COMMISSION OF THE EUROPEAN COMMUNITIES

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COMMISSION STAFF WORKING DOCUMENT

Draft position of the Community on the report of the meeting of the Bureau of the OIE terrestrial animal health code [Paris December 2003] to be submitted for consideration and possible adoption in the 72nd General Session to be held in May 2004 in Paris

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EXPLANATORY MEMORANDUM

The World Organisation for Animal Health (OIE) is an International organisation designated under the Agreement on the Application of Sanitary and Phytosanitary Measures in application of the World Trade Organisation rules as responsible for the establishment of international animal health rules for trade in animals and their products. These codes and manuals are published following proposals by the various OIE bodies and adoption at the General Session which meets annually in Paris.

The comments of the Community on preliminary texts to be submitted by the OIE for adoption and consideration in the 72nd General Session to be held in May 2004 have been sent to the OIE [SEC (2003) 1177 by letter D(2003) 521805] signed by Mr R. Coleman and Dr R. Marabelli CVO of Italy (Council Presidency).

The following OIE meeting has taken place and reports and proposals submitted to the OIE member countries:

The OIE Terrestrial Animal Health Standards 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 on 5 December 2003.

These proposals for modifications are for adoption or consideration at the next General Session to be held in Paris between 23-28 May 2004.

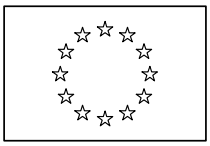
These reports and proposals have been circulated to member countries with requests for comments. In view of the status of these Health Codes, in particular in making recommendations for international trade in animals and their products, it is necessary for the Community to take a common position on this matter.

The Commission therefore proposes to the Council to authorise the Commission:

- to present, as since 1995, the following written positions at Annex I to OIE prior to submission of the final versions to the General Session in May 2004. The cover letter to be sent with our response (possibly together with a document concerning Community views on avian influenza) is attached (see document D(2004)/520193 at Annex A). In order to facilitate the examination of the Community positions, they have been incorporated in boxes into the OIE reports. In this context, the Community thanks the OIE for providing the electronic version of the Reports.

- to co-ordinate consultations with Member States in order to reach a Community position on matters raised during the General Session of the OIE. Daily co-ordination meetings will be organised on-the-spot.

ANNEX A



UNION EUROPEENNE

Bruxelles, le
D(2004) 520193 HLB

Objet : **Session générale de l'OIE**

Monsieur le Directeur Général,

Je vous prie de bien vouloir trouver en annexe les commentaires de l'Union européenne sur les rapports du bureau de la Terrestrial Animal Health Standards Commission en vue de la préparation de la Session Générale de mai 2004.

Je vous saurai gré de bien vouloir prendre en compte ces commentaires lors de la Session Générale de l'OIE.

Je tiens également à vous remercier pour l'excellente collaboration entre nos services et vous prie d'agréer l'expression de mes sentiments distingués.

Dr.Jaana Husu-Kallio
Directeur Général Adjoint

Annex: 1

Copie: Tous les directeurs/chefs de service vétérinaire de la Communauté et ACs

Dr. B. Vallat
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ANNEX 1

Original: English
December 2003

PRELIMINARY FINAL REPORT OF THE MEETING OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 1-12 December 2003

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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 two subtypes.

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

The Code Commission examined draft revised *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 yellow background is used to distinguish amendments and deletions made at this meeting from those made at the meeting of the Bureau in July 2004.

The Code Commission noted that only three Member Countries (Australia, India 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)

Community position:

The Community can support the proposal in Appendix III but the Community would ask the OIE to look again at the proposed new definition of an outbreak in this Chapter in particular in relation to the agreed definitions concern foot and mouth disease. What is meant by "occurrence" , e.g. is this clinical disease and/or isolation of the infective agent, in addition there is no reference to a case? .

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 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)

Community position:
The Community can support this proposal but would like the comments in Appendix IV taken on board.

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 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)

Community position:
The Community can support this proposal but would like the comments in Appendix III and V taken on board.

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)

Community position:
The Community can support this proposal but would like the comments in Appendix VI taken on board.

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)

Community position:
The Community could support this proposal but would like the comments in Appendix VII taken on board and in addition Aethina tumida must be added to the list of notifiable bee disease.

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 is in Section C at Appendix XXVII. Member Countries are requested to review the proposed criteria 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.

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.

6. Zoning and regionalisation (Chapter 1.3.5)

Community position:
The Community can support this proposal but would like the comments in Appendix VIII taken on board.

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)

Community position:
The Community can only support this proposal if the comments in Appendix IX taken on board.

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

Community position:
The Community can support this proposal but would like the comments in Appendix X taken on board.

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)

8. Bovine spongiform encephalopathy (Chapter 2.3.13)

Community position:

The Community can support this proposal but would like the comments in Appendix XI and XII taken on board.

As a general comment, The Community would like to emphasize the importance of active surveillance in categorising countries. The active surveillance should be complementary to the passive surveillance and adapted to the risk. The current Appendix on surveillance is not appropriate in this regard and should not be used for the categorisation of countries. In addition the Community stresses the importance to follow a risk-based approach when modifying the current categorisation criteria leading to trade rules for every risk category which will give the necessary guarantees to protect animal and public health for the importing countries.

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 passive and active surveillance.

Community position:

The Community welcomes the more explicit reference to surveillance and the increase of the cut-off limit in category 3. The Community would however point out that with the present wording it is not clear to which extent Appendix 3.8.4 requires both passive surveillance and active monitoring. The present text seems to indicate that active monitoring need only be carried out if passive surveillance does not generate sufficient numbers of samples. The Community considers that at least in countries in category 3-4 active monitoring should be compulsory <u>in addition to, and not instead of, passive surveillance.</u>

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 2.3.13.2 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.

Community position:

The objective of a categorisation according the BSE risk is to define trade rules for every risk category which will give the necessary guarantees to protect animal and public health for the importing countries. It should be noted that certain products, such as meat, meat products, tallow and gelatine can safely be traded from countries with BSE, even with a high incidence, provided that certain conditions are respected. The conditions for such trade are already laid down in the current recommendations of the Terrestrial Animal Health Code.

However the experience has clearly demonstrated that the current trade standards are not respected by most importing countries. This may be due to the absence of a trustworthy categorisation system based on objective parameters.

The EU fully supports the proposed basis on which the categorisation should be based upon i.e.

- an initial <u>risk assessment</u> and

- the implementation of a <u>surveillance programme.</u>

However the EU opposes to make the link to the current Appendix when evaluating the implementation of the surveillance programme in the frame work of the categorisation of the country according to the BSE risk. The EU re-iterates the

comments made on the Appendix 3.8.4. on surveillance and monitoring systems for bovine spongiform encephalopathy

The current Appendix only provides general guidelines for risk groups to be sampled as well as the number of samples. By specifying only the minimum amount of surveillance required, a country with negligible risk is in effect expected to undertake the same amount of surveillance as a country with an increased level of risk – when in fact a country with an increased level of risk might reasonably be expected to have undertaken surveillance that exceeds the minimum surveillance requirement specified.

However a comprehensive surveillance programme is necessary to provide statistically valid information on the prevalence of BSE within the cattle population of a country and to follow the evolution of the prevalence over time, with a view to eventually eradicate BSE in the cattle population in a country. Furthermore surveillance data can be used to evaluate the proper implementation of the risk management measures in place to prevent the transmission of BSE to new animals, such as the feed ban.

The OIE and Community Reference laboratory for TSEs, Weybridge, United Kingdom (CRL), have analysed the results of the Community BSE monitoring programme and are developing, on the basis of such analysis, an integrated approach to initial and continuing evaluation of country BSE status.

The Community proposes that the CRL study be used to define the parameters for the minimal surveillance. Such surveillance would not lead to a quantifiable assessment of the BSE incidence level on its own, but it could be used to ascertain the outcome of the risk assessment, if the outcome indicates a negligible BSE risk. The requirements would be flexible and take into account the original risk identified, as well as the time period during which the surveillance has been carried out

Surveillance programmes exceeding the minimum requirements and allowing the quantification of the incidence level would be taken into consideration in the initial risk assessment.

Number of categories

Apart from countries with negligible BSE risk or an identified BSE risk, intermediate categories should be available for countries which do not meet all the requirements to be considered to have a negligible risk and for countries where the risk assessment has not been finalised or countries not complying with the minimal surveillance parameters.

The Community therefore proposes the following four categories in the initial stage i.e.:

- Country with a negligible BSE risk (no SRM removal)

- Country with provisional negligible BSE risk (no SRM removal)

- Country with a controlled BSE risk (SRM removal)

- Country with undetermined BSE risk (more extensive list for SRM removal)

The category "country with provisional negligible BSE risk" should be limited in time.

After 5 – 10 years, the categorisation into two categories is envisaged after the countries in the intermediate categories have completed their risk assessment or carried out surveillance for a sufficient period:

Country with a negligible BSE risk

Country with controlled BSE risk

9. Rinderpest (Chapter 2.1.4.

Community position:
The Community can support this proposal in Appendix XIII. Community experts would be prepared to participate in developing this work and will comment further when a new draft is received.

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)

Community position:
The Community can support the proposal to delete this Chapter.

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)

Community position:
The Community cant support this proposal as it is presently drafted. The Community does not agree with the new risk based type approach taken to amend the whole chapter and would point out that the intention was to only have amended this Chapter with regard to additions for food safety aspects. The Community is submitting extensive comments in Appendix XIV.

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)

Community position:
The Community can only support this proposal if the comments in Appendix XV taken on board.

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 carcases 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)

Community position:
The Community can support this proposal in Appendix XVI.

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)

Community position:
The Community can support this proposal in Appendix XVII.

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)

Community position:
The Community can only support this proposal in Appendix XVIII if the comment concerning the test is taken on board.

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)

Community position:
The Community can support this proposal for temporary deletion of Article 2.2.6.2 in Appendix XIX.

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)

Community position:
The Community would like to thank the OIE for the excellent work on these Chapters. However it is very surprised that a new Chapter on Aethina tumida (small hive beetle) has not been introduced. This disease must also be added to the list of OIE notifiable diseases. It considers this to a very dangerous emerging pest and has recently made the disease notifiable as well as Tropileaeps. In addition it would like the comments in Appendix XX taken on board.

