluation by a prospective or actual *importing country* of the *Veterinary Services* of a prospective or actual *exporting country*;
 - verification or re-verification of an evaluation in the course of a visit to the *exporting country* by the *importing country*.

Article 1.3.4.3.

Evaluation criteria for the organisational structure of the Veterinary Services

1. A key element in the evaluation is the study of the organisation and structure of the official *Veterinary Services*. The *Veterinary Services* should define and set out their policy, objectives and commitment to quality systems and standards. These organisational and policy statements should be described in detail. Organisational charts and details of functional responsibilities of staff should be available for evaluation. The role and responsibility of the Chief Veterinary Officer/Veterinary Director should be clearly defined. Lines of command should also be described.
2. The organisational structure should also clearly set out the interface relationships of government Ministers and departmental Authorities with the Chief Veterinary Officer/Veterinary Director and the *Veterinary Services*. Formal relationships with statutory authorities and with industry organisations and associations should also be described. It is recognised that Services may be subject to changes in structure from time to time. Major changes should be notified to trading partners so that the effects of re-structuring may be assessed.

Appendix XXVIII (contd)Appendix V (contd)

3. Organisational components of *Veterinary Services* which have responsibility for key functional capabilities should be identified. These capabilities include epidemiological surveillance, disease control, import controls, animal disease reporting systems, animal identification systems, traceability systems, animal movement control systems, communication of epidemiological information, training, inspection and certification. Laboratory and field systems and their organisational relationships should be described.
4. To reinforce the reliability and credibility of their services, the *Veterinary Services* may have set up quality systems that correspond with their fields of activity and to the nature and scale of activities that they carry out. Evaluation of such systems should be as objective as possible.
5. The *Veterinary Administration* alone speaks for the country as far as official international dialogue is concerned. This is also particularly important to cases where zoning and regionalisation are being applied. The responsibilities of the national *Veterinary Administration* and all *Veterinary Authorities* in that country should be made clear in the process of evaluation of *Veterinary Services*.
6. A *Veterinary Authority* is defined in Chapter 1.1.1. of the *Terrestrial Code*. As some countries have some official veterinary authority roles vested in autonomous sub-national (state/provincial, municipal) government bodies, there is an important need to assess the role and function of these Services. Details of their roles, relationship (legal and administrative) to each other and to the national *Veterinary Services* should be available for evaluation. Annual reports, review findings and access to other information pertinent to the animal health activities of such bodies should also be available.
7. Similarly, where the national *Veterinary Services* have arrangements with other providers of relevant services such as universities, laboratories, information services, etc., these arrangements should also be described. For the purposes of evaluation, it is appropriate to expect that the quality of organisational and functional standards which apply to *Veterinary Services* should also apply to the services of these other providers.

Article 1.3.4.4.

Evaluation criteria for quality systems

1. The *Veterinary Services* should demonstrate a commitment to the quality of the processes and outputs of their services. Where services or components of services are delivered under a formal quality systems programme which is based on OIE recommended standards or, especially in the case of laboratory components of *Veterinary Services* other internationally recognised quality standards, the *Veterinary Services* undergoing evaluation should make available evidence of accreditation, details of the documented quality processes and documented outcomes of all relevant audits undertaken.
2. Where the *Veterinary Services* undergoing evaluation make large use of formal quality systems in the delivery of their services, it is appropriate that greater emphasis be placed on the outcomes of evaluation of these quality systems than on the resource and infrastructural components of the services.

Article 1.3.4.5.

Evaluation criteria for human resources

1. The *Veterinary Services* should demonstrate that their human resource component includes an integral core of full-time civil service employees. This core must include graduate veterinarians, **veterinary para-professionals**. ~~It should also and should include other qualified professional officers, and administrative officials and technical support staff.~~ The human resources ~~does not exclude~~ should also include the possibility of employing, in addition, part-time veterinarians and **veterinary para-professionals** and ~~para-veterinary staff,~~ and private sector veterinarians and **veterinary para-professionals**. It is essential that all the above categories of staff be subject to legal disciplinary provisions. Data relating to the resource base of the *Veterinary Services* undergoing evaluation should be available.

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2. In addition to raw quantitative data on this resource base, the functions of the various categories of staff in the *Veterinary Services* should be described in detail. This is necessary for analysis and estimation of the appropriateness of the application of qualified skills to the tasks undertaken by the *Veterinary Services* and may be relevant, for example, to the roles of *veterinarians* and ~~animal-technical assistants~~ ~~health~~ *veterinary para-professionals* in field services. In this case, the evaluation should provide assurances that disease monitoring is being conducted by a sufficient number of qualified, experienced field veterinarians who are directly involved in farm visits; there should not be an over-reliance on ~~technical-assistant staff~~ *veterinary para-professionals* for this task.
3. Analysis of these data can be used to estimate the potential of the *Veterinary Services* to have reliable knowledge of the state of animal health in the country and to support an optimal level of animal disease control programmes. A large population of private *veterinarians practitioners* would not provide the *Veterinary Services* with an effective epizootiological information base without legislative (e.g. compulsory reporting of notifiable diseases) and administrative (e.g. official animal health surveillance and reporting systems) mechanisms in place.
4. These data should be assessed in close conjunction with the other information described in this Chapter. For example, a large field staff (*veterinarians* and *veterinary para-professionals* ~~animal health technical assistants~~) need fixed, mobile and budgetary resources for animal health activities in the livestock farming territory of the country. If deficiencies are evident, there would be reason to challenge the validity of epizootiological information.

Article 1.3.4.6.

Evaluation criteria for material resources1. Financial

Actual yearly budgetary information regarding the *Veterinary Services* should be available and should include the details set out in the model questionnaire outlined in Article 1.3.4.13. Information is required on conditions of service for veterinary staff (including salaries and incentives) and should provide a comparison with the private sector and perhaps with other professionals. Information should also be available on non-government sources of revenue available to veterinarians in their official responsibilities.

2. Administrative

a) Accommodation

The *Veterinary Services* should be accommodated in premises suitable for efficient performance of their functions. The component parts of the *Veterinary Services* should be located as closely as possible to each other at the central level, and in the regions where they are represented, in order to facilitate efficient internal communication and function.

b) Communications

The *Veterinary Services* should be able to demonstrate that they have reliable access to effective communications systems, especially for animal health surveillance and control programmes. Inadequate communications systems within the field services components of these programmes or between outlying offices and headquarters, or between the *Veterinary Services* and other relevant administrative and professional services, signify an inherent weakness in these programmes. Adequate communications systems between laboratories and between field and laboratory components of the *Veterinary Services* should also be demonstrated.

Examples of types of communications which should be routinely available on an adequate country-wide basis are national postal, freight and telephone networks. Rapid courier services, facsimile and electronic data interchange systems (e.g. e-mail and Internet services) are examples of useful communication services which, if available, can supplement or replace the others. A means for rapid international communication should be available to the national *Veterinary Services*, to permit reporting of changes in national disease status consistent with OIE recommendations and to allow bilateral contact on urgent matters with counterpart *Veterinary Services* in trading-partner countries.

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c) Transport systems

The availability of sufficient reliable transport facilities is essential for the performance of many functions of *Veterinary Services*. This applies particularly to the field services components of animal health activities (e.g. emergency response visits). Otherwise, the *Veterinary Services* cannot assure counterpart services in other countries that they are in control of the animal health situation within the country.

Appropriate means of transport are also vital for the satisfactory receipt of samples to be tested at veterinary laboratories, for inspection of imports and exports, and for the performance of *animal* and animal product inspection in outlying production or processing establishments.

3. Technical

Details available on laboratories should include resources data, programmes under way as well as those recently completed and review reports on the role or functions of the laboratory. Information as described in the model questionnaire should be used in the evaluation of laboratory services.

a) Cold chain for laboratory samples and veterinary medicines

Adequate refrigeration and freezing systems should be available and should be used throughout the country to provide suitable low temperature protection for laboratory samples in transit or awaiting analysis, as well as veterinary medical products (e.g. vaccines) when these are required for use in animal disease control programmes. If these assurances cannot be given, it may be valid to discount many types of test results, as well as the effectiveness of certain disease control programmes and the export inspection system in the country undergoing evaluation.

b) Diagnostic laboratories

Analysis of the laboratory service component of *Veterinary Services*, which would include official governmental laboratories and other laboratories accredited by the *Veterinary Services* for specified purposes, is an essential element of the evaluation process. The quality of the veterinary diagnostic laboratories of a country underpins the whole control and certification processes of the zoonitary/sanitary status of exported *animals* and animal products, and therefore these laboratories should be subject to rigid quality assurance procedures and should use international quality assurance programmes (wherever available) for standardising test methodologies and testing proficiency. An example is the use of International Standard Sera for standardising reagents.

This emphasis is valid whether one relates it to the actual testing performed on individual export consignments or to the more broad and ongoing testing regimes which are used to determine the animal health and veterinary public health profiles of the country and to support its disease control programmes. For the purposes of evaluation, veterinary diagnostic laboratories include those which are concerned with either animal health or veterinary public health activities. The *Veterinary Services* must approve and designate these laboratories for such purposes and have them audited regularly.

c) Research

The scope of animal disease and veterinary public health problems in the country concerned, the stages reached in the controls which address those problems and their relative importance can be measured to some degree by analysis of information on government priorities and programmes for research in animal health. This information should be accessible for evaluation purposes.

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Article 1.3.4.7.

Functional capabilities and legislative support1. Animal health and veterinary public health

The *Veterinary Services* should be able to demonstrate that they have the capacity, supported by appropriate legislation, to exercise control over all animal health matters. These controls should include, where appropriate, compulsory notification of prescribed animal diseases, inspection, movement controls including registration of holdings and animal identification, quarantine of infected premises/areas, testing, treatment, destruction of infected *animals* or contaminated materials, controls over the use of veterinary medicines, etc. The scope of the legislative controls should include domestic animals and their reproductive material, animal products, wildlife as it relates to the transmission of diseases to domestic animals, and other products subject to veterinary inspection. Arrangements should exist for co-operation with the veterinary authorities of the neighbouring countries for the control of animal diseases in border areas and for establishing linkages to recognise and regulate trans-boundary activities, including the movements of veterinarians and para-professionals. Information on the veterinary public health legislation covering the production of products of animal origin for national consumption may be also considered in the evaluation.

2. Export/import inspection

National *Veterinary Services* should have appropriate legislation and adequate capabilities to prescribe the methods for control and to exercise systematic control over the import and export processes of *animals* and animal products in so far as this control relates to sanitary and zoonosantary matters. The evaluation should also involve the consideration of administrative instructions to ensure the enforcement of *importing country* requirements during the pre-export period.

In the context of production for export of foodstuffs of animal origin, the *Veterinary Services* should demonstrate that comprehensive legislative provisions are available for the oversight by the relevant authorities of the hygienic process and to support official inspection systems of these *commodities* which function to standards consistent with or equivalent to relevant Codex Alimentarius and OIE standards.

Control systems should be in place which permit the exporting *Veterinary Authorities* to approve export premises. The *Veterinary Services* should also be able to conduct testing and treatment as well as to exercise controls over the movement, handling and storage of exports and to make inspections at any stage of the export process. The product scope of this export legislation should include, *inter alia*, *animals* and animal products (including animal semen, ova and embryos), and animal feedstuffs.

The national *Veterinary Services* should be able to demonstrate that they have adequate capabilities and legislative support for zoonosantary control of imports and transit of *animals*, animal products and other materials which may introduce animal diseases. This could be necessary to support claims by the *Veterinary Services* that the animal health status of the country is suitably stable, and that cross-contamination of exports from imports of unknown or less favourable zoonosantary status is unlikely. The same considerations should apply in respect of veterinary control of public health. The *Veterinary Services* should be able to demonstrate that there is no conflict of interest when certifying veterinarians are performing official duties.

Legislation should also provide the right to deny and/or withdraw official certification. Penalty provisions applying to malpractice on the part of certifying officials should be included.

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The *Veterinary Services* should demonstrate that they are capable of providing accurate and valid certification for exports of *animals* and animal products, based on Section 1.2. of the *Terrestrial Code*. They should have appropriately organised procedures which ensure that sanitary/animal health certificates are issued by efficient and secure methods. The documentation control system should be able to correlate reliably the certification details with the relevant export consignments and with any inspections to which the consignments were subjected.

Security in the export certification process, including electronic documentation transfer, is important. A system of independent compliance review is desirable, to safeguard against fraud in certification by officials and by private individuals or corporations. The certifying veterinarian should have no conflict of interest in the commercial aspects of the animal or product being certified and be independent from the commercial parties.

Article 1.3.4.8.

Animal health controls1. Animal health status

An updated assessment of the present animal disease status of a country is an important and necessary procedure. For this undertaking, studies of the OIE publications such as *World Animal Health*, the *Bulletin* and *Disease Information* must be fundamental reference points. The evaluation should consider the recent history of the compliance of the country with its obligations regarding international notification of animal diseases. In the case of an OIE Member Country, failure to provide the necessary animal health reports consistent with OIE requirements will detract from the overall outcome of the evaluation of the country.

An *exporting country* should be able to provide further, detailed elaboration of any elements of its animal disease status as reported to the OIE. This additional information will have particular importance in the case of animal diseases which are foreign to or strictly controlled in the *importing country* or region. The ability of the *Veterinary Services* to substantiate elements of their animal disease status reports with surveillance data, results of monitoring programmes and details of disease history is highly relevant to the evaluation. In the case of evaluation of the *Veterinary Services* of an *exporting country* for *international trade* purposes, an *importing country* should be able to demonstrate the reasonableness of its request and expectations in this process.

2. Animal health control

Details of current animal disease control programmes should be considered in the evaluation. These programmes would include epidemiological surveillance, official government-administered or officially-endorsed, industry-administered control or eradication programmes for specific diseases or disease complexes, and animal disease emergency preparedness. Details should include enabling legislation, programme plans for epidemiological surveillance and animal disease emergency responses, quarantine arrangements for infected and exposed animals or herds, compensation provisions for animal owners affected by disease control measures, training programmes, physical and other barriers between the free country or zone and those infected, incidence and prevalence data, resource commitments, interim results and programme review reports.

3. National animal disease reporting systems

The presence of a functional animal disease reporting system which covers all agricultural regions of the country and all veterinary administrative control areas should be demonstrated.

An acceptable variation would be the application of this principle to specific zones of the country. In this case also, the animal disease reporting system should cover each of these zones. Other factors should come to bear on this situation, e.g. the ability to satisfy trading partners that sound animal health controls exist to prevent the introduction of disease or export products from regions of lesser veterinary control.

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Article 1.3.4.9.

Veterinary public health controls1. Food hygiene

The national *Veterinary Services* should be able to demonstrate effective responsibility for the veterinary public health programmes relating to the production and processing of animal products, especially for export. If the national *Veterinary Services* do not exercise responsibility over these programmes, the evaluation should include a comprehensive review of the role and relationship of the organisations (national, state/provincial, and municipal) which are involved. In such a case, the evaluation should consider whether the national *Veterinary Services* can provide guarantees of responsibility for and effective control of the sanitary status of animal products prior to export, especially *meat* and *meat products* throughout the slaughter, processing, transport and storage periods.

2. Zoonoses

Within the structure of *Veterinary Services*, there should be appropriately qualified staff whose responsibilities include the monitoring and control of zoonotic diseases and, where appropriate, liaison with medical authorities.

3. Chemical residue testing programmes

Adequacy of controls over chemical residues in exported *animals*, animal products and feedstuffs should be demonstrated. Statistically-based surveillance and monitoring programmes for environmental and other chemical contaminants in *animals*, in animal-derived foodstuffs and in animal feedstuffs should be favourably noted. These programmes should be coordinated nationwide. Correlated results should be freely available on request to existing and prospective trading partner countries. Analytical methods and result reporting should be consistent with internationally recognised standards. If official responsibility for these programmes does not rest with the *Veterinary Services*, there should be appropriate provision to ensure that the results of such programmes are made available to the *Veterinary Services* for assessment.

4. Veterinary medicines

It should be acknowledged that primary control over veterinary medicinal products may not rest with the veterinary authorities in some countries, owing to differences between governments in the division of legislative responsibilities. However, for the purpose of evaluation, the *Veterinary Services* should be able to demonstrate the existence of effective controls (including nationwide consistency of application) over the manufacture, or importation, exportation, registration, supply, sale and use of veterinary medicines, biologicals and diagnostic reagents, whatever their origin. The control of veterinary medicines has direct relevance to the areas of animal health and public health.

In the animal health sphere, this has particular application to biological products. Inadequate controls on the registration and use of biological products leave the *Veterinary Services* open to challenge over the quality of animal disease control programmes and over safeguards against animal disease introduction in imported veterinary biological products.

It is valid, for evaluation purposes, to seek assurances of effective government controls over veterinary medicines in so far as these relate to the public health risks associated with residues of these chemicals in *animals* and animal-derived foodstuffs. This process should be consistent with the standards set by the Codex Alimentarius or with alternative requirements set by the *importing country* where the latter are scientifically justified.

5. Integration between animal health controls and veterinary public health

The existence of any organised programme which incorporates a structured system of information feedback from inspection in fresh meat or dairy product establishments and applies this in animal health control should be favourably noted. Such programmes should be integrated within a national epizootiological surveillance scheme.

Veterinary Services which direct a significant element of their animal health programmes specifically towards minimising microbial and chemical contamination of animal-derived products in the human food chain should receive favourable recognition in the evaluation. There should be evident linkage between these programmes and the official control of veterinary medicines and relevant agricultural chemicals.

Article 1.3.4.10.

Performance assessment and audit programmes

1. Strategic plans

The objectives and priorities of the *Veterinary Services* can be well evaluated if there is a published official strategic plan which is regularly updated. Understanding of functional activities is enhanced if an operational plan is maintained within the context of the strategic plan. The strategic and operational plans, if these exist, should be included in the evaluation.

Veterinary Services which use strategic and operational plans may be better able to demonstrate effective management than countries without such plans.

2. Performance assessment

If a strategic plan is used, it is desirable to have a process which allows the organisation to assess its own performance against its objectives. Performance indicators and the outcomes of any review to measure achievements against pre-determined performance indicators should be available for evaluation. The results should be considered in the evaluation process.

3. Compliance

Matters which can compromise compliance and adversely affect a favourable evaluation include instances of inaccurate or misleading official certification, evidence of fraud, corruption, or interference by higher political levels in international veterinary certification, and lack of resources and poor infrastructure.

It is desirable that the *Veterinary Services* contain (or have a formal linkage with) an independent internal unit/section/commission the function of which is to critically scrutinise their operations. The aim of this unit should be to ensure consistent and high integrity in the work of the individual officials in the *Veterinary Services* and of the corporate body itself. The existence of such a body can be important to the establishment of international confidence in the *Veterinary Services*.

An important feature when demonstrating the integrity of the *Veterinary Services* is their ability to take corrective action when miscertification, fraud or corruption has occurred.

A supplementary or an alternative process for setting performance standards and application of monitoring and audit is the implementation of formal quality systems to some or all activities for which the *Veterinary Services* are responsible. Formal accreditation to international quality system standards should be utilised if recognition in the evaluation process is to be sought.

Appendix XXVIII (contd)Appendix V (contd)4. Veterinary Services administration

a) Annual reports

Official government annual reports should be published, which provide information on the organisation and structure, budget, activities and contemporary performance of the *Veterinary Services*. Current and retrospective copies of such reports should be available to counterpart Services in other countries, especially trade partners.

b) Reports of government review bodies

The reports of any periodic or ad hoc government reviews of *Veterinary Services* or of particular functions or roles of the *Veterinary Services* should be considered in the evaluation process. Details of action taken as a consequence of the review should also be accessible.

c) Reports of special committees of enquiry or independent review bodies

Recent reports on the *Veterinary Services* or elements of their role or function, and details of any subsequent implementation of recommendations contained in these reports should be available. The *Veterinary Services* concerned should recognise that the provision of such information need not be detrimental to the evaluation outcome; in fact, it may demonstrate evidence of an effective audit and response programme. The supplying of such information can reinforce a commitment to transparency.

d) In-service training and development programme for staff

In order to maintain a progressive approach to meeting the needs and challenges of the changing domestic and international role of *Veterinary Services*, the national administration should have in place an organised programme which provides appropriate training across a range of subjects for relevant staff. This programme should include participation in scientific meetings of animal health organisations. Such a programme should be used in assessing the effectiveness of the Services.

e) Publications

Veterinary Services can augment their reputation by demonstrating that their staff publish scientific articles in refereed veterinary journals or other publications.

f) Formal linkages with sources of independent scientific expertise

Details of formal consultation or advisory mechanisms in place and operating between the *Veterinary Services* and local and international universities, scientific institutions or recognised veterinary organisations should be taken into consideration. These could serve to enhance the international recognition of the *Veterinary Services*.

g) Trade performance history

In the evaluation of the *Veterinary Services* of a country, it is pertinent to examine the recent history of their performance and integrity in trade dealings with other countries. Sources of such historical data may include Customs Services.

Article 1.3.4.11.

Participation in OIE activities

Questions on a country's adherence to its obligations as a member of the OIE are relevant to an evaluation of the *Veterinary Services* of the country. Self-acknowledged inability or repeated failure of a Member Country to fulfil reporting obligations to the OIE will detract from the overall outcome of the evaluation. Such countries, as well as non-member countries, will need to provide extensive information regarding their *Veterinary Services* and sanitary/zoosanitary status for evaluation purposes.

Article 1.3.4.11.bis

Evaluation of veterinary statutory body

In the evaluation of the *veterinary statutory body*, the following items may be considered, depending on the purpose of the evaluation:

- ≡ human resources, including the appropriateness composition and representation of the body's membership for veterinarians and para-professionals;
- ≡ institutional arrangements, accountability and transparency of decision-making procedures, including;
- ≡ sources and management of funding financial resources;
- ≡ functional capabilities, including the ability to enforce its decisions (for example regarding registration requirements, standards of conduct deregistration and disciplinary procedures);
- ≡ administration of continuing professional development and education programmes for veterinarians and veterinary para-professionals;
- ≡ legislative basis, including autonomy.

Article 1.3.4.12.

1. The *Veterinary Services* of a country may undertake self-evaluation against the above criteria for such purposes as national interest, improvement of internal efficiency or export trade facilitation. The way in which the results of self-evaluation are used or distributed is a matter for the country concerned.
2. A prospective *importing country* may undertake an evaluation of the *Veterinary Services* of an *exporting country* as part of a risk analysis process, which is necessary to determine the sanitary or zoosanitary measures which the country will use to protect human or animal life or health from disease or pest threats posed by imports. Periodic evaluation reviews are also valid following the commencement of trade.
3. In the case of evaluation for the purposes of *international trade*, the authorities of an *importing country* should use the principles elaborated above as the basis for the evaluation and should attempt to acquire information according to the model questionnaire outlined in Article 1.3.4.13. The *Veterinary Services* of the *importing country* are responsible for the analysis of details and for determining the outcome of the evaluation after taking into account all the relevant information. The relative ranking of importance ascribed, in the evaluation, to the criteria described in this document will necessarily vary according to case-by-case circumstances. This ranking should be established in an objective and justifiable way. Analysis of the information obtained in the course of an evaluation study must be performed in as objective a manner as possible. The validity of the information should be established and reasonableness should be employed in its application. The assessing country must be willing to defend any position taken on the basis of this type of information, if challenged by the other party.

Article 1.3.4.13.

This Article outlines appropriate information requirements for the self-evaluation or evaluation of the *Veterinary Services* of a country.

1. Organisation and structure of Veterinary Services
 - a) National Veterinary Services
 - Organisational chart including numbers, positions and numbers of vacancies.

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b) Sub-national Veterinary Services

Organisational charts including numbers, positions and number of vacancies.

c) Other providers of Veterinary Services

Description of any linkage with other providers of *Veterinary Services*.

2. National information on human resources

a) Veterinarians

i) Total numbers of:

- veterinarians registered by the veterinary statutory body of in the country who are graduates from internationally recognised veterinary schools which are registered accordingly in the WHO/FAO World Directory of Veterinary Schools;

- graduate veterinarians not included above;

ii) Numbers of:

- full time government veterinarians: national and sub-national;
- part time government veterinarians: national and sub-national;
- private veterinarians authorised by the *Veterinary Services* to perform official veterinary functions [*Describe accreditation standards, responsibilities and/or limitations applying to these private veterinarians*];

= other veterinarians.

iii) Animal health:

Numbers associated with farm livestock sector on a majority time basis in a veterinary capacity, by geographical area [*Show categories and numbers to differentiate staff involved in field service, laboratory, administration, import/export and other functions, as applicable*]:

- full time government veterinarians: national and sub-national;
- part time government veterinarians: national and sub-national;
- ~~privately employed~~ other veterinarians.

iv) Veterinary public health:

Numbers employed in food inspection on a majority time basis, by commodity [*Show categories and numbers to differentiate staff involved in inspection, laboratory and other functions, as applicable*]:

- full time government veterinarians: national and sub-national;
- part time government veterinarians: national and sub-national;
- ~~privately employed~~ other veterinarians.

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- v) Numbers of veterinarians relative to certain national indices:
- per total human population;
 - per farm livestock population, by geographical area;
 - per livestock-farming unit, by geographical area.
- vi) Veterinary education:
- number of veterinary schools;
 - length of veterinary course (years);
 - international recognition of veterinary degree.
- vii) Veterinary professional associations
- b) Graduate staff (non-veterinary)
- Details to be provided by category (including biologists, biometricians, economists, engineers, lawyers, other science graduates and others) on numbers within national *Veterinary Services* and available to national *Veterinary Services*.
- c) ~~Technical assistants~~ *Veterinary para-professionals* employed by the *Veterinary Services*
- i) Animal health:
- Categories and numbers involved with farm livestock on a majority time basis:
 - . by geographical area;
 - . proportional to numbers of field Veterinary Officers in the *Veterinary Services*, by geographical area.
 - Education/training details.
- ii) Veterinary public health:
- Categories and numbers involved in food inspection on a majority time basis:
 - . meat inspection: export meat establishments with an export function and domestic meat establishments (no export function);
 - . dairy inspection;
 - . other foods.
 - Numbers in import/export inspection.
 - Education/training details.
- d) Support staff
- Numbers directly available to *Veterinary Services* per sector (administration, communication, transport).
- e) Descriptive summary of the functions of the various categories of staff mentioned above

Appendix XXVIII (contd)Appendix V (contd)f) Veterinary, veterinary para-professional, livestock owner, farmer and other relevant associations

g) Additional information and/or comments.

3. Financial management information

- a) Total budgetary allocations to the *Veterinary Services* for the current and past two fiscal years:
 - i) for the national *Veterinary Services*;
 - ii) for each of any sub-national veterinary authorities;
 - iii) for other relevant government-funded institutions.
- b) Sources of the budgetary allocations and amount:
 - i) government budget;
 - ii) sub-national authorities;
 - iii) taxes and fines;
 - iv) grants;
 - v) private services.
- c) Proportional allocations of the amounts in a) above for operational activities and for the programme components of *Veterinary Services*.
- d) Total allocation proportionate of national public sector budget (*This data may be necessary for comparative assessment with other countries which should take into account the contexts of the importance of the livestock sector to the national economy and of the animal health status of the country.*)
- e) Actual and proportional contribution of animal production to gross domestic product.

4. Administration details

a) Accommodation

Summary of the numbers and distribution of official administrative centres of the *Veterinary Services* (national and sub-national) in the country.

b) Communications

Summary of the forms of communication systems available to the *Veterinary Services* on a nation-wide and local area bases.

c) Transport

- i) Itemised numbers of types of functional transport available on a full-time basis for the *Veterinary Services*. In addition provide details of transport means available part-time.
- ii) Details of annual funds available for maintenance and replacement of motor vehicles.

5. Laboratory services

a) Diagnostic laboratories (laboratories engaged primarily in diagnosis)

- i) Descriptive summary of the organisational structure and role of the government veterinary laboratory service in particular its relevance to the field *Veterinary Services*.

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- ii) Numbers of veterinary diagnostic laboratories operating in the country:
 - government operated laboratories;
 - private laboratories accredited by government for the purposes of supporting official or officially–endorsed animal health control or public health testing and monitoring programmes and import/export testing.
 - iii) Descriptive summary of accreditation procedures and standards for private laboratories.
 - iv) Human and financial resources allocated to the government veterinary laboratories, including staff numbers, graduate and post–graduate qualifications and opportunities for further training.
 - v) List of diagnostic methodologies available against major diseases of farm livestock (including poultry).
 - vi) Details of collaboration with external laboratories including international reference laboratories and details on numbers of samples submitted.
 - vii) Details of quality control and assessment (or validation) programmes operating within the veterinary laboratory service.
 - viii) Recent published reports of the official veterinary laboratory service which should include details of specimens received and foreign animal disease investigations made.
 - ix) Details of procedures for storage and retrieval of information on specimen submission and results.
 - x) Reports of independent reviews of the laboratory service conducted by government or private organisations (if available).
 - xi) Strategic and operational plans for the official veterinary laboratory service (if available).
 - b) Research laboratories (laboratories engaged primarily in research)
 - i) Numbers of veterinary research laboratories operating in the country:
 - government operated laboratories;
 - private laboratories involved in full time research directly related to animal health and veterinary public health matters involving production animal species.
 - ii) Summary of human and financial resources allocated by government to veterinary research.
 - iii) Published programmes of future government sponsored veterinary research.
 - iv) Annual reports of the government research laboratories.
6. Functional capabilities and legislative support
- a) Animal health and veterinary public health
 - i) Assessment of the adequacy and implementation of relevant legislation (national or sub–national) concerning the following:
 - animal and veterinary public health controls at national frontiers;
 - control of endemic animal diseases, including zoonoses;
 - emergency powers for control of exotic disease outbreaks, including zoonoses;
 - inspection and registration of facilities;

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- veterinary public health controls of the production, processing, storage and marketing of meat for domestic consumption;
 - veterinary public health controls of the production, processing, storage and marketing of fish, dairy products and other foods of animal origin for domestic consumption;
 - registration and use of veterinary pharmaceutical products including vaccines.
 - ii) Assessment of ability of *Veterinary Services* to enforce legislation.
 - b) Export/import inspection
 - i) Assessment of the adequacy and implementation of relevant national legislation concerning:
 - veterinary public health controls of the production, processing, storage and transportation of meat for export;
 - veterinary public health controls of production, processing, storage and marketing of fish, dairy products and other foods of animal origin for export;
 - animal health and veterinary public health controls of the export and import of *animals*, animal genetic material, animal products, animal feedstuffs and other products subject to veterinary inspection;
 - animal health controls of the importation, use and bio-containment of organisms which are aetiological agents of animal diseases, and of pathological material;
 - animal health controls of importation of veterinary biological products including vaccines;
 - administrative powers available to *Veterinary Services* for inspection and registration of facilities for veterinary control purposes (if not included under other legislation mentioned above);
 - documentation and compliance.
 - ii) Assessment of ability of *Veterinary Services* to enforce legislation.
7. Animal health and veterinary public health controls
- a) Animal health
 - i) Description of and sample reference data from any national animal disease reporting system controlled and operated or coordinated by the *Veterinary Services*.
 - ii) Description of and sample reference data from other national animal disease reporting systems controlled and operated by other organisations which make data and results available to *Veterinary Services*.
 - iii) Description and relevant data of current official control programmes including:
 - epidemiological surveillance or monitoring programmes;
 - officially approved industry-administered control or eradication programmes for specific diseases.
 - iv) Description and relevant details of animal disease emergency preparedness and response plans.

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- v) Recent history of animal disease status:
- animal diseases eradicated nationally or from defined sub-national zones in the last ten years;
 - animal diseases of which the prevalence has been controlled to a low level in the last ten years;
 - animal diseases introduced to the country or to previously free sub-national regions in the last ten years;
 - emerging diseases in the last ten years;
 - animal diseases of which the prevalence has increased in the last ten years.
- b) Veterinary public health
- i) Food hygiene
- Annual national slaughter statistics for the past three years according to official data by species of animals (bovine, ovine, porcine, caprine, poultry, farmed game, wild game, equine and other).
 - Estimate of total annual slaughterings which occur but are not recorded under official statistics.
 - Proportion of total national slaughter which occurs in registered export establishments, by category of animal.
 - Proportion of total national slaughter which occurs under veterinary control, by category of animal.
 - Numbers of commercial fresh meat establishments in the country which are registered for export by national *Veterinary Services*:
 - . slaughterhouses (indicate species of *animals*);
 - . cutting/packing plants (indicate meat type);
 - . meat processing establishments (indicate meat type);
 - . cold stores.
 - Numbers of commercial fresh meat establishments in the country approved by other *importing countries* which operate international assessment inspection programmes associated with approval procedures.
 - Numbers of commercial fresh meat establishments under direct public health control of the *Veterinary Services* (including details of category and numbers of inspection staff associated with these premises).
 - Description of the veterinary public health programme related to production and processing of animal products for human consumption (including fresh meat, poultry meat, meat products, game meat, dairy products, fish, fishery products, molluscs and crustaceans and other foods of animal origin) especially including details applying to exports of these *commodities*.
 - Descriptive summary of the roles and relationships of other official organisations in public health programmes for the products listed above if the national *Veterinary Services* do not have responsibility for those programmes which apply to national production destined to domestic consumption and/or exports of the *commodities* concerned.

Appendix XXVIII (contd)Appendix V (contd)

- ii) Zoonoses
 - Descriptive summary of the numbers and functions of staff of the *Veterinary Services* involved primarily with monitoring and control of zoonotic diseases.
 - Descriptive summary of the role and relationships of other official organisations involved in monitoring and control of zoonoses to be provided if the national *Veterinary Services* do not have these responsibilities.
- iii) Chemical residue testing programmes
 - Descriptive summary of national surveillance and monitoring programmes for environmental and chemical residues and contaminants applied to animal-derived foodstuffs, *animals* and animal feedstuffs.
 - Role and function in these programmes of the national *Veterinary Services* and other *Veterinary Services* to be described in summary form.
 - Descriptive summary of the analytical methodologies used and their consistency with internationally recognised standards.
- iv) Veterinary medicines
 - Descriptive summary of the administrative and technical controls involving registration, supply and use of veterinary pharmaceutical products especially including biological products. This summary should include a focus on veterinary public health considerations relating to the use of these products in food-producing *animals*.
 - Role and function in these programmes of the national *Veterinary Services* and other *Veterinary Services* to be described in summary form.

8. Quality Systems

a) Accreditation

Details and evidence of any current, formal accreditation by external agencies of the *Veterinary Services* of any components thereof.

b) Quality manuals

Documented details of the quality manuals and standards which describe the accredited quality systems of the *Veterinary Services*.

c) Audit

Details of independent (and internal) audit reports which have been undertaken of the *Veterinary Services* of components thereof.

9. Performance assessment and audit programmes

a) Strategic plans and review

i) Descriptive summary and copies of strategic and operational plans of the *Veterinary Services* organisation.

ii) Descriptive summary of corporate performance assessment programmes which relate to the strategic and operational plans – copies of recent review reports.

b) Compliance

Descriptive summary of any compliance unit which monitors the work of the *Veterinary Services* (or elements thereof).

Appendix XXVIII (contd)Appendix V (contd)

c) Annual reports of the national Veterinary Services

Copies of official annual reports of the national (sub-national) *Veterinary Services*.

d) Other reports

i) Copies of reports of official reviews into the function or role of the *Veterinary Services* which have been conducted within the past three years.

ii) Descriptive summary (and copy of reports if available) of subsequent action taken on recommendations made in these reviews.

e) Training

i) Descriptive summary of in-service and development programmes provided by the *Veterinary Services* (or their parent Ministries) for relevant staff.

ii) Summary descriptions of training courses and duration.

iii) Details of staff numbers (and their function) who participated in these training courses in the last three years.

f) Publications

Bibliographical list of scientific publications by staff members of *Veterinary Services* in the past three years.

g) Sources of independent scientific expertise

List of local and international universities, scientific institutions and recognised veterinary organisations with which the *Veterinary Services* have consultation or advisory mechanisms in place.

10. Membership of the OIE

State if country is a member of the OIE and period of membership.

11. Other assessment criteria

 — text deleted



Original: English
July 2003

REPORT OF THE MEETING OF THE OIE AD HOC GROUP ON DISEASES OF BEES

Paris, 29-31 July 2003

The OIE *Ad hoc* Group on diseases of bees held its first meeting at the OIE Headquarters from 29-31 July 2003.

The members of the OIE *Ad hoc* Group and other participants are listed in [Appendix I](#). The Agenda adopted is given in [Appendix II](#). Mr Paul Bolger was appointed Chair of the *Ad hoc* Group.

On behalf of the Director General of the OIE, Dr David Wilson, Head of the International Trade Department, welcomed the members of the *Ad hoc* Group and thanked them for their willingness to be involved in the OIE's work in addressing requests from Member Countries to update the OIE *Terrestrial Animal Health Code* (hereafter referred to as the "*Terrestrial Code*") chapters on diseases of bees to provide greater security in international trade in bees and bee products. He recalled the history of the revision of the chapters and appendix in the *Terrestrial Code*, and indicated that the task of the *Ad hoc* Group was to make recommendations for revision of the texts based on the latest scientific information, taking comments from Member Countries into account.

The *Ad hoc* Group firstly agreed on a general approach to the listed diseases of bees and recommended a new definition and a revised definition ([Appendix III](#)). In this discussion, it acknowledged that very few OIE Member Countries could make genuine claims for freedom from most of the diseases of bees, and examined the usefulness of categorising importing countries as 'officially free', 'infected', 'with an official control programme' or 'of unknown status'. It decided however, at this stage, to align its approach with that of the remainder of the *Terrestrial Code* chapters, that is to base its recommendations on the assumption that the importing country was 'officially free' of the disease, either due to historical freedom or as a result of an eradication campaign. As a result, no reference is made to the status of the importing country. It then addressed each disease and made appropriate recommendations ([Appendices IV to IX](#)). Explanations for the recommendations are given below. The *Ad hoc* Group also revised Appendix 3.4.2 of the *Terrestrial Code* ([Appendix X](#)).

Due to the extensive changes recommended, Appendices IV to XI are presented as clean text.

***Terrestrial Animal Health Code* chapters**

Acarapisosis (Chapter 2.9.1) (modified title)

Dr Anderson

The *Ad hoc* Group noted that there was little likelihood of the eradication of acarapisosis from infected countries where there is a feral population of *A. mellifera* L.

Appendix XXIX (contd)**American foulbrood (Chapter 2.9.2)**

Mr Bolger

European foulbrood (Chapter 2.9.3)

Mr Bolger

Nosemosis (Chapter 2.9.4)

The *Ad hoc* Group recommended that the chapter on nosemosis be removed from the *Terrestrial Code* as the agent of nosemosis (*Nosema apis*) is ubiquitous (there is no potential for further international spread), as no Member Country is in a position to claim freedom or impending freedom and as the disease is neither an emerging disease nor a zoonosis.

Varroosis (Chapter 2.9.5)

Dr Anderson

***Tropilaelaps* infestation**

Dr Anderson

Small hive beetle of honey bees (*Aethina tumida*)

The *Ad hoc* Group discussed information received from an expert on this beetle and decided that they would draft a new chapter for examination by the Terrestrial Animal Health Standards Commission.

Dr Anderson should send to Mr Bolger a booklet to help him draft a new chapter.

Work programme

The *Ad hoc* Group devised the following work programme:

- inactivation of American and European foulbroods (Dr Anderson)
- targeted surveillance for all diseases (including time periods) (Dr Aubert)
- detection of European foulbrood infection in queens in quarantine (Dr Anderson)
- definition of 'bee equipment' (Dr Bacci)
- inclusion of bee viruses in the *Terrestrial Code* (Mr Bolger).

.../Appendices

MEETING OF THE OIE AD HOC GROUP ON DISEASES OF BEES

Paris, 29–31 July 2003

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MEETING OF THE OIE *AD HOC* GROUP ON DISEASES OF BEES

Paris, 29–31 July 2003

Agenda adopted

- 1) Introduction
 - 2) Update on significant scientific advances on diseases of bees
 - 3) Revision of the *Terrestrial Code* chapters and appendix on bee diseases
 - 4) Revision of the international health certificates
 - 5) Conclusions
-

SECTION 1.1.
GENERAL DEFINITIONS AND
NOTIFICATION OF ANIMAL DISEASES

CHAPTER 1.1.1.
GENERAL DEFINITIONS

Article 1.1.1.1.

For the purposes of the *Terrestrial Code*:

...

Apiary

means a ~~collection~~ hive or group of hives whose management allows them to be considered as a single epidemiological unit situated in the same bee-keeping establishment.

...

Beehive

means a structure for the keeping of honey bee colonies that is being used for that purpose, including frameless hives, fixed frame hives and all designs of moveable frame hives (including nucleus hives), but not including packages or cages used to confine bees for the purpose of transport or isolation.

...

CHAPTER 2.9.1.

ACARAPISOSIS OF HONEY BEES

Article 2.9.1.1.

For the purposes of this chapter, acarapisosis, acarine disease or tracheal mite infestation is a disease of the adult honey bee *Apis mellifera* L., and possibly of other *Apis* species (such as *Apis cerana*). It is caused by the Tarsonemid mite *Acarapis woodi* (Rennie). The mite is an internal obligate parasite of the respiratory system, living and reproducing mainly in the large prothoracic trachea of the bee. Early signs of infection normally go unnoticed, and only when infection is heavy does it become apparent; this is generally in the early spring. The infection spreads by direct contact from adult bee to adult bee, with newly emerged bees under 10 days old being the most susceptible. The mortality rate may range from moderate to high.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 2.9.1.2.

The acarapisosis status of a country or zone can only be determined after considering the following criteria:

- 1) a risk assessment has been conducted, identifying all potential factors for acarapisosis occurrence and their historic perspective;
- 2) acarapisosis should be notifiable in the whole country or zone and all clinical signs suggestive of acarapisosis should be subjected to field and laboratory investigations;
- 3) an on-going awareness programme should be in place to encourage reporting of all *cases* suggestive of acarapisosis;
- 4) the *Veterinary Administration* or other competent authority with responsibility for the health of honey bees should have current knowledge of, and authority over, all domesticated apiaries in the whole country.

Article 2.9.1.3.

Country or zone officially free from acarapisosis1) Historically free status

A country or zone may be considered free from acarapisosis after conducting a risk assessment as referred to in Article 2.9.1.2. but without formally applying a specific surveillance programme (historical freedom) if the country or zone complies with the provisions of Article 3.8.1.2.

2) Free status as a result of an eradication programme

A country or zone which does not meet the conditions of point 1) above may be considered free from acarapisosis after conducting a risk assessment as referred to in Article 2.9.1.2. and when:

- a) the *Veterinary Administration* or other competent authority with responsibility for the health of honey bees has current knowledge of, and authority over, all domesticated apiaries existing in the country or zone;
- b) acarapisosis is notifiable in the whole country or zone, and any clinical cases suggestive of acarapisosis are subjected to field and laboratory investigations;

Appendix XXIX (contd)Appendix IV (contd)

- c) for the 3 years following the last reported *case* of acarapisosis, annual surveys supervised by the *Veterinary Administration*, with negative results, have been carried out on a representative sample of apiaries in the country or zone to provide a confidence level of at least 95% of detecting acarapisosis if at least 1% of the apiaries were infected at a within-apiary prevalence rate of at least 5% of the hives; such surveys may be targeted towards apiaries, areas and seasons with a higher likelihood of disease;
- d) to maintain free status, an annual survey supervised by the *Veterinary Administration*, with negative results, is carried out on a representative sample of apiaries in the country or zone to indicate that there has been no new *cases*; such surveys may be targeted towards areas with a higher likelihood of disease;
- e) there is no self-sustaining feral population of *A. mellifera* or other possible host species in the country or zone;
- f) the importation of the *commodities* listed in this Chapter into the country or zone is carried out in conformity with the recommendations of this Chapter.

Article 2.9.1.4.

Regardless of the acarapisosis status of the *exporting country*, *Veterinary Administrations* should authorise without restriction the import or transit through their territory of the following commodities:

- 1) honey bee semen and honey bee venom;
- 2) used equipment associated with beekeeping;
- 3) honey, beeswax, honey bee-collected pollen, propolis and royal jelly.

Article 2.9.1.5.

Veterinary Administrations of *importing countries* should require:

for live queen honey bees, worker bees and drones with or without associated brood combs

the presentation of an *international veterinary certificate* attesting that the bees come from a country or zone officially free from acarapisosis.

Article 2.9.1.6.

Veterinary Administrations of *importing countries* should require:

for eggs, larvae and pupae of honey bees

the presentation of an *international veterinary certificate* attesting that the products:

- 1) were sourced from an officially free country or zone; or
- 2) were examined by an official laboratory and declared free of all life stages of *A. woodi*; or
- 3) have originated from queens in a *quarantine station* and were examined microscopically and found free of all life stages of *A. woodi*.

CHAPTER 2.9.2.

AMERICAN FOULBROOD OF HONEY BEES

Article 2.9.2.1.

For the purposes of this chapter, American foulbrood is a disease of the larval and pupal stages of the honey bee *Apis mellifera* and other *Apis* spp., and occurs in most countries where such bees are kept. *Paenibacillus larvae subsp. larvae*, the causative organism, is a bacterium that can produce over one billion spores in each infected larva. The spores are very long-living and extremely resistant to heat and chemical agents, and only the spores are capable of inducing the disease.

Combs of infected apiaries may show distinctive clinical signs which can allow the disease to be diagnosed in the field. However, subclinical infections are common and require laboratory diagnosis.

For the purposes of this *Terrestrial Code*, the *incubation period* for American foulbrood shall be 15 days (not including the wintering period which may vary according to country).

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 2.9.2.2.

The American foulbrood status of a country or zone can only be determined after considering the following criteria:

- 1) a risk assessment has been conducted, identifying all potential factors for American foulbrood occurrence and their historic perspective;
- 2) American foulbrood should be notifiable in the whole country or zone and all clinical signs suggestive of American foulbrood should be subjected to field and/or laboratory investigations;
- 3) an on-going awareness programme should be in place to encourage reporting of all cases suggestive of American foulbrood;
- 4) the *Veterinary Administration* or other competent authority with responsibility for the health of honey bees should have current knowledge of, and authority over, all domesticated apiaries in the country.

Article 2.9.2.3.

Country or zone with an official control programme for American foulbrood

To be considered as a country or zone with an official control programme for American foulbrood, a country or zone should meet the following requirements:

- 1) the *Veterinary Administration* has current knowledge of, and authority over, all apiaries existing in the country or zone;
- 2) the control programme complies with the general provisions of Appendix 3.4.2., and is supervised by the *Veterinary Administration* or other competent authority with responsibility for the health of honey bees;
- 3) American foulbrood is notifiable in the whole country, and any clinical cases suggestive of American foulbrood are subjected to field and/or laboratory investigations;

Appendix XXIX (contd)Appendix V (contd)

- 4) a surveillance programme should exist under which hives and/or honey in the country or zone are inspected by a competent authority and/or sampled and tested for American foulbrood. The surveillance programme should indicate the location of infected apiaries as well as the estimated prevalence rate within those areas;
- 5) all infected hives should be either treated with appropriate antimicrobials, processed to ensure the destruction of both bacillary and spore forms of *P. larvae larvae*, in conformity with one of the procedures referred to in Appendix XXX (under study) or destroyed.

Article 2.9.2.4.

Country or zone officially free from American foulbrood1) Historically free status

A country or zone may be considered free from the disease after conducting a risk assessment as referred to in Article 2.9.2.2. but without formally applying a specific surveillance programme (historical freedom) if the country or zone complies with the provisions of Article 3.8.1.2.

2) Free status as a result of an eradication programme

A country or zone which does not meet the conditions of point 1) above may be considered free from American foulbrood after conducting a risk assessment as referred to in Article 2.9.2.2. and when:

- a) the *Veterinary Administration* or other competent authority with responsibility for the health of honey bees has current knowledge of, and authority over, all domesticated apiaries existing in the country or zone;
- b) American foulbrood is notifiable in the whole country or zone, and any clinical cases suggestive of American foulbrood are subjected to field and/or laboratory investigations;
- c) for the 5 years following the last reported isolation of the American foulbrood agent, an annual survey supervised by the *Veterinary Administration*, with negative results, have been carried out on a representative sample of apiaries in the country or zone to provide a confidence level of at least 95% of detecting American foulbrood if at least 1% of the apiaries were infected at a within-apiary prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with the last reported isolation of the American foulbrood agent;
- d) to maintain free status, an annual survey supervised by the *Veterinary Administration*, with negative results, is carried out on a representative sample of hives in the country or zone to indicate that there has been no new isolations; such surveys may be targeted towards areas with a higher likelihood of isolation;
- e) there is no self-sustaining feral population of *A. mellifera* or other possible host species in the country or zone;
- f) all equipment associated with previously infected apiaries has been sterilised or destroyed;
- g) the importation of the *commodities* listed in this Chapter into the country or zone is carried out in conformity with the recommendations of this Chapter.

Appendix XXIX (contd)Appendix V (contd)

Article 2.9.2.5.

Regardless of the American foulbrood status of the *exporting country*, *Veterinary Administrations* should authorise without restriction the import or transit through their territory of honey bee semen and honey bee venom.

Article 2.9.2.6.

Veterinary Administrations of *importing countries* officially free from American foulbrood should require: for live queen honey bees, worker bees and drones with or without associated brood combs

the presentation of an *international veterinary certificate* attesting that the bees come from a country or zone officially free from American foulbrood.

Article 2.9.2.7.

Veterinary Administrations of *importing countries* officially free from American foulbrood should require: for eggs, larvae and pupae of honey bees

the presentation of an *international veterinary certificate* attesting that the products:

- 1) were sourced from an officially free country or zone; or
- 2) have been isolated from queens in a *quarantine station*.

Article 2.9.2.8.

Veterinary Administrations of *importing countries* officially free from American foulbrood should require: for used equipment associated with beekeeping

the presentation of an *international veterinary certificate* attesting that the equipment was sterilised under the supervision of the *Veterinary Authority* by either immersion in 1% sodium hypochlorite for at least 30 minutes (suitable only for non-porous materials such as plastic and metal), gamma irradiation using a cobalt-60 source at a dose rate of 10 kGy, or processing to ensure the destruction of both bacillary and spore forms of *P. larvae larvae*, in conformity with one of the procedures referred to in Appendix XXX (under study).

Article 2.9.2.9.

Veterinary Administrations of *importing countries* officially free from American foulbrood should require: for honey, honey bee-collected pollen, beeswax, propolis and royal jelly

the presentation of an *international veterinary certificate* attesting that the products:

- 1) were collected in a country or zone officially free from American foulbrood; or
- 2) have been processed to ensure the destruction of both bacillary and spore forms of *P. larvae larvae*, in conformity with one of the procedures referred to in Appendix XXX (under study).

CHAPTER 2.9.3.

EUROPEAN FOULBROOD OF HONEY BEES

Article 2.9.3.1.

For the purposes of this chapter, European foulbrood is a disease of the larval and pupal stages of the honey bee *Apis mellifera* and other *Apis* spp., and occurs in most countries where such bees are kept. The causative agent is the non-sporulating bacterium *Melissococcus pluton*. Subclinical infections are common and require laboratory diagnosis. Infection remains enzootic because of mechanical contamination of the honeycombs. Recurrences of disease can therefore be expected in subsequent years.

For the purposes of this *Terrestrial Code*, the *incubation period* for European foulbrood shall be 15 days (not including the wintering period which may vary according to country).

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 2.9.3.2.

The European foulbrood status of a country or zone can only be determined after considering the following criteria:

- 1) a risk assessment has been conducted, identifying all potential factors for European foulbrood occurrence and their historic perspective;
- 2) European foulbrood should be notifiable in the whole country or zone and all clinical signs suggestive of European foulbrood should be subjected to field and laboratory investigations;
- 3) an on-going awareness programme should be in place to encourage reporting of all cases suggestive of European foulbrood;
- 4) the *Veterinary Administration* or other competent authority with responsibility for the health of honey bees should have current knowledge of, and authority over, all apiaries in the whole country.

Article 2.9.3.3.

Country or zone officially free from European foulbrood1) Historically free status

A country or zone may be considered free from the disease after conducting a risk assessment as referred to in Article 2.9.3.2. but without formally applying a specific surveillance programme (historical freedom) if the country or zone complies with the provisions of Article 3.8.1.2.

2) Free status as a result of an eradication programme

A country or zone which does not meet the conditions of point 1) above may be considered free from European foulbrood after conducting a risk assessment as referred to in Article 2.9.3.2. and when:

- a) the *Veterinary Administration* or other competent authority with responsibility for the health of honey bees has current knowledge of, and authority over, all domesticated apiaries existing in the country or zone;

Appendix XXIX (contd)Appendix VI (contd)

- b) European foulbrood is notifiable in the whole country or zone, and any clinical cases suggestive of European foulbrood are subjected to field and laboratory investigations;
- c) for the 3 years following the last reported isolation of the European foulbrood agent, an annual survey supervised by the *Veterinary Administration*, with negative results, have been carried out on a representative sample of apiaries in the country or zone to provide a confidence level of at least 95% of detecting European foulbrood if at least 1% of the apiaries were infected at a within-apiary prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with the last reported isolation of the European foulbrood agent;
- d) to maintain free status, an annual survey supervised by the *Veterinary Administration*, with negative results, is carried out on a representative sample of hives in the country or zone to indicate that there has been no new isolations; such surveys may be targeted towards areas with a higher likelihood of isolation;
- e) there is no self-sustaining feral population of *A. mellifera* or other possible host species in the country or zone;
- f) the importation of the *commodities* listed in this Chapter into the country or zone is carried out in conformity with the recommendations of this Chapter.

Article 2.9.3.4.

Regardless of the European foulbrood status of the exporting country, *Veterinary Administrations* should authorise without restriction the import or transit through their territory of honey bee semen and honey bee venom.

Article 2.9.3.5.

Veterinary Administrations of *importing countries* should require:

for live queen honey bees, worker bees and drones with or without associated brood combs

the presentation of an *international veterinary certificate* attesting that the bees come from a country or zone officially free from European foulbrood.

Article 2.9.3.6.

Veterinary Administrations of *importing countries* should require:

for eggs, larvae and pupae of honey bees

the presentation of an *international veterinary certificate* attesting that the products:

- 1) were sourced from an officially free country or zone; or
- 2) have been isolated from queens in a *quarantine station*, and all workers which accompanied the queen or a representative sample of eggs or larvae were examined for the presence of *Melissococcus pluton* by bacterial culture or PCR.

Appendix XXIX (contd)

Appendix VI (contd)

Article 2.9.3.7.

Veterinary Administrations of importing countries should require:

for used equipment associated with beekeeping

the presentation of an *international veterinary certificate* attesting that the equipment was sterilised under the supervision of the *Veterinary Authority* by either immersion in 0.5% sodium hypochlorite for at least 20 minutes (suitable only for non-porous materials such as plastic and metal), gamma irradiation using a cobalt-60 source at a dose rate of 10 kGy, or processing to ensure the destruction of *Melissococcus pluton*, in conformity with one of the procedures referred to in Appendix XXX (under study).

Article 2.9.3.8.

Veterinary Administrations of importing countries should require:

for honey, honey bee-collected pollen, beeswax, propolis and royal jelly

the presentation of an *international veterinary certificate* attesting that the products:

- 1) were collected in a country or zone officially free from European foulbrood; or
- 2) have been processed to ensure the destruction of *Melissococcus pluton*, in conformity with one of the procedures referred to in Appendix XXX (under study).

CHAPTER 2.9.5.

VARROOSIS OF HONEY BEES

Article 2.9.5.1.

For the purposes of this chapter, varroosis is a disease of the honey bee *Apis mellifera* L. It is caused by the Korea and Japan haplotypes of the mite *Varroa destructor*, the original hosts of which are the Korea and Japan haplotypes of *Apis cerana*. The mite is an ectoparasite of adults and brood of *Apis mellifera* L. Early signs of infection normally go unnoticed, and only when infection is heavy does it become apparent. The infection spreads by direct contact from adult bee to adult bee, and by the movement of infested bees and bee brood. The mite can also act as a vector for viruses of the honey bee.

The number of parasites steadily increases with increasing brood activity and the growth of the bee population, especially late in the season when clinical signs of infestation can first be recognised. The life span of the mite depends on temperature and humidity but, in practice, it can be said to last from some days to a few months.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 2.9.5.2.

The varroosis status of a country or zone can only be determined after considering the following criteria:

- 1) a risk assessment has been conducted, identifying all potential factors for varroosis occurrence and their historic perspective;
- 2) varroosis should be notifiable in the whole country or zone and all clinical signs suggestive of varroosis should be subjected to field and laboratory investigations;
- 3) an on-going awareness programme should be in place to encourage reporting of all cases suggestive of varroosis;
- 4) the *Veterinary Administration* or other competent authority with responsibility for the health of honey bees should have current knowledge of, and authority over, all domesticated apiaries in the whole country.

Article 2.9.5.3.

Country or zone with an official control programme for varroosis

To be considered as a country or zone with an official control programme for varroosis, a country or zone should meet the following requirements:

- 1) the *Veterinary Administration* has current knowledge of, and authority over, all apiaries existing in the country or zone;
- 2) the control programme complies with the general provisions of Appendix 3.4.2., and is supervised by the *Veterinary Administration*;
- 3) varroosis is notifiable in the whole country or zone, and any clinical cases suggestive of varroosis are subjected to field and laboratory investigations;

Appendix XXIX (contd)Appendix VII (contd)

- 4) a surveillance programme should exist under which hives and/or honey in the country or zone are inspected by a competent authority and/or sampled and tested for varroosis. The surveillance programme should indicate the location of infected apiaries as well as the estimated prevalence rate within those areas;
- 5) all infected hives should be either treated with an appropriate acaricide or destroyed.

Article 2.9.5.4.

Country or zone officially free from varroosis1) Historically free status

A country or zone may be considered free from the disease after conducting a risk assessment as referred to in Article 2.9.5.2. but without formally applying a specific surveillance programme (historical freedom) if the country or zone complies with the provisions of Article 3.8.1.2.

2) Free status as a result of an eradication programme

A country or zone which does not meet the conditions of point 1) above may be considered free from varroosis after conducting a risk assessment as referred to in Article 2.9.5.2. and when:

- a) the *Veterinary Administration* or other competent authority with responsibility for the health of honey bees has current knowledge of, and authority over, all domesticated apiaries existing in the country or zone;
- b) varroosis is notifiable in the whole country or zone, and any clinical cases suggestive of varroosis are subjected to field and laboratory investigations;
- c) for the 3 years following the last reported case of varroosis, annual surveys supervised by the *Veterinary Administration*, with negative results, have been carried out on a representative sample of apiaries in the country or zone to provide a confidence level of at least 95% of detecting varroosis if at least 1% of the apiaries were infected at a within-apiary prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with a higher likelihood of disease;
- d) to maintain free status, an annual survey supervised by the *Veterinary Administration*, with negative results, is carried out on a representative sample of apiaries in the country or zone to indicate that there has been no new cases; such surveys may be targeted towards areas with a higher likelihood of disease;
- e) there is no self-sustaining feral population of *A. mellifera*, the Korea and Japan haplotypes of *Apis cerana* or other possible host species in the country or zone;
- f) the importation of the *commodities* listed in this Chapter into the country or zone is carried out in conformity with the recommendations of this Chapter.

Article 2.9.5.5.

Regardless of the varroosis status of the *exporting country*, *Veterinary Administrations* should authorise without restriction the import or transit through their territory of the following commodities:

- 1) honey bee semen, honey bee eggs and honey bee venom;
- 2) extracted honey and beeswax (not in the form of honeycomb).

Appendix XXIX (contd)Appendix VII (contd)

Article 2.9.5.6.

Veterinary Administrations of importing countries should require:

for live queen honey bees, worker bees and drones with or without associated brood combs

the presentation of an *international veterinary certificate* attesting that the bees come from a country or zone officially free from varroosis.

Article 2.9.5.7.

Veterinary Administrations of importing countries should require:

for larvae and pupae of honey bees

the presentation of an *international veterinary certificate* attesting that the products:

- 1) were sourced from an officially free country or zone; or
- 2) have originated from queens in a *quarantine station* and were inspected and found free of *Varroa destructor*.

Article 2.9.5.8.

Veterinary Administrations of importing countries should require:

for used equipment associated with beekeeping

the presentation of an *international veterinary certificate* attesting that the equipment:

- 1) comes from a country or zone officially free from varroosis; or
- 2) contains no live honey bees or bee brood and has been held away from contact with live honey bees for at least 7 days prior to shipment; or
- 3) has been treated to ensure the destruction of *Varroa destructor*, in conformity with one of the procedures referred to in Appendix XXX (under study).