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

Community position:
The Community can support this proposal at appendix XXI and draws the attention of the OIE to the experts proposal for deletion of Article 3.2.1.10. which is out of date. It presumes that it will not be deleted but updated.

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)

Community position:
The Community could support this proposal if the comments in Appendix XXII are taken on board.

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

Community position:
The Community is very pleased with the work done by the OIE in this field and can fully support this proposal but would like the minor drafting changes in Appendix XXIII taken on board.

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. OgTHER ISSUES CONSIDERED

21. Avian influenza (Chapter 2.1.15)

The Community welcomes the further development of the chapter but would like the comments in Appendix XXIV taken on board and is prepared to assist in this work.

It would like to point out that with the adoption of this chapter detailed rules for compartmentalisation in this Chapter must be laid down in order to make trade on a compartment basis acceptable. In this context please find annexed a policy paper on the future strategy for AI control in the EU

The Community fully agrees with the proposed differentiation between HPAI and LPAI but is particularly concerned that this approach is not fully followed throughout the chapter and should further be elaborated for the different commodities. The Community agrees with most of the proposals but can only support this Chapter if the comments below are taken into account.

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 transmitting 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

Community position:
The Community supports this initiative and its experts would be pleased to participate in the work.

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)

Community position:
The Community supports this initiative and its experts would be pleased to participate in the work.

The Code Commission noted that the Scientific Commission had approved a proposed *Terrestrial Code* chapter on the general principles of surveillance which is being circulated in the report of that Commission. Member Countries are encouraged to send

comments on that document to the Scientific Commission to enable the Scientific and Code Commissions to revise the document at their next meetings.

24. Bluetongue (Chapter 2.1.9)

Community position:
The Community supports this initiative and its experts would be pleased to participate in the work.

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)

Community position:
The Community supports this and its experts would be pleased to participate in the work.

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)

Community position:
The Community supports this initiative and its experts would be pleased to participate in the work.

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)

Community position:
The Community supports this initiative and its experts would be pleased to participate in the work.

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)

Community position:
The Community supports this initiative and its experts would be pleased to participate in the work.

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)

Community position:
The Community supports this initiative and its experts would be pleased to participate in the work.

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)

Community position:
The Community supports this initiative and its experts would be pleased to participate in the work.

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)

Community position:
The Community supports this initiative and its experts would be pleased to participate in the work. The Community will be pleased to comment when the proposals are received.

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

Community position:
The Community supports this initiative and its experts would be pleased to participate in the work. The Community will be pleased to comment when the proposals are received.

Code Commission endorsed the report of the June 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

Community position:
The Community will be pleased to comment when any proposals are received but fully endorses the comments of the Code Commission that the development of such an 'export zone or compartment' should not be an alternative to appropriate resourcing of, and certification by, Veterinary Services..

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

Community position:
The Community supports this proposals.

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, especially of developing countries. The OIE has already committed itself thorough 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.

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. Food Safety Working Group (Appendix XXXI)

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

Appendix I

MEETING OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 1-12 December 2003

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Appendix II

MEETING OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 1-12 December 2003

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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 (Chapter1.1.3)**
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 (Chapter2.3.3)**
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)**

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 (Chapter1.1.3)**

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)**

Appendix III

CHAPTER 1.1.1.

GENERAL DEFINITIONS

Community position:
The Community supports this proposal but would ask the OIE to look again at the definition of an outbreak in this Chapter in particular in relation to the agreed definitions concern foot and mouth disease. What is meant by "occurrence" ?

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.~~

~~***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.*

Community position:

The Community points out that in some cases the veterinary statutory body is part of the Veterinary services and therefore may not be autonomous however it should of course be impartial and independent of political influence. The Community suggests the following wording "means the authority or body regulating veterinarians and para-veterinarians".

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 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.

~~***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 *beehives.*

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.*

Community position:
The Community does not believe that this definition is broad enough. It proposes the following new wording "'zoonosis' means any disease and/or infection which is naturally transmissible directly or indirectly between animals and humans". Besides that the WHO definition should be looked into.

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.*~~

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.

Community position:

The Community would ask the OIE to look again at the definition of an outbreak in this Chapter in particular in relation to the agreed definitions concern foot and mouth disease and to clarify the situation with regard to outbreaks in wildlife and it is presumed that grazing land is included above. What is meant by "occurrence", e.g. is it clinical disease and or isolation of the infective agent in addition there is no reference to a case?

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CHAPTER 1.2.1.

GENERAL OBLIGATIONS

Community position:
The Community can support this proposal and thanks the OIE for taking its suggestion on board.

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 science 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.

   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*.

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CHAPTER 1.3.3.

EVALUATION OF VETERINARY SERVICES

Community position:
The Community can support this proposal.

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.

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;

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,

~~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 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.

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

Community position:
The Community can support this proposal if the 2 points in the text below are taken on board and thanks the OIE for taking other suggestion on board. It would point out that it commented on the definition of *veterinary statutory body* earlier in the document and proposes the change in the text below to reflect the fact that some *veterinary statutory bodies* are part of the 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.

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.~~

Community position:
The Community maintains its request that the word "if " should replace the word 'While' as in some instances the statutory body is part of the Veterinary Services.

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.

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. 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~~ 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 resources

1. 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.

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 support

1. 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 zoosanitary 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 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.

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 controls

1. 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.

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.

Community position:

The Community does not understand why the scope of the intergration between animal health and public health should be limited to meat and dairy products. It proposes the following wording "The existence of any organised programme which incorporates a structured system of information feedback from inspection in establishments producing products animal origin in particular meat or dairy and applies this in animal health control should be favourably noted."

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 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. it/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.

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.

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.

      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 associations

b) 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.

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.

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.
- 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*.

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.

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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— text deleted

CHAPTER 1.3.7.

GUIDELINES FOR REACHING A JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES

Community position:
The Community can support this proposal but would like the comments noted below taken on board.

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.

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 science based risk analysis) to the extent practicable in establishing the basis for a judgement of equivalence.

Community position:
The Community proposes that the bracket in the last line above is deleted.

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;~~

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;

Community position:
The Community again proposes that in order to be consistent with Article 1.3.7.2 where in the fourth paragraph it is stated 'To facilitate the judgement of equivalence, Member Countries are encouraged to base their sanitary measures on OIE standards, guidelines and recommendations' then the words "to the extent possible" should be added at the end of the sentence.

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

Community position:
The Community again suggests that not only 'changes to infrastructure, health status or programmes' but also other measures may have an impact on equivalence. Therefore it proposes after the word programmes the words "or any other relevant measure" is added.

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);

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

Community position:

The Community can support this proposal if swine vesicular disease and the other diseases mentioned below are included and the other comments taken on board. It would like to remind the OIE that it was clearly stated that the list would remain the same until the criteria were agreed and would then be reviewed at a later date. However this would not prevent new diseases being included. It feels that SVD has been forgotten to include in the list of swine diseases.

Article 1.1.2.1.

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

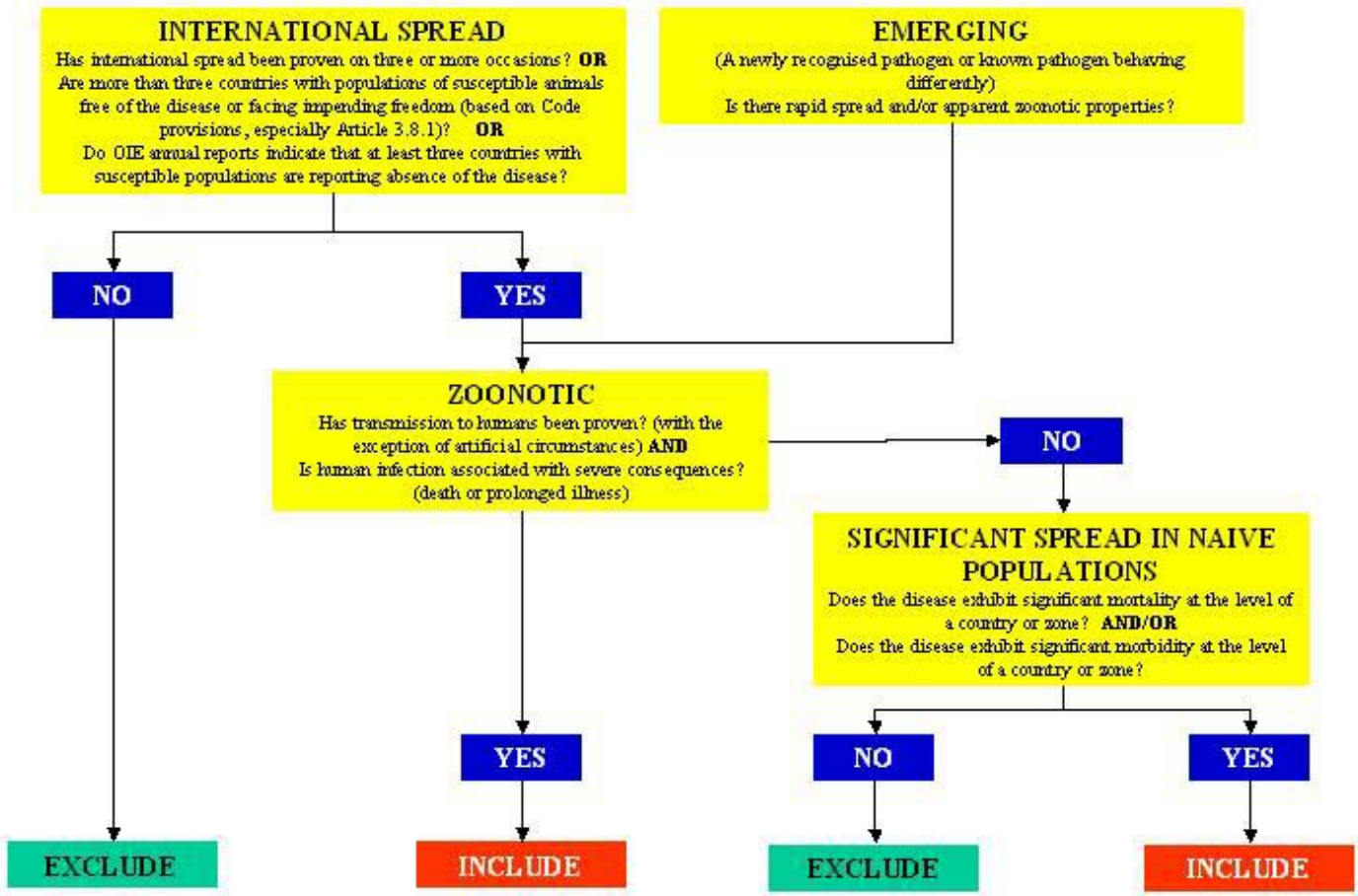
International Spread	Has international spread been proven on three or more occasions? **OR** Are more than three countries with populations of susceptible animals free of the disease or facing impending freedom (based on Code provisions, especially Appendix 3.8.1)? **OR** Do OIE annual reports indicate 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?