Article 2.9.5.9.

Veterinary Administrations of importing countries should require:

for honey-bee collected pollen, beeswax (in the form of honeycomb), comb honey and propolis

the presentation of an *international veterinary certificate* attesting that the products:

- 1) come from a country or zone officially free from varroosis; or
- 2) contain no live honey bees or bee brood and has been held away from contact with live honey bees for at least 7 days prior to shipment; or
- 3) have been treated to ensure the destruction of *Varroa destructor*, in conformity with one of the procedures referred to in Appendix XXX (under study).

CHAPTER 2.9.X.

TROPILAEELAPS INFESTATION OF HONEY BEES

Article 2.9.X.1.

For the purposes of this chapter, *Tropilaelaps* infestation of the honey bee *Apis mellifera* L. is caused by the mite *Tropilaelaps clareae* and *T. koenigerum*. The mite is an ectoparasite of brood of *Apis mellifera* L., *Apis laboriosa* and *Apis dorsata*, and cannot survive for periods of more than 7 days away from bee brood.

Early signs of infection normally go unnoticed, but the growth in the mite population is rapid leading to high hive mortality. The infection spreads by direct contact from adult bee to adult bee, and by the movement of infested bees and bee brood. The mite can also act as a vector for viruses of the honey bee.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 2.9.X.2.

The *Tropilaelaps* status of a country or zone can only be determined after considering the following criteria:

- 1) a risk assessment has been conducted, identifying all potential factors for *Tropilaelaps* occurrence and their historic perspective;
- 2) *Tropilaelaps* infestation should be notifiable in the whole country or zone and all clinical signs suggestive of *Tropilaelaps* infestation should be subjected to field and laboratory investigations;
- 3) an on-going awareness programme should be in place to encourage reporting of all cases suggestive of *Tropilaelaps* infestation;
- 4) the *Veterinary Administration* or other competent authority with responsibility for the health of honey bees should have current knowledge of, and authority over, all domesticated apiaries in the country.

Article 2.9.X.3.

Country or zone with an official control programme for *Tropilaelaps* infestation

To be considered as a country or zone with an official control programme for *Tropilaelaps* infestation, a country or zone should meet the following requirements:

- 1) the *Veterinary Administration* has current knowledge of, and authority over, all apiaries existing in the country or zone;
- 2) the control programme complies with the general provisions of Appendix 3.4.2., and is supervised by the *Veterinary Administration*;
- 3) *Tropilaelaps* infestation is notifiable in the whole country or zone, and any clinical cases suggestive of *Tropilaelaps* infestation are subjected to field and laboratory investigations;
- 4) a surveillance programme should exist under which hives and/or honey in the country or zone are inspected by a competent authority and/or sampled and tested for *Tropilaelaps* infestation. The surveillance programme should indicate the location of infected apiaries as well as the estimated prevalence rate within those areas;

Appendix XXIX (contd)Appendix VIII (contd)

- 5) all infected hives should either have the brood removed for a period of at least 7 days, be treated with an appropriate acaricide or be destroyed.

Article 2.9.X.4.

Country or zone officially free from *Tropilaelaps* spp1) Historically free status

A country or zone may be considered free from the disease after conducting a risk assessment as referred to in Article 2.9.X.2. but without formally applying a specific surveillance programme (historical freedom) if the country or zone complies with the provisions of Article 3.8.1.2.

2) Free status as a result of an eradication programme

A country or zone which does not meet the conditions of point 1) above may be considered free from *Tropilaelaps* infestation after conducting a risk assessment as referred to in Article 2.9.X.2. and when:

- a) the *Veterinary Administration* or other competent authority with responsibility for the health of honey bees has current knowledge of, and authority over, all domesticated apiaries existing in the country or zone;
- b) *Tropilaelaps* infestation is notifiable in the whole country or zone, and any clinical cases suggestive of *Tropilaelaps* infestation are subjected to field and laboratory investigations;
- c) for the 3 years following the last reported case of *Tropilaelaps* infestation, annual surveys supervised by the *Veterinary Administration*, with negative results, have been carried out on a representative sample of apiaries in the country or zone to provide a confidence level of at least 95% of detecting *Tropilaelaps* infestation if at least 1% of the apiaries were infected at a within-apiary prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with a higher likelihood of infestation;
- d) to maintain free status, an annual survey supervised by the *Veterinary Administration*, with negative results, is carried out on a representative sample of apiaries in the country or zone to indicate that there has been no new cases; such surveys may be targeted towards areas with a higher likelihood of disease;
- e) there is no self-sustaining feral population of *A. mellifera*, *A. dorsata* or *A. laboriosa*, or other possible host species in the country or zone;
- f) the importation of the *commodities* listed in this Chapter into the country or zone is carried out, in conformity with the recommendations of this Chapter.

Article 2.9.X.5.

Regardless of the status of the *exporting country* with regard to *Tropilaelaps* infestation, *Veterinary Administrations* should authorise without restriction the import or transit through their territory of the following commodities:

- 1) honey bee semen, honey bee eggs and honey bee venom;
- 2) extracted honey and beeswax (not in the form of honeycomb).

Appendix XXIX (contd)Appendix VIII (contd)

Article 2.9.X.6.

Veterinary Administrations of importing countries should require:

for live queen honey bees, worker bees and drones with associated brood combs

the presentation of an *international veterinary certificate* attesting that the bees come from a country or zone officially free from *Tropilaelaps* infestation.

Article 2.9.X.7.

Veterinary Administrations of importing countries should require:

for live queen honey bees, worker bees and drones without associated brood combs

the presentation of an *international veterinary certificate* attesting that the bees have been held in isolation from brood and bees with access to brood, for a period of at least 7 days.

Article 2.9.X.8.

Veterinary Administrations of importing countries should require:

for used equipment associated with beekeeping

the presentation of an *international veterinary certificate* attesting that the equipment:

- 1) comes from a country or zone officially free from *Tropilaelaps* infestation; or
- 2) contains no live honey bees or bee brood and has been held away from contact with live honey bees for at least 7 days prior to shipment; or
- 3) has been treated to ensure the destruction of *Tropilaelaps* spp., in conformity with one of the procedures referred to in Appendix XXX (under study).

Article 2.9.X.9.

Veterinary Administrations of importing countries should require:

for honey-bee collected pollen, beeswax (in the form of honeycomb), comb honey and propolis

the presentation of an *international veterinary certificate* attesting that the products:

- 1) come from a country or zone officially free from *Tropilaelaps* infestation; or
- 2) contain no live honey bees or bee brood and has been held away from contact with live honey bees for at least 7 days prior to shipment; or
- 3) have been treated to ensure the destruction of *Tropilaelaps* spp., in conformity with one of the procedures referred to in Appendix XXX (under study).

CHAPTER 2.9.X.

AETHINA TUMIDA INFESTATION OF HONEY BEES

Article 2.9.X.1.

APPENDIX 3.4.2.

OFFICIAL PROGRAMMES FOR THE CONTROL
OF HONEY BEE DISEASES

Article 3.4.2.1.

Countries wishing to implement an official programme for the control of any of the honey bee diseases mentioned in the *Terrestrial Code* should include in the programme the following:

- a) an organisation for permanent health surveillance;
- b) an official laboratory for diagnosis of the disease;
- c) notification of the disease or any suspicion thereof;
- d) the *Veterinary Administration* or other competent authority with responsibility for the health of honey bees in the country;
- e) annual surveys to detect the potential presence of the disease within the honey bee population; such surveys may be targeted towards areas or apiaries with a higher likelihood of infestation;
- f) a requirement for periodic inspection of a representative sample of apiaries for the disease;
- g) a requirement to either treat or destroy any apiaries or beehives found to be infected with the disease;
- h) a contingency plan describing controls and follow-up activities, as relevant to the disease, over the movement of, and *international trade* in, honey bees, drones, brood combs, used equipment associated with beekeeping, honey, honey bee-collected pollen, beeswax, propolis and royal jelly;
- i) measures for cleaning, *disinfection* and *disinfestation* of apicultural equipment.

Article 3.4.2.2.

Organisation for permanent official sanitary surveillance of apiaries

Permanent official sanitary surveillance of apiaries should be under the authority of the *Veterinary Administration* or other competent authority with responsibility for the health of honey bees and should be performed either by representatives of the *Veterinary Authority* or by representatives of an approved organisation, with the possible assistance of bee-keepers specially trained to qualify as 'health inspectors and advisers'.

The official surveillance service thus established should carry out the following tasks:

1. visit a representative sample of apiaries:
 - a) annual visits during the most appropriate periods to detect the disease;
 - b) unexpected visits to apiaries where breeding or transport operations are carried out for trade or transfer to other zones within the country or to *importing countries*, or any other purpose whereby the disease could be spread, as well as to apiaries located in the vicinity;
 - c) special visits for sanitary surveillance to sectors where apiaries are producing stock or products for export purposes;

Appendix XXIX (contd)Appendix X (contd)

2. collect samples required for the diagnosis of the disease and despatch them to an official laboratory; it should be mandatory for the laboratory to communicate the results of its examinations promptly to the *Veterinary Authority*;
3. ensure that appropriate sanitary measures are applied, in particular treatment of colonies of bees, as well as *disinfection* of the equipment and possibly the destruction of infected or suspect colonies and of the contaminated equipment, so as to ensure rapid eradication of any *outbreak* of a disease.

Article 3.4.2.3.

Conditions for approval of breeding apiaries for export trade

The apiaries must have received, for at least the past 2 years, visits by a health inspector or adviser, carried out at least 3 times a year (in spring, during the breeding period and in autumn), for the systematic examination of the hives containing bees and of all the apicultural equipment, and for the collection of samples to be sent to an official laboratory.

Bee-keepers should be required to:

1. immediately notify the *Veterinary Authority* of any suspicion of the disease of bees in the apiary and in other apiaries in the vicinity;
2. not introduce into the apiary any bee (at any stage of development) or apicultural material or product originating from another apiary unless health control has been previously performed by the *Veterinary Authority* or its representatives;
3. apply appropriate sanitary techniques to minimise the likelihood of outside contamination, especially for the breeding and sending of queen honey bees and accompanying bees;
4. collect and send to the official laboratory, at the times specified by the legislation applicable to the disease, samples from breeding material, brood-combs, queen-bees and bees (including possibly separately raised accompanying bees), as relevant.

Article 3.4.2.4.

Disinfection of apicultural equipment

Veterinary Administrations should regulate the use of products and means for the *disinfection* of apicultural equipment, taking into account the following guidelines.

1. Any apicultural equipment which has been recognised as being infected by the disease should be subjected to sanitary measures ensuring the elimination of pathogens.
2. In all cases, these measures comprise the initial cleaning and scraping of the equipment, followed by sanitation or *disinfection* according to the disease concerned.
3. The kind of equipment (hives, small hives, combs, extractor, small equipment, appliances for handling or storage) should be taken into account in the choice of procedures to be applied.
4. Infected or contaminated equipment which cannot be subjected to the above-mentioned measures should be destroyed, preferably by burning.
5. The products and means used for sanitation and *disinfection* should be recognised as being effective by the *Veterinary Administration* and should be used in such a manner as to exclude any risk of soiling the equipment which could eventually affect the health of honey bees or adulterate the products of the hive.

Appendix XXIX (contd)

Appendix X (contd)

6. When these procedures are not performed, the products should be kept away from the bees and sheltered from any contact with apicultural equipment and products.
7. Waste water from the cleaning, sanitation and *disinfection* of apicultural equipment should be kept away from the bees at all times.

Article 3.4.2.5.

Preparation of international veterinary certificates for export

International veterinary certificates relating to honey bees, drones, brood combs, used equipment associated with beekeeping, honey, honey bee-collected pollen, propolis and royal jelly should be prepared in accordance with the principles of certification provided for in Chapter 1.2.2.

Model *international veterinary certificates* are presented in Part 4 of the *Terrestrial Code*.

SECTION 3.6.
INACTIVATION OF PATHOGENS AND VECTORS
APPENDIX 3.6.X.
HONEY BEE DISEASES

Article 3.6.X.1.

Acarapisosis of honey bees

nil

Article 3.6.X.2.

American foulbrood of honey bees

Processing to ensure the destruction of both bacillary and spore forms of *P larvae larvae*

1. In used equipment associated with beekeeping
 - a) immersion in 1% sodium hypochlorite for at least 30 minutes (suitable only for non-porous materials such as plastic and metal, free from wax and propolis);
 - b) Virkon® (90% for 10 minutes) (suitable only for non-porous materials such as plastic and metal, free from wax and propolis);
 - c) gamma irradiation using a cobalt-60 source at a dose rate of 10 kGy.
2. In wooden hive parts (excluding comb and plastic components)
 - a) immersion in paraffin wax at 160°C for at least 10 minutes;
 - b) gamma irradiation using a cobalt-60 source at a dose rate of 10 kGy.
3. In beeswax
 - a) gamma irradiation using a cobalt-60 source at a dose rate of 10 kGy;
 - b) processed so that it is free of pollen and honey.
4. In propolis

Processed so that it is free of wax, pollen and honey.
5. In bee-collected pollen

Gamma irradiation using a cobalt-60 source at a dose rate of 10 kGy.

Appendix XXIX (contd)Appendix XI (contd)

Article 3.6.X.3.

European foulbrood of honey bees

Processing to ensure the destruction of *Melissococcus pluton*

1. In used equipment associated with beekeeping:

- a) immersion in 1% sodium hypochlorite for at least 30 minutes (suitable only for non-porous materials such as plastic and metal, free from wax and propolis);
- b) Virkon® (90% for 10 minutes) (suitable only for non-porous materials such as plastic and metal, free from wax and propolis);
- c) gamma irradiation using a cobalt-60 source at a dose rate of 14 kGy.

2. In honey and royal jelly

- a) gamma irradiation using a cobalt-60 source at a dose rate of 14 kGy;
- b) heat treated at one of the following core time/temperature combinations:

Temperature (°C)	Time
50	48h
55	25h
60	13h
65	7h
70	3.5h
75	2h
80	1h

3. In beeswax

Gamma irradiation using a cobalt-60 source at a dose rate of 14 kGy

4. In propolis

Processed so that it is free of wax, pollen and honey.

5. In bee-collected pollen

Gamma irradiation using a cobalt-60 source at a dose rate of 14 kGy

6. In wooden hive parts (excluding comb and plastic components)

- a) immersion in paraffin wax at 160°C for at least 10 minutes;
- b) gamma irradiation using a cobalt-60 source at a dose rate of 14 kGy.

Appendix XXIX (contd)Appendix XI (contd)

Article 3.6.X.4.

Varroosis of honey bees

nil

Article 3.6.X.5.

***Tropilaelaps* infestation of honey bees**

nil

Article 3.6.X.6.

***Aethina tumida* infestation of honey bees**

nil



Original: English
August 2003

REPORT OF THE FIRST MEETING OF THE OIE *AD HOC* GROUP ON THE HUMANE KILLING OF ANIMALS FOR DISEASE CONTROL PURPOSES

Paris, 14-16 October 2003

The OIE *Ad hoc* Group on the humane killing of animals for disease control purposes held its first meeting at the OIE Headquarters from 14-16 October 2003.

The members of the OIE *Ad hoc* Group are listed in [Appendix I](#). The Agenda adopted is given in [Appendix II](#). Dr John Galvin was appointed Chair of the *Ad hoc* Group.

On behalf of the Director General of the OIE, Dr David Wilson welcomed the members of the *Ad hoc* Group and thanked them for their willingness to be involved in addressing the new mandate of the OIE for animal welfare. He recalled the outcomes of the first meeting of the Working Group on Animal Welfare and explained that the OIE planned to hold a meeting of each *Ad hoc* Group dealing with the prioritised animal welfare issues prior to the OIE Global Animal Welfare Conference (to be held in February 2004). He also noted the recommendation of the Working Group that *Ad hoc* Groups initially develop more detailed statements on policies and principles, specific to their subject, as a bridge between the generic OIE statement on policies and principles, and specific animal welfare standards.

The *Ad hoc* Group discussed the scope of its work, noting that the animal welfare aspects of disease control procedures needed to be addressed within broader constraints, including those posed by human safety and biosecurity considerations. Within this scope, it examined and made recommendations on operational procedures for the killing of animals and the required competencies of personnel, to minimise adverse welfare impacts. The *Ad hoc* Group confined its considerations to the procedures that need to occur from the time that the decision is taken to kill animals for diseases control purposes, until the animals are dead, and to the killing of cattle, sheep, goats, pigs and poultry.

The agreed terms of reference for the *Ad hoc* Group are at [Appendix III](#).

The *Ad hoc* Group addressed the general principles of humane killing, organisational structure, the responsibilities and competencies of personnel working on affected premises, planning the humane killing of animals, and recommends various killing methods. The recommendations do not contain detailed, specific operating procedures as these are available elsewhere in emergency disease control plans and equipment manufacturer recommendations. This level of detail was considered beyond the scope of the *Ad hoc* Group's terms of reference. The recommendations also include comments on operator safety and biosecurity, as these two factors cannot be separated from the killing of animals.

Appendix XXX (contd)

The recommendations aim to give those personnel responsible for the killing of animals, information on which to decide the most humane procedures applicable to the particular circumstances they face, noting that the circumstances will usually be less than ideal, and operations will generally need to be conducted within short timeframes.

The *Ad hoc* Group recognised that using competent personnel is critical to ensuring the highest possible animal welfare standards. The *Ad hoc* Group identified veterinarians as the best-qualified generalists in animal welfare matters but recognised the need for specialist knowledge when supervising the humane killing of livestock for disease control purposes. The *Official Veterinarian* needed to be aware of the welfare attributes of the available methods and the justification for their selection to meet the specific circumstances on the premises. The *Ad hoc* Group believed that Continual Professional Development (CPD) programmes (that contain elements of animal welfare and the scientific research that underpins the preferred killing methods) should be available for *Official Veterinarians*.

The *Ad hoc* Group considered that the team leader and veterinarian within the operational groups also require a training programme that is explicit to the operation of the team and their defined roles. Detailed training should include humane killing methods and focus on the welfare evaluation of the use of the methods with cattle, sheep, goats, pigs and poultry. Formal training and assessment of competency should also be introduced for animal handlers and slaughtermen.

The *Ad hoc* Group also recognised that the principles developed for killing animals for disease control purposes may also be applicable for the killing of animals following natural disasters and in emergency slaughter situations.

The *Ad hoc* Group drafted guidelines for the humane killing of animals for disease control purposes, commencing with general principles and following with more specific recommendations relating to species and methodologies adopted. The draft guidelines are at Appendix IV.

.../Appendices

**MEETING OF THE OIE AD HOC GROUP ON
HUMANE KILLING OF ANIMALS FOR DISEASE CONTROL PURPOSES**

Paris, 14–16 October 2003

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**MEETING OF THE OIE *AD HOC* GROUP ON
HUMANE KILLING OF ANIMALS FOR DISEASE CONTROL PURPOSES**

Paris, 14–16 October 2003

Approved Agenda

- 1) Introduction
 - Discussions in the OIE Working Group on Animal Welfare
 - Other relevant discussions
 - 2) Discussion on context, scope, timetable
 - 3) Drafting of specific guiding principles and standards
 - 4) Drafting of operational procedures
 - 5) Work programme
-

**OIE AD HOC GROUP ON
HUMANE KILLING OF ANIMALS FOR DISEASE CONTROL PURPOSES**

Terms of reference

- First output – draft guiding principles (rather than a prescriptive approach to procedures) specifically addressing depopulation for disease control purposes, based on the generic OIE guiding principles and policies for animal welfare
- Final output – draft standards / guidelines for OIE *Code* based on these guiding principles
- Address appropriately religious and cultural dimensions and the needs of pregnant animals
- Identify future directions in which the *Ad hoc* Group might need to move
- Produce drafts for review by Animal Welfare Working Group and then by Code Commission

Species to be covered

- cattle, sheep, goats
- pigs
- poultry

The species below will be addressed as resources permit and/or expertise is available

- horses
- other farmed ungulates, including deer and camelids
- ratites
- rabbits
- fish

Working Group member as point of reference

- Dr Andrea Gavinelli
-

DEFINITIONS***Stockmanship***

good stockmanship means a professional and sympathetic response to an animal's welfare requirements.

Stunning

means immediate loss of consciousness.

Death

means irreversible loss of brain activity as demonstrated by loss of brain stem reflexes.

Pithing

means the physical destruction of the brain and upper regions of the spinal cord, through the insertion of a rod or cane through the shot hole.

RMS

(Steve Wotton to provide)

Appendix XXX (contd)Appendix IV (contd)**GUIDELINES FOR THE HUMANE KILLING OF ANIMALS
FOR DISEASE CONTROL PURPOSES****Article 1****General principles of humane killing**

- 1) Disease control contingency plans should be in place at a national level and should contain details of management structure, disease control strategies and operational procedures; animal welfare considerations should be addressed within these disease control contingency plans.
- 2) Disease control strategies should also address the animal welfare issues that may result from animal movement controls.
- 3) The following principles apply after a decision to kill the animals has been made.
- 4) All personnel involved in the humane killing of animals should have the relevant skills and competencies.
- 5) As necessary, operational procedures should be adapted to the specific circumstances operating on the premises and should address, apart from animal welfare, operator safety and biosecurity.
- 6) Following the decision to kill the animals, killing should be carried out as quickly as possible and normal husbandry should be maintained until the animals are killed.
- 7) The handling and movement of animals should be minimised and when done, it should be done in accordance with the operational procedures described below.
- 8) Animal restraint should be sufficient to facilitate effective killing, and in accordance with animal welfare and operator safety requirements; when restraint is required, killing should follow with minimal delay.
- 9) When animals are killed for disease control purposes, methods used should result in immediate death or immediate loss of consciousness lasting until death; when loss of consciousness is not immediate, induction of unconsciousness should be non-aversive and should not cause anxiety, pain, distress or suffering in the animals.
- 10) For animal welfare considerations, young animals should be killed before older animals; for biosecurity considerations, infected animals should be killed first, followed by in-contact animals, and then the remaining animals.
- 11) There should be continuous monitoring of the procedures to ensure they are consistently effective with regard to animal welfare, operator safety and biosecurity.
- 12) When the operational procedures are concluded, there should be a written report describing the practices adopted and their effect on animal welfare, operator safety and biosecurity.
- 13) To the extent possible to minimise public distress, killing of animals and carcase disposal should be carried out away from public view.
- 14) These general principles should also apply when animals need to be killed for other purposes such as after natural disasters.

Article 2

Organisational structure

The operational activities should be led by an *official veterinarian* who has the authority to ensure that animal welfare standards are adhered to and who should ensure that the personnel involved has the required competencies.

The *official veterinarian* should be responsible for all activities across one or more affected premises and should be supported by coordinators for planning (including communications), operations and logistics to facilitate efficient operations.

The *official veterinarian* should provide overall guidance to personnel and logistic support for operations on all affected premises to ensure consistency in adherence to animal welfare standards.

A specialist team, led by a designated team leader, should be deployed to work on each affected premises. The team should consist of personnel with the skills and competencies to conduct all required operations. In considering the animal welfare issues associated with killing animals, the key personnel, their responsibilities and skills required are described in Article 3.

Article 3

Responsibilities and skills of the specialist team

Team leader

- Responsibilities
 - plan overall operations on an affected premises
 - determine and address requirements for animal welfare, operator safety and biosecurity
 - organise, brief and manage team of people to facilitate humane killing of the relevant animals on the premises in accordance with national regulations and these guidelines
 - determine logistics required
 - monitor operations to ensure animal welfare, operator safety and biosecurity requirements are met
 - report upwards on progress and problems
 - provide a written report at the conclusion of the killing, describing the practices adopted and their effect on animal welfare
- Skills
 - specialised training in relevant skills and procedures
 - skills to manage all activities on premises and deliver outcomes on time
 - awareness of psychological effects on farmer, team members and general public
 - effective communication skills

Appendix XXX (contd)Appendix IV (contd)**Veterinarian**

- Responsibilities
 - plan and implement procedures to ensure that animals are killed without avoidable pain and distress
 - determine and implement requirements for animal welfare, including the order of killing
 - minimise the risk of disease spread within and from the premises and supervise other biosecurity personnel
 - continuously monitor animal welfare and biosecurity procedures
 - in cooperation with the leader, prepare a written report at the conclusion of the killing, describing the practices adopted and their effect on animal welfare
- Skills
 - ability to assess animal welfare, especially the effectiveness of stunning and killing
 - ability to assess biosecurity risks

Animal handlers

- Responsibilities
 - review on-site facilities in terms of their appropriateness
 - design and construct temporary animal handling facilities, when required
 - move and restrain animals
- Skills
 - good stockmanship
 - awareness of animal behaviour
 - experience of animal handling in emergency situations and in close confinement

Slaughterers

- Responsibilities
 - ensure humane killing of animals through effective stunning and killing
- Skills
 - when required by regulations, licensed to use necessary equipment or licensed to be slaughterers
 - competent to use and maintain relevant equipment
 - competent to use techniques for the species involved
 - competent to assess effective stunning and killing

Appendix XXX (contd)Appendix IV (contd)**Carcase disposal personnel**

- Responsibilities
 - ensure efficient carcase disposal to ensure killing operations are not hindered
- Skills
 - competent to use and maintain available equipment and apply techniques for the species involved

Farmer / owner / manager

- Responsibilities
 - assist where possible
- Skills
 - specific knowledge of his/her animals and their environment

Article 4**Operational procedures****Planning the humane killing of animals**

Many activities will need to be conducted on affected premises, including the humane killing of animals. The team leader should develop a plan for humanely killing animals on the premises which should include consideration of:

- Minimising handling and movement of animals
- Killing the animals on the affected premises; however, there may be circumstances where the animals may need to be moved to another location for killing
- The species, number, age and size of animals to be killed, and the order of killing them
- Methods of killing the animals, and their cost
- Housing and location of the animals
- The availability and effectiveness of equipment needed for killing of the animals
- The facilities available on the premises that will assist with the killing
- Biosecurity issues
- The health and safety of personnel conducting the killing
- Any legal issues that may be involved, for example where restricted veterinary drugs or poisons may be used, or where the process may impact on the environment, and
- The presence of other nearby premises holding animals.

In designing a killing plan, it is essential that the method chosen is consistently reliable to ensure that all animals are humanely and quickly killed.

Appendix XXX (contd)Appendix IV (contd)

Article 5

Table summarising killing methods

Method	Procedure	Induction of unconsciousness	Animal welfare concerns	Key requirements	Applicable species
Mechanical	free bullet	immediate	targeting, calibre	accuracy	cattle, sheep and goats, pigs and poultry
	captive bolt - penetrating, followed by pithing or bleeding	immediate	targeting, velocity of bolt, physical destruction of CNS, vessels severed	restraint, accuracy	cattle, sheep and goats, pigs
	captive bolt - non-penetrating	immediate	velocity of bolt	restraint	poultry
	cervical dislocation (manual and mechanical)	not immediate	pain to animal	restraint and repeatability	poultry
	percussive blow	immediate	potential for pain to animal	restraint, accuracy and repeatability	neonate sheep, goats and pigs; poultry
	decapitation	not immediate	pain to animal	restraint and suitable equipment	poultry
	maceration	immediate	speed of entry and particulate size	restraint and suitable equipment	neonate poultry and eggs
Electrical	split application	immediate	electrode positions, current and voltage	restraint and suitable equipment	calves, sheep, goats and pigs
	single application (including waterbath)	immediate	electrode positions; current and voltage	restraint and suitable equipment	calves, sheep, goats and pigs; poultry
Gaseous	CO ₂ air mixture	not immediate	CO ₂ concentration	suitable equipment	poultry and neonate sheep, goats and pigs
	inert gas CO ₂ mixture	not immediate	CO ₂ concentration	suitable equipment	poultry
	inert gases	not immediate	O ₂ concentration	suitable equipment	poultry
	CO	not immediate	impurities	suitable equipment	piglets and poultry

Appendix XXX (contd)Appendix IV (contd)

Method	Procedure	Induction of unconsciousness	Animal welfare concerns	Key requirements	Applicable species
Lethal injection	barbiturates and others	not immediate	dosage and route of application	restraint and accuracy	cattle, sheep and goats, pigs and poultry
Other	addition of anaesthetics to feed or water	not immediate	dosage	application methodology	poultry

Article 6**Free bullet****Introduction**

A free bullet is a projectile fired from a shotgun, rifle, handgun or purpose-made humane killer.

A free bullet should be aimed to penetrate the skull or soft tissue at the top of the neck of the animal, to cause irreversible concussion and death.

Requirements for effective use

- The marksman should take account of human safety in the area in which he/she is operating
- The marksman should ensure that the animal is in the correct position to enable accurate targeting
- The correct cartridge, calibre and type of bullet for the different species age and size should be used
- Shot animals should be checked to ensure the absence of brain stem reflexes

Advantages

- Used properly, it provides a quick and effective method for killing
- It requires minimal or no restraint and can be used to kill from a distance
- It is suitable for killing agitated animals in open spaces

Disadvantages

- Potentially dangerous to humans and other animals in the area
- Potential for non-lethal wounding
- Destruction of brain tissue may preclude diagnosis of some diseases
- Leakage of bodily fluids may present a biosecurity risk
- Legal requirements may preclude or restrict use
- Unavailability of competent personnel

Appendix XXX (contd)Appendix IV (contd)**Recommendations**

- A suitable method for cattle, sheep and goats, pigs and poultry, including large animals in open spaces

Article 7**Penetrating captive bolt****Introduction**

A penetrating captive bolt is fired from a gun powered by either compressed air or a blank cartridge. There is no free projectile.

The captive bolt should be aimed on the skull in a position to penetrate the cortex and mid-brain of the animal. The impact of the bolt on the skull produces unconsciousness. Physical damage to the brain caused by penetration of the bolt may result in death, however pithing or bleeding should be performed immediately after the shot in order to ensure the death of the animal.

Requirements for effective use

- The operator should ensure that the animal's head is accessible
- The operator should fire the captive bolt at right angles to the skull in the optimal position
- The cartridge strength and calibre, and the length of the bolt should be appropriate to the species and type of animal
- A back-up gun should be available in the event of an ineffective shot
- Captive bolt guns should be frequently cleaned and maintained in good working condition
- Pithing or bleeding should be performed immediately after stunning to ensure the death of the animal
- Animals should be restrained, as a minimum free-standing in a pen
- Animals should be monitored to ensure the absence of brain stem reflexes

Advantages

- Mobility of equipment
- Immediate onset of a sustained period of unconsciousness
- Improved operator safety over use of a free bullet

Disadvantages

- Misfirings and inaccuracies may result in poor animal welfare
- Need for suitable restraint facilities on-site

Appendix XXX (contd)Appendix IV (contd)

- Post stun convulsions may make pithing difficult and hazardous
- Difficult to apply in agitated animals
- Repeated use may result in over-heating of the gun
- Leakage of bodily fluids may present a biosecurity risk
- Destruction of brain tissue may preclude diagnosis of some diseases

Recommendation

A suitable method for cattle, sheep, goats and pigs.

Article 8**Captive bolt - non-penetrating****Introduction**

A non-penetrating captive bolt device is designed and constructed to deliver a percussive blow to the head of birds, which results in immediate unconsciousness and death.

Requirements for effective use

- Birds should be restrained in cones, shackles, crushes or by hand (provided operator safety is not compromised by the design of the gun). The comb or sides of the beak should be held between thumb and forefinger. The gun barrel should be placed firmly onto the rear of the head behind the comb before firing. The bird's head should be allowed to be propelled out of the hand upon firing
- Captive bolt guns should be frequently cleaned and maintained in good working condition

Advantages

- Immediate induction of unconsciousness (≥ 40 psi) followed by death of the bird through profound brain dysfunction and physical damage
- The air-powered device is inexpensive to operate and requires minimum training of operators
- Multiple air-powered devices can be powered by a single compressor

Disadvantages

- Should only be applied to small poultry whilst they are restrained manually or on a shackle (turkeys/geese can be humanely killed whilst free-standing).
- Laying hens in cages have to be removed from their cages and all birds have to be restrained
- Produces post stun/kill convulsions

Recommendations

- A suitable method for large numbers of chickens, turkeys, geese and ducks, following their manual removal from the house or yard.

Appendix XXX (contd)Appendix IV (contd)**Article 9****Cervical dislocation (manual and mechanical)****Introduction**

Poultry may be killed by either manual cervical dislocation (stretching) or mechanical neck crushing with a pair of pliers. Both methods result in death from asphyxiation and/or cerebral anoxia, and neither is likely to produce immediate unconsciousness.

Requirements for effective use

- Animals need to be handled and restrained
- Personnel performing the kill need to be trained and competent
- Killing should be performed under veterinary supervision
- Killing should be performed in one stretch to sever the spinal cord; mechanical pliers should be used to crush the cervical vertebrae with consequent major damage to the spinal cord; breathing should then stop and pupils should be dilated
- Consistent results require strength and skill so the personnel should be rested regularly to ensure consistently reliable results

Advantages

- It is the cheapest method for killing poultry, not requiring equipment
- It is a non-invasive killing method

Disadvantages

- Requires animal handling, restraint and inversion
- Neck stretching / pliers do not consistently stun poultry
- Since death caused by cerebral anoxia in poultry takes a longer time (more than 1 minute), poultry are not immediately rendered unconscious and there may be pain and/or distress during the process
- Consistent and reliable results are difficult to achieve if large numbers of poultry need to be killed
- Operator fatigue
- The method is more difficult in larger birds
- The method may not be aesthetically pleasing

Recommendations

- This method should only be applied on small numbers of poultry on a premises (less than 1000) where other methods are unavailable.

Appendix XXX (contd)

Appendix IV (contd)

Article 10

Percussive blow

Introduction

- A percussive blow to the head kills animals by causing depression of the CNS and destruction of brain tissue.
- Its use should be limited to poultry and neonatal sheep, goats and pigs which have thin cranial bones.

Requirements for effective use

- A single sharp blow should be delivered to the central skull bones, either by an implement (such as a hammer or a commercially-available poultry killer)
- It is essential that the central skull bones and underlying brain tissues be destroyed during the procedure
- The procedure should be carried out only by trained and competent personnel
- The procedure should be closely monitored to ensure consistent accuracy

Advantages

- Results in immediate death
- Requires no specialized equipment and can be implemented quickly
- Powered equipment minimises operator fatigue

Disadvantages

- Poor technique or operator fatigue can cause pain and distress to the animal
- Animals need be handled extensively
- The method is not aesthetically pleasing and may distress personnel

Recommendations

- Killing by a single, sharp percussive blow to the head is an acceptable method for poultry and neonatal sheep, goats and pigs.

Article 11

Decapitation

Introduction

Decapitation results in death by cerebral ischaemia, however some residual brain activity continues after severance (for a considerable time in some species) which raises animal welfare concerns. Decapitation requires the rapid severing of the head from the body, using a guillotine or sharp blade.

Appendix XXX (contd)Appendix IV (contd)**Requirements for effective use**

- Animals should be manually restrained
- The equipment should be kept in good working order
- Personnel must be competent in the procedures
- Continuous monitoring is required

Advantages

- The technique is quick and easy

Disadvantages

- Decapitation does not produce immediate unconsciousness
- Death is not immediate in any species and is prolonged in poultry
- Blood contaminates the working area
- Procedure is not aesthetically pleasing and may distress personnel
- The necessary handling and restraint will distress the poultry
- Operator safety issues

Recommendation

- This method should be considered only for killing poultry.

Article 12**Maceration****Introduction**

Maceration causes immediate death through the destruction of the brain (and other) tissues.

Requirements

- Maceration requires specialised equipment which must be kept in excellent working order
- Personnel trained in the use and maintenance of the equipment
- Neonate poultry and eggs are fed into the equipment via a hopper and the rate of introducing the birds should not allow the equipment to jam, birds to rebound from the blades or the birds to suffocate before they are macerated

Advantages

- Procedure results in immediate death
- Large numbers can be killed quickly

Appendix XXX (contd)

Appendix IV (contd)

Disadvantages

- Not aesthetically pleasing
- Specialised equipment is required
- Operator safety issues

Recommendation

- Maceration should be used only for killing neonatal poultry and eggs.

Article 13

Electrical – split application

Introduction

A split application of an electric current comprises two parts - an application of current to the head by scissor-type tongs, immediately followed by an application of the tongs across the chest in a position that spans the heart.

The application of sufficient electric current to the head will induce ‘tonic/clonic’ epilepsy and unconsciousness. Low frequency electric currents applied across the chest will induce ventricular fibrillation (cardiac arrest) resulting in death. The latter should only be applied to unconscious animals to prevent unacceptable levels of pain.

Requirements for effective use

- Appropriate protective clothing (including rubber gloves and boots) should be worn
- Two operators are required, the first to apply the electrodes and the second to manipulate the position of the animal to allow the second application to be made
- Animals should be restrained, as a minimum free-standing in a pen, close to an electrical supply
- The stunner control device should generate a low frequency (30 – 60 Hz) current with a minimum voltage of 250 volts true RMS under load
- A stunning current should be applied via scissor-type stunning tongs in a position that spans the brain for a minimum of 3 seconds; immediately following the application to the head, the electrodes should be transferred to a position that spans the heart and the electrodes for a minimum of 3 seconds
- Electrodes should be cleaned regularly and after use to enable optimum electrical contact to be maintained
- Animals should be monitored to ensure the absence of brain stem reflexes

Appendix XXX (contd)Appendix IV (contd)**Advantages**

- Immediate in action
- Particularly effective with pigs, where post-stun convulsions are minimised
- Non-invasive technique minimises biosecurity risk

Disadvantages

- Requires a reliable supply of electricity.
- The electrodes must be applied and maintained in the correct positions to produce an effective stun and kill
- The procedure may be physically demanding leading to operator fatigue
- Potential for painful and lethal shocks to the operator

Recommendations

- A suitable method for calves, sheep and goats, and especially for pigs (over one week of age)

Article 14**Electrical – single application****Introduction**

Method 1 comprises the single application of sufficient electrical current (either head-to-back or head-to-body) to simultaneously stun the animal and fibrillate the heart. Provided sufficient current is applied in a position that spans both the brain and heart, the animal will not recover.

Method 2 stuns/kills by drawing inverted and shackled poultry through an electrified waterbath. Electrical contact is made between the 'live' water and earthed shackle and, when sufficient current is applied, poultry will be stun/killed.

Method 1**Requirements for effective use**

- Method 1 should only be used on sheep, goats and pigs that are appropriately restrained
- A low frequency (30 – 60 Hz) stunner control device should generate a minimum voltage of 250 volts true RMS under load
- Animals must be restrained as maintenance of physical contact between the stunning electrodes and the animal is necessary for effective use
- Appropriate protective clothing (including rubber gloves and boots) should be worn
- A single operative is required to apply the electrodes mounted on a handset in a position that spans both the brain and the heart

Appendix XXX (contd)Appendix IV (contd)

- The front electrodes should be applied in a position that is forward of the eyes and the rear electrode to the back, above or behind the heart, with current applied for a minimum of 3 seconds
- Electrodes should be cleaned regularly between animals and after use to enable optimum electrical contact to be maintained
- Where sheep are stunned/killed, water or saline should be used to improve electrical contact with the animal
- An effective stun/kill should be verified by the absence of rhythmic breathing

Advantages

- Immediate in action
- Particularly effective with pigs, because post-stun convulsions are minimised
- Low running costs

Disadvantages

- Requires appropriate animal restraint
- Regular maintenance and testing of the handset, electrodes, connecting cable and control unit is a requirement for both operator safety and animal welfare
- The electrodes must be applied in a position that spans the brain to produce an effective stun
- Not recommended for piglets under 1 week of age

Recommendations

- The induction of ventricular fibrillation at the point of stun offers a very effective killing method, however appropriate animal restraint is required in order to ensure good electrical contact.
- A suitable method for calves, sheep and goats, pigs (over 1 week of age) and poultry

Method 2**Requirements for effective use**

- Birds need to be manually removed from their cage, house or yard, inverted and shackled onto a line which conveys them through a waterbath
- A low frequency (50 Hz) current applied for a minimum of 10 seconds is necessary to stun/kill the birds
- Required minimum currents to stun/kill are:
 - Quail - 100 mA
 - Chickens – 160 mA
 - Ducks & Geese – 200 mA
 - Turkeys – 250 mA
- An effective stun/kill should be verified by the absence of rhythmic breathing.

Appendix XXX (contd)Appendix IV (contd)**Advantages**

- Immediate in action
- Capable of processing large numbers of birds reliably and effectively
- Low running costs
- Simple to clean/disinfect

Disadvantages

- Relatively high capital investment
- Requires a supply of mains electricity or built-in generator
- Handling, inversion and shackling of birds are required

Recommendations

A very effective method of stun/killing large numbers of birds however, the procedure requires the removal of birds from their husbandry system, their inversion and shackling.

Article 15**CO₂ / air mixture****Introduction**

Gas killing is performed by exposing animals to a predetermined gas mixture either while contained within a room or via the gas being brought into the animal house.

Inhalation of carbon dioxide (CO₂) induces respiratory and metabolic acidosis and hence reduces the pH of cerebrospinal fluid (CSF) and neurones thereby causing unconsciousness and, after prolonged exposure, death.

Requirements for effective use

- When CO₂ is introduced into a house containing poultry, the house should be gradually filled until all birds are exposed to a concentration of >40% until they are dead
- When animals are exposed to the gas individually or in small groups in a room, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the animals and allow them to be observed; animals should be introduced into the room after it has been filled with the required CO₂ concentration and held in this atmosphere until death is confirmed
- Operators should ensure that there is sufficient time allowed for each batch of birds to die before subsequent ones are introduced into the room
- Rooms should not be overcrowded and measures are needed to avoid animals climbing on top of each other while entering the room to prevent suffocation

Appendix XXX (contd)Appendix IV (contd)

- Houses and rooms should have devices whereby the gas concentration can be easily and accurately measured

Advantages

- Applying gas to animals *in situ* eliminates the need to manually remove live animals
- CO₂ is readily available
- Application methods are simple

Disadvantages

- Welfare problems in the induction phase due to the aversive nature of high CO₂ concentrations
- Difficulty in maintaining adequate concentrations of CO₂ in some poultry houses and rooms
- Difficulty in verifying death while the animals are in the poultry house.

Recommendation

Suitable for use in poultry and neonatal sheep, goats and pigs, especially when applied *in-situ* to poultry housed in closed-environment sheds

Article 16**Inert gas / CO₂ mixtures****Introduction**

Carbon dioxide may be mixed in various proportions with an inert gas eg nitrogen or argon, and the inhalation of such mixtures leads to hypercapnic-hypoxia. This method involves the introduction of a mixture into a poultry house or piggery or introduction of animals into a room containing the gases. Such mixtures do not induce immediate loss of consciousness, therefore the aversiveness of various gas mixtures and the respiratory distress occurring during the induction phase are important animal welfare considerations.

Pigs and poultry appear not to find 30% by volume of carbon dioxide strongly aversive, and therefore, a mixture of nitrogen and / or argon with up to 30% by volume of carbon dioxide has been used for stunning / killing pigs and poultry.

Requirements for effective use

- The room in which animals are exposed to the gas, and the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the animals and allow them to be supervised, and have devices whereby the gas concentration can be easily and accurately measured
- If animals are to be introduced into a room, it should be only after it has been filled with the required gas mixture concentration such that the oxygen concentration is below 2%
- Animals should be immersed in the required gas concentration as fast as possible and remain in this atmosphere until death is confirmed

Appendix XXX (contd)Appendix IV (contd)

- Care is needed to ensure that there is sufficient time allowed for each batch of birds to die before subsequent ones are introduced into the room
- Rooms should not be overcrowded and measures are needed to avoid animals climbing on top of each other while entering the room
- If gas mixtures are used to kill pigs or poultry in their houses, they should be administered in such a way that they gradually fill the houses from the floor to a level well above the heads of animals in a 'monolayer' housing systems (e.g. pig sheds and poultry on deep litter)

Advantages

- Additional handling and restraint may not be required
- CO₂ in combination with an inert gas produces an increased rate of induction of unconsciousness

Disadvantages

- Possible aversiveness of various gas mixtures
- Some mixtures may not lead to immediate loss of consciousness, and exposure times required to kill pigs and poultry are considerable
- Need for a properly designed room
- Maintenance of gas mixtures to produce less than 2% O₂ is difficult in houses

Recommendation

A suitable method for poultry and neonatal sheep, goats and pigs, especially when applied in-situ in closed-environment sheds.

Article 17**Inert gasses****Introduction**

This method involves the introduction of inert gases such as xenon, krypton and argon which have anaesthetic properties into a poultry house or piggery or introduction of animals into a room containing the gases. The gas leads to anaesthesia, unconsciousness and death resulting from hypoxia.

Xenon is an anaesthetic gas under normal atmospheric pressure, whereas argon and krypton have anaesthetic properties only under hyperbaric conditions. However, owing to the high costs associated with the use of xenon and krypton, argon- or nitrogen-induced hypoxia at normobaric conditions is commercially used to stun or stun / kill poultry.

Research has shown that hypoxia is not aversive to pigs and poultry and it doesn't induce any signs of respiratory distress prior to loss of consciousness

Appendix XXX (contd)

Appendix IV (contd)

Requirements for effective use

- The room where the animals are exposed to the gases should be designed, constructed, and maintained in such a way as to avoid injury to the animals and allows them to be supervised
- If the animals are introduced into the room, it should be only after it has been filled with 100% of inert gases
- The concentration of residual oxygen in the room should be continuously monitored to ensure that it remains at less than 2% by volume
- Animals should remain in the room until they are dead

Advantages

- Replacement of oxygen by inert gases is not aversive to animals
- It can induce unconsciousness without causing distress and suffering before the animals are dead
- Additional handling and restraint may not be required

Disadvantages

- Need for a properly designed room
- High cost of gases
- Prolonged exposure to these gases can be harmful to personnel

Recommendation

A suitable method for poultry and neonatal sheep, goats and pigs, especially when applied in-situ in closed-environment sheds.

Article 18

Carbon monoxide

Introduction

Carbon monoxide (CO) induces unconsciousness and death through cerebral anoxia.

Requirements for effective use

- A closed-environment poultry house which can be sealed or a room designed, constructed, and maintained in such a way as to avoid injury to the animals and allowed them to be supervised
- If the animals are introduced into a room, it should be only after it has been filled with a CO concentration of at least 1% by volume
- The concentration of CO should be continuously monitored

Appendix XXX (contd)Appendix IV (contd)

- If the CO is produced by a diesel engine, the gas should be cooled to ambient temperature and filtered to remove impurities in the gas
- Animals should remain in the room until they are dead
- An efficient exhaust or ventilation system needs to be provided
- The risks to human health need to be advised to all personnel and preventive measures put in place

Advantages

- If a closed-environment poultry housing is available, it is a relatively easy way to kill poultry without moving and handling them
- Application methods are simple

Disadvantage

- CO is a highly toxic gas, which is harmful to humans
- If the gas is produced by a diesel engine, impurities in the gas can be aversive prior to unconsciousness being induced

Recommendation

CO should only be used after a careful assessment of all hazards and in a well ventilated area. CO is suitable for use in poultry and neonatal sheep, goats and pigs, especially when applied *in-situ* to poultry housed in closed-environment sheds.

Article 19**Lethal injection****Introduction**

A lethal injection using high doses of anaesthetic and sedative drugs causes CNS depression, unconsciousness and death. In practice, barbiturates and combinations of hypnotic and curareform drugs are commonly used.

Requirements for effective use

- Doses and routes of administration that cause rapid loss of consciousness followed by death should be used.
- Prior sedation may be necessary for some formulations
- Intravenous administration is preferred but intraperitoneal or intracardiac administration may be appropriate, especially if the agent is non-irritating
- Animals should be restrained to allow effective administration
- Animals should be monitored to ensure the absence of brain stem reflexes

Advantages

- The method can be used in all species
- Death can be induced smoothly

Appendix XXX (contd)Appendix IV (contd)**Disadvantages**

- For practical reasons, the method may be most applicable for use in small animals
- Highly trained personnel is required for administration
- Restraint and/or sedation may be necessary prior to injection
- Some routes of administration (eg intra-cardiac) may be painful and should be used only on unconscious animals
- Legal requirements may restrict use to veterinarians

Recommendation

A suitable method for killing cattle, sheep, pigs and poultry

Article 20**Addition of anaesthetics to feed or water****Introduction**

An anaesthetic agent which can be mixed with poultry feed or water may be used to anaesthetise poultry in houses or wild birds, which are then killed by another method

Requirements for effective use

- Sufficient quantities of anaesthetic need to be ingested rapidly for effective response
- Intake of sufficient quantities is facilitated if the animals are fasted
- Must be followed by killing if birds are only anaesthetised

Advantages

- Suitable for wild species which would otherwise not be able to be killed
- May result in death
- May be biosecurity advantages in the case of large numbers of diseased birds

Disadvantages

- Non-target animals may accidentally access the medicated feed or water when provided in an open environment
- Dose taken is unable to be regulated and variable results may be obtained
- Animals may reject adulterated feed or water due to illness or adverse flavour
- May need to be followed by killing.

Appendix XXX (contd)

Appendix IV (contd)

- Care is essential in the preparation and provision of treated feed or water, and in the disposal of uneaten treated feed/water and contaminated carcasses

Recommendation

A suitable method for wild birds and may be suitable for poultry in houses.



Original: English
November 2003

REPORT OF THE FIRST MEETING OF THE OIE *AD HOC* GROUP ON THE SLAUGHTER OF ANIMALS FOR HUMAN CONSUMPTION

Paris 3-5 November 2003

The OIE *Ad hoc* Group on the slaughter of animals for human consumption held its first meeting at the OIE Headquarters from 3-5 November 2003.

The members of the OIE *Ad hoc* Group are listed in [Appendix I](#). The Agenda adopted is given in [Appendix II](#). Dr Arnon Shimshony was appointed Chair of the *Ad hoc* Group.

Dr Bernard Vallat, the Director General of the OIE, welcomed the members of the *Ad hoc* Group and thanked them for their willingness to be involved in the OIE's work on this very important topic. He recalled the history of the OIE's involvement in animal welfare, based on the linkages between animal health and animal welfare, and in particular the resolution of the 2002 General Session which established priorities for the OIE's work (animal transport, killing for disease control purposes and humane slaughter for human consumption). In slaughter for human consumption, he considered that ethnic, cultural and religious factors would need to be addressed to enable the standards to be universally applicable.

Dr Andrea Gavinelli (member of the Working Group on Animal Welfare) presented the outcomes of the first meeting of the Working Group. He explained the approach of the Working Group which was to rely on outside expertise in the form of *Ad hoc* Groups to draft specific guiding principles and standards for the prioritised topics, and he emphasised that *Ad hoc* Groups needed to concentrate on desired goals rather than detailed procedures. He encouraged the *Ad hoc* Group to focus on the commercial, larger scale aspects of slaughter.

The *Ad hoc* Group saw its role as that of evaluating procedures and preparing guidelines designed to minimise avoidable pain and suffering at every stage during the pre-slaughter and slaughter processes, until the death of the animal. To ensure that its work harmonised with the work of the *Ad hoc* Groups on land and sea transport, the *Ad hoc* Group decided that the scope of its work would be taken to commence at the end of the journey to the slaughterhouse. The terms of reference are at [Appendix III](#).

The *Ad hoc* Group approached its work by assessing the animal welfare concerns associated with every procedure during the pre-slaughter and slaughter processes, reviewing them on the basis of the available scientific data, independent of any religious or cultural context. Once those animal welfare concerns were qualified, the *Ad hoc* Group considered the specific issues associated with slaughter without stunning, such as the necessary restraint, the pain likely to be associated with the cut (for which it noted that there were no definitive data) and distress prior to unconsciousness (using available data to estimate the length of this period).

Appendix XXX (contd)

The *Ad hoc* Group acknowledged the significance of religious requirements, and ritual, cultural and ethnic factors associated with some forms of slaughter. The *Ad hoc* Group felt it important that these should not be treated as exempt from these guidelines, which are intended to provide a framework within which variations to certain steps in the process may be practised to improve animal welfare or without compromising it.

The *Ad hoc* Group believed that methods of lairaging, and the moving and restraining of animals prior to and during religious slaughter are separate issues from religious slaughter requirements; with regard to restraint, there is a wide variation in methods, ranging from those with acceptable animal welfare to some which are totally unacceptable under any slaughter method. The *Ad hoc* Group also contended that some distressful and painful methods applied to conscious animals such as shackling and hoisting by the hind leg(s) or dragging by the leg(s) are not part of any religious requirements, are unacceptable in all circumstances, and should be phased out.

The *Ad hoc* Group encouraged Member Countries to approach the guidelines with a commitment to continuous incremental improvement to the process of managing animals prior to and during slaughter. It recognised that the sensitivity of addressing possible changes which are designed to improve animal welfare during stunning and slaughter would necessitate those changes being discussed with and within the relevant communities, with a view to achieving their voluntary adoption. The *Ad hoc* Group was aware of advances in animal welfare which have already been achieved in relation to such practices and encourages further improvements, in particular related to pre-slaughter restraining methods.

The *Ad hoc* Group also believed that Member Countries should address the management of foetuses during the slaughter of pregnant animals, and has drafted an article on that issue.

The *Ad hoc* Group reviewed the General Guidelines for the welfare of animals proposed by other *Ad hoc* Groups, and recommended no changes to Articles 1 and 2, and some to Article 3. The *Ad hoc* Group then began the process of drafting guidelines for the slaughter of animals for human consumption. The draft guidelines prepared so far are at Appendix IV and remain to be completed. During that process, more explanatory detail will be provided of the various slaughter methods, with special reference to their respective animal welfare aspects.

.../Appendices

**MEETING OF THE OIE AD HOC GROUP ON
THE SLAUGHTER OF ANIMALS FOR HUMAN CONSUMPTION**

Paris, 3-5 November 2003

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**MEETING OF THE OIE *AD HOC* GROUP ON
THE SLAUGHTER OF ANIMALS FOR HUMAN CONSUMPTION**

Paris, 3-5 November 2003

Approved Agenda

- 1) Introduction
 - Discussion in OIE Working Group on Animal Welfare
 - Other relevant discussions
 - 2) Update on recent significant issues regarding the humane slaughter of animals
 - 3) Development of specific guiding principles and standards
 - 4) Work programme
-

**MEETING OF THE OIE *AD HOC* GROUP ON
THE SLAUGHTER OF ANIMALS FOR HUMAN CONSUMPTION**

Paris, 3-5 November 2003

TERMS OF REFERENCE

- First output – draft guiding principles specifically addressing humane slaughter, (based on the generic OIE guiding principles and policies for animal welfare)
 - Final output – draft standards / guidelines for the OIE *Terrestrial Animal Health Code* based on these guiding principles
 - Identify future directions in which *Ad hoc* Group might need to move
 - Produce drafts for review by the OIE Working Group and then by the Code Commission
 - Focus on commercial scale slaughter
 - Take account of religious and cultural dimensions through a sub-group examining these dimensions for cattle, sheep, goats and poultry and reporting to main *Ad hoc* Group
 - Cover as a priority the following species: cattle, sheep, goats, pigs and poultry.
-

INTRODUCTION TO OIE GUIDELINES FOR THE WELFARE OF ANIMALS

Article 1

Guiding principles for animal welfare

- That there is a critical relationship between animal health and animal welfare.
- That the internationally recognised ‘five freedoms’ (freedom from hunger, thirst and malnutrition; freedom from fear and distress; freedom from physical and thermal discomfort; freedom from pain, injury and disease; and freedom to express normal patterns of behaviour) provide valuable guidance in animal welfare.
- That the internationally recognised ‘three Rs’ (reduction in numbers of animals, refinement of experimental methods and replacement of animals with non-animal techniques) provide valuable guidance for the use of animals in science.
- That the scientific assessment of animal welfare involves diverse elements which need to be considered together, and that selecting and weighing these elements often involves value-based assumptions which should be made as explicit as possible.
- That the use of animals in agriculture and science, and for companionship, recreation and entertainment, makes a major contribution to the wellbeing of people.
- That the use of animals carries with it a duty to ensure the welfare of such animals to the greatest extent practicable.
- That improvements in farm animal welfare can often improve productivity and food safety, and hence lead to economic benefits.
- That equivalent outcomes (performance criteria), rather than identical systems (design criteria), be the basis for comparison of animal welfare standards and guidelines.

Article 2

Scientific basis for guidelines

- Welfare is a broad term which describes how well individuals are coping with their environment, and includes their health, their feelings and other good and bad effects on brain and body mechanisms for dealing with problems.
- Welfare can be scientifically evaluated and can be shown to range from very good to very poor. The study of how to assess animal welfare has progressed rapidly in recent years and evidence from such studies has been used in the formulation of these guidelines.
- Some studies of animal welfare involve assessing the extent of stress, which occurs when individuals are not able to cope with the consequences of treatment by humans or other impacts on the animal’s environment. Other indicators of poor welfare reveal how much the individual is having to do in order to cope with problems.

Appendix XXX (contd)Appendix IV (contd)

- Other areas of animal welfare research provide further information about the needs of animals by measuring the strengths of their positive and negative preferences. Once the needs of animals are known, conditions and treatment methods which fulfil these needs can be devised and used.
- Some measures of poor welfare involve assessing the extent of pain or impaired functioning associated with injury or disease. Many of the problems can be revealed by an inspection of the animal.
- Many measurements of animal welfare can be used as performance indicators in the evaluation of general methods for the keeping and treatment of animals and the actions of individuals who have an impact on those animals. Using such evidence, the acceptability of systems and of human performance can be decided.

Article 3**Ethical basis for guidelines**

- Those who use animals have obligations concerning the welfare of those animals. Actions should be taken to minimise pain, anxiety and stress experienced by animals throughout their life, and to maximise welfare through the use of adequate housing and ethically accepted methods of treatment, inspection, training and management.

Article 4**Definitions**

For the purposes of this Code, the following definitions apply:

Slaughterhouse: means premises, including facilities for moving or lairaging animals, used for the slaughter of *animals* for human consumption or animal feeding, and approved by the *Veterinary Services* or other competent authority.

lairaging: the keeping of animals in stalls, pens, covered areas or fields in order to give them necessary attention (including water, fodder, rest) before they are moved on or used for specific purposes including slaughter;

restraint: the application to an animal of any procedure designed to restrict its movements in order to facilitate effective stunning or killing;

stunning: any mechanical, electrical, chemical or other procedure which causes immediate loss of consciousness which lasts through to death;

killing: any procedure which causes the death of an animal;

slaughter - any procedure which causes the death of an animal by bleeding;

death – means irreversible loss of brain activity as demonstrated by loss of brain stem reflexes

Halal (Zabiha) / Kosher (Shechita) slaughter - severance of both jugular veins and carotid arteries, oesophagus and trachea, without severing the spinal cord, by slaying the animal with a swift stroke using a sharp knife of proper size.

Appendix XXX (contd)

Appendix IV (contd)

GUIDELINES FOR THE SLAUGHTER OF ANIMALS FOR HUMAN CONSUMPTION

Article 1

General principles for slaughter

These guidelines address the need to ensure the welfare of food animals during pre-slaughter and slaughter processes, until they are dead.

These guidelines apply to those domestic animals commonly slaughtered in slaughterhouses, that is: cattle, buffalo, sheep, goats, deer, horses, pigs, ratites and poultry. Other animals, wherever they have been reared, should be managed to ensure that their transport, lairaging, restraint and slaughter is carried out without causing undue stress to the animals; the principles underpinning these guidelines apply also to these animals.

Personnel

Persons engaged in the unloading, moving, lairaging, care, restraining, stunning and bleeding of animals play an important role in the welfare of those animals. For this reason, there should be a sufficient number of personnel, who should be patient, considerate, competent and familiar with the provisions in these guidelines and in the applicable legislation.

The management of the slaughterhouse and the *Veterinary Services* should ensure that slaughterhouse staff carry out their tasks in accordance with the principles of animal welfare.

Animal behaviour

Animal handlers should be experienced and competent in handling and moving farm livestock, and understand the behaviour patterns of animals and the underlying principles necessary to carry out their tasks.