Community position:
The Community believes that the 'or' in the section on International Spread should be replaced with "and" so that it reads
"Has international spread been proven on three or more occasions? And,
Are more than three countries with populations of susceptible animals free of the disease or facing impending freedom (based on Code provisions, especially Appendix 3.8.1)? And ……."

The Community believes a further criterion should be added:
"Disease Eradication - Difficulty in eradicating the disease once entered a country?"

Article 1.1.2.2.

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



Community position:

The Community believes a further criteria should be added to the right hand yellow box:

"Is the disease difficult to eradicate once it has entered a country?"

Article 1.1.2.3.

The following diseases are included in the *List*:

~~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.~~

~~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
– 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 piroplasmosis
– Equine rhinopneumonitis
– Glanders
– Horse pox
– Equine viral arteritis
– Japanese encephalitis
– Horse mange
– Surra (*Trypanosoma evansi*)
– Venezuelan equine encephalomyelitis
= African horse sickness.

Community position:
The Community believes a further disease should be added: "West Nile fever"

~~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.

Community position:
The Community believes that "swine vesicular disease" must be included here.

~~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)
– 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.

Community position:
The Community believes that Nosemosis should be deleted if the Chapter on this disease is to be deleted and that Aethina tumida (small hive beetle) and Tropilealaps should be added.

~~Article 1.1.2.10.~~

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

– Leishmaniosis.

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CHAPTER 1.1.3.

NOTIFICATION AND EPIDEMIOLOGICAL INFORMATION

Community position:
The Community supports this proposal but would like the comments below taken on board.

In addition it would like to repeat that there should be a reflection by the OIE that by combining the lists the focus on the importance of certain diseases and the priority which was accorded them by governments in particular concerning resources has been decreased. Certain trans-boundary diseases have been listed by the FAO and this approach to highlight certain diseases could be useful for some veterinary services.

Article 1.1.3.1.

For the purposes of the *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:

Community position:
The Community would point out that usually it is not the Delegate but a responsible person designated by the Delegate who sends in the form on his behalf.

~~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;~~

~~c) 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;

Community position:
The Community would like to point out that this may need to be clarified as the free status may have been lost so the disease situation may be brought under control but the "free" status of the country may have been lost.

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.

Community position:

The Community proposes that in view of the change to the requirements for notification which may well increases the reports to OIE the requirements for monthly reports and their proposed content should be reviewed. It should be stated when (specific date) that the annual reports have to be submitted to the OIE and a reference to the format required should be included.

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*.

Community position:

The Community proposes that reference is made to inclusion of this information on the web-site of the OIE for transparency.

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.

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Appendix VIII

CHAPTER 1.3.5.

ZONING, ~~AND~~ REGIONALISATION AND COMPARTMENTALISATION

Community position:
The Community is very pleased with the concepts and principles put forward and can support this proposal.

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 ~~their~~ 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.

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CHAPTER 2.1.1.

FOOT AND MOUTH DISEASE

Community position:
The Community would like to thank the OIE for the improvements made to this Chapter but it can only support this proposal if the comments below are taken on board.

Article 2.1.1.1.

For the purposes of the *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:

Community position:

The following wording is suggested:

"In addition to the definition of an *outbreak*, 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;

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;

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:

Community position:

It is proposed to replace the introductory text by the following:

Subject to the effective implementation of animal health measures that effectively prevent the entry of the virus, an FMD free zone where vaccination is practised can be established

- **either in an FMD free country where vaccination is not practised, in which case the FMD free zone where vaccination is practised must be surrounded by a *surveillance zone*, or physical or geographical barriers which effectively prevents the spread of FMD virus, or**
- **in a country of which parts are still infected, in which case the FMD free zone where vaccination is practices must be surrounded by a *buffer zone* as part of the contiguous infected area, or physical or geographical barriers.**

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 a FMD free zone where vaccination is practised.

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,

Community position:

The paragraph 4 (b) should be replaced by the following:

"the boundaries of the FMD free zone where vaccination is practised and of the *surveillance* and *buffer zone* as 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),

Community position:

The paragraph 4 (c) should be replaced by the following:

"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 for preventing the movement of vaccinated animals into the FMD free zone where vaccination is not practised,"

   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.

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

Community position:

The Community strongly disagrees with the opinion of the Code Commission and insists that this condition is in contradiction to the definition of a free country or zone with vaccination laid down in Article 2.1.1.3., and in particular in paragraph 2 (a) thereof.

The following is proposed:

"b) 12 months after the last *case* where a *stamping-out policy* is applied provided that surveillance demonstrates the absence of clinical *cases*, and serological surveillance in accordance with Appendix 3.8.6. are applied, provided that the serological surveillance based on the detection of antibodies to non-structural proteins of FMDV demonstrates the absence of infection, or"

Alternatively it is possible to introduce the transitional status of temporary freedom which is characterised by absence of clinical disease in an area practising vaccination and would allow trade in de-boned, matured and pH-controlled meat only.

   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.;

Community position:

Paragraph 6 to be replaced by:

"all products obtained from these animals and any products derived from other animals but which came into contact with them 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;

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.

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.

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:

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:

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.

Community position:

The Community reiterates its deep concern about this Article and draws again the attention of the OIE to the need for a very careful assessment of the situation in a country applying for that status.
It furthermore warns about the imminent risks associated with such approach. In countries free with vaccination, surveillance is not carried out permanently and before the possible introduction has been detected in a vaccinated population by surveillance in accordance with Appendix 3.8.6., infection may have got hold in animals destined for slaughter for export.

In addition the risks may even be higher where the status free with vaccination has been regained in accordance with Article 2.1.7. (2) (b) as currently in force.

The Community is of course aware that this question is a quantitative one and that infection may be undetected also in non-vaccination areas for a certain time.

See also the alternative proposal under the Commission position in Article 2.1.1.7.(2) (b).

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;

Community Position:

There is no rational behind this requirement, notably in relation to meat derived from vaccinated pigs, and therefore it is contradicting Article 2.1.1.20.

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;

   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.

Community position:

It is suggested to add:

"the necessary precautions were taken after processing to avoid contact of the *meat* with any potential source of FMD virus"

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:

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 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.

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

Community position:
The Community can support this Chapter.

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 vaccine 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.

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 practised

1) 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 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.

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*.

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.

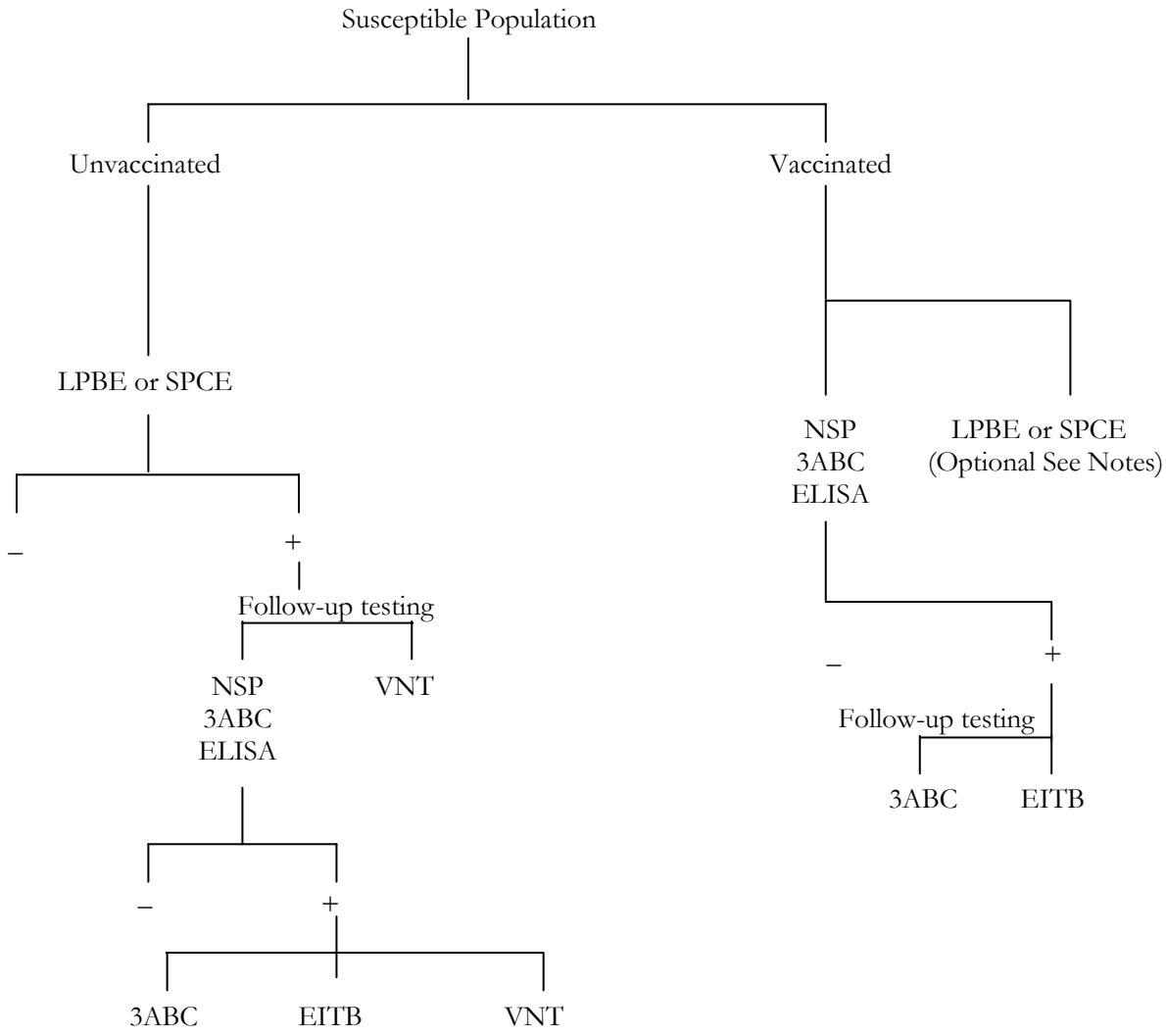
As indicated above, the diagnostic sensitivity of tests used influences the numbers of animals that need to be sampled in a survey to provide evidence of absence of infection. The diagnostic specificity of the test influences the proportion and number of positive results to be expected in the absence 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 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;

~~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

This comprises an assessment of 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

This comprises an assessment of 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;

Community position:

The EU supports the modification proposed. The surveillance should be integrated into the risk assessment, rather than being assessed only independently according to certain rigid standards. Even if the risk assessment points to a certain risk this could be compensated by an intensive surveillance allowing quantification of the incidence level in the relevant age cohorts.