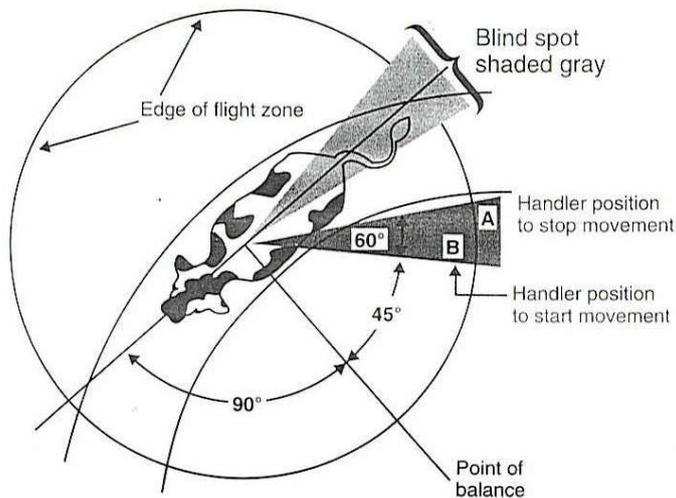
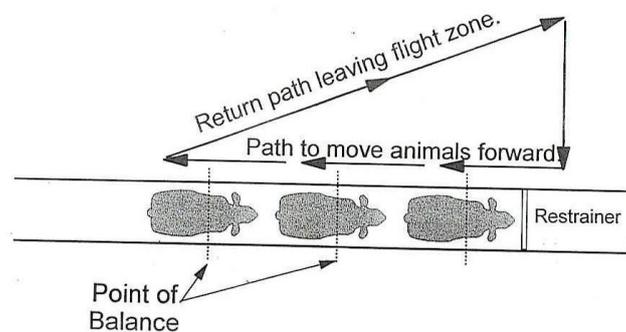
The behaviour of individual animals or groups of animals will vary, depending on their breed, sex, temperament and age and the way in which they have been reared and handled. Despite these differences, the following behaviour patterns which are always present to some degree in domestic animals, should be taken into consideration in handling and moving the animals.

Most animals belonging to domestic livestock are kept in herds and follow a leader by instinct. In free-moving animals, to exploit herding and following behaviour, animals for slaughter should be kept to the extent possible in the groups in which they were reared.

Animals which are unaccustomed or hostile to each other should not be mixed at slaughterhouses.

The desire of some animals to control their personal space should be taken into account in designing facilities.

Domestic animals will try to escape if an animal handler approaches closer than a certain distance. This critical distance, which defines the flight zone, varies among species and individuals of the same species, and depends upon previous contact with humans. Animals reared in close proximity to humans ie tame have no flight zone, whereas those kept in free range or extensive systems may have flight zones which may vary from one metre to many metres. Animal handlers should avoid sudden penetration of the flight zone which may cause a panic reaction which could lead to aggression or attempted escape.

Appendix XXX (contd)Appendix IV (contd)**FLIGHT ZONE****HANDLER MOVEMENT PATTERN TO MOVE CATTLE FORWARD**

Animal handlers should use the point of balance at an animal's shoulder to move animals, adopting a position behind the point of balance to move an animal forward and in front of the point of balance to move it backward.

Domestic animals have wide-angle vision but only have limited forward binocular vision and poor perception of depth. This means that they can detect objects and movements beside and behind them, but can only judge distances directly ahead.

Although all domestic animals have a highly sensitive sense of smell, they react in different ways to the smells of slaughterhouses. Smells which cause fear or other negative responses should be taken into consideration when managing animals.

Appendix XXX (contd)Appendix IV (contd)

Domestic animals can hear over a greater range of frequencies than humans and are more sensitive to higher frequencies. They tend to be alarmed by constant loud noise and by sudden noises, which may cause them to panic.

Distractions and their removal

Distractions that may cause approaching animals to stop, baulk or turn back should be designed out from new facilities or removed from existing ones. Below are examples of common distractions and methods for eliminating them:

- Reflections on shiny metal or wet floors - move a lamp or change lighting.
- Dark entrances to chutes, races, stun boxes or conveyor restrainers - illuminate with indirect lighting which does not shine directly into the eyes of approaching animals.
- Animals seeing moving people or equipment up ahead - install solid sides on chutes and races or install shields.
- Chains or other loose objects hanging in chutes or on fences - remove them.
- Uneven floors or a sudden drop in floor levels at the entrance to conveyor restrainers – avoid uneven floor surfaces or install a solid false floor under the restrainer to provide an illusion of a solid and continuous walking surface.
- Sounds of air hissing from pneumatic equipment - install silencers or use hydraulic equipment.
- Clanging and banging of metal objects - install rubber stops on gates and other devices to reduce metal to metal contact.
- Air currents from fans or air curtains blowing into the face of animals - redirect or reposition equipment.

Article 2**Moving and handling animals**

The following principles should apply to unloading animals, moving them into lairage pens, out of the lairage pens and up to the slaughter point.

- The use of force on animals that have little or no room to move should not occur.
- The use of instruments which administer electric shocks (eg goads and prods) and their power output should be restricted to that necessary to assist movement of the animals. If such use is necessary, it should be limited to the hindquarters of pigs and large ruminants, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.
- Performance standards should be established in which numerical scoring is used to evaluate the use of such instruments and to measure the percentage of animals moved with an electric instrument. In properly designed and constructed facilities with competent animal handlers, it should be possible to move 75% or more of the animals without the use of electric instruments.
- Useful and permitted aids for moving animals include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles; they should be used in a manner sufficient to encourage and direct movement of the animals but without physical contact with them.

Appendix XXX (contd)Appendix IV (contd)

- Shouting or yelling at animals to encourage them to move should not occur as such actions may make the animals agitated, leading to crowding or falling.
- Implements which cause pain and suffering such as large sticks, sticks with sharp ends, metal piping, fencing wire or heavy leather belts should not be used to move animals.
- Animals should be grasped or lifted in a manner which avoids pain or suffering and physical damage (eg bruising, fractures, dislocations). In the case of quadrupeds, manual lifting by a person should only be used in young animals or small species, and in a manner appropriate to the species; grasping or lifting such animals only by their wool, hair, feet, neck, ears or tails causing pain or suffering should not be permitted, except in an emergency where animal welfare or human safety may otherwise be compromised.
- Conscious animals should not be thrown or dragged.
- Animals should not be forced to move at a speed greater than their normal walking pace, in order to minimise injury through falling or slipping. Performance standards should be established where numerical scoring of the prevalence of animals slipping or falling is used to evaluate whether animal moving practices and/or facilities should be improved. In properly designed and constructed facilities with competent animal handlers, it should be possible to move 99% of animals without their falling.
- Under no circumstances should animal handlers resort to violent acts to move animals, such as crushing or breaking animals' tails, grasping animals' eyes or pulling them by their ears. Animal handlers should never apply an injurious object or irritant substance to sensitive areas such as eyes, mouth, ears, anogenital region or belly.

Requirements for animals delivered in containers

- Containers in which animals are transported should be handled with care, and should not be thrown, dropped or knocked over. Where possible, they should be loaded and unloaded horizontally and mechanically.
- Animals delivered in containers with perforated or flexible bottoms should be unloaded with particular care in order to avoid injury. Where appropriate, animals should be unloaded from the containers individually.
- Animals which have been transported in containers should be slaughtered as soon as possible; animals which are not taken directly upon arrival to the place of slaughter should have drinking water available to them from appropriate facilities at all times. Animals which have not been slaughtered within 12 hours of their arrival should be fed, and should subsequently be given moderate amounts of food at appropriate intervals.

Methods for restraining and containing animals

Methods of restraint causing avoidable suffering, such as the following, should not be used in conscious animals:

- suspending or hoisting animals (other than poultry or rabbits) by the feet or legs
- indiscriminate and inappropriate use of stunning equipment on conscious animals
- mechanical clamping of an animal's legs or feet (other than shackles used in poultry) as the sole method of restraint

- cutting tendons or blinding animals in order to immobilise them
- using electric currents to immobilise animals, except for proper stunning.

Article 3

Lairage design and construction

The lairage should be designed and constructed to hold the maximum number of animals in relation to the throughput of the slaughterhouse without compromising the welfare of the animals.

In order to permit operations to be conducted as smoothly and efficiently as possible without injury or undue stress to the animals, the lairage areas should be designed and constructed so as to allow the animals to move freely in the required direction, using their behavioural characteristics and without undue penetration of their flight zone.

The following guidelines may help to achieve this.

Design

- The lairage should be designed to allow a one-way flow of animals from unloading to the point of slaughter, with a minimum of abrupt corners to negotiate.
- Pens, passageways and races should be arranged in such a way as to permit inspection of any animal at any time, and to permit the removal of sick or injured animals for which separate appropriate accommodation should be provided.
- Each animal should have room to stand up and lie down and, when confined in a pen, to turn around. The lairage should have sufficient accommodation for the number of animals intended to be held. Drinking water should always be available to the animals, and the method of delivery should be appropriate to the type of animal held. Troughs should be designed and installed in such a way as to minimise the risk of fouling by faeces.
- Holding pens should be rectangular rather than square, to allow as many animals as possible to stand or lie down against a wall. Where feed troughs are provided, they should be placed along the walls rather than in the centre of the pens, and should be sufficient in number to allow all animals to feed undisturbed.
- Where tethers, ties or individual stalls are used, these should be designed so as not to cause injury or distress especially when the animals are lying down, standing up, drinking and feeding.
- Passageways and races should be either short and straight, or slightly curved, as appropriate to the animal species. Passageways and races should have solid sides, but when there is a double race the shared partition should allow adjacent animals to see each other. For pigs and sheep, passageways should be wide enough to enable two or more animals to walk side by side for as long as possible. At the point where passageways are reduced in width, this should be done by a means which prevents excessive bunching of the animals.
- Animal handlers should be positioned alongside races and passageways on the inside radius of any curve, to take advantage of the natural tendency of animals to circle an intruder. Where one-way gates are used, they should be of a design which avoids bruising. Races should be horizontal but where there is a slope, they should be constructed to allow the free movement of animals without injury.

Appendix XXX (contd)Appendix IV (contd)

- There should be a waiting pen, with a level floor and solid sides, between the holding pens and the race leading to the point of stunning or slaughter, to ensure a steady supply of animals for stunning or slaughter and to avoid having animal handlers trying to rush animals from the holding pens. The waiting pen should preferably be circular, but in any case, so designed that animals cannot be trapped or trampled.

Construction

- Lairages should be constructed and maintained so as to provide protection from unfavourable climatic conditions, using strong and resistant materials such as concrete and metal which has been treated to prevent corrosion. Surfaces should be easy to clean. There should be no sharp edges or protuberances which may injure the animals.
- Floors should be well drained and not slippery; they should not cause injury to the animals' feet. Where necessary floors should be insulated or provided with appropriate bedding. Drainage grids should be placed at the sides of pens and passageways and not where animals would have to cross them. Discontinuities or changes in floor patterns or texture which could cause baulking in the movement of animals should be avoided.
- Lairages should be provided with adequate lighting, but care should be taken to avoid harsh lights and shadows, which frighten the animals or affect their movement. The fact that animals will move more readily from a darker area into a well-lit area might be exploited by providing for lighting that can be regulated accordingly.
- Lairages should be well ventilated, and the air flow should be arranged so that odours and draughts do not adversely affect the health and welfare of the animals.
- Care should be taken to protect the animals from excessively or potentially disturbing noises, for example by avoiding the use of noisy hydraulic or pneumatic equipment, and muffling noisy metal equipment by the use of suitable padding, or by minimising the transmission of such noise to the areas where animals are held and slaughtered.
- Where animals are kept in outdoor lairages without natural shelter or shade, they should be protected from the effects of adverse weather conditions.

Article 4**Care in lairages**

Animals in lairages should be cared for in accordance with the following guidelines:

- As far as possible established groups of animals should be kept together. Each animal should have enough space to stand up, lie down and turn around. Animals hostile to each other should be separated.
- Where tethers, ties or individual stalls are used they should allow animals to stand up and lie down without causing injury or distress.
- Animals should be kept securely in the lairage and care should be taken to prevent them from escaping and from predators.
- Suitable drinking water should be available to the animals on their arrival and at all times to animals in lairages unless they are to be slaughtered without delay.
- If animals are not to be slaughtered as soon as possible, suitable feed should be available to the animals on arrival and at intervals appropriate to the species. Unweaned animals should be slaughtered as soon as possible.

Appendix XXX (contd)Appendix IV (contd)

- In order to prevent heat stress, animals subjected to high temperatures, particularly pigs and poultry, should be cooled by the use of water sprays, fans or other suitable means.
- That lairage area should be well lit in order to enable the animals to see clearly without being dazzled. During the night, the lights should be dimmed.
- The condition and state of health of the animals in a lairage should be inspected at least every morning and evening by a veterinarian, or, under the latter's responsibility, by another competent person. Animals which are sick, weak, injured or showing visible signs of distress should be killed immediately.
- Lactating dairy animals should be slaughtered as soon as possible. Dairy animals with obvious udder distension should be milked to minimise udder discomfort.
- Pregnant animals giving birth during the journey or in the lairage should be slaughtered as soon as possible or provided with conditions which are appropriate for suckling and the welfare of the newborn.

Recommendations for specific species are described in detail in Appendices XXX.

Article 5

Management of foetuses during slaughter of pregnant animals

The welfare of foetuses during slaughter of pregnant animals can be safeguarded by following the guidelines outlined below:

- After slaughter of a pregnant animal, if the foetus does not inflate its lungs and breathe air, it does not become conscious and therefore cannot suffer.
- When uterine, placental or foetal tissues, including foetal blood, are not to be collected as part of the post-slaughter processing of pregnant animals, all foetuses should be left inside the unopened uterus until they are dead. This is especially important if the foetuses are apparently mature, ie close to birth at the end of a full-length pregnancy.
- When uterine, placental or foetal tissues are to be collected, where practical, foetuses should not be removed from the uterus until at least 15-20 minutes after the maternal neck or chest cut. Foetal death or irreversible brain damage will usually have occurred by 15-20 minutes after slaughter of the dam.
- Foetuses should not be removed from the uterus sooner than five minutes after the maternal neck or chest cut to ensure that their brain electrical activity is flat at that point. A foetal heartbeat will usually still be present and gasping and other foetal movements may occur at this stage after the maternal neck or chest cut.
- If a living foetus removed from the uterus must be prevented from inflating its lungs and breathing air.
- A foetus which may breathe air, or which is exposed earlier than the 5-minute minimum waiting time after slaughter of the pregnant animals, must be killed with a captive bolt firearm or a blow to the head with a suitable blunt instrument.

The above guidelines do not refer to fetal rescue. Fetal rescue is the practice of attempting to revive fetuses found alive at evisceration of the dam.

Appendix XXX (contd)

Appendix IV (contd)

Fetal rescue may lead to serious welfare complications. These include impaired brain function resulting from oxygen shortage before rescue is completed, compromised breathing and heat production because of fetal immaturity, and an increased incidence of infections in the rescued young due to a lack of colostrum. Foetal rescue should therefore not be attempted during normal commercial slaughter.

Article 6

Summary of slaughter methods and their respective animal welfare issues (under development)



Original: English
August 2003

REPORT OF THE FIRST MEETING OF THE OIE *AD HOC* GROUP ON LAND TRANSPORT OF ANIMALS

Paris, 6-8 August 2003

The OIE *Ad hoc* Group on land transport of animals held its first meeting at the OIE Headquarters from 6-8 August 2003.

The members of the OIE *Ad hoc* Group and other participants are listed in [Appendix I](#). The Agenda adopted is given in [Appendix II](#). Professor Donald Broom was appointed Chair of the *Ad hoc* Group.

On behalf of the Director General of the OIE, Dr David Wilson welcomed the members of the *Ad hoc* Group and thanked them for their willingness to be involved in addressing the new mandate of the OIE for animal welfare. He recalled the outcomes of the recent meeting of the Working Group on Animal Welfare and explained that the OIE planned to hold a meeting of each *Ad hoc* Group dealing with the prioritised animal welfare issues prior to the OIE Global Animal Welfare Conference to be held in February 2004. He also noted the recommendation of the Working Group that *Ad hoc* Groups initially develop more detailed statements on policies and principles, specific to their subject, as a bridge between the generic OIE statement on policies and principles, and future specific animal welfare standards.

The *Ad hoc* Group recognised the value in working towards specific principles for the species for which information was available but also recognised the importance of addressing the welfare of other species as resources permitted. This may include the welfare of non-human primates.

The *Ad hoc* Group decided to include in the scope of its work the welfare of animals in vehicles on roll-on-roll-off ferries travelling over relatively short distances. The *Ad hoc* Group also noted the importance of land transport in the transport of animals by sea and air, and stressed the need for an 'origin to destination' approach to animal welfare transport to ensure that no aspects are left unaddressed, and responsibilities at each stage are clearly described.

The *Ad hoc* Group discussed the need to develop criteria for risk analysis for animal welfare to assist Member Countries in drafting their own standards based on specific guiding principles, and included this work in its terms of reference. The agreed terms of reference for the *Ad hoc* Group are at [Appendix III](#).

The *Ad hoc* Group recommended that OIE set aside a separate public page on its Web site for animal welfare, and also a private page for members' use in circulating and commenting on draft documents.

Appendix XXX (contd)

The *Ad hoc* Group drafted general guidelines for the welfare of animals commencing with general statements of the scientific and ethical basis for animal welfare and some proposed definitions. The *Ad hoc* Group then developed more specific guiding principles addressing land transport, concerning the responsibilities of various parties, the training and documentation required, preparation for transport, loading and unloading, and journey issues. The draft guidelines are at Appendix IV.

.../Appendices

MEETING OF THE OIE AD HOC GROUP ON LAND TRANSPORT OF ANIMALS

Paris, 6-8 August 2003

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MEETING OF THE OIE *AD HOC* GROUP ON LAND TRANSPORT OF ANIMALS

Paris, 6–8 August 2003

Agenda adopted

- 1) Introduction
 - 2) Update on recent significant issues regarding land transport
 - 3) Development of specific guiding principles and standards
 - 4) Work programme
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TERMS OF REFERENCE

Terms of reference

- First output – draft guiding principles specific for land transport (rather than a prescriptive approach to limits) based on the generic OIE guiding principles and policies for animal welfare
- Draft criteria for animal welfare risk analysis
- Review existing standards for animal transport in the OIE *Code* relating to land transport
- Final output – draft standards / guidelines for the OIE *Code* based on these guiding principles
- Identify future directions in which the *Ad hoc* Group might need to move
- Produce drafts for review by the Working Group and then by the Code Commission.

Species to be covered

- cattle, sheep, goats
- pigs
- poultry (including young birds)
- horses
- other farmed ungulates, including deer and camelids*
- fish*
- ratites*.

(* as resources permit and/or expertise is available)

INTRODUCTION TO OIE GUIDELINES FOR THE WELFARE OF ANIMALS

Article 1

Guiding principles for animal welfare

- That there is a critical relationship between animal health and animal welfare.
- That the internationally recognised ‘five freedoms’ (freedom from hunger, thirst and malnutrition; freedom from fear and distress; freedom from physical and thermal discomfort; freedom from pain, injury and disease; and freedom to express normal patterns of behaviour) provide valuable guidance in animal welfare.
- That the internationally recognised ‘three Rs’ (reduction in numbers of animals, refinement of experimental methods and replacement of animals with non-animal techniques) provide valuable guidance for the use of animals in science.
- That the scientific assessment of animal welfare involves diverse elements which need to be considered together, and that selecting and weighing these elements often involves value-based assumptions which should be made as explicit as possible.
- That the use of animals in agriculture and science, and for companionship, recreation and entertainment, makes a major contribution to the wellbeing of people.
- That the use of animals carries with it a duty to ensure the welfare of such animals to the greatest extent practicable.
- That improvements in farm animal welfare can often improve productivity and hence lead to economic benefits.
- That equivalent outcomes (performance criteria), rather than identical systems (design criteria), be the basis for comparison of animal welfare standards and guidelines.

Article 2

Scientific basis for guidelines

- Welfare is a broad term which describes how well individuals are coping with their environment, and includes their health, their feelings, and other good and bad effects on brain and body mechanisms for dealing with problems.
- Welfare can be scientifically evaluated and can be shown to range from very good to very poor. The study of how to assess animal welfare has progressed rapidly in recent years and evidence from such studies has been used in the formulation of these guidelines.
- Some studies of animal welfare involve assessing the extent of stress, which occurs when individuals are not able to cope with the consequences of treatment by humans or other impacts on the animal’s environment. Other indicators of poor welfare reveal how much the individual is having to do in order to cope with problems.

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- Other areas of animal welfare research provide further information about the needs of animals by measuring the strengths of their positive and negative preferences. Once the needs of animals are known, conditions and treatment methods which fulfil their needs can be devised and used.
- Some measures of poor welfare involve assessing the extent of pain or impaired functioning associated with injury or disease. Many of the problems can be revealed by an inspection of the animal.

Many measurements of animal welfare can be used as performance indicators in the evaluation of general methods for the keeping and treatment of animals and the actions of individuals who have an impact on those animals. Using such evidence, the acceptability of systems and of human performance can be decided.

Ethical basis for guidelines

- Those who use animals have obligations concerning the welfare of those animals. Poor welfare should be minimised and good welfare maximised by the use of adequate housing and ethically accepted methods of treatment, inspection, training and management.

Article 3

Definitions

- **Transport.** The procedures associated with the carrying of animals from one location to another by road, rail, ship or air.
- **Journey.** An animal transport journey should be regarded as commencing when the first animal is loaded onto a *vehicle* and as ending when the last animal is unloaded, and includes any stationary resting / holding periods of less than 48 hours.

The same animals should not be regarded as commencing a new journey until a period of over 48 hours sufficient for rest and recuperation of the animals with adequate food and water provided, has passed since the end of the previous journey.

- **Travel.** The movement of a *vehicle* carrying animals from one location to another.
- **Pre-journey period.** The period during which animals are identified, and often assembled for the purpose of loading them.
- **Post-journey period.** The period between unloading and recovery from the effects of the journey.
- **Loading / unloading.** **Loading** is the procedure of moving animals onto a vehicle from the pre-loading site; **unloading** is the procedure of moving animals off a vehicle.
- **Space allowance** is the area on a vehicle, or volume of water in the case of aquatic animals, per individual or body weight of animals transported.
- **Stocking density** is the number or body weight of animals per unit area on a *vehicle*, or per unit volume of water in the case of aquatic animals.

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- **Staging point** means a place where the journey is interrupted to rest, feed or water the animals; the animals may remain in the vehicle or be unloaded.
 - **Container** means a non-powered receptacle for holding animals during a journey by one or several means of transport.
 - **Competent animal handler** means a person with a knowledge of the behaviour and needs of animals which, with a professional and sympathetic response to an animal's welfare requirements, results in effective management and good welfare.
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Appendix XXX (contd)Appendix IV (contd)**GUIDING PRINCIPLES FOR THE LAND TRANSPORT OF ANIMALS****Article 1****Responsibilities**

The welfare of animals during their transport is the joint responsibility of all people involved. The roles of each of those responsible are defined below:

- Owners and managers of animals are responsible for the general health of the animals and their fitness for the journey.
- Business or buying/selling agents have a joint responsibility with owners for the selection of animals that are fit to travel. They have a joint responsibility with market owners and managers of facilities at the start and at the end of the journey for the availability of suitable facilities for the assembly, loading, transport, unloading and holding of animals, and for emergencies.
- Animal handlers have a personal responsibility for the humane handling and care of animals, especially during loading and unloading. To carry out these responsibilities, they should be properly trained in these procedures.
- Transport companies, vehicle owners and drivers are responsible for planning the journey to ensure the care of the animals:
 - transport companies and vehicle owners are responsible for choosing appropriate vehicles and ensuring that properly trained staff are available for loading and caring for animals,
 - transport companies and vehicle owners are responsible for developing and keeping up to date contingency plans to address emergencies and minimise stress during transport,
 - drivers are responsible for correct loading of the vehicle, for regular inspections during the journey and for appropriate responses to problems arising. To carry out these responsibilities, drivers should be properly trained in transport regulations, correct vehicle and equipment usage, humane handling and the care of animals.
- Managers of facilities at the start and at the end of the journey, and at staging points are responsible for:
 - providing suitable premises for loading, unloading and securely holding the animals in lairage, with water and feed, when required, until further transport, sale or other use (including rearing or slaughter),
 - providing competent animal handlers to load, unload, drive and hold animals in a manner that causes minimum stress and injury,
 - minimising the opportunities for disease transmission while the animals are in the facilities,
 - providing appropriate facilities, with water and feed when required,
 - providing appropriate facilities for emergencies,
 - providing facilities for washing and disinfecting vehicles after unloading,

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- providing facilities and veterinarians or competent animal handlers capable of performing euthanasia or urgent slaughter when required,
- ensuring proper rest times and minimal delay during lairage.
- The responsibilities of *veterinary services* include:
 - establishing minimum standards for animal welfare, including requirements for inspection of animals before, during and after their travel, and appropriate certification and record keeping,
 - approving vehicles for the transport of animals,
 - ensuring appropriate awareness and training,
 - setting licensing standards for drivers, animal handlers and managers,
 - implementation of the standards, including through accreditation of / interaction with other organisations,
 - monitoring and evaluating health and welfare performance.
- Private veterinarians and para-professionals involved in transporting animals and the associated handling procedures should receive specialist training.

Article 2**Training**

- All people handling animals in the pre or post-journey periods or driving transport vehicles, or who are otherwise responsible for animals during journeys, should receive adequate training according to their responsibilities listed in Article 4.
- Training courses should be provided by formal educational institutions such as veterinary faculties.
- The training courses should address:
 - animal behaviour, physiology, ~~and~~ general signs of disease, ~~in relation to pain~~ and indicators of poor animal welfare such as pain and fatigue,
 - transport regulations,
 - methods of animal handling during transport and associated activities such as assembling, loading, unloading, and driving,
 - methods of inspecting animals, managing situations frequently encountered during transport such as adverse weather conditions, and dealing with emergencies,
 - species-specific aspects of animal handling and care, whenever necessary.

Appendix XXX (contd)Appendix IV (contd)**Article 3****Documentation**

- Animals should not be loaded until the required documentation is complete.
- The documentation accompanying the consignment (the journey log) should include:
 - journey travel plan,
 - date, time, and place of loading,
 - veterinary certification, when required,
 - driver's competencies,
 - animal identification to allow traceback of individual animals to the premises of departure, and where possible to the premises of origin,
 - details of animals at risk,
 - documentation of the period of rest, and access to feed and water prior to the journey,
 - stocking density estimate for each load in the consignment.
- When veterinary certification is required to accompany consignments of animals, it should include:
 - appropriate animal identification (description, number, etc.),
 - health status including test, treatment and vaccination status,
 - factors affecting fitness to travel.

Article 4**Planning the journey****General**

- Adequate planning is a key factor affecting the welfare of animals during a journey.
- Regulations concerning drivers (for example maximum driving periods) should be harmonised with maximum transport journey intervals appropriate for the species.
- Before initiation of travel, plans should be made in relation to:
 - type of transport vehicle required,
 - route, taking into account distance, type and quality of road, topography, traffic conditions, availability of resting sites for animals and drivers, and
 - duration of journey.

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- There should be planning for water and feed availability during the journey. Feed should be of appropriate quality and composition for the species, age, condition of the animals, climatic conditions, etc.
- Animals should be rested at staging posts at appropriate intervals during the journey. The type of transport and species being transported should determine the frequency of rest stops and whether the animals are unloaded. There should be planning for water and feed availability during rest stops.
- Extreme weather conditions are hazards for animals undergoing transport and require appropriate vehicle design to minimise risks. Special precautions should be taken for animals that have not been acclimatised or which are unsuited to either hot or cold conditions. In some extreme conditions of heat or cold, animals should not be transported at all. Animals such as pigs which are adversely affected by moderately high temperatures may need to be transported at night.
- In some species, transportation during the night may reduce external stimuli, resulting in lower stress levels.
- Behaviour-modifying medication should not be used routinely during transport. Such medicines should only be administered when a problem exists in an individual animal, and should be administered by a veterinarian or other person who has been instructed in their use by a veterinarian.
- As animal transport is often a significant factor in the spread of infectious diseases, journey planning should take the following into account:
 - mixing of animals from different sources in a single consignment should be minimised,
 - contact at staging points between animals from different sources should be avoided,
 - the use of markets should be minimised,
 - when possible, animals should be vaccinated against diseases to which they are likely to be exposed at their destination,
 - medications used prophylactically or therapeutically should only be administered by a veterinarian or other person who has been instructed in their use by a veterinarian.

Vehicle design and maintenance

- Vehicles used for the transport of animals should be designed, constructed and fitted as appropriate to the species, size and weight of the animals to be transported; special attention should be paid to the avoidance of injury to animals through the use of secure smooth fittings free from sharp protrusions.
- In order to minimise the likelihood of the spread of pathogenic agents during transport, vehicles should be designed to permit thorough cleaning and disinfection, and the containment of faeces and urine during a journey.
- Vehicles should be maintained in good mechanical and structural condition.

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- Vehicles should have adequate ventilation which can be adjusted to meet variations in climate and the needs of the animal species being transported.
- Vehicles should be designed so that the faeces or urine from animals on upper levels do not soil animals on lower levels.
- When road or rail vehicles are carried on board ferries, facilities for adequately securing them should be available.
- If feeding or watering while the vehicle is moving may be required, adequate facilities on the vehicle should be available.
- Sand or other appropriate material should be used in vehicles when the floor is slippery, for example in icy conditions.
- Suitable bedding, such as straw or wood shavings, should be added to vehicle floors to assist absorption of urine and faeces, provide better footing for animals and protect animals (especially young animals) from hard flooring surfaces and adverse weather conditions.

Containers

- The above principles apply also to containers used for the transport of animals.
- Containers carried on vehicles should be adequately secured.

Ability to inspect animals en route in relation to journey duration

- Animals should be positioned to enable them to be inspected regularly during the journey to ensure their safety and good welfare, for example at compulsory driver rest points. The first inspection should be undertaken shortly after departure.
- To allow an adequate inspection of animals en route, it should be possible for each animal to be clearly observed by the driver or other responsible person.
- If the animals are in crates or on multi-tiered vehicles which do not allow free access for observation, for example where the roof of the tier is too low (i.e. less than 1.3 m), animals cannot be inspected adequately, and serious injury or disease could go undetected. In these circumstances, a shorter journey duration should be allowed and the maximum duration will vary according to the rate at which problems arise in the species and under the conditions of transport.

Space allowance

- The number of animals which should be transported on a vehicle and their allocation to different compartments on the vehicle should be determined before the vehicle is loaded.
- The space required on vehicles depends upon whether or not the animals need to lie down (for example pigs and poultry), or to stand (horses). Most animals will stand when first loaded and if a vehicle is driven badly, so these situations do not indicate the animals' needs.

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- Calculations according to the space allowance permitted for each animal should be carried out, using the figures given in these guidelines or, in their absence, in a relevant national or international document. The size of existing groups will affect the number and size of the pens, and the distribution of animals in pens on the vehicle.
- The amount of headroom necessary depends on the species of animal. Each animal should be able to assume its natural position for transport (including during loading and unloading) without coming into contact with the roof or upper deck of the vehicle.
- Animals should have sufficient space to adopt a braced standing position without contacting other animals.
- Where animals lie down, they should be able to adopt a comfortable, normal lying posture which allows necessary thermoregulation. There should be space for the animal to carry out normal lying down and standing up movements.
- The same principles apply when animals are transported in containers.

Article 5**Pre-journey period****General**

- Pre-journey rest is necessary if the welfare of animals has become poor during the collection period because of major physical or social problems.
- The provision of feed and water pre-journey is necessary if the journey duration is greater than the normal inter-feeding and drinking interval for the animal.
- For animals such as pigs which are susceptible to motion sickness, and in order to reduce urine and faeces production during the journey, a short period of feed deprivation prior to loading is desirable.
- When animals will be provided with a novel diet or method of water provision during or after transport, an adequate period of pre-exposure is necessary.
- All vehicles and containers for animals should be thoroughly cleaned and, if necessary disinfected before animals are loaded.
- Before a journey, animals should be inspected, where possible by a veterinarian.

Selection of compatible groups

- Compatible groups should be selected before transport to avoid adverse animal welfare consequences. The following guidelines should be applied when assembling groups of animals:
 - animals of different species should not be mixed unless they have been reared together for a long period,

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- animals of the same species can be mixed unless there is a significant likelihood of aggression,
- young or small animals should be separated from older or larger animals,
- animals with horns or antlers should not be mixed with animals lacking horns and antlers,
- aggressive individuals should be segregated,
- animals reared together should be maintained as a group; animals with a strong social bond, such as a dam and offspring, should be transported together.

Effect of travel experience, long and short term

- Consideration should be given to an animal's previous transport experience, training and conditioning as these may reduce fear and stress in animals. Animals that are carefully and regularly transported may show less adverse responses to transport.
- Exposure to familiar personnel should reduce the fearfulness of animals and improve their approachability during transport procedures.

Fitness to travel

- Animals found unfit to travel following inspection by farm staff, drivers or veterinarians should not be loaded onto a vehicle, except for transport to receive veterinary treatment.
- Humane and effective arrangements should be made by the owner or agent for the handling and care of any animal rejected as unfit to travel.
- Animals that are unfit to travel include:
 - those that are sick, injured, weak, disabled or fatigued,
 - those that are unable to stand unaided and bear weight on each leg,
 - those that are blind in both eyes,
 - those that cannot be moved without causing them additional suffering,
 - pregnant animals which are likely to give birth during the journey,
 - in hot and cold weather, those whose body condition would result in poor welfare.
- Risks during transport can be reduced by selecting animals best suited to the conditions of travel and those that are acclimatised to expected weather conditions.
- Animals at risk and requiring better conditions and additional attention during transport (such as in facility and vehicle design, and animal handling) include:
 - very large or obese individuals,
 - very young or old animals,

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- wild or feral animals,
- excitable or aggressive animals,
- animals which have had little contact with humans,
- females in late pregnancy or heavy lactation,
- those with a history of exposure to stressors or pathogenic agents prior to transport.

Specific species requirements

Transport procedures should be able to take account of variations in the behaviour of the species. Flight zones, social interactions and other behaviour vary significantly among species and even within species. Facilities and handling procedures that are successful with one species are often ineffective or dangerous with another.

- Recommendations for specific species are described in detail in Appendices XXX.

Shelter in the holding area

- Holding areas should be designed to:
 - securely contain the animals,
 - maintain a safe environment from hazards, including predators and disease,
 - protect animals from exposure to severe weather conditions, and
 - allow for companionship, rest, watering and feeding.

Article 6**Loading****Experienced supervision**

- Since loading has been shown to be the procedure most likely to be the cause of poor welfare in transported animals, the methods to be used should be carefully planned.
- Loading should be supervised by competent animal handlers with knowledge and experience of the behavioural and physical characteristics of the animal species being loaded. These animal handlers should ensure that animals are loaded quietly and without unnecessary noise, harassment or force, and that untrained assistants or spectators do not impede the process.

Facilities

- The facilities for loading including the collecting area, races and loading ramps should be designed and constructed to take into account of the needs and abilities of the animals with regard to dimensions, slopes, surfaces, absence of sharp projections, flooring, etc.

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- All loading facilities should be properly illuminated to allow the animals to be easily inspected by the handler(s), and to allow the animals' ease of movement at all times. Facilities should provide uniform lighting directly over approaches to sorting pens, chutes, loading ramps, and entrance to transport vehicles.
- Before each journey, vehicles should be thoroughly cleaned and disinfected, and when necessary cleaned of arthropod and other parasites for animal and public health purposes, using chemicals approved by the *Veterinary Authority*. When these procedures are necessary during a journey, they should be carried out with the minimum of stress to the animals.
- Ventilation during loading and the journey should provide for fresh air, the removal of heat and noxious fumes, and the prevention of accumulations of ammonia and carbon dioxide. Under warm and hot conditions, ventilation should allow for the adequate convective cooling of each animal. In some instances, adequate ventilation can be achieved by increasing the space allowance for animals. Likely hotspots should be identified and rectified.

Goads and other aids

- The following principles should apply:
 - Force should not be used on animals that have little or no room to move.
 - Battery powered electric prods only should be used and their use restricted to that necessary to assist the movement of the animals. Goads should not be used on sensitive areas such as the eyes, mouth, anogenital regions or belly.
 - Electric prods and twitches should not be used on horses.
 - Flappers (a length of cane with a short strap of leather or canvas attached) or "metallic rattles" should be used in place of goads or sticks as they encourage movement in response to sound.
 - Canvas slappers, boards, canes or other materials used as an extension of the arm to direct animals are useful and permitted aids for handling.
 - The use of well trained dogs to help with the loading of some species may be acceptable.
 - Large sticks, sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts should not be used to strike animals.
 - Manual lifting is permissible for young animals that may have difficulty negotiating ramps, but the grasping or lifting of sheep or other species by their wool or hair should not be permitted.

Article 7**Travel**

- Drivers should check the load immediately before departure to ensure that the animals have been properly loaded. Each load should be checked again early in the trip and adjustments made as appropriate. Periodic checks should be made throughout the trip.
- Drivers should utilise smooth, defensive driving techniques, without sudden turns or stops to minimise uncontrolled movements of the animals.

Appendix XXX (contd)Appendix IV (contd)**Methods of restraining or containing animals**

- Methods of restraining animals should be appropriate to the species involved and the training of the individual animal.
- Recommendations for specific species are described in detail in Appendices XXX.

Regulating microclimate, including during journey stops

- Animals should be protected against harm from hot or cold conditions during travel. Procedures for maintaining microclimate in vehicles will vary between cold and hot, humid conditions but will require similar prevention against the build-up of noxious gases and carbon dioxide.
- Microclimate in hot weather can be regulated by the flow of air produced by the movement of the vehicle. In warm and hot weather, the duration of journey stops should be minimised and vehicles should be parked in shade.

Sick and injured animals

- Animals should not travel or rest on a surface covered with urine or faeces so, when necessary, urine and faeces should be removed from floors in a way which will not lead to spread of disease.
- During travel, sick or dead animals should be reported to the nearest *Veterinary Authority*, so that appropriate sanitary measures can be taken and the disposal of dead animals determined.
- During the journey, when disposal of a body, manure or litter becomes necessary, this should be carried out in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.
- Ferries (roll-on roll-off) should have facilities to isolate sick, injured or dead animals during the journey.
- In order to reduce the likelihood that animal transport will increase the spread of infectious disease, contact between transported animals, or the products of the transported animals, and other farm animals should be minimised.
- When animals are transported to a farm, they should be isolated on arrival at the farm.

Water and feed requirements

- If journey duration is such that feeding or watering is required or if the species requires food or water throughout, access to suitable feed and water for all the animals carried in the vehicle should be provided and there should be adequate space for all animals to move to the food and water sources and due account taken of likely competition for food.
- The maximum periods of deprivation of water and food for different species are described in Appendix XXX.

Journey nature and duration

- The maximum journey time for each load will depend on the conditions under which the journey takes place, including space allowances, vehicle design, road conditions, driving quality, the ability of the animals to cope with the stress of transport (such as very young, old or pregnant animals), the animals' previous transport experiences, and adverse weather conditions.

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- The increase in fatigue, need for food and water, and susceptibility to injury and disease with increasing duration of the journey, should be taken into account.

Rest periods and conditions including hygiene

- Animals that are being transported should be rested at appropriate intervals during the journey and offered food and water, either on the vehicle or, if necessary, unloaded into suitable facilities.
- Suitable facilities should be used en route, when resting requires the unloading of the animals. These facilities should meet the needs of the particular animal species and should allow access of all animals to feed and water.

In-transit inspections

- Consignments by road should be inspected soon after a journey is commenced and after that, at least every 2–3 hours as well as whenever the driver has a rest stop. After meal breaks and refuelling stops, the animals should be inspected immediately prior to departure.
- Every opportunity must be taken to inspect the animals during rail transport. The rail transporter should monitor the progress of trains carrying cattle and take all appropriate action to minimise delays.
- Inspections should be made during stops to ensure that animals are properly confined, that they have enough food and water and that their physical condition is satisfactory.

Emergency procedures - training and authority

- When euthanasia is necessary, the person responsible for the animals must ensure that it is carried out humanely and results in immediate death. When necessary, assistance should be sought from a veterinarian or other person(s) trained and competent in euthanasia procedures.
- Recommendations for specific species are described in detail in Appendices XXX.

Article 8**Unloading and post-journey handling****General**

- The principles of good animal handling during loading apply equally during unloading.
- Animals should be unloaded from the vehicle into appropriate facilities as soon as possible after arrival at the destination but sufficient time should be allowed for unloading to proceed quietly and without unnecessary noise, harassment or force.
- Unloading should be supervised by competent animal handlers with knowledge and experience of the behavioural and physical characteristics of the species being unloaded.
- Facilities should provide all animals with appropriate care and comfort, adequate space, access to quality feed and clean drinking water, and shelter from extreme weather conditions.

Appendix XXX (contd)Appendix IV (contd)**Sick and injured animals**

- An animal that becomes sick, injured or disabled during a journey must be taken to the nearest appropriate place for treatment. The driver should notify and transfer responsibility of the animal's welfare to a suitable person at the destination. When necessary, veterinary advice should be sought in the care and treatment of these animals.
- There should be appropriate facilities and equipment for the humane unloading of animals that are non-ambulatory due to fatigue, injury or sickness. These animals should be unloaded in a manner that causes the least amount of suffering. After unloading, separate pens and other appropriate facilities should be available for sick or injured animals.

Animal health procedures (e.g. quarantine)

- The following should be taken into account in addressing the greater risk of disease due to the stress of transport:
 - the extent of resistance of pathogens to environmental changes,
 - an increase in disease levels due to immunosuppression,
 - enhanced infectiousness - transmission of a pathogenic agent with shedding from an infected host through oronasal fluids, respiratory aerosols, faeces or other secretions or excretions; for example rota virus through faeces and bovine herpesvirus-1 (BHV-1) through the respiratory route,
 - enhanced contact - survivability of pathogen increases with close contact,
 - pathogenic agents resistant to environmental factors - contamination of vehicles, staging points, markets, will be a source of indirect transmission to animals by pathogens resistant to environmental conditions.
- Animals which could have become infected during the journey should be examined by qualified personnel after unloading and if necessary either quarantined or slaughtered.

Facilities

- Unloading can be associated with traumatic experiences for animals; so procedures should be planned and facilities carefully designed to facilitate unloading without poor welfare.
- Animals should be given adequate opportunity to familiarise themselves before attempts are made to move them.
- Animals which have been transported are likely to be fatigued and should be handled carefully.
- All unloading facilities should be properly illuminated to allow the animals to be easily inspected by the handler(s), and to allow the animals' ease of movement at all times. Facilities should provide uniform lighting directly over approaches to sorting pens, chutes, unloading ramps and the entrance to the transport vehicle.

Appendix XXX (contd)Appendix IV (contd)**Cleaning and disinfection**

- Disposal of a body, manure, litter or bedding after unloading should be carried out in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.
- Vehicles, crates, containers, etc. used to carry the animals should be cleaned and disinfected before re-use. This includes the physical removal of manure and bedding by scraping, washing and flushing vehicles and containers with water and detergent, followed by disinfection.
- Establishments like livestock markets, slaughterhouses, resting sites, railway stations, etc. where animals are unloaded should be provided with appropriate areas for the cleaning and disinfection of vehicles.
- Precautions should be taken to protect the unloaded animals against local diseases at destination, for example through insect proofing.
- Where disinfestation is necessary, it should be carried out with the minimum stress to the animals.

Ventilation

- Shelter such as shade, windbreaks, open or closed sheds (depending upon weather conditions) is required to protect animals that are likely to be tired after a journey and to allow recovery and the restoration of normal feeding, drinking and resting patterns. Closed sheds should be well ventilated to prevent the build-up of heat.

Feed and water

- All animals should be offered water and feed as soon as possible after the end of the journey.
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Original: English
November 2003

**REPORT OF THE FIRST MEETING OF
THE OIE AD HOC GROUP ON
THE TRANSPORT OF ANIMALS BY SEA**

Paris, 19-21 November 2003

The OIE *Ad hoc* Group on the transport of animals by sea held its first meeting at the OIE Headquarters from 19-21 November 2003.

The members of the OIE *Ad hoc* Group and other participants are listed in [Appendix I](#). Dr Richard Norris was appointed Chair of the *Ad hoc* Group. The Agenda adopted is given in [Appendix II](#). The agreed terms of reference for the *Ad hoc* Group are at [Appendix III](#).

The Director General of the OIE, Dr Bernard Vallat, welcomed the members of the *Ad hoc* Group and thanked them for their willingness to be involved in addressing the new mandate of the OIE for animal welfare. He noted the recommendation of the Working Group that *Ad hoc* Groups initially develop detailed statements on policies and principles, specific to their subject, as a bridge between the generic OIE statement on policies and principles, and future specific animal welfare standards. He also explained the OIE's aims in holding the OIE Global Animal Welfare Conference in February 2004.

The *Ad hoc* Group adopted an 'origin to destination' approach to animal welfare transport by sea to ensure responsibilities at each stage were clearly attributed, but noted that a sea voyage may be preceded and/or followed by land transport. The *Ad hoc* Group believed that the overriding principle was that a single person (who may not be the owner of the animals) should be responsible for overall planning of the journey and the welfare of the animals throughout the journey. However, the ownership of the animals may change during the journey, as well as the relevant authority.

The *Ad hoc* Group recognised that the OIE had in place a mechanism to settle disputes among Member Countries but noted that, to be initiated, the procedure needed the agreement of both parties. The *Ad hoc* Group believed that the procedure needed to address the possibly urgent animal welfare issues associated with the rejection of a shipload of animals. It proposed that the OIE procedure be modified to allow for an inspection of the animals as a matter of urgency by an OIE appointed veterinarian (even in the absence of agreement by both parties) to help clarify their animal health status and the animal welfare situation on board. This expert report should be used in discussions determining the destination of the animals. Payment of the costs associated with these procedures would need to be determined.

Appendix XXX (contd)

The *Ad hoc* Group drafted specific guiding principles addressing transport by sea, using the following documents as sources of information:

- Animal Transport Association (AATA) Manual for the Transportation of Live Animals (2nd ed)
- Council of Europe European Convention for the protection of animals during international transport (revised 2003)
- Australian Livestock Export Standards (November 2002)
- Australian Maritime Safety Authority Marine Orders part 43 (2001).

The *Ad hoc* Group decided that it would address species-specific guidelines under the following headings:

- special characteristics
- accommodation requirements
- preparation before loading
- space requirements
- loading and unloading
- general care and management
- feeding and watering
- stockman skills
- accompanying documentation.

The draft guidelines are at Appendix IV.

.../Appendices

MEETING OF THE OIE AD HOC GROUP ON THE TRANSPORT OF ANIMALS BY SEA

Paris, 19-21 November 2003

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MEETING OF THE OIE *AD HOC* GROUP ON THE TRANSPORT OF ANIMALS BY SEA

Paris, 19-21 November 2003

Agenda adopted

- 1) Introduction
 - Discussion in the OIE Working Group on Animal Welfare
 - Other relevant discussions
 - 2) Update on recent significant issues regarding transport of animals by sea
 - 3) Development of specific guiding principles and standards
 - 4) Work programme
 - 5) Conclusions
-

TERMS OF REFERENCE

- First output – draft guiding principles (rather than a prescriptive approach to limits) specifically addressing transportation (based on the generic OIE guiding principles and policies for animal welfare)
 - Final output – draft standards / guidelines for the OIE *Terrestrial Animal Health Code* based on approved guiding principles
 - Review of existing standards in the OIE *Terrestrial Animal Health Code*
 - Identification of future directions in which the *Ad hoc* Group might need to move
 - Produce drafts for review by the Working Group and then by the OIE Terrestrial Animal Health Standards Commission
 - Species to be covered
 - cattle, sheep, goats
 - pigs
 - horses.
-

INTRODUCTION TO OIE GUIDELINES FOR THE WELFARE OF ANIMALS

Article 1

Guiding principles for animal welfare

- That there is a critical relationship between animal health and animal welfare.
- That the internationally recognised ‘five freedoms’ (freedom from hunger, thirst and malnutrition; freedom from fear and distress; freedom from physical and thermal discomfort; freedom from pain, injury and disease; and freedom to express normal patterns of behaviour) provide valuable guidance in animal welfare.
- That the internationally recognised ‘three Rs’ (reduction in numbers of animals, refinement of experimental methods and replacement of animals with non-animal techniques) provide valuable guidance for the use of animals in science.
- That the scientific assessment of animal welfare involves diverse elements which need to be considered together, and that selecting and weighing these elements often involves value-based assumptions which should be made as explicit as possible.
- That the use of animals in agriculture and science, and for companionship, recreation and entertainment, makes a major contribution to the wellbeing of people.
- That the use of animals carries with it a duty to ensure the welfare of such animals to the greatest extent practicable.
- That improvements in farm animal welfare can often improve productivity and hence lead to economic benefits.
- That equivalent outcomes (performance criteria), rather than identical systems (design criteria), be the basis for comparison of animal welfare standards and guidelines.

Article 2

Scientific basis for guidelines

- Welfare is a broad term which describes how well individuals are coping with their environment, and includes their health, their feelings, and other good and bad effects on brain and body mechanisms for dealing with problems.
- Welfare can be scientifically evaluated and can be shown to range from very good to very poor. The study of how to assess animal welfare has progressed rapidly in recent years and evidence from such studies has been used in the formulation of these guidelines.
- Some studies of animal welfare involve assessing the extent of stress, which occurs when individuals are not able to cope with the consequences of treatment by humans or other impacts on the animal’s environment. Other indicators of poor welfare reveal how much the individual is having to do in order to cope with problems.

Appendix XXX (contd)Appendix IV (contd)

- Other areas of animal welfare research provide further information about the needs of animals by measuring the strengths of their positive and negative preferences. Once the needs of animals are known, conditions and treatment methods which fulfil their needs can be devised and used.
- Some measures of poor welfare involve assessing the extent of pain or impaired functioning associated with injury or disease. Many of the problems can be revealed by an inspection of the animal.
- Many measurements of animal welfare can be used as performance indicators in the evaluation of general methods for the keeping and treatment of animals and the actions of individuals who have an impact on those animals. Using such evidence, the acceptability of systems and of human performance can be decided.

Ethical basis for guidelines

- Those who use animals have obligations concerning the welfare of those animals. Poor welfare should be minimised and good welfare maximised by the use of adequate housing and ethically accepted methods of treatment, inspection, training and management.

Article 3**Definitions**

- **Exporter** means the person with overall responsibility for the organisation, carrying out and completion of the journey, regardless of whether duties are subcontracted to other parties during transport. Such a person is usually the person who plans, makes arrangements for and defines the conditions to be met by other parties.
- **Person in charge of the welfare of the animals** means the person who has direct physical responsibility for the care of the animals during transport. Such a person may be the attendant or the captain of a vessel if fulfilling the same role.
- **Competent animal handler** means a person with a knowledge of the behaviour and needs of animals which, with a professional and sympathetic response to an animal's welfare requirements, results in effective management and good welfare.
- **Transport.** The procedures associated with the carrying of animals from one location to another by road, rail, ship or air.
- **Journey.** An animal transport journey should be regarded as commencing when the first animal is loaded onto a *vehicle* or *vessel* and as ending when the last animal is unloaded, and includes any stationary resting / holding periods of less than 48 hours.

The same animals should not be regarded as commencing a new journey until a period of over 48 hours sufficient for rest and recuperation of the animals with adequate food and water provided, has passed since the end of the previous journey.

- **Travel.** The movement of a *vessel* carrying animals from one location to another.
- **Pre-journey period.** The period during which animals are identified, and often assembled for the purpose of loading them.

Appendix XXX (contd)Appendix IV (contd)

- **Post-journey period.** The period between unloading and recovery from the effects of the journey.
 - **Loading / unloading.** **Loading** is the procedure of moving animals onto a vessel from the pre-loading site; **unloading** is the procedure of moving animals off a vessel.
 - **Space allowance** is the area on a vessel, or volume of water in the case of aquatic animals, per individual or body weight of animals transported.
 - **Stocking density** is the number or body weight of animals per unit area on a *vessel*, or per unit volume of water in the case of aquatic animals.
 - **Staging point** means a place where the journey is interrupted to rest, feed or water the animals; the animals may remain in the *vessel* or be unloaded.
 - **Container** means a non-powered receptacle for holding animals during a journey by one or several means of transport.
 - **Vehicle** includes any container, truck, ship or receptacle that carries an animal.
-

Appendix XXX (contd)Appendix IV (contd)**GUIDING PRINCIPLES FOR THE TRANSPORT OF ANIMALS BY SEA****Article 1****Responsibilities**

Once the decision to transport animals by sea has been made, the welfare of animals during their transport is paramount and is the joint responsibility of all people involved.

The management of animals at post-discharge facilities is outside the scope of this document.

The roles of each of those responsible are defined below:

- Exporters, owners and managers of animals are responsible for the general health of the animals and their fitness for the journey. The exporter is responsible for ensuring compliance of the animals with the veterinary certification and other documentation of the importing and exporting countries.
- Business or buying/selling agents have a joint responsibility with owners for the selection of animals that are fit to travel. They have a joint responsibility with masters of vessels and managers of facilities at the start and at the end of the journey for the availability of suitable facilities for the assembly, loading, transport, unloading and holding of animals, and for emergencies.
- Animal handlers have a personal responsibility for the humane handling and care of animals, especially during loading and unloading. To carry out these responsibilities, they should be competent in these procedures.
- The exporter, the shipping company and the master of the vessel are responsible for planning the journey to ensure the care of the animals, including:
 - choosing appropriate vessels and ensuring that competent animal handlers are available for loading and caring for animals throughout the journey,
 - developing and keeping up to date contingency plans to address emergencies (including adverse weather conditions) and minimise stress during transport,
 - correct loading of the ship, regular inspections during the journey and for appropriate responses to problems arising.
- To carry out these responsibilities, staff should be competent regarding transport regulations, equipment usage, humane handling and the care of animals.
- Managers of facilities during loading of the animals are responsible for:
 - providing suitable premises for loading the animals?
 - providing competent animal handlers to load the animals in a manner that causes minimum stress and injury,
 - providing appropriate facilities for emergencies,
 - providing facilities and veterinarians or competent animal handlers capable of performing euthanasia or urgent slaughter when required,

Appendix XXX (contd)Appendix IV (contd)

- Managers of facilities at the end of the journey are responsible for:
 - providing suitable facilities for unloading the animals onto transport vehicles for immediate movement or securely holding the animals in lairage, with shelter, water and feed, when required, for transit,
 - providing competent animal handlers to unload the animals with minimum stress and injury,
 - minimising the opportunities for disease transmission while the animals are in the facilities,
 - providing appropriate facilities for emergencies,
 - providing facilities and veterinarians or competent animal handlers capable of performing euthanasia or urgent slaughter when required.
- The responsibilities of the *veterinary services* of the exporting country include:
 - establishing minimum standards for animal welfare, including requirements for inspection of animals before and during their travel, and for certification and record keeping,
 - approving facilities, containers and vessels for the holding and transport of animals,
 - setting competence standards for animal handlers and managers,
 - implementation of the standards, including through accreditation of / interaction with other organisations and competent authorities,
 - monitoring and evaluating health and welfare performance, including the use of any veterinary medications.
- The responsibilities of the *veterinary services* of the importing country include:
 - establishing minimum standards for animal welfare, including requirements for inspection of animals after their travel, and for certification and record keeping,
 - approving facilities, containers and vehicles for the unloading, holding and transport of animals,
 - setting competence standards for animal handlers and managers,
 - implementation of the standards, including through accreditation of / interaction with other organisations and competent authorities,
 - ensuring that the vessels transporting animals meet the required standards?
 - monitoring and evaluating health and welfare performance, including the use of any veterinary medications.
- Private veterinarians and para-professionals involved in transporting animals and the associated handling procedures should receive specialist training.

Appendix XXX (contd)Appendix IV (contd)**Article 2****Training**

- All people handling animals or who are otherwise responsible for animals during journeys, should receive adequate training according to their responsibilities listed in Article 4.
- Training should address:
 - animal behaviour, physiology, general signs of disease, and indicators of poor animal welfare such as stress, pain and fatigue,
 - transport regulations,
 - methods of animal handling during transport and associated activities such as assembling, loading, and unloading,
 - methods of inspecting animals, managing situations frequently encountered during transport such as adverse weather conditions, and dealing with emergencies,
 - species-specific aspects of animal handling and care, whenever necessary,
 - appropriate record keeping, and journey log.

Article 3**Documentation**

- Animals should not be loaded until the documentation required to that point is complete.
- The documentation accompanying the consignment should include:
 - journey travel plan,
 - date and place of loading,
 - daily record of inspection and important events (the journey log) which includes records of mortality, temperature, food and water consumed, medication provided, mechanical defects,
 - date and place of arrival and unloading,
 - veterinary certification, when required,
 - animal identification to allow traceback of individual animals to the premises of departure, and where possible to the premises of origin,
 - details of animals at risk,
 - number of animal handlers on board,
 - stocking density estimate for each load in the consignment.
- Veterinary certification should be required to accompany consignments of animals and address:
 - cleaning and disinfection,
 - fitness to travel,
 - animal identification (description, number, etc.),
 - health status including tests, treatment and vaccinations, if required.

Article 4

Planning the journey

General

- Adequate planning is a key factor affecting the welfare of animals during a journey.
- Before initiation of travel, plans should be made in relation to:
 - type of transport vessel required,
 - route, taking into account distance, expected weather and sea conditions and
 - duration of journey
 - mixing of animals from different sources in a single consignment,
- Preconditioning may be required, eg for dry food.
- Potential for spread of infectious disease
 - when requested by *Veterinary Authorities* of the importing country, animals should be vaccinated against diseases to which they are likely to be exposed at their destination.
- There should be planning for water and feed availability during the journey. Feed should be of appropriate quality and composition for the species, age, condition of the animals, climatic conditions, etc.
- Extreme weather conditions are hazards for animals undergoing transport and require appropriate vessel design to minimise risks. Special precautions should be taken for animals that have not been acclimatised or which are unsuited to either hot or cold conditions. In some extreme conditions of heat or cold, animals should not be transported at all.
- Behaviour-modifying or other medication should not be used routinely during transport. Such medicines should only be administered when a problem exists in an individual animal, and should be administered by a veterinarian or other person who has been instructed in their use by a veterinarian.

Vessel design and maintenance

- Vessels used for the sea transport of animals should be designed, constructed and fitted as appropriate to the species, size and weight of the animals to be transported; special attention should be paid to the avoidance of injury to animals through the use of secure smooth fittings free from sharp protrusions.
- Vessels should be designed to permit thorough cleaning and disinfection, and the management of faeces and urine.
- Vessels should be maintained in good mechanical and structural condition.
- Vessels should have adequate ventilation to meet variations in climate and the needs of the animal species being transported.

Appendix XXX (contd)Appendix IV (contd)

- Vessels should be designed so that the faeces or urine from animals on upper levels do not soil animals on lower levels, or their feed or water.
- Stowage of feed and bedding should be carried out in such a way to ensure protection from the elements and sea water
- Suitable bedding, such as straw or wood shavings, may be added to vessel floors to assist absorption of urine and faeces, provide better footing for animals and protect animals (especially young animals) from hard or rough flooring surfaces and adverse weather conditions.
- The above principles apply also to containers used for the transport of animals.

Special provisions for transport in road vehicles on roll-on/roll-off vessels or for containers

- Road vehicles and containers should be equipped with a sufficient number of adequately designed, positioned and maintained securing points enabling them to be securely fastened to the vessel.
- Road vehicles and containers should be secured to the ship before the start of the sea journey to prevent them being displaced by the motion of the vessel.

Ability to inspect animals en route

- Animals should be positioned to enable them to be inspected regularly during the journey to ensure their safety and good welfare. The first inspection should be undertaken shortly after departure.
- To allow an adequate inspection of animals en route, it should be possible for each animal to be clearly observed by the animal handler or other responsible person.

Space allowance

- The number of animals which should be transported on a vessel and their allocation to different pens on the vessel should be determined before loading.
- The amount of space required, including headroom, depends on the species of animal and should allow the necessary thermoregulation. Each animal should be able to assume its natural position for transport (including during loading and unloading) without coming into contact with the roof or upper deck of the vessel. Where animals lie down, they should have the space to adopt a comfortable, normal lying posture.
- Calculations for the space allowance for each animal should be carried out, using the figures given in these guidelines or, in their absence, in a relevant national or international document. The size of pens will affect the number of animals in each.
- The same principles apply when animals are transported in containers.