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 and 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;

Community position

The wording related to the progeny and the cohort would suggest that the affected cattle could be kept alive until slaughter. The paragraph should be reworded more clearly by specifying that the affected cattle should be destroyed and that 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

Furthermore the possibility of imports of cohort animals should be taken into account. Therefore the Community proposes to reword the current point b), first paragraph as follows:

"b) all *cases* of BSE have been clearly demonstrated to originate directly from the importation of live cattle, and the affected cattle have been completely destroyed. If the affected cattle 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 .

Imported bovine animals 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.

where the results of the investigation are inconclusive, all imported 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.

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, 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.~~

Community position

The wording would suggest that the affected cattle could be kept alive until slaughter.

Article 2.3.13.3, point c) iii) should be amended as follows:

"iii) the affected cattle has been destroyed and :

- **if the affected cattle 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."

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:

Community position:

The wording would suggest that the affected cattle could be kept alive until slaughter. The paragraph should be reworded more clearly by specifying that the affected cattle should be destroyed and that 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

The possibility of imports of cohort animals should be taken into account. Therefore the Community proposes to reword the current point b), first paragraph as follows:

"b) all *cases* of BSE have been clearly demonstrated to originate directly from the importation of live cattle, and the affected cattle has been completely destroyed. If the affected cattle 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.

Imported bovine animals 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.

where the results of the investigation are inconclusive, all imported 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."

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) 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.

Community position

The wording would suggest that the affected cattle could be kept alive until slaughter.

Article 2.3.13.5, point b) iii) should be amended as follows:

"iii) the affected cattle has been destroyed and :

- if the affected cattle 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."

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~~.

Community position

The wording would suggest that the affected cattle could be kept alive until slaughter.

Article 2.3.13.6, point 3) should be amended as follows:

"3) the affected cattle has been destroyed and :

- if the affected cattle 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."

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.

Community position

Referring to the comments made in Article 2.3.13.4., point 2), the Community proposes the following amendment to Article 2.3.13.10., point 2):

"**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 exposed cattle as described in point 2) b) iii) of Article 2.3.13.5.;2),b).**

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;

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;

Community position

The wording would suggest that the affected cattle could be kept alive until slaughter.

Article 2.3.13.13, point 3) should be amended as follows:

"3) the affected cattle has been destroyed and :

- if the affected cattle 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."

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:

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.

Community position:

The Community feels that for control reasons the harvesting of mechanically recovered meat from the skull or vertebral column of bovine animals of any age should be prohibited.

The Community reserves its opinion on the age limit for the inclusion of vertebral column pending internal discussions.

The Commission proposes that the age limit should brought in line with the age limit referred to I Article 2.3.13.19 for moderate risk countries

In view of this the Community suggest replacing article 2.3.13.16 point 5 with:

"5) the fresh meat and meat products destined for export do not contain skull, brain, eyes, tonsils or spinal cord of bovine animals over 12 months, nor intestine of bovine animals of any age, all of which have been completely removed in a manner

to avoid contamination with these tissues. Neither do they contain mechanically separated meat from skull or vertebral column of bovine animals."

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;

Community position

Reference to the age limit for the specified risk material should be made mentioned in this article. The Community proposes to amend this point as follows:

"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 over 12 months of age, 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

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.~~

Community position

The wording would suggest that the affected cattle could be kept alive until slaughter.

Article 2.3.13.17, point 9) should be amended as follows:

"9) the affected cattle has been destroyed and :

- if the affected cattle 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."

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.

~~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.~~

Community position

The above-mentioned paragraph is redundant and should be deleted

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 ≥138°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

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:

1) precautions to avoid contamination during collection of tissues;

2) the process to which the material will be subjected during manufacture;

3) the amount of material to be administered;

4) the route of administration.

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APPENDIX 3.8.4.

SURVEILLANCE AND MONITORING SYSTEMS FOR BOVINE SPONGIFORM ENCEPHALOPATHY

Community position

The current Appendix only provides general guidelines for risk groups to be sampled as well as the number of samples. By specifying only the minimum amount of surveillance required, a country with negligible risk is in effect expected to undertake the same amount of surveillance as a country with an increased level of risk – when in fact a country with an increased level of risk might reasonably be expected to have undertaken surveillance that exceeds the minimum surveillance requirement specified.

However a comprehensive surveillance programme is necessary to provide statistically valid information on the prevalence of BSE within the cattle population of a country and to follow the evolution of the prevalence over time, with a view to eventually eradicate BSE in the cattle population in a country. Furthermore surveillance data can be used to evaluate the proper implementation of the risk management measures in place to prevent the transmission of BSE to new animals, such as the feed ban.

The OIE and Community Reference laboratory for TSEs, Weybridge, United Kingdom (CRL), have analysed the results of the Community BSE monitoring programme and are developing, on the basis of such analysis, an integrated approach to initial and continuing evaluation of country BSE status.

The Community proposes that the CRL study be used to define the parameters for the minimal surveillance. Such surveillance would not lead to a quantifiable assessment of the BSE incidence level on its own, but it could be used to ascertain the outcome of the risk assessment, if the outcome indicates a negligible BSE risk. The requirements would be flexible and take into account the original risk identified, as well as the time period during which the surveillance has been carried out .

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~~s~~ 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.

Community position:

The recommendation could be misinterpreted. According to the present wording the surveillance should sample sub-populations identified in Articles 3.8.4.2. and 3.8.4.3. The sample size is defined in both Articles. However, if the country fails to meet the requirements for the sampling of cattle displaying clinical signs consistent with bovine spongiform encephalopathy, the surveillance should be enhanced by testing larger numbers of cattle identified in Article 3.8.4.3.

Thus the present text seems to indicate that active monitoring need only be carried out if passive surveillance does not generate sufficient numbers of samples. The Community considers that at least in countries in category 3-4 active monitoring should be compulsory in addition to, and not instead of, passive surveillance.

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.

Community position:

The Community would point out that only a small part of clinical BSE cases actually display CNS signs. A larger part are just non-ambulatory. Therefore any surveillance focussing only on animals displaying CNS signs will by definition miss a number of clinical cases. If the number of clinical BSE cases is one in a million, the number of clinical BSE cases with CNS signs will be lower, and the total number of BSE cases (including preclinical cases which will be slaughtered or die before any clinical symptoms appear) will be much higher. In conclusion, a surveillance targeting only animals with CNS signs is ineffective and should be complemented by active monitoring of non-ambulatory animals, but the number to be examined in the latter group is much higher.

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 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

This comprises an assessment of 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

This comprises an assessment of 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 xxx 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.

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

- 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;

- 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

- 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;
- 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.
- 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 3.8.3., 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?

Community position

Within the risk assessment not only the processing standard should be taken into account but also the way of collection and disposal of the animal waste. Therefore the Community suggest amending the question as follows:

"How has animal waste been collected and 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.

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

Community position:
The Community supports this proposal.

Article 2.1.4.1.

For the purposes of the *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.

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:

<u>for ruminants and swine</u>

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:

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:

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;

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:

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.

Article 2.3.13.4.

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;

   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;

   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:

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

Community position:

The Community cannot support this Chapter as presently proposed.

It would also like to point out that it was the intention to review the Chapter to address food safety issues and not to re-write the whole chapter.

1) The Community proposes that the word "geographical" before the word compartment is deleted as this corresponds to a zone. The herd would correspond to a compartment. It is important to avoid confusion now that these words have been defined more exactly earlier in the Code.

2) There should be a reason for the use of the wording "free-living animal species" instead of the classical "wildlife". Does free-living animal species include farmed deer and fighting bulls or other free-living bovines (e.g. in Camargue (FR))?

3) There may be problems with the definitions of "maintenance host species" and "spill-over species" as for ungulates in which category should be included these species:

- **deer (domestic and wild)**
- **goat (domestic and wild)**
- **sheep**
- **badger**

Maybe that for several diseases it is possible to classify easily, but for the Mycobacterial diseases it is not so easy to determinate if one particular species can sustain in the long term the infection or not.

It appears that each country is establishing if a species is maintainance or a spill-over species within its territory on the basis of evidence, but this could be too vague.

4) The surveillance system proposed for considering a territory as free (the disappearance of officially free could lead to misunderstanding) presents some weaknesses:

i. The system is designed to detect annual HERD prevalence. It appears that all animals in a herd should be tested unless a double stratified sampling system is proposed

ii. Sampling procedures for detecting disease have to be based on a RIGID COMPULSORY random procedure

iii. Sample size estimation is usually based (always in practice) on the assumption of sensitivity of the test = 100 %. In dealing with TB the sensitivity of the approved tests in live animal (tuberculin) is 70-75%. Therefore tables and estimation of size should be carefully reviewed.

iv. The minimum sample size for a very large bovine population, e.g. 100.000 herds, is 2950 herds to be tested. Note that this is extremely small when talking about tuberculin test but as it is not defined, it could be considered valid a surveillance system based on detecting TB in the slaughterhouse in samples of the herds in the

country. So by examining carcasses from 2950 herds the status is granted for all the country which would not be acceptable

v. The appropriate surveillance system for the spill-over species is not defined

5) There is no link between the requirements to consider a country as free and the requirement to classify a herd as free. So why qualify herds following that classic and heavy procedure? The procedure for classifying herds remains the same but in a completely different framework because qualifying herds is currently the only way to qualify a country

6) The new concept country provisionally free from bovine tuberculosis is artificial and not justified:

i. Why is the threshold HERD prevalence given as 0,5%?

ii. How is this prevalence to be estimated? If it is to be estimated by a sample procedure, then the maximum absolute error should be defined. But it is necessary to define a very small absolute error (if the cut-off is 0,5%, the error should not be over 0,02%...) In addition the sensitivity of the test must be considered

iii. The appropriate surveillance system for the spill-over species is not defined

7) For the tests and conditions for trade for live animals for breeding, there are significant differences:

i. Tests are not necessary anymore for free countries (now is compulsory)

ii. In non-free countries it is necessary for two tests (now if the herd is free, only one test is necessary)

8) For the tests and conditions for trade for live animals for slaughter there is no requirement for testing when coming from a free herd (now it is necessary to come from an officially free herd or tested)

Conclusions:

A). The philosophy behind this new approach is absolutely different from the rule we have been applying in the EU

B). There are many gaps and uncertainties in the procedures related to sampling. Use of statistics for determining the sample size only provides a good level of certainty when appropriately justified and clarified

C). Mycobacterial diseases are characterised by:

a. Extremely low prevalence is possible at herd and national level so freedom of the disease only can be guaranteed only after thorough investigations

b. Diagnostic tests are far from perfect. The lack of sensitivity is concerning and requires extensive use of testing before guaranteeing freedom

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/compartment, with respect to bovine tuberculosis, can be determined on the basis of the following criteria, which may be applied within a country or zone/compartment, 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/compartment;

   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.;

3) continuing monitoring and surveillance based on the guidelines in Appendix 3.X.X.X., including compulsory notification and investigation of all suspected cases of *M. bovis* infection.

Article 2.3.3.3.

Country or zone/compartment free from bovine tuberculosis

A country or zone/compartment 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/compartment may be considered to be free from bovine tuberculosis when:

1) the criteria outlined in Article 2.3.3.2. are met; and

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.); 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/compartment 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/compartment 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:

Community position:
The Community proposes that the word geographical is deleted as this corresponds to a zone. The herd(s) would correspond to a compartment. It is important to avoid confusion now that these words have been defined more exactly earlier in the Code

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.); 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 trade

For 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.

Article 2.3.3.7.

Conditions providing negligible animal health risk in international trade

For 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. 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 trade

For 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.]; 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 trade

For meat and meat products

Meat and meat products 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.]; 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 trade

For 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.]; 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.

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 that the consignment meets the measures specified in Article 2.3.3.10. for milk and milk products.

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* 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.

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CHAPTER 2.1.13.

CLASSICAL SWINE FEVER

Community position:
The Community can only support this proposal if the comments below taken on board.

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 the *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.

Article 2.1.13.4.

Country or zone free of CSF in domestic and wild pigs

1) 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;~~

~~c) 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;~~

Community position:
The Community repeats its request that these paragraphs be retained. It is very important that identification and thereby traceability for disease purposes is possible. Concerning swill the first introduction of disease agents into a country have in many cases been linked to swill whether legal or illegal feeding. The Community has taken strong measures to ban swill feeding and considers it very important that the risks of feeding swill even in a free country is highlighted. Concerning point d above this is an important point to ensure maintenance of the disease freedom however it could agree to a reduction in the time foreseen to 12 months.
In addition it would like to point out that in any case the numbering is incorrect (see below).

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.

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:

<u>for domestic pigs</u>

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:

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;

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;

   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;

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:

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;

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.

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CHAPTER 2.1.6.

CONTAGIOUS BOVINE PLEUROPNEUMONIA

Community position:
The Community can support this proposal.

Article 2.1.6.1.

For the purposes of the *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:

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:

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;

   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.

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CHAPTER 2.5.5.

EQUINE INFLUENZA

Community position:
The Community can support this proposal.

Article 2.5.5.1.

For the purposes of the *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;

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.~~

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CHAPTER 2.2.5.

RABIES

Community proposal:
The Community can only support this proposal if the comments below are taken on board.

Article 2.2.5.1.

For the purposes of the *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.

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;

Community proposal:

The Community requests that this be re-instated or amended as in the new version of the Manual the ELISA will be described but is not "a prescribed test for international trade" which is explicitly used for the FAVN and RFFIT. The Community therefore proposes to replace the word "described " by "prescribed". The tests referred to in the Code must simply be the tests prescribed for international trade in the Manual and when in the Manual "a prescribed test for international trade" will be added to the ELISA paragraph, the problem will be solved.

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.

Community position:
The Community believes that the separation should only apply to non-flying wild animals (e.g. bats). Therefore it proposes the words "(non-flying animals)" be inserted after the word 'wild'.

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 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.]

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— text deleted

Appendix XIX

CHAPTER 2.2.6.

PARATUBERCULOSIS

Community position:
The Community can support this proposal for a temporary deletion of this Article.

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.~~

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~~—~~ text deleted

CHAPTER 2.9.1.

ACARAPISOSIS OF HONEY BEES

Community position:
Firstly the Community would like to see a Chapter on Aethina tumida (small hive beetle) included urgently.
Secondly the Community could only support this proposal if the comments below are taken into account. In particular throughout the Chapter reference is made to compartment. The requirements of a compartment in this particular case must be clearly specified in particular as the host is capable of flying quite long distances!!

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/compartment 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/compartment and all clinical signs suggestive of acarapisosis should be subjected to field and laboratory investigations;

Community position:
The Community does not agree that disease notification can be limited to a compartment or even a zone. The words compartment and also zone must be deleted indeed this is reflected in the requirement in 4) below.

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/compartment free from acarapisosis

1) Historically free status

A country or zone/compartment 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/compartment complies with the provisions of Article 3.8.1.2.

2) Free status as a result of an eradication programme

A country or zone/compartment 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/compartment;

b) acarapisosis is notifiable in the whole country or zone/compartment, and any clinical cases suggestive of acarapisosis are subjected to field and laboratory investigations;

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/compartment 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/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* or other possible host species in the country or zone/compartment;

Community position:
The Community believes that this is an impossible requirement as feral populations are always present to a greater or lesser extent.

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 2.9.1.4.

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/compartment free from acarapisosis.

Community position:
The Community proposes that the requirement for freedom can only be requested by a country which is free or has an official eradication programme.

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/compartment; 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

Community position:
Firstly the Community would like to see a Chapter on Aethina tumida (small hive beetle) included urgently.
Secondly the Community could support this proposal if the comments below are taken into account. Throughout the Chapter reference is made to compartment. The requirements of a compartment in this particular case must be clearly specified in particular as the host is capable of flying quite long distances!!

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.

Community position:
The reference to *Paenibacillus larvae subsp. Larvae* 'subsp.' should not be in italics for the nomenclature to be correct.

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/compartment 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/compartment and all clinical signs suggestive of American foulbrood should be subjected to field and/or laboratory investigations;

Community position:
The Community does not agree that disease notification can be limited to a compartment or even a zone. The words compartment and also zone must be deleted indeed this is reflected in the requirement in 4) below.

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/compartment free from American foulbrood

1) Historically free status

A country or zone/compartment 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/compartment complies with the provisions of Article 3.8.1.2.

2) Free status as a result of an eradication programme

A country or zone/compartment 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/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;

Community proposal:
The Community questions the need for a difference in the times for this disease and others such as European foulbrood where 3 years is required. The Community therefore proposes that in the first sentence the number '5' be replaced by "3" and the first sentence also should read: '…..an annual survey….. has been carried out…'.

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;

Community position:
The Community believes that this is an impossible requirement as feral populations are always present to a greater or lesser extent.

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.

Community position:
The Community proposes that the requirement for freedom can only be requested by a country which is free or has an official eradication programme.

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).

Community proposal:
The Community proposes that the word 'bacillary' be replaced by "vegetative" in the above sentence.

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).

Community proposal:
The Community proposes that the word 'bacillary' be replaced by "vegetative" in the above sentence.

CHAPTER 2.9.3.

EUROPEAN FOULBROOD OF HONEY BEES

Community position:
Firstly the Community would like to see a Chapter on Aethina tumida (small hive beetle) included urgently.
Secondly the Community could support this proposal if the comments below are taken into account. Throughout the Chapter reference is made to compartment. The requirements of a compartment in this particular case must be clearly specified in particular as the host is capable of flying quite long distances!!

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.

Community position:
Second sentence: The causative organism is *Melissococcus plutonius* (Trüper and de' Clari, 1998) and not as written. This must be changed throughout document.

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/compartment can only be determined after considering the following criteria:

Community position:

Change all references to American foulbrood. Should refer to European foulbrood throughout text!!

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/compartment and all clinical signs suggestive of American foulbrood should be subjected to field and laboratory investigations;

Community position:
The Community does not agree that disease notification can be limited to a compartment or even a zone. The words compartment and also zone must be deleted indeed this is reflected in the requirement in 4) below.

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/compartment free from European foulbrood

1) Historically free status

A country or zone/compartment 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/compartment complies with the provisions of Article 3.8.1.2.

2) Free status as a result of an eradication programme

A country or zone/compartment 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/compartment;

b) European foulbrood is notifiable in the whole country or zone/compartment, 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/compartment 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/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;

Community position:
The Community believes that this is an impossible requirement as feral populations are always present to a greater or lesser extent.

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 2.9.3.4.

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/compartment free from European foulbrood.

Community position:
The Community proposes that the requirement for freedom can only be requested by a country which is free or has an official eradication programme.

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/compartment; 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

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).

~~CHAPTER 2.9.4.~~

~~NOSEMOSIS OF BEES~~

Community position:
The Community can support the deletion of this disease Chapter.

~~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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— text deleted

CHAPTER 2.9.5.

VARROOSIS OF HONEY BEES

Community position:
Firstly the Community would like to see a Chapter on Aethina tumida (small hive beetle) included urgently.
Secondly the Community could support this proposal if the comments below are taken into account. Throughout the Chapter reference is made to compartment. The requirements of a compartment in this particular case must be clearly specified in particular as the host is capable of flying quite long distances!!