Appendix XXX (contd)

Appendix IV (contd)

Article 5

Pre-journey period

General

- All vessels and containers for animals should be thoroughly cleaned and, if necessary disinfected before animals are loaded.
- Before a journey, animals should be inspected, where possible by a veterinarian.
- In many cases of sea transport, animals may require pre-journey assembly. In these circumstances, the following points should be considered:
 - For animals such as pigs which are susceptible to motion sickness, and in order to reduce urine and faeces production during the journey, a short period of feed deprivation prior to loading is desirable.
 - When animals will be provided with a novel diet or method of water provision during or after transport, an adequate period of pre-exposure is necessary. Preconditioning to the feed to be used on the vessel may be necessary in such cases.
- Before each journey, vessels should be thoroughly cleaned and disinfected, and when necessary cleaned of arthropod and other parasites for animal and public health purposes, using chemicals approved by the *Veterinary Authority*. When these procedures are necessary during a journey, they should be carried out with the minimum of stress to the animals.

Shelter in the holding area

- Holding areas should be designed to:
 - securely contain the animals,
 - maintain a safe environment from hazards, including predators and disease,
 - protect animals from exposure to severe weather conditions, and
 - allow for companionship, rest, watering and feeding.

Fitness to travel

- Animals found unfit to travel following inspection by farm staff, animal handlers or veterinarians should not be loaded onto a vessel.
- Humane and effective arrangements should be made by the owner or agent for the handling and care of any animal rejected as unfit to travel.
- Animals that are unfit to travel include:
 - those that are sick, injured, weak, disabled or fatigued,
 - those that are unable to stand unaided and bear weight on each leg,
 - those that are blind in both eyes,
 - those that cannot be moved without causing them additional suffering,

Appendix XXX (contd)Appendix IV (contd)

- newborn with an unhealed navel,
- females which have given birth with the previous 48 hours,
- pregnant animals which would be in the final 10% of their gestation period at the time of unloading,
- in hot and cold weather, those whose body condition would result in poor welfare.
- Risks during transport can be reduced by selecting animals best suited to the conditions of travel and those that are acclimatised to expected weather conditions.
- Animals at risk and requiring better conditions and additional attention during transport include:
 - very large or obese individuals,
 - very young or old animals,
 - excitable or aggressive animals,
 - animals which have had little contact with humans,
 - females in late pregnancy or heavy lactation,
 - those with a history of exposure to stressors or pathogenic agents prior to transport.
- Hair or wool length needs consideration in relation to the weather conditions expected.

Selection of compatible groups

- Compatible groups should be selected before transport to avoid adverse animal welfare consequences. The following guidelines should be applied when assembling groups of animals:
 - animals of different species should not be mixed unless they have been reared together for a long period,
 - animals of the same species can be mixed unless there is a significant likelihood of aggression,
 - young or small animals may need to be separated from older or larger animals,
 - animals with horns or antlers should not be mixed with animals lacking horns and antlers,
 - aggressive individuals should be segregated,
 - animals reared together should be maintained as a group; animals with a strong social bond, such as a dam and offspring, should be transported together.

Specific species requirements

- Recommendations for specific species are described in detail in Appendices XXX.

Article 6

Loading

Experienced supervision

- Loading should be carefully planned as it has the potential to be the cause of poor welfare in transported animals.
- Loading should be supervised by competent animal handlers with knowledge and experience of the behavioural and physical characteristics of the animal species being loaded. These animal handlers should ensure that animals are loaded quietly and without unnecessary noise, harassment or force, and that untrained assistants or spectators do not impede the process.

Facilities

- The facilities for loading including the collecting area at the wharf, races and loading ramps should be designed and constructed to take into account of the needs and abilities of the animals with regard to dimensions, slopes, surfaces, absence of sharp projections, flooring, etc.
- All loading facilities should be properly illuminated to allow the animals to be easily inspected by the handler(s), and to allow the animals' ease of movement at all times.

Goads and other aids

- The following principles should apply:
 - Force should not be used on animals that have little or no room to move.
 - Useful and permitted aids for moving animals include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles; they should be used in a manner sufficient to encourage and direct movement of the animals but without physical contact with them.
 - Unsuitable implements such as large wooden sticks, sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts should not be used to strike animals.
 - The use of instruments which administer electric shocks (e.g. goads and prods) and their power output should be restricted to that necessary to assist movement of the animals. If such use is necessary, it should be limited to the hindquarters of pigs and large ruminants, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.
 - The use of well trained dogs to help with the loading of some species may be acceptable.
 - Manual lifting is permissible for young animals that may have difficulty negotiating ramps, but the grasping or lifting of animals by their wool or hair should not be permitted.

Appendix XXX (contd)Appendix IV (contd)**Article 7****Travel**

Animal handlers should check the consignment immediately before departure to ensure that the animals have been properly loaded. Each consignment should be checked again early in the journey and adjustments made as appropriate. Periodic checks should be made throughout the journey.

Methods of restraining or containing animals

- Methods of restraining animals should be appropriate to the species involved and the training of the individual animal.
- Recommendations for specific species are described in detail in Appendices XXX.

Regulating microclimate, including during journey stops

- Ventilation during the journey should provide for fresh air, the removal of heat and noxious gases. Ventilation should provide for the adequate thermo-regulation of each animal. In some instances, adequate ventilation can be achieved by increasing the space allowance for animals. Likely hotspots should be identified and rectified.
- Animals should be protected against harm from hot or cold conditions during travel. Procedures for maintaining microclimate in vessels will vary between cold and hot, humid conditions but will require similar prevention against the build-up of noxious gases and carbon dioxide.

Sick and injured animals

[to write appropriate section]

Water and feed requirements

- Adequate access to suitable feed and water should be provided and due account taken of likely competition for food.
- Further information regarding water and food requirements for different species is available in Appendix XXX.

Emergency procedures - training and authority

- When euthanasia is necessary, the person responsible for the animals must ensure that it is carried out humanely and results in immediate death. When necessary, assistance should be sought from a veterinarian or other person(s) trained and competent in euthanasia procedures.
- Recommendations for specific species are described in detail in Appendices XXX.

Appendix XXX (contd)

Appendix IV (contd)

Article 8

Unloading and post-journey handling

General

- A livestock vessel should have priority attention when arriving in port and have priority access to a berth with suitable unloading facilities.
- The principles of good animal handling during loading apply equally during unloading.
- The accompanying *veterinary certificate* and other documents should meet the requirements of the importing country. Veterinary inspections should be completed as quickly as possible.
- As soon as possible after the ship's arrival at the port and acceptance of the consignment by the Veterinary Authority, animals should be unloaded into appropriate facilities. Sufficient time should be allowed for unloading to proceed efficiently and without unnecessary noise, harassment or force.
- Procedures should be planned and facilities carefully designed to facilitate unloading. All unloading facilities should be properly illuminated to allow the animals' ease of movement at all times.
- Unloading should be supervised by the *Competent Authority* and managed by animal handlers with knowledge and experience of the behavioural and physical characteristics of the species being unloaded.
- In case of emergencies, port facilities should provide animals with appropriate care and comfort, adequate space, access to quality feed and clean drinking water, and shelter from extreme weather conditions.

Sick and injured animals

- There should be appropriate facilities and equipment for the humane unloading of animals that are non-ambulatory due to fatigue, injury or sickness. These animals should be unloaded in a manner that causes the least amount of suffering. After unloading, separate pens and other appropriate facilities should be available for sick or injured animals.

Special provisions for transport in road vehicles or containers on roll-on/roll-off vessels

- Road vehicles and containers should be equipped with a sufficient number of adequately designed, positioned and maintained securing points enabling them to be securely fastened to the vessel. Road vehicles and containers should be secured to the ship before the start of the sea journey to prevent them being displaced by the motion of the vessel.

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APPENDIX XXX
SPECIES SPECIFIC GUIDELINES

Special characteristics

Accommodation requirements

Preparation before loading

Space requirements

Loading and unloading

General care and management

Feeding and watering

Stockman skills

Accompanying documentation



Original: English
July 2003

REPORT OF THE SECOND MEETING OF THE OIE WORKING GROUP ON ANIMAL PRODUCTION FOOD SAFETY

Rome (Italy), 8-9 July 2003

The OIE Working Group on Animal Production Food Safety held its second meeting at the FAO Headquarters in Rome from 8-9 July 2003.

The members of the OIE Working Group and other participants are listed in [Appendix I](#); apologies were received from Dr Coulibaly. The Agenda adopted is given in [Appendix II](#).

Coordination with Codex work

The Working Group agreed that Dr Bill James (representing the Chair of the Codex Committee on Food Hygiene) would participate as an observer and report back to that Committee on the Working Group discussions, to enhance cooperation on work programmes. Mr Billy advised that the Codex Committee on Meat Hygiene may be adjourned in 2004 and that the Codex Committee on Food Hygiene could be the prime contact for the Working Group within Codex. The Working Group noted that the Codex Committee on Food Hygiene will have prime input into the agenda of the Joint FAO/WHO Expert Committee on Microbiological Risk Assessment (JEMRA).

It was also noted that much of the Codex technical work was done outside Codex Committees and that there may be some benefit in having these technical experts attending relevant sessions of Working Group meetings.

Discussions at recent OIE and CAC fora

The Chair reported on his presentation at the OIE General Session (May 2003) and noted the strong support for the work of the Working Group.

The Codex Secretariat reported on standards adopted at the CAC meeting the previous week.

OIE/CAC review of current standards

Dr Wilson reported on progress made in the OIE/CAC review of the existing and draft standards of both organisations, as a result of a meeting of OIE and CAC officials in Paris. A paper summarising relevant standards was updated in line with decisions made at the CAC meeting and is given in [Appendix III](#).

Appendix XXXI (contd)

The Working Group agreed that the OIE and CAC should work together in developing principles on traceability/traceback as a precursor to guidelines/standards.

The Working Group discussed the development of guidelines on 'good farming practice' as a joint publication of OIE/FAO/WHO. The OIE and CAC could then reference the document in their standards. Dr Chmitelin indicated that she would draft a scoping paper on the subject for examination by the Working Group.

The Working Group noted that the Executive Committee of Codex was now responsible for monitoring progress in the development of Codex standards and saw benefit in OIE writing to the new Chair and Secretariat of Codex outlining the Working Group's priorities and seeking Codex commitment to linking with the OIE in this work.

Review of progress in revising the OIE Terrestrial Code chapters on bovine tuberculosis and bovine brucellosis

The Chair outlined progress in revising the OIE *Terrestrial Animal Health Code* (the *Terrestrial Code*) chapter on bovine tuberculosis.

He believed that the chapter (and all *Code* chapters dealing with zoonoses) should contain a chapeau outlining the animal health and public health objectives of the recommendations. The Working Group noted that the usual OIE approach is to provide recommendations which allow 'safe trade' in various commodities and which are based on an assessment of the likelihood of the specified pathogen being transmissible via such commodities.

Dr Wilson advised the Working Group that the OIE was revising the criteria for making diseases notifiable, including on an emergency basis, and that such criteria would contain reasons for listing diseases. Dr James outlined the criteria used by the US USDA/FSIS to determine whether a disease or syndrome was of concern to the agency: was the disease or syndrome found in the food animal class in question? was it found in the geographic location in question? was it a zoonoses? and was it food borne?

The Working Group agreed that the OIE would provide to the Chair comments on the initial revision of the tuberculosis chapter, and that subsequently a revised document would be circulated to all Working Group members for comment. The document would then be reviewed at the December meeting of the OIE Terrestrial Animal Health Standards Commission.

Discussion of the Chair's scoping paper on the role and functionality of veterinary services in food safety

The Chair advised that the purpose of the paper was to promote discussion of the dual roles / functionalities of veterinary services throughout the food chain, by laying out a strategy for consideration.

It was agreed that the paper would be circulated for Member Country reaction as a Working Group paper (Appendix IV). In revising the paper, the Working Group discussed various issues including:

- . changing perceptions worldwide of the food safety responsibilities of regulatory agencies;
- . 'competent authority' and the criteria for the skills and competencies needed to address animal health and public health;
- . difficulties of addressing the multiple but interdependent functions of animal health and public health;
- . roles of veterinarians in risk assessment and risk management;
- . need for review of the definition of 'veterinary services';
- . need for the roles of veterinary services to be tailored to the particular needs of the country, for example whether their focus should be on animal pathogens or on residues/hazards not causing disease in animals.

OIE input into the Codex Committee on Meat Hygiene

The Chair introduced the issue of OIE involvement in the work of Codex Committees and specifically in the work of the Codex Committee on Meat Hygiene. He believed that the Working Group could provide a balanced view regarding appropriate OIE input to address:

Appendix XXXI (contd)

- . relevant OIE texts which should influence the development of CAC documents; and
- . OIE texts which should be modified as a result of CAC work.

The Working Group agreed on a procedure for the OIE to access relevant CAC documents, distribute them to Working Group members for comment and provide an appropriate response to CAC.

Codex Committees and other groups considered relevant included:

- . Codex Committee on Meat Hygiene
- . Codex Committee on Food Hygiene
- . Codex Committee on Milk and Milk Products
- . Ad hoc Task Force on Animal Feeding
- . Codex Committee on Residues of Veterinary Drugs in Food
- . Codex Committee on Fish and Fishery Products
- . Codex Committee on Food Inspection and Certification Systems
- . Codex Committee on Food Additives and Contaminants
- . Codex Committee on Pesticide Residues.

The Working Group then discussed modifications to the draft standard proposed by the Chair to address the need perceived by the OIE to expand the text on ante- and post-mortem procedures to better address the interdependence of animal health and public health objectives.

Resolutions and recommendations arising from the OIE General Session and Regional meetings

The Working Group examined Resolution XXVII adopted at the OIE General Session and considered that its work programme adequately addressed the second recommendation.

The Working Group also examined recommendations arising from meeting of the regional Commissions for Europe and the Americas, and considered that all were adequately addressed by the work programme.

Work programme

The Working Group reviewed and modified priorities for its work programme, which is given in Appendix V.

Other business

The Working Group discussed principles of membership with regard to OIE Regional representation, and experts from relevant Codex Committees and other groups.

The Working Group agreed that the meeting agenda would determine which experts should be invited to attend a particular agenda item, and that the Chair would seek advice from the OIE Director-General prior to each meeting.

The Working Group recommended that the OIE Director-General re-examine the representation from Africa, Asia and South America, to enhance the participation of developing countries in the Working Group.

Next meeting

The Working Group agreed that its next meeting would be held in Paris in April 2004.

.../Appendices

MEETING OF THE OIE WORKING GROUP ON ANIMAL PRODUCTION FOOD SAFETY

Rome, 8-9 July 2003

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MEETING OF THE OIE WORKING GROUP ON ANIMAL PRODUCTION FOOD SAFETY***Rome, 8-9 July 2003***

Adopted Agenda

1. Introduction
 - discussion at OIE General Session
 - discussions at CAC
 2. OIE/CAC review of current standards
 3. Review of progress in revising the Terrestrial Code chapters on bovine tuberculosis and bovine brucellosis
 4. Discussion of the Chair's scoping paper
 5. Codex Committee on Meat Hygiene – OIE input
 6. Resolutions and recommendations arising from the OIE General Session and Regional meetings
 7. Work programme
 8. Other business
 9. Next meeting
-

Table of correspondence of CAC/OIE standards				
Subject	OIE standard	OIE texts under discussion	Codex standard	Codex texts under discussion
General definitions	<p><i>Terrestrial Code</i> chapter 1.1.1 on 'General Definitions'</p> <p>Manual Glossary of Terms</p> <p>Definitions relevant to specific chapters in <i>Terrestrial Code</i> and <i>Terrestrial Manual</i></p>		<p>Definitions in 12th edition of Procedural Manual</p> <p>Specific definitions in different Standards</p>	
Import risk analysis	<p><i>Terrestrial Code</i> section 1.3 on 'Import Risk Analysis' (Chapters 1.3.1 on General considerations and 1.3.2 on Guidelines for risk analysis)</p> <p><i>Terrestrial Code</i> section 1.5 on 'Risk Analysis for Biologicals for Veterinary Use' (Chapters 1.5.1 to 1.5.3)</p> <p>Some specific chapters in <i>Terrestrial Code</i> refer to need for risk-based approach in determining disease status</p>	Planned minor changes to incorporate food safety aspects	<p>Principles and guidelines for the conduct of microbiological risk assessment (GL-30 1999)</p> <p>Working principles for risk analysis in the framework of the Codex Alimentarius</p>	<p>Proposed draft principles and guidelines for the conduct of microbiological risk management (CXFH) (ALINORM 03/13A step 2)</p> <p>Proposed draft working principles for risk analysis for food safety (CCGP, ALINORM 03/33A, step 2)</p>
Traceability		OIE to develop guidelines covering animal health and food safety from OIE <i>Scientific Revue</i> papers		<p>CCGP is developing a definition of 'traceability/product tracing' (CCGP ALINORM 03/33A)</p> <p>Drafts of specific texts under early discussion in CCFICS, CCFH, TFAF and TFFDB (ALINORM 03/30 A)</p>

Appendix XXXI (contd)

Appendix III

Subject	OIE standard	OIE texts under discussion	Codex standard	Codex texts under discussion
Equivalence	<i>Terrestrial Code</i> chapter 1.3.7 (Guidelines for reaching a judgement of equivalence of sanitary measures)		Guidelines for the development of equivalence agreements regarding food import and export inspection and certification systems (GL-34) Guidelines on the judgement of equivalence of sanitary measures associated with food inspection and certification systems	
Testing, inspection and certification procedures	<i>Terrestrial Code</i> chapter 1.2.2 (Certification procedures) <i>Terrestrial Manual</i> chapter 1.1.1 (Sampling methods)		Principles for food import and export inspection and certification (GL-20 1995) Guidelines for ... food import and export inspection and certification systems (GL-26 1997) Draft guidelines for food import control systems	
Evaluation of Veterinary Services and Competent Authorities	<i>Terrestrial Code</i> chapters 1.3.3 (Evaluation of veterinary services) and 1.3.4 (Guidelines for the evaluation of veterinary services) <i>Aquatic Code</i> chapter 1.4.3 (Evaluation of Competent Authorities)	Draft guidelines on use of para-professionals and private veterinarians in veterinary services under discussion		

Appendix XXXI (contd)

Appendix III

subject	OIE standard	OIE texts under discussion	Codex standard	Codex texts under discussion
Surveillance and monitoring	<p><i>Terrestrial Code</i> chapter 1.3.6 (Surveillance and monitoring of animal health)</p> <p><i>Terrestrial Code</i> appendix 3.8.1 (General principles for recognising a country or zone free from a given disease/infection)</p> <p><i>Terrestrial Code</i> appendix 3.8.4 (Surveillance and monitoring systems for BSE)</p> <p>Specific guidelines incorporated into some disease chapters</p>	More disease-specific guidelines under development	<p>Elements exist in the Codes covering meat (RCP-11, RCP 29, RCP 41, RCP 13, RCP 14); these will be replaced by the general principles of meat hygiene and proposed draft code of hygienic practice for meat</p> <p>General principles of meat hygiene (CCMPH)</p>	Elements exist in proposed draft code of hygienic practice for meat (CCMPH ALINORM 03/16 A App III)
Notification	<p><i>Terrestrial Code</i> chapter 1.1.3 (Notification and epidemiological information)</p> <p>OIE emergency disease notification procedures (EWS)</p>	Chapter under revision to incorporate single list of diseases (zoonotic potential is one criteria for listing), to be implemented on 1 January 2005	Codex Guidelines for the exchange of information in food control emergency situations (CCFICS) (GR-19/1995)	Proposed draft revision of the Guidelines (CCFICS ALINORM 03/30 A)
General food hygiene provisions			<p>Code of practice – general principles of food hygiene (RCP1 1969, rev3 1997, amended 1999)</p> <p>Principles for the establishment and application of microbiological criteria for foods (GL-21 1997)</p>	

Appendix XXXI (contd)

Appendix III

Subject	OIE standard	OIE texts under discussion	Codex standard	Codex texts under discussion
Zoonoses able to be transmitted through meat, milk and eggs	Bovine tuberculosis <i>Terrestrial Code</i> chapter 2.3.3	revised chapters will better address food safety	Code of practice for control of the use of veterinary drugs (vol 3) (RCP-38 1993)	Proposed draft code of practice of good animal feeding (TFAF) (ALINORM 03/38 App II)
	Bovine brucellosis <i>Terrestrial Code</i> chapter 2.3.1		Guidelines for the establishment of a regulatory programme for the control of veterinary drug residues in food (GL-16 1993)	Proposed draft guidelines for the control of <i>Listeria monocytogenes</i> in foods (CXFH) (ALINORM 03/8)
	Porcine brucellosis <i>Terrestrial Code</i> chapter 2.6.2		Code of hygienic practice for egg products (RCP-15 1976)	Proposed draft code of hygienic practice for milk and milk products (CCFH) (ALINORM 03/13 A App III)
	Caprine and ovine brucellosis <i>Terrestrial Code</i> chapter 2.4.2		headings addressing hygiene in the standards for meat and meat products (vol 10), milk and milk products (vol 12)	Proposed draft revision of the Code of hygienic practice for egg products (CXFH ALINORM 03/13 A)
	Bovine cysticercoses <i>Terrestrial Code</i> chapter 2.3.		Codes covering meat (RCP-11, RCP 29, RCP 41, RCP 13, RCP 14); these will be replaced by the general principles of meat hygiene and proposed draft code of hygienic practice for meat	Proposed draft revised Guidelines for the establishment of a regulatory programme for the control of veterinary drug residues in food GL-16 under revision by CCRVDF (ALINORM 03/31 A)
	Salmonellosis <i>Terrestrial Code</i> chapter 2.10.2 (<i>Salmonella enteritidis</i> and <i>S. typhimurium</i>)		General principles of meat hygiene	Proposed draft code of hygienic practice for meat (CCMPH ALINORM 03/16 A App III)
	Bovine campylobacteriosis <i>Terrestrial Code</i> chapter 2.3.2			
	Trichinellosis <i>Terrestrial Code</i> chapter 2.2.9			
	Listeriosis (milk and milk products) nil			
	Conditions arising from enterotoxigenic <i>E. coli</i> nil			

Appendix XXXI (contd)Appendix III

Subject	OIE standard	OIE texts under discussion	Codex standard	Codex texts under discussion
Fish	<i>Aquatic Animal Health Code</i>		<p>Headings addressing hygiene in the standards for fish (vol 9A)</p> <p>Guidelines for the organoleptic evaluation of laboratories for fish, molluscs and crustaceans (GL-31 1999)</p> <p>Code of practice for fish and fishery products (general sections, fresh, frozen, minced, canned fish and frozen surumi)</p>	Draft code of practice for fish and fishery products (other sections and certificates) (CCFFP ALINORM 03/18)

ROLE AND FUNCTIONALITY OF VETERINARY SERVICES¹ IN FOOD SAFETY THROUGHOUT THE FOOD CHAIN

OIE Working Group on Animal Production Food Safety

1 Introduction

Food safety is an issue of increasing concern world wide and prioritisation of food safety as an essential public health function was advocated recently by the World Health Assembly. Better monitoring and surveillance demonstrates that the main burden of food-borne disease is due to microbiological pathogens of animal origin and this has important implications for the veterinary profession at both the international and the national level. The possibility of chemical residues in food is also causing growing anxiety amongst consumers.

In a contemporary food safety environment, veterinarians have an essential and rapidly changing role in the prevention and control of food-borne zoonoses (even when animals are not clinically affected), other sources of food-borne disease and chemical contaminants of foods. In many situations, this role is achieved in parallel to prevention and control of diseases and conditions of animal health importance.

A 'production-to-consumption', risk-based approach to food control demands integrated involvement throughout the food chain. Where zoonoses are concerned, it is clear that there is an overlap between public health and animal health objectives, and a duality of veterinary functions. Veterinary competence can also be shared even when public health and animal health objectives are separate and distinct, and a number of countries are exploring such synergies in the reform of regulatory systems.

The World Organization for Animal Health (OIE) has a SPS responsibility for elaborating standards and related texts for the prevention, control and eradication of animal diseases and zoonoses, while the Codex Alimentarius Commission (CAC) elaborates standards and related texts for both safety and suitability aspects of food control. CAC and the OIE have strategies and mechanisms in place to co-ordinate and integrate food safety activities across the production to consumption continuum and so enhance the safety of foods of animal origin on a world-wide basis. A part of OIE's strategy was the setting up of a permanent Working Group on Animal Production Food Safety to review, develop and/or contribute to international food safety standards and guidelines, incorporating good animal production practice (including veterinary aspects) as it relates to food safety and taking into account a risk-based 'production to consumption' approach.

The OIE Working Group on Animal Production Food Safety

The OIE Working Group on Animal Production Food Safety has developed a work programme to enhance the effectiveness of *Veterinary Services* in improving food safety at both the international and national level. The Working Group will advise the Director General on implementation of the OIE strategy regarding²:

- Consideration all food-borne hazards arising from animals according to global food safety priorities;
- Reviewing OIE outputs to ensure animal production food safety is integrated in OIE Specialist Commissions and ad hoc group activities;
- Fully contributing to food standards development by CAC.

¹ For the purposes of this paper, 'veterinary services' is an Official Inspection System as defined in the CAC Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems.

² Report of the meeting of the OIE *Ad hoc* Group on Food Safety. Paris, 18-19 April 2002

Appendix XXXI (contd)

Appendix IV (contd)

There is a clear need for detailed exploration of the inter-related roles and functionality of veterinary services in the outputs of OIE and CAC. This paper proposes a Joint OIE / Codex text on the dual role and overall functionality of veterinary services in food safety and animal health throughout the food chain. The proposal includes reference to regulatory, industry and public aspects of veterinary effort, and promotes the opportunity for enhancement of dual food safety and animal health roles.

2 Elements of the contemporary food safety environment

2.1 Risk analysis

The emergence of risk-based approaches in elaboration of international standards has been highly influenced by the World Trade Organisation (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). A primary tenet of this Agreement is that “Members shall ensure that their sanitary and phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal, or plant life or health, taking into account risk assessment techniques developed by the relevant international organisations”.

In developing the *Terrestrial Animal Health Code*, OIE focuses on standards for specified hazards of biological origin. In contrast, CAC has primarily addressed biological hazards in food by developing general hygiene provisions i.e. codes of practice for different food commodities, as well as addressing chemical hazards by establishing maximum control limits.

Risk analysis offers new opportunities to OIE and CAC in the elaboration of optimal sanitary measures, either as international standards or as technical advice to national governments. In the case of food safety, improvements must be brought about in the face of ever-changing patterns of primary production, processing technology and consumer behaviour.

The application of a generic risk management framework is increasingly being recognised as a cross-sectoral means of bringing about a reduction in risks to human and animal health³ (see below).

2.2 Assessment and management of hazards and risks

Consideration of all food-borne hazards and their significance in terms of risks to human health is an essential food safety activity and a core component of HACCP. Most food-borne hazards of animal origin will be either intrinsic to the live animal (as a result of production or environmental factors) or introduced during handling and processing of the product.

Food safety hazards arising from animals can be grouped into several categories e.g. zoonoses resulting from clinical disease in animals, zoonoses resulting from asymptomatic infections in animals, zoonoses arising from environmental contamination, and chemical sources.

Hazards can also be introduced into the food chain from environmental sources, and zoonoses can obviously result from occupational exposure. As some food-borne zoonoses may occur independently of the consumption of animal products e.g. contamination via irrigation of vegetables with animal-derived pathogens, these pathways also need to be considered in terms of prevention and control.

At the same time, hazards of animal health significance that can be detected in animal populations need to be identified and managed.

³ Risk Analysis in Biosecurity for Food and Agriculture by S. C. Hathaway. *In* Report of an Expert Consultation on Biosecurity in Food and Agriculture. FAO, Rome 10-13 September 2002

Management of all these hazards by veterinary services needs to be carried out in a way which optimises the use of available resources.

2.3 "Production-to-consumption" approach

Currently, Codex codes of practice for food commodities of animal origin constitute one expression of a 'production-to-consumption' approach to food control. However, for the most part, they only include general references to primary production at the farm level.

The Proposed Draft Code of Practice for Meat Hygiene identifies a number of generic segments in the food chain⁴ and these could be used as a partial template in development of a Joint OIE/CAC standard for veterinary involvement in meat hygiene activities throughout the food chain. It should be noted that many aspects of meat hygiene require iterative loops between different segments in the food chain for optimal risk management. Effective functioning of good hygienic practice (GHP) and HACCP is reliant on such information exchange.

Several other OIE and Codex standards can be utilised to describe veterinary involvement in food safety throughout the food chain e.g., Principles for Food Import and Export Inspection and Certification (CAC/GL 20 - 1995), Recommendations of the *Ad hoc* Intergovernmental Task Force on Animal Feeding (Alinorm 01/38 and Alinorm 01/38A). A range of stakeholders may be involved in implementation of food safety controls e.g. regulatory authorities, industry and the public, and measures that are decided on may not necessarily be mandatory regulatory controls e.g. consumer education in safe food handling practices.

There should be an integrated approach to the design and implementation of regulatory systems covering the 'production-to-consumption' continuum. This approach should include:

- Monitoring and surveillance at the farm level, including consideration of data from non-regulatory sources, and monitoring at other steps in the food chain, including meat inspection;
- Monitoring and risk management of the use of veterinary drugs, including antimicrobial resistance;
- Exchange of monitoring information with all interested parties;
- Animal identification systems and traceability of animal products;
- Utilisation of diagnostic tests;
- Assessment / recognition of the competence of food safety authorities in exporting countries;
- Certification and official assurances;
- Emergency response capability;
- Integrated database management, epidemiological investigations and predictive microbiology;
- Potential effects on food safety of the transport of live animals.

2.4 Risk assessment and risk management

Food-borne hazards to human health

At present, there is room for significant improvement in many aspects of food safety, especially in the areas of ante- and post-mortem inspection and microbiological process control. Measures should be tailor-made to the range and prevalence of hazards in the particular animal population, focused on the most significant risks to human health, and focused at those steps in the 'production-to-consumption' continuum where they have the highest likelihood of reducing food-borne risks.

⁴ Proposed Draft Code of Hygienic Practice for Meat. Alinorm 03/16A, Appendix III. Codex Alimentarius Commission

Appendix XXXI (contd)

Appendix IV (contd)

Other aspects include:

- Performance-based inspection for process control;
- Establishing decision criteria for the outcome of risk reductions;
- Risk-based surveillance of live animals and monitoring of animal products throughout the food chain;
- Effective information exchange and risk communication between all interested parties.