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/compartment 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/compartment and all clinical signs suggestive of varroosis should be subjected to field and laboratory investigations;

Community position:
The Community does not agree that disease notification can be limited to a compartment or even a zone. The words compartment and also zone must be deleted indeed this is reflected in the requirement in 4) below.

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/compartment free from varroosis

1) Historically free status

A country or zone/compartment 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/compartment complies with the provisions of Article 3.8.1.2.

2) Free status as a result of an eradication programme

A country or zone/compartment 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/compartment;

b) varroosis is notifiable in the whole country or zone/compartment, 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, 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 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;

Community position:
The first sentence should read: '…..an annual survey….. has been carried out…'.

Also, in connection with the American foulbrood section earlier above, why annual surveys for 3 years following the last reported isolation of the European foulbrood agent, when the American foulbrood chapter proposes 5. There needs to be consistency between the two chapters for the length of time; both should be either 3 years or 5 years.

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*, the Korea and Japan haplotypes of *Apis cerana* or other possible host species in the country or zone/compartment;

Community position:
The Community believes that this is an impossible requirement as feral populations are always present to a greater or lesser extent.

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 2.9.5.4.

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/compartment officially free from varroosis.

Community position:
The Community proposes that the requirement for freedom can only be requested by a country which is free or has an official eradication programme.

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/compartment; or

2) have originated from queens in a *quarantine station* and were inspected and found free of *Varroa destructor*.

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).

CHAPTER 2.9.X.

TROPILAELAPS INFESTATION OF HONEY BEES

Community position:
Firstly this pest should be included in the list of notifiable diseases laid down in Chapter 1.1.2.3
Secondly the Community would like to see a Chapter on Aethina tumida (small hive beetle) included urgently as has been done for this pest.
Thirdly the Community could support this proposal if the comments below are taken into account. Throughout the Chapter reference is made to compartment. The requirements of a compartment in this particular case must be clearly specified in particular as the host is capable of flying quite long distances!!

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.

Community position:
The word "can" should be replaced by "could" as there appears to be no definitive reports of Tropilaelaps transmitting bee viruses..

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

Article 2.9.X.2.

The *Tropilaelaps* status of a country or zone/compartment 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/compartment and all clinical signs suggestive of *Tropilaelaps* infestation should be subjected to field and laboratory investigations;

Community position:
The Community does not agree that disease notification can be limited to a compartment or even a zone. The words compartment and also zone must be deleted indeed this is reflected in the requirement in 4) below.

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/compartment free from *Tropilaelaps* spp

1) Historically free status

A country or zone/compartment 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/compartment complies with the provisions of Article 3.8.1.2.

2) Free status as a result of an eradication programme

A country or zone/compartment 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/compartment;

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;

Community position:
The first sentence should read: '…..an annual survey….. has been carried out…'.

Also, in connection with the American foulbrood section earlier above, why annual surveys for 3 years following the last reported isolation of the Tropilaeps, when the American foulbrood chapter proposes 5. There needs to be consistency between the two chapters for the length of time; both should be either 3 years or 5 years.

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;

Community position:
The Community believes that this is an impossible requirement as feral populations are always present to a greater or lesser extent.

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.

Community position:
The Community proposes that the requirement for freedom can only be requested by a country which is free or has an official eradication programme.

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:

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).

CHAPTER 2.3.1.

BOVINE BRUCELLOSIS

Community position:
The Community can support this proposal.

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;

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:

<u>for cattle for breeding or rearing (except castrated males)</u>

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

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

   ~~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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— text deleted

Appendix XXII

APPENDIX 3.9.4.

RISK ANALYSIS FOR ANTIMICROBIAL RESISTANCE

Community position:
The Community can only support this proposal if the comments below are taken on board.
In addition the risk management part is much too short and risk communication is not included so if the title is not restricted to Risk assessment then these 2 additional parts must be developed and in any case the title should include at the end the following words "…arising from the use of antimicrobials in animals."

Article 3.9.4.1.

Guidelines for analysing the risks to animal and public health from antimicrobial resistant bacteria of animal origin

1) 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.

Community position:

The wording of the introduction should be reconsidered. It is not only the incorrect use but all use of antimicrobials, which contributes to the development of resistance. Antimicrobials are valuable in the treatment of infectious diseases in human *medicine and veterinary medicine*. For these reasons the following changes are proposed:

"Antimicrobials are valuable substances in the treatment of infectious diseases in animals and humans. The use of antimicrobials *in animals for therapeutic, preventative and growth promotion purposes* can reduce their efficacy in veterinary 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*.

Community position:

The Community asks the OIE to clarify if "generic" is right term or should this term be "general risk analysis process"? The Community assumes that generic is equivalent to general.

A qualitative risk assessment should always be undertaken. Its outcome will determine whether progression to a quantitative risk assessment is feasible and/or necessary.

Community position:

The Community proposes to add semi-quantitative risk assessment to qualitative and quantitative ones so the text above becomes "A qualitative risk assessment should always be undertaken. Its outcome will determine whether progression to a semi-quantative or 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:

Community position:The Community questions if pet animals should also be included in the risk assessment? Resistant bacteria can be transmitted to humans in food or through contact with animals, including pets. The human contact with pet animals is often very close. Furthermore, broad-spectrum antimicrobials are particularly often used for pets. Therefore the Community proposes the following sentence "The assessment of the risk to human and animal health from antimicrobial-resistant bacteria resulting from the use of antimicrobials in <u>both</u> food-producing <u>and pet</u> 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.

Article 3.9.4.2.

Analysis of risks to human health

1) <u>Definition of the risk</u>

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) <u>Hazard identification</u>

– 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) <u>Release assessment</u>

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*

–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.

Community position:The amount of antimicrobials used should also be included besides the numbers of animals treated etc. The route of administration has been included but also duration of use should be taken into account. The Community propose to amend the 3rd indent. as follows: "proposed conditions of use (e.g. route of administration, dosage regimen, proposed indication for use of the antimicrobial)"
Resistance to antimicrobials can arise from new mutations or through the acquisition of genes coding for resistance – development of new resistance determinants is not necessary. Evolution of resistance is facilitated by the presence of resistance determinants in transferable genetic elements, and antimicrobials exert selective pressure;

The properties of antimicrobials affect the development of resistance: bacteria can particularly rapidly develop resistance to certain drugs:

The Community therefore proposes that the following factors should be added to be considered in the release assessment:

"- amount of antimicrobials used in animals
- the availability of pre-existing resistance genes - pharmacokinetics/pharmacodynamics of antimicrobial administered".

In addition it is not clear what is meant by "waste products" in the following bullet point:
- Surveillance of animals, animal products and waste products for the existence of resistant bacteria.
The Community assumes that this means animal by products but would ask the OIE to clarify this.

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.

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

Community position:
The Community considers that the 13th bullet point concerning the capacity of resistant bacteria to transfer resistance to human commensal bacteria should be changed as follows: "capacity of resistant bacteria to transfer resistance to human commensal bacteria and zoonotic agents."

Resistance genes are not necessarily destroyed when the bacteria carrying these traits are, which should be considered in association with microbial decontamination. Has the possibility of resistance genes from dead bacteria being a source of uptake of resistance genes by other bacteria been considered?

–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

Community position:

The term variation in susceptibility needs to be clarified. It is not clear if it means susceptibility to infectious disease(s) or susceptibility of bacterial populations to antimicrobials.

–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

–associated costs

–interference with a classical first line of antimicrobial therapy in humans

Community position:

The term "a classical first line of antimicrobial therapy in humans" should be clarified and if available, the reference to any internationally recognized document defining the substances belonging to this group should be provided.

–perceived future usefulness of the drug (time reference).

Community position:

The word 'drug' should be replaced by "antimicrobial"

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

Community position:

The word 'infectious' should be introduced before "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

Community position:

The word "target" should be introduced before '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;).

Community position:
One consequence of resistance is that older and inexpensive antimicrobials become ineffective thus increasing the treatment costs. Therefore the Community proposes that this should be one of the factors to be considered in risk estimation. The Community proposes that associated costs be added as follows:

"(e.g. illness, hospitalisation and associated costs)."

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 health

1) 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.

Community position:
The Community propose to amend the 4th indent as follows:"-proposed conditions of use (e.g route of administration , dosage regimen , proposed indication for use of the antimicrobial)".

In addition it is not clear what is meant by "waste products" in the indent
- surveillance of animals, animal products and waste products for resistant bacteria.

The Community assumes that this means animal by products but would ask the OIE to clarify this.

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.

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

Community position:

The variation in susceptibility needs to be clarified Does it mean susceptibility to infectious diseases or susceptibility to antimicrobials? The Community believes it is the latter,

–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).

Community position:

The following factor should be added to be considered in the consequence assessment

"- changes in animal management practices resulting from reduced confidence in antimicrobials".

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

Community position:

After costs the words "(e.g. antimicrobial treatment; veterinary services, husbandry, reduced income, loss of market) " are introduced as it is developed in the document Rev.sci.tech.Off.int.Epiz.2001,20(3),811-827
http://www.oie.int/eng/publicat/rt/2003/a_r20314.htm

–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

Community position:
The Community is very pleased at the excellent progress being made in this important new area of work for the OIE. Some minor drafting comments are included in the text below.

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.

Community position:
This wording needs some clarification.

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.

Community position:
The word 'economic 'should be replaced by "socio-economic".

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.

Community position:
The word 'problems' needs clarification.

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.

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 there needs can be devised and used.

Community position:
The word 'there' should be replaced by "their".

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.

Community position:
The last sentence above should be replaced by "Using such evidence, the acceptability of systems and of human performance in animal keeping and treatment 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

Community position:

The Community welcomes the further development of the chapter and is prepared to assist in this work. It is appreciated that the approach of differentiating between HPAI LPAI has been taken on board, but this approach is not fully followed throughout the chapter and should further be elaborated for the different commodities. The Community agrees with most of the proposals but can only support this Chapter if the comments below are taken into account. However, it must be pointed out that with the adoption of this Chapter detailed rules for compartmentalisation must already have been laid down in order to make trade on a compartment basis acceptable.

In this context please find annexed a policy paper on the future strategy for AI control in the EU.

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 8 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

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.

Community position:
The zones of 3 km and 1 km should also be free within the past 21 days. Furthermore the establishment should be protected from wild birds.

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 *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 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*.

Community position:
It is suggested to differntiate between NHPAI and NLPAI as concerns the slaughter of birds, in the case of NHPAI stamping-out should be compulsory.

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.

Community position:
Instead of "at a minimum interval" it should read "at a maximum interval".

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.]*~~

Community position:
We are concerned that in the case of trade from a free compartment NAI could occur in the direct neighbourhood so the risk of disease transmission could not be excluded.

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;

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 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.

Community position:
A further requirement should be added:
"3) are not directly dispatched from a holding and that a packing centre should not be located on a holding."

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.

Community position:
The OIE should consider if there are not other possibilities to minimise the risk of transmitting AI viruses via egg shells instead of repeated testing. In addition serology is not a useful method in this context and should therefore be deleted. It appears that PCR seems to be a suitable test, but is probably too expensive and too sophisticated for some countries.

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 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.

Community position:
The Community request that the OIE develop an Annex with detailed methods for virus destruction in the different commodities as soon as posssible.

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 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/compartment 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;

Community position:
The Community would like the OIE to explore in more depth the latest developments on work on infectivity of meat and the risk for disease transmission.
On serology the Community draws the attention of OIE to the comments in Article 2.1.14.6ter.
For virus isolation the 7 days prior to slaughter is too short and should be replaced by 10 days and in addition 5% prevalence should be replaced by 25%.

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;

Community position:
Please refer to the comments in Article 2.1.14.10ter regarding the time and prevalence.

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.

Community position:
Please see the comment in Article 2.1.14.7ter.

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.

Community position:
Please see the comment in Article 2.1.14.7ter.

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.

Community position:
Please see the comment in Article 2.1.14.7ter.

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.

Community position:
Please see the comment in Article 2.1.14.7ter.

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ANNEX - SANCO/10076/2004-27-1-2004

CONTROL OF AVIAN INFLUENZA

LESSONS LEARNED IN THE EU AND DEVELOPMENT OF INTERNATIONAL TRADE STANDARDS

1. INTRODUCTION

1.1. Influenza viruses

Influenza viruses are found in a very large number of different species of birds and mammals, including humans. They are classified into three groups – A, B and C – based on differences in the serological cross reactivity of their nucleoprotein (NP) and Matrix (M1) protein components.

Only Influenza A viruses have been described to cause natural infections in birds. Influenza B and C types usually affect humans, whilst only infrequently isolated from other mammals. Influenza A viruses are frequently detected in pigs and horses worldwide.

The viral nucleic acid (RNA) of Influenza viruses is segmented into 8 distinct genes, which code for 10 proteins. Two of the 8 genes code for the surface glycoproteins Haemagglutinin (HA) and Neuraminidase (NA). Within type A, 15 HA subtypes have also been recognised (H1-H15) and 9 NA subtypes (N1-N9). Each Influenza A virus has one HA and one NA antigen, apparently in any combination.

Because the RNA is segmented, genetic reassortment can occur in mixed infections of the same host with different strains of Influenza A viruses. This means that when two different viruses infect the same cell, progeny viruses may inherit sets of RNA segments made up of combinations of segments of nucleic acid identical to those of either of the parent viruses. As a result of genetic re-assortment a 'new' virus may appear which shows antigenic and virulence features inherited from one or the other of the parent viruses[1].

Further to reassortment, Influenza virus genes also show a high degree of variation, due to gradual accumulation of mutations in the nucleic acid sequence of the genes. HA and NA are the most important antigens for inducing protective immunity and show the greatest variation, probably as a consequence of the selective pressure of the immune system of the host.

Due to reassortment and mutation, a huge variety of genetically different Influenza viruses circulate in nature, which show a different degree of "adaptation" to bird or mammal (including human) hosts and capability of crossing the species barrier.

As a further consequence of genetic variation, Influenza viruses may induce disease with different degrees of severity in the various hosts, ranging from sub-clinical

[1] For example the AI virus subtype H7 N7 which caused the recent epidemic in the Netherlands is thought to be derived from the reassortment of two AI viruses previously detected in wild birds: one of subtype H7N3 found in a mallard duck and the other of subtype H11 N7 from a shoveller.

localised infection in the intestinal and/or respiratory tract to generalised infection leading to very serious disease with very high mortality rates.

1.2. HPAI and LPAI

Avian Influenza (AI) is a highly contagious viral infection caused by Influenza viruses of type A, which can affect all species of birds.

Influenza A viruses are divided into two groups on the bases of their ability to cause disease:

- **highly pathogenic Avian Influenza (HPAI)** viruses which cause an extremely contagious and serious disease characterised by generalised infection of the infected poultry, where they may induce very high mortality (up to 100%), and

- low pathogenic Avian Influenza (LPAI) viruses which cause a mild disease in poultry, unless there is exacerbation by other infections or factors.

Wild birds, especially migratory waterfowl, play a very important role as Influenza A virus reservoir, as shown by the isolation of nearly all possible combinations of HA and NA subtypes. Generally, only LPAI viruses are detected in wild birds.

Primary introduction of AI viruses in poultry farms most likely originates from direct or indirect contact with wild birds.

In domestic poultry farms, these LPAI viruses introduced from the wild reservoir may circulate undetected, as clinical signs are often mild or absent[2].

Once introduced in poultry LPAI virus strains of H5 and H7 subtypes may then mutate into HPAI strains, which are, conversely, considered to be absent from the wild reservoir. To date only viruses of the H5 and H7 subtypes have shown to cause HPAI.

Even though it is speculated that environmental factors, high density of poultry and the poultry species affected may influence this incident, current knowledge suggests that virus mutation from LPAI into HPAI is a random event.

Therefore, it is impossible to predict if and when this mutation will occur. However, it can be assumed that the wider the circulation of LPAI in poultry, the higher the chance that mutation into HPAI occurs.

Data on the major ways of HPAI transmission between poultry farms are reported in Annex I. Proximity of poultry farms and indirect contacts (vehicles, personnel, etc.) play a major role in disease spread.

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[2] LPAI infection may sometimes cause serious disease in poultry, particularly turkey, mainly if it is associated with other agents such as E. coli, Pasteurella multocida or Mycoplasma spp..

Certain species of poultry - like turkeys and ducks - seem to be more susceptible than other to LPAI viruses, e.g. they can be infected with lower amounts of virus. However, this would depend in a large extent on the degree of adaptation of single virus strains to the species in question.

1.3. AI epidemics in the last 5 years

Between 1959 and 1998 17 HPAI viruses - all of them of H5 and H7 subtypes - have been isolated worldwide. Since 1999 it appears that there is a rise in the occurrence of HPAI epidemics (see attached table, Annex II).

There is accumulating evidence that HPAI viruses arise from LPAI H5 or H7 viruses when spreading from free-living birds to poultry. When and if at all these viruses may become virulent after introduction into domestic poultry remains unpredictable.

Presumably in outbreaks of HPAI such as that occurring in England in 1991, in which only a single house of turkeys was affected the mutation may take place very quickly after introduction. The same appears to have happened during the AI outbreaks in Chile in 2002. In Australia in 1976 there was evidence of limited spread before mutation took place, whereas in Pennsylvania in 1983, in Mexico in 1993/94/96 and in Italy in 1999/2000 there had been extensive circulation of LPAI viruses for a considerable period of time before the emergence of HPAI. It can only be assumed that mutation to virulence is a random event. In that case the longer the presence and greater the spread in poultry the more likely it is that HPAI virus will emerge. It would therefore seem appropriate to implement a policy to limit the spread and presence of LPAI viruses of H5 and H7 subtype in poultry to limit the probability of a mutational event occurring.

The serious HPAI epidemic in Italy in 1999-2000 was caused by mutation of an LPAI virus subtype H7N1 which had been circulating for several months in the poultry population, before HPAI of the same subtype emerged. Conversely surveillance results during the recent epidemic in the Netherlands (2003), suggest that mutation to HPAI subtype H7N7 had occurred rather quickly after LPAI virus introduction in domestic poultry.

These two epidemics had catastrophic consequences as they occurred in areas with a very intense and highly integrated poultry industry and a large number of poultry farms in close proximity to each other. From the Netherlands secondary spread of disease has happened into the bordering areas of Belgium and Germany.

1.4. Public health aspects

Influenza viruses of avian origin may also rarely affect mammals, including humans. The problems posed by AI viruses for humans are very well elucidated and discussed in a very recent paper of Alexander et al., in the light of the most updated knowledge and experience on this matter (see Annex III).

Usually, the disease induced in humans by AI viruses is not serious and causes conjunctivitis, and/or some respiratory signs. However, a total of 7 fatal cases has been reported in Hong Kong during two recent episodes of HPAI viruses transmission to humans.

Then, during the recent epidemic of HPAI in the Netherlands, 82 human cases of eye infection due to AI virus occurred in workers directly exposed to infected birds. Some secondary cases also occurred in relatives who lived in contact with the affected personnel. Furthermore, a veterinarian died of pneumonia after visiting an affected farm. Following the *post-mortem* examination, the NL authorities arrived to the conclusion that his death was most likely linked to the circulating AI virus.

Conversely, in Italy the recent outbreaks of LPAI and HPAI have not lead to any infection in humans.

The data reported by Alexander at al. also suggest that:

- the vast majority of human infections with AI have been caused by HPAI viruses, as a result of direct exposure to infected birds or anyhow related to HPAI epidemics in poultry. Conversely, transmission of LPAI viruses from birds to humans seems a rather infrequent event, despite the wide occurrence of these viruses in nature, particularly in wild birds.

- so far direct contact with infected poultry has been the only recognised way of transmission of AI viruses from poultry to humans,

- human-to-human transmission of AI viruses has been very limited, and only associated with HPAI viruses,

- only HPAI viruses have been associated with human deaths.

The above data suggest that the risk for human health is mostly related to HPAI.

However, scientists also consider that there is a possibility that "new" AI viruses - highly contagious and virulent for humans - could emerge due to genetic reassortment between AI viruses of avian origin and other Influenza A viruses already adapted to humans. In principle, this reassortment might occur in any animal species (such as birds, humans, pigs or horses, etc.) if it is infected with viruses of both Avian and human origin.

Such a "new" virus - for which the human population could be fully susceptible due to the absence of immunity in the population in relation to previous infection caused by H5 or H7 viruses - might cause a pandemic, as the ones occurred in 1918, 1957, 1968 and 1977[3].