Animal health hazards

In determining the role and functionality of veterinary services in food safety throughout the 'production-to-consumption' continuum, hazards of animal health significance that can be detected in animal populations must first be identified, the risks assessed and properly managed, so as to optimise use of the available resources of veterinary services.

Veterinarians involved in food safety can also make a significant contribution to achieving animal health goals through application of animal health measures, and the extent to which animal health risk management functions should be carried out by veterinarians involved in food safety should be fully assessed, in order to maximise benefits to both sectors.

2.5 Food suitability

Beyond the assessment and management of food safety risks, assuring food suitability is an accepted component of a food safety programme.

CAC describes food hygiene as all conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain, and suitability as the assurance that food is acceptable for human consumption according to its intended use. As a result, the detection and removal of abnormalities in animal products that are not of public health significance are an accepted component of food safety programmes. Other aspects of suitability relating to consumer expectations include certification requirements e.g. Codex General Guidelines for Use of the Term 'Halal' (CAC/GL 24-1997).

2.6 Functionality

Functionality aspects of veterinary food safety services in relation to other veterinary activities that have no bearing on food safety or suitability is a key contemporary issue.

Effective food safety requires a high level of interaction and risk communication with many interested parties. Veterinarians may be called on to play a major role in these processes, especially in respect of the interface between different veterinary services and other government agencies that may be involved in food safety.

Further, food safety regulatory reform in a number of countries is changing the traditional roles of such parties. In an increasing number of countries, industry now has the primary responsibility for implementing food safety measures, and regulatory authorities are increasingly moving towards verification and audit roles. This provides new opportunities and responsibilities for veterinarians.

2.7 Animal welfare

Although animal welfare is beyond the mandate of CAC, it is a new part of the OIE's mandate. References to guidelines and recommendations on animal welfare may therefore be included in any standard resulting from this OIE/CAC cooperation.

2.8 Multidisciplinary framework

“Effective food control requires multidisciplinary scientific and technical inputs. Further, utilising risk assessment in a contemporary food safety environment is a multidisciplinary responsibility”⁵.

Any standard resulting from this OIE/CAC cooperation will benefit from multidisciplinary inputs to food safety.

3 Standards

OIE has identified that co-operation with CAC will enhance the scope and scientific quality of international standards, guidelines and related texts, especially in regard to food safety measures applicable at the farm level⁶.

According to its Statutes, CAC should "promote coordination of all food standards work undertaken by intergovernmental and non-governmental organisations" (Article 1[b]). Objective 3 of the CAC Strategic Framework recognises that CAC needed to interact closely with OIE; this has been confirmed at the 26th Session of the CAC.

Possible results⁷ may be:

- Joint Codex/OIE standards or related texts developed through joint committees or similar mechanisms;
- Codex or OIE standards or related texts elaborated by one party (and other co-operating organisations) on behalf of the other;
- Substantial co-operation at the initial drafting stages of Codex or OIE standards or related texts, with either party acting as a subsidiary body.

4 Development of an international standard on veterinary services' involvement in food safety activities

Development of a CAC/OIE standard or related text (hereafter referred to as "standard") on the roles and functionality of veterinary services in food safety is an important initiative of the OIE Working Group on Animal Production Food Safety.

The standard should cover the involvement of veterinary services in food safety activities which encompass food safety and suitability and zoonoses. Activities in these areas will variably contribute to "reducing food-borne risks to human health by preventing, eliminating or controlling hazards arising from animals prior to primary processing of animals and animal products"⁸. Further, the standard should cover veterinary competence in other aspects of food safety risk management e.g. public health policy, integrated design of surveillance systems for chemical hazards, certification, risk communication.

In addition, functionality aspects of veterinary services must be considered in respect of animal health activities that have no bearing on food safety or suitability.

⁵ Future Trends in Veterinary Public Health. Report of a WHO Study Group. WHO, Geneva 2002

⁶ Resolution No. XV. 70th General Session of the OIE, 2003

⁷ Codex Alimentarius Commission (2003). Guidelines for co-operation with intergovernmental organisations. CX/GP 03/8

⁸ Report of the Meeting of the OIE Working Group on Animal Production Food Safety. Paris, 18-20 November 2002

Appendix XXXI (contd)Appendix IV (contd)**4.1 Format**

The suggested format for elaboration of the "standard" is:

- Overarching principles for the involvement of veterinary services and other veterinary activities in food safety;
- A "code of practice" format that progresses through a "production-to-consumption" approach to food safety;
- Subsections that develop principles and guidelines according to the particular segment of the food chain;
- Specific linkages to other OIE and Codex texts describing detailed aspects of possible veterinary inputs e.g. on antimicrobial resistance.

4.2 Criteria

Suggested criteria for elaboration of the "standard" are:

- Consideration of food-borne risks to human health as a result of hazards arising from animals prior to primary processing of animals and animal products;
- Inclusion of animal health and welfare functions (including epidemiological surveillance) that may be carried out by veterinarians whose primary focus is food safety;
- Representation of a "production-to-consumption" approach to food safety;
- Reflection on effective use of veterinary services and other competent authorities;
- Utilisation of risk assessment wherever possible and practical;
- Inclusion of HACCP where appropriate;
- Inclusion of food suitability⁹ as well as food safety;
- Identification of the contributions of public and private sector veterinarians, and para-professionals.

Many of the above criteria are "horizontal" in nature will need to be applied at each segment of the 'production-to-consumption' continuum, with a description of iterative loops to veterinary inputs at other segments.

4.3 Ad hoc Groups

The Working Group is proposing that several *Ad hoc* Groups be formed to draft different modules for the "standard". Each *Ad hoc* Group should apply a generic framework for managing food-borne risks to consumers and describe veterinary inputs.

Each *Ad hoc* Group should consider modular and "horizontal" aspects of:

- Regulatory frameworks and responsibilities;
- Veterinary activities relating to food safety and suitability, zoonoses and animal health, and welfare;
- The relative contributions of public and private sector veterinarians, and para-professionals, and other stakeholders;
- The functionality of sharing veterinary competence to meet public health and animal health goals.

The Working Group is proposing that three *Ad hoc* Groups be set up to address the following priority issues:

- ante- and post-mortem activities in the production of meat to reduce hazards of public and animal health significance;
- involvement of veterinary services in risk reduction regarding *Salmonella enteritidis* in eggs;
- the role of veterinary services in the reduction of chemical hazards of public and animal health significance at the farm level.

⁹ Food suitability is described by CAC as "assurance that food is acceptable for human consumption according to its intended use"

Appendix XXXI (contd)

Appendix IV (contd)

Scope, terms of reference and membership for the *Ad hoc* Groups will be further developed by the Working Group out of session.

Appendix XXXI (contd)Appendix IV (contd)**Appendix****Generic framework for managing public and animal health risks**

To the greatest extent possible and practicable, design and implementation of sanitary measures should be based on application of four components of a generic framework:

Preliminary activities by the risk manager

Following identification of a public health or animal health issue by the risk manager, this initial process may include establishment of a risk profile to place the issue within a particular context, and provide as much information as possible to guide further action. The risk manager may commission a detailed risk assessment as an independent scientific process to inform decision-making, and if so, risk assessment policy should be established¹⁰. Once a risk assessment has been received, the last step in preliminary risk management activities is to consider the results for completeness and appropriateness.

Evaluation of risk management options

This is the process whereby potential risk management options are identified, and then selected according to appropriate decision-making criteria. It will usually involve balancing expectations in light of scientific information on risks and available measures. “Optimisation” of selected measures in terms of their efficiency, technological feasibility and practicality is an important goal.

Implementation of measures

Implementation of public or animal health measures will usually involve regulatory requirements, with a particular focus on HACCP. Flexibility in choice of individual measures applied by industry is a desirable element, as long as the overall programme can be objectively shown to achieve stated goals. On-going verification of sanitary measures by the competent authority is an essential action.

Monitoring and review of appropriateness of options chosen

This is the gathering and analysing of public and animal health data. Monitoring (which includes surveillance) should identify new problems as they emerge. Where there is evidence that required public and animal goals are not being achieved, redesign of measures will be needed.

¹⁰ Risk assessment policy refers to the documented guidelines (provided by the risk manager) for policy choices and scientific value judgements that may be necessary at specific points in the risk assessment.

Priorities for work programme

Procedures

In its meeting in November 2002, the OIE Working Group on Animal Production Food Safety identified a need for procedures to be developed between the OIE and the Codex Alimentarius Commission (CAC) on:

- . the development, adoption and publication of joint standards (where appropriate),
- . the mutual recognition of standards adopted by either organisation, and
- . the establishment of linkages between standards dealing with related subject areas.

Priorities

At its July 2003 meeting, the Working Group identified the following priorities for the OIE:

1. Horizontal issues covered or under discussion by CAC and OIE requiring joint inputs:

- import risk analysis
- surveillance and monitoring
- traceability
- equivalence
- evaluation of veterinary services / competent authorities
- testing, inspection and certification procedures

2. OIE texts addressing areas of interest to CAC

Zoonoses addressed in the *Terrestrial Code*

- bovine tuberculosis (Chapter 2.3.3 of the *Terrestrial Code*)
- bovine brucellosis (Chapter 2.3.1 of the *Terrestrial Code*)
- porcine brucellosis (Chapter 2.6.2 of the *Terrestrial Code*)
- caprine and ovine brucellosis (Chapter 2.4.2 of the *Terrestrial Code*)
- bovine cysticercoses (Chapter 2.3.1 of the *Terrestrial Code*)
- trichinellosis (Chapter 2.2.9 of the *Terrestrial Code*)

Zoonoses not always affecting animals

- bovine campylobacteriosis (Chapter 2.3.2 of the *Terrestrial Code*)
- salmonellosis (Chapter 2.10.2 of the *Terrestrial Code*)
- listeriosis (nil)
- conditions arising from enterotoxigenic *E. coli* (nil)

3. CAC texts addressing issues of interest to OIE

- General Principles of Meat Hygiene
- draft Code of Practice for Meat Hygiene
- General Principles of Food Hygiene
- Code of Practice for Milk and Milk Products
- draft Code of Practice for Animal Feeding
- Guidelines for the Use of Veterinary Drugs
- Code of Practice for Fish and Fishery Products
- draft Code of Practice for Aquaculture
- standards on contaminants
- standards on maximum limits for pesticide residues

4. OIE/CAC relationship

- OIE letter to new CAC Chair regarding CAC Executive Secretariat
- cooperation of key horizontal committees

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5. Role and functionality of veterinary services in food safety throughout the food chain, with the following issues identified as priorities:
 - the ante- and post-mortem activities in the production of meat to reduce hazards of public and animal health significance;
 - involvement of veterinary services in risk reduction regarding *Salmonella enteritidis* in eggs;
 - the role of veterinary services in the reduction of chemical hazards of public and animal health significance at the farm level.
 6. Scoping paper on 'good farming practices'
 7. Other texts of importance to the work of the Working Group
 - equivalence (Chapter 1.3.7 of the *Terrestrial Code*)
 - BSE (Chapter 2.1.13 of the *Terrestrial Code*).
-

PROPOSED NEW APPENDIX ON ANIMAL HEALTH SURVEILLANCE: GENERAL PRINCIPLES AND PRACTICES

1. Introduction

Animal health surveillance should be conducted for a defined purpose. In the context OIE-related activities it is generally aimed at either demonstrating the absence of disease or infection or establishing the occurrence and distribution of disease or infection, including the early detection of exotic or emerging diseases when they occur. The nature of the surveillance applied depends on the desired outputs needed; for example, to support applications for recognition of freedom from disease/infection or decision-making in relation to disease control or eradication strategies.

The guidelines contained in this chapter may be applied to all diseases, their agents and susceptible species as listed in the *Terrestrial Code*, and are designed to assist with the conduct of cost-effective surveillance. Except where specific surveillance for certain diseases or infections is already described in the *Terrestrial Code*, the guidelines in this chapter are recommended to define the general approach for all diseases/infections. The guidelines should be supplemented when necessary with those available in standard texts on surveillance.

Surveillance is an essential component of claims for freedom from disease or infection and provides data to support the risk analysis process and that required to substantiate the rationale for animal health control measures. Furthermore, surveillance data underpin the quality of disease status reports.

Essential prerequisites to enable a Member Country to provide information for the evaluation of its animal health status are:

- compliance with the provisions of Chapter 1.3.3 of the *Code* for the evaluation of the Veterinary Services;
- provision, where possible, of complementary data derived from other sources of information e.g. scientific publications, research data, documented field observations and other non-survey data;
- transparency in the planning and execution of surveillance activities, the conduct of analyses and accessibility of the data and information obtained.

2. Definitions

The following definitions apply for the purposes of this chapter.

- **Case**

A case definition is a set of criteria used to classify an animal or unit as a case or non-case.

- **Confidence**

In the context of demonstrating freedom from infection, confidence is the probability that the type of surveillance applied would detect the presence of infection if the population were infected. The confidence depends on *inter alia* the expected prevalence, or the assumed level of infection in an infected population. Confidence therefore refers to the confidence in the ability of the surveillance system applied to detect disease or infection.

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- **Early detection system**

A system for the timely detection and identification of an incursion or emergence of disease/infection in a country, zone or compartment. An early detection system should be under the control of the *Veterinary Services* and should include the following aspects:

- representative coverage of the animal populations in the country, zone or compartment concerned by the *Veterinary Services* ;
- ability to undertake effective disease investigation and reporting;
- access to laboratories capable of diagnosing and differentiating relevant diseases;
- a training programme for veterinarians, animal health professionals and others involved in handling animals for detecting and reporting unusual animal health incidents.

- **Epidemiological unit**

A group of animals with a defined epidemiological relationship that share approximately the same likelihood of exposure to a pathogen. This may be because they share a common environment (e.g. animals in a pen), or because of common management practices. Usually, this is a herd or flock; however, an epidemiological unit may also refer to groups of animals such as those belonging to residents of a village, or for example animals sharing a communal dipping tank system.

- **Outbreak**

An outbreak definition is a set of criteria used to classify the occurrence of one or more cases in a group of animals or units.

- **Probability sampling**

A sampling strategy in which every unit has a known non-zero probability of inclusion in the sample.

- **Sample**

Elements drawn from a sampling unit, on which *tests* are performed to provide surveillance information.

- **Sampling units**

The *unit* that is sampled, either in a random or in a non-random survey. This may be an individual animal or a group of animals (eg an *epidemiological unit*). Together, they comprise the sampling frame.

- **Sensitivity**

The proportion of truly positive units that are correctly identified as positive by a test.

- **Specificity**

The proportion of truly negative units that are correctly identified as negative by a test.

- **Study population**

The population from which surveillance data is derived. This may be the same as the target population or a subset of it.

- **Surveillance system**

A method of surveillance that may involve one or more component activities that generates information on the animal health status of populations.

- **Target population**

The population about which conclusions are to be drawn from a study.

- **Test**

A procedure used to classify a unit as either positive or negative with respect to an infection or disease.

- **Test system**

A combination of multiple tests and rules of interpretation which are used for the same purpose as a test.

- **Units**

Individually identifiable elements. This is a generic concept used to describe, for example, the members of a population, or the elements selected when sampling. In these contexts, examples of units include individual animals, pens, farms, holdings, villages, districts etc.

3. Types of surveillance

Surveillance can be classified in a number of ways. One approach, which is used here, is to based on sources of surveillance data. In this chapter, surveillance data is classified as follows:

3.1. Structured population-based surveys, such as:

- systematic sampling at slaughter;
- random surveys

3.2. Structured non-random data sources, such as:

- disease reporting or notifications;
- control programs / health schemes;
- disease specific testing / screening;
- ante- and post-mortem inspections;
- laboratory investigation records;
- sentinel units
- field observations;
- farm production records;

Appendix XXXII (contd)

In addition, surveillance data needs to be supported by related information sources, such as:

- data on the epidemiology of the infection, including environmental, host population distribution, and climatic information;
- data on animal movements and trading patterns for animals and animal products;
- history of imports of potentially infected material; and
- bio-security measures in place.

The sources of information should be fully described. In the case of a structured survey, this should include a description of the sampling strategy used for the selection of units for testing. For structured non-random data sources, a full description of the system is required including the source(s) of the data, when the data were collected, and a consideration of any biases that may be inherent in the system.

4. Critical elements for conducting surveillance

The quality of a surveillance system depends on the following critical elements (over and above quality of veterinary services - Chapter 1.3.3).

4.1. Populations

Surveillance should be carried out in such a way as to take into account all animal species susceptible to the infection in a country, *zone/region* or *compartment*. The surveillance activity may involve all individuals in the population or part of it. In the latter case, the individuals must be chosen in such a way that the results achieved from surveillance in the subset can be correctly extrapolated to the entire susceptible populations. Care should be taken during the planning of the survey to identify potential biases that can inadvertently lead to an over-estimate or an under-estimate of the parameters of interest. However, in the case of targeted surveillance a particular subset of a population may be targeted because the probability of detecting the condition in question is greater than for the population as a whole. In that case the survey is intentionally biased. All that is needed is that the bias is recognised.

4.2. Epidemiological Unit

The relevant epidemiological unit for the surveillance system should be defined and documented to ensure that it is representative of the population in the case of random surveillance or of the subset of the population when using targeted surveillance. Therefore, epidemiological units need to be chosen taking into account factors such as carriers, reservoirs, vectors, immune status, genetic resistance and other host characteristics such as age and sex.

4.3. Clustering

Infection in countries, zones/regions or compartments usually occur in clusters rather than being uniformly or randomly distributed through a population. Clustering may occur at a number of different levels such as a cluster of infected animals within a herd, a cluster of pens in a building, or a cluster of farms in a compartment. However, animal populations themselves are frequently clustered in their distribution and therefore apparent clustering of disease judging from simple distribution maps may be misleading. In such cases more formal cluster analysis may be necessary but that requires specialized knowledge to apply correctly.

4.4. Testing

Surveillance involves the detection of disease or infection by the use of one or more tests for evidence of infection. In this context, a test may range from detailed laboratory examinations to field observations and the analysis of production records. The performance of a test at the population level is dependent upon its sensitivity and specificity as these will have an impact on the interpretation of results and therefore on the conclusions reached. These factors should therefore be taken into account in the design of surveillance systems and analysis of surveillance data. The values of sensitivity and specificity for the tests used should therefore be specified, and the method used to determine or estimate these values should be documented. Where values for sensitivity and/or specificity for a particular test are specified in the *Manual*, these values may be used without justification. It also needs to be borne in mind that the prevalence of the condition under investigation will affect the predictive values of tests and therefore their interpretation. This becomes particularly important when surveillance is being conducted to show absence of disease/infection from a population. In such cases it is impossible to prove freedom in absolute terms (i.e. without sampling the whole population) and therefore the surveillance design needs to incorporate the expected prevalence so that absence can be shown not to be higher than the level set in the population sampled. Often this prevalence is set at 1% between herds (sampling units) and 5% within herds (sampling elements) and the level of statistical confidence set to 95%. However, if the test or series of tests employed to survey for the disease/infection concerned have net specificities below 100% (no test so far devised has 100% specificity) the positive predictive value of individual tests will be below 100% which in turn implies that a proportion of the test results will be false positives.

Addressing this issue is vital in eradication programmes and mechanisms that are needed to differentiate false- from true positives need to be put in place before the programme begins.

4.5. Data collection and management

The success of a surveillance system is dependent on a reliable process for data collection and management. The process may be based on paper records or computerised data. Even where data are collected for non-survey purposes e.g. during disease control interventions, inspections for movement control or during disease eradication schemes, the consistency of data collection and event reporting in a format that facilitates analysis, is important .

5. General principles for structured population-based surveys

5.1. Survey design

The objective of the intended survey should be clearly defined i.e. what question need to be answered by conducting the survey. in the most cost-effective way i.e. should a targeted or a random surveillance be conducted.

The population of epidemiological units and the sampling units appropriate for each stage, depending on the design of the survey, should then be accordingly defined.

The design of the survey is critical for the success of the outcome of the survey and will depend on several factors such as the size and structure of the population being studied, the epidemiology of the infection and the resources available.

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5.2. Sampling

The objective of sampling from a population is to select a subset of units from the population that is representative of the population with respect to the object of the study such as the presence or absence of infection. Sampling should be carried out in such a way as to provide the best likelihood that the sample will be representative of the population, within the practical constraints imposed by different environments and production systems. In order to detect the presence or absence of infection in a population of unknown disease status or where the expected prevalence of disease is very low, targeted sampling methods that optimise the detection of infection should be used. In such cases, the results should not be used to infer the prevalence of infection in the population as a whole. The sampling method used at all stages should be fully documented and justified.

5.3. Sample size

The method used to calculate sample size for surveys depends on the purpose of the survey, the expected prevalence, the level of confidence desired of the survey results and the performance of the tests used. The purpose of the survey and the desired outcome, should however, always be measured against the cost of a survey. In general targeted surveys are less costly while in the case of random sampling, the cost will increase relative to the expected prevalence of a disease and the degree of confidence set for the expected outcome of the survey. A sample strategy aiming at a 95% probability of detecting disease in 1% of the primary sampling units could for example be more costly than aiming at a 95% probability of detecting disease in 5% of the primary sampling units.

6. General principles for structured non-random surveillance

Surveillance systems routinely use structured non-random data, either alone or in combination with surveys. There are however, a number of critical factors which should be taken into account when using structured non-random surveillance data such as coverage of the population, duplication of data, and sensitivity and specificity of tests that may give rise to difficulties in the interpretation of data. Surveillance data from non-random data sources may increase the level of confidence or be able to detect a lower level of prevalence with the same level of confidence compared to structured surveys

Different statistical methodologies including both quantitative and qualitative approaches may also be used for the analysis of non-random surveillance data as long as they are based on valid scientific principles and clearly documented.

6.1. Common non-random surveillance sources

A wide variety of non-random surveillance sources may be available. These vary in their primary purpose and the type of surveillance information they are able to provide. Some systems are primarily established as early detection systems, but may also provide valuable information to demonstrate freedom from infection. Other systems provide cross-sectional information suitable for prevalence estimation, either once or repeatedly, while yet others provide continuous information, suitable for the estimate of incidence data or the presence or absence of disease (e.g. disease reporting systems, sentinel sites, testing schemes).

6.1.1 Disease reporting or notification systems

Data derived from disease reporting systems can be used in combination with other data sources to substantiate claims of animal health status, to generate data for risk analysis, or for early detection. Effective laboratory support is an important component of any reporting system. Reporting systems relying on laboratory confirmation of clinical suspects often have low sensitivity, but good specificity

6.1.2 Control programs / health schemes

Animal disease control programs or health schemes, while focusing on the control or eradication of specific diseases, should be planned and structured in such a manner as to generate data that are scientifically verifiable and contribute to structured surveillance.

6.1.3 Specific disease testing / screening

This may involve testing targeted to selected sections of the population (sub populations), in which disease may have more significant consequences. Examples include testing at markets, slaughterhouses, or of animals at the top of breeding pyramid.

6.1.4 Ante- and post-mortem inspections

Inspections of animals at abattoirs may provide valuable surveillance data. The sensitivity and specificity of such inspections for the detection of disease will be influenced by:

- The level of training and experience of the staff doing the inspections, and the ratio of staff of different levels of training;
- The quality of construction of abattoir, speed of slaughter chain, lighting quality etc; and
- Staff morale and the role at the Competent Authority.

Abattoir inspections are likely to provide good coverage only for particular age groups and geographical areas. Biases are likely to be towards larger, better managed farms rather than smallholder or backyard production, healthy and cull stock rather than diseased animals.

Both for traceback in the event of detection of disease, and for analysis of spatial and herd-level coverage, there should be an effective identification system which relates each animal in the abattoir with its property of origin.

6.1.5 Laboratory investigation records

Analysis of laboratory investigation records may provide useful surveillance information. The coverage of the system will be increased if analysis is able to incorporate records from government, accredited, university and non-accredited private laboratories. Valid analysis of data from different laboratories depends on the existence of standardised diagnostic procedures and standardised methods for interpretation and data recording. As with abattoir inspections, there needs to be a mechanism to relate specimens to the farm of origin.

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6.1.6 Biological specimen banks

Specimen banks consist of stored specimens, gathered either through representative sampling or opportunistic collection or both. Specimen banks may contribute to retrospective studies, including providing support for claims of historical freedom from infection, and may allow certain studies to be conducted more quickly and at lower cost than alternative approaches.

6.1.7 Sentinel sites

Sentinel sites involve the identification and regular testing of groups of animals of known health/immune status in a specified geographical location to detect the occurrence of disease (usually serologically). They are particularly useful for surveillance of diseases with a strong spatial component, such as vector-borne diseases. Sentinel sites provide the opportunity to target surveillance depending on the likelihood of infection (related to vector habitats and host population distribution), cost and other practical constraints. Sentinel sites may provide evidence of freedom from infection, or provide data on prevalence and incidence as well as the distribution of disease.

6.1.8 Field observations

Clinical observations of animals in the field are an important source of surveillance data. The sensitivity and specificity of field observations may be relatively low, but these can be more easily determined and controlled if a clear, unambiguous and easy to apply standardised case definition is applied. Education of potential field observers in application of the case definition and reporting is an important component. Ideally, both the number of positive observations and the total number of observations should be recorded.

6.1.9 Farm production records

Systematic analysis of farm production records may be used as an indicator of the presence or absence of disease at the herd or flock level. In general, the sensitivity of this approach may be quite high (depending on the disease), but the specificity is often quite low.

7. General principles for recognising a country or zone free from a given disease/infection

7.1. Introduction

This section provides general principles for declaring a country or zone/region or compartment free from *disease/infection* in relation to the time of last occurrence and in particular for the recognition of historical freedom.

The provisions of this section are based on the principles described in sections 1 to 3 of this chapter and the following premises:

- 1) in the absence of disease and vaccination, the animal population would become susceptible over a period of time;
- 2) the disease agents to which these provisions apply are likely to produce identifiable clinical signs in susceptible animals

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- 3) competent and effective *Veterinary Services* will be able to investigate, diagnose and report disease, if present;
- 4) the absence of *disease/infection* over a long period of time in a susceptible population can be substantiated by effective disease investigation and reporting by the Veterinary Services of an OIE Member Country

7.2. Requirements to declare a country or compartment free from infection without pathogen specific surveillance

7.2.1. Historically free

Unless otherwise specified in the relevant disease chapter, a country or zone/region may be recognised free from infection without formally applying a pathogen-specific surveillance programme when:

- a) there has never been occurrence of disease; or
- b) eradication has been achieved or the disease/infection has ceased to occur for at least 25 years,
provided that for at least the past 10 years:
 - c) it has been a notifiable disease;
 - d) an *early detection* system has been in place;
 - e) measures to prevent disease/infection introduction have been in place;
 - f) no vaccination against the disease has been carried out unless otherwise provided in the *Code*.
 - g) Infection is not known to be established in wildlife within the country or zone/region intended to be declared free.

7.2.2. Last occurrence within the previous 25 years

Countries or zones/regions that have achieved eradication (or in which the disease/infection has ceased to occur) within the previous 25 years, should follow the pathogen-specific surveillance requirements in the *Code* if they exist. In the absence of specific requirements for surveillance in the *Code*, countries should follow the general guidelines for surveillance to demonstrate animal health status outlined in this chapter provided that for at least the past 10 years:

- a) it has been a notifiable disease;
- b) an early detection system has been in place;
- c) measures to prevent disease/infection introduction have been in place;
- d) no vaccination against the disease has been carried out unless otherwise provided in the *Code*.
- e) infection is not known to be established in wildlife within the country or compartment intended to be declared free.

Appendix XXXII (contd)**7.3. Guidelines for the discontinuation of pathogen-specific surveillance after recognition of freedom from infection**

A country or zone/region that has been recognised free from infection following the provisions of the *Code* may discontinue pathogen-specific surveillance while maintaining the infection-free status provided that:

- 1) it is a notifiable disease;
- 2) an *early detection* system is in place;
- 3) measures to prevent disease/infection introduction are in place;
- 4) vaccination against the disease is not applied;
- 5) infection is known not to be established in wildlife. (Specific surveillance in wildlife has demonstrated the absence of infection).

7.4. International recognition of disease/infection free status

For diseases for which procedures exist whereby the OIE can officially recognise the existence of a disease free country or zone/region, a Member Country wishing to apply for recognition of this country or zone shall, via its Permanent Delegate, send the OIE all the relevant documentation relating to the country or zone/region. Such documentation should be presented according to guidelines prescribed by the OIE Scientific Commission for Animal Diseases.

7.5. Demonstration of freedom from infection

A surveillance system to demonstrate freedom from infection should meet the following requirements in addition to the general requirements for surveillance outlined in section 3.2 of this chapter.

Freedom from infection implies the absence of the pathogenic agent in the country or zone/region or compartment. Scientific methods cannot provide absolute certainty of the absence of infection. Demonstrating freedom from infection involves providing sufficient evidence to demonstrate (to a level of confidence acceptable to Member Countries) that infection with a specified pathogen is not present in a population. In practice, it is not possible to prove (i.e., be 100% confident) that a population is free from infection (unless every member of the population is examined simultaneously with a perfect test with both sensitivity and specificity equal to 100%). Instead, the aim is to provide adequate evidence (to an acceptable level of confidence), that infection, if present, is present in less than a specified proportion of the population

7.6. General principles for surveillance for distribution and occurrence of infection

Surveillance for distribution and occurrence of infection or of other relevant health related events is widely used to assess progress in the control or eradication of selected diseases and pathogens and an aid to decision making. It has, however, relevance for the international movement of animals and products when movement occurs between infected countries.

In contrast to surveillance to demonstrate freedom from infection, surveillance used to assess progress in control or eradication of selected diseases and pathogens is usually designed to collect data about a number of variables of animal health relevance for example:

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- Prevalence or incidence of infection,
 - Morbidity and mortality rates,
 - Frequency of disease/infection risk factors and their quantification when the risk factors are expressed by continuous [real numbers] or discrete [integers] variables,
 - Frequency distribution of herd sizes or the sizes of other epidemiological units,
 - Frequency distribution of antibody titres
 - Proportion of immunised animals after a vaccination campaign,
 - Frequency distribution of the number of days elapsing between suspicion of infection and laboratory confirmation of the diagnosis and/or to the adoption of control measures,
 - Farm production records, etc
-

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