Pigs have been considered to be the mammalian species where virus re-assortment might more easily take place, as in general they are rather susceptible to Influenza viruses of both avian and human origin. The recent cases of direct transmission of AI viruses from birds to humans have, however, raised concern about the possibility that

[3] The origin of the pandemic of 1918 - which led to the death of about 40 million people - is unclear. However, scientists deem that it is highly likely that the pandemics of 1957 and 1968 were caused by viruses including some genes of avian origin.

no “intermediate” host – such as the pig - may be necessary for the emergence of a “new” pandemic virus and emphasised the need to prevent this event.

For this reason during the recent HPAI epidemic in the NL, once it become evident that the HPAI virus strain causing the epidemics in poultry was able to spread to humans, the personnel exposed to infected birds was vaccinated against the Influenza virus circulating in the human population and treated with antiviral drugs to reduce replication of any Influenza virus and thus possibility of virus reassortment.

Given also that HPAI viruses contain genes leading to generalised infections in the animal host[4] and that there is a potential that the mechanisms by which this occurs may also apply to mammalian hosts, it can be assumed that virus reassortment involving HPAI viruses may lead to more serious consequences for human health than in the case that a LPAI virus is involved.

Influenza pandemics in humans are, however, rare events despite the wide circulation of Influenza viruses in birds and mammals. Possibly, there may be some other unknown restriction in the spread and transmission of re-assorted viruses in humans.

2. CONTROL STRATEGIES APPLIED IN THE EU AND LESSONS LEARNED

2.1. Control of HPAI

The Italian and Dutch experiences suggest that the HPAI is extremely difficult to control in areas with a high density of poultry, even if a draconian stamping-out policy is adopted, including pre-emptive depopulation of non-infected farms. Indeed, the stamping out policy which has been applied to eradicate these two major epidemics has even included the establishment of a large ‘fire-wall’ of emptied poultry farms around the infected areas.

However, virus circulation has only been stopped after a massive depopulation of poultry farms in the affected areas. During both epidemics a total of 50 Million birds had to be killed and destroyed.

While in many circumstances no alternatives probably exist to massive depopulation of poultry farms in case of HPAI, there is however a need to consider vaccination as a possible additional tool for disease control.

2.2. Control of LPAI

Reoccurring LPAI infections spreading easily from farm to farm are increasingly detected in the USA and are currently ongoing in Northern Italy, where turkeys are the most affected species.

[4] However, no human fatalities due to AI viruses so far recorded have been associated with generalised infection of the infected patients.

Spread of infection is mainly related to direct (animal movements) and indirect (vehicles, personnel, etc.) contacts between poultry farms.

Control of LPAI should be based on rapid identification of infection in farms (based on targeted surveillance), application of stringent bio-safety measures to prevent farm-to-farm transmission of LPAI virus, restriction to movements (quarantine) and slaughter of infected birds. This strategy could also be supported by vaccination, to be applied in particular where LPAI viruses show the tendency to become endemic, perhaps as a consequence of a good adaptation of virus to a certain species (e.g. recent LPAI outbreaks in turkeys in Italy).

2.3 Vaccination

Following the experience of 1999 (emergence of HPAI after a circulation of LPAI), vaccination of poultry against LPAI was authorised in Italy in 2000 and 2002 by Commission Decisions 2000/721/EC and 2002/975/EC, following a further detection of LPAI and submission of an emergency vaccination programme by Italy.

AI vaccination in Italy has been approved and applied in the context of a DIVA (**D**ifferentiation between **I**nfected and **V**accinated **A**nimals) strategy, which is based on the principle that the vaccine strain differs from the field strain. In the vaccine strain, the HA which is responsible for immunity is the same of the field virus, whilst the NA is different. The immune response of vaccinated birds can thus be differentiated from the one induced by the field strain.

For this purpose a "discriminatory test" able to recognise the different NA antibodies was developed in the National Laboratory for AI in Italy and approved by the Commission, following an evaluation of the discriminatory test by Community experts.

The approved vaccination programmes were linked to a stringent monitoring scheme of the vaccinated and unvaccinated flocks in the area and a prohibition of trade in live poultry, hatching eggs and table eggs from the vaccination area. However, the DIVA strategy made possible under certain conditions the dispatch for intra-Community trade of meat derived from vaccinated turkeys, as it was possible to exclude with high degree of certainty any infection due to AI virus.

The first Italian vaccination campaign was directed against the reoccurrence of H7N1 LPAI infections in the area, where HPAI had previously caused the epidemic. This vaccination programme in combination with the slaughter of LPAI positive flocks led to the elimination of the circulating virus and was phased out after duration of one and half year, without the recourse to massive slaughter and destruction of poultry, resulting in considerable economic savings.

The DIVA strategy was therefore well accepted at international level and by the scientific community throughout the world.

The second vaccination campaign has proven to be less successful. Reasons for that are:

- the infection had spread within a very large area requiring therefore a larger vaccination zone,

- the rules for the administration of the vaccine and accompanying bio-security measures have often not been correctly implemented by the farmers due to their increasing reluctance to support the costly set of disease control measures imposed by the authorities. In particular in relation to the "controlled marketing" of slaughter turkeys contamination of the poultry production chain occurred due to indirect contacts between farms and insufficient implementation of bio-security measures , causing further spread of infection in the affected area and in its surroundings.

It further has to be noted that the duration of immunity in turkeys is very short and therefore repeated vaccination is necessary to protect birds at a late stage of their life span. However, vaccination of laying hens has been very effective.

In the context of the epidemic of 2003 in the Netherlands, Belgium and Germany, vaccination of birds kept in zoos and approved bodies was permitted under certain recording and testing requirements, e.g. their free movement was restricted.

Only inactivated vaccines have been used so far in the EU[5]. These vaccines must be administered individually and a reliable immunity only builds up after further "booster" injections. Currently, a three-shot vaccination scheme is applied in meat turkeys in Italy, which is rather expensive.

In accordance with the Italian experience, the major advantages of vaccination are related to:

a) the protection of the vaccinated bird from clinical signs,
b) decrease in sensitivity to AI infection of the vaccinated bird compared to the non vaccinated ones, as a higher virus amount is needed for infection, and decrease in virus shedding by the vaccinated and then infected bird, thus considerably reducing virus spread into and from the vaccinated population,
c) good acceptance of vaccination by the farmers and the public, compared with stamping-out
d) possibility to trade internationally from the vaccinated farms, thanks to the implementation of a DIVA strategy.

The disadvantages of vaccination are related to the fact that vaccinated and then infected birds shed AI virus - even though at a much lower level than the non-vaccinated ones - and therefore may further spread the infection. For this reason certain additional surveillance and restrictions as regards trade in live birds are appropriate.

5 A recombinant fowlpox-based vaccine is also used in the USA, Mexico and Guatemala. It is not approved in the EU. Its use may pose some technical problems due to the interference of the antibodies induced by the natural fowlpox infection in the birds to be vaccinated.

Furthermore, the time (a few weeks) necessary for the induction of a good immunity, the need for repeated injections of each bird and the cost are major constraints for a wider application of vaccination.

However, LPAI and HPAI disease control strategies could also be supplemented by vaccination, as done in Italy, taking into account the advantages of the DIVA strategy. It must be pointed out that vaccination against LPAI also induces protection against HPAI and in principle it reduces the risks related to virus replication.

Indeed, for the future the possibility of vaccination might not be strictly limited to emergency cases, but for certain at-risk or particularly valuable categories of birds as pet poultry, rare birds, turkeys or free-ranging laying hens, prophylactic vaccination might also be appropriate provided that additional surveillance and certain protective measures, including trade restrictions and additional surveillance, are also applied as regards the vaccinated farms or "compartments".

However, it is well known that vaccination against AI will protect the birds against clinical signs of disease, but it may not prevent infection, if bio-security rules are not properly applied. The risk of a "masked infection" with possible undetected spread of infection via vaccinated birds does exist. In general, only a DIVA vaccination strategy should therefore be applied to overcome this problem.

The DIVA strategy should be accompanied by a strict monitoring programme complementing the vaccination campaign in order to detect possible virus circulation in vaccinated and unvaccinated flocks in the vaccination area.

In case of favourable results of this additional surveillance, no specific international trade restrictions should be applied as regards poultry meat and table eggs, as under these circumstances the risks posed by these commodities can be considered as negligible.

3. FUNDAMENTAL STEPS TO ENSURE A BETTER CONTROL OF AI AND PREVENTION OF ITS SPREAD VIA INTERNATIONAL TRADE

3.1. The reasons for change and the objectives of changing

So far, disease control measures in the EU and international trade standards have been focused on HPAI.

The recent increased knowledge on LPAI suggest that there is an urgent need to review the strategies applied to control HPAI and envisage disease control measures and trade standards also for LPAI caused by H5 and H7 subtypes, to protect poultry from devastating HPAI epidemics. It is expected that this approach would also lead to a reduction of the potential risks for human health related to the possible transmission of AI viruses to humans.

The reasons to establish a new policy for the control of LPAI and the prevention of its spread via trade are summarised as follows:

- an effective and rapid control of HPAI is very difficult to achieve, in particular in areas with a high density of poultry, as the disease is extremely contagious;

- the economic and social costs of HPAI epidemics have shown to be very high;

- there is a potential risk for public health related to AI virus circulation in poultry, particularly in case of HPAI;

- the most effective way to prevent mutation of LPAI into HPAI virus and thus reduce the risks for animal and public health is to limit the occurrence and spread of LPAI caused by viruses of H5 and H7 subtypes in poultry as early and effectively as possible.

However, disease control measures and trade standards should be proportioned to the different risks posed by HPAI and LPAI infections.

3.2 Risks posed by HPAI and LPAI and trade standards

The difference in virulence between LPAI and HPAI affects the virus amount in internal organs and meat and the possibility of spreading the infection via poultry products. In the absence of viraemia, the amount of AI viruses in the meat is probably extremely low or nil. The same is valid for eggs, as there is no evidence of any possibility of transovarial transmission of AI virus into eggs. Taking into account the pathogenesis of LPAI infections, the major potential risks of virus transmission via eggs or meat would be linked to faecal contamination of these products.

Available evidence and experience suggests that LPAI viruses mostly spread from poultry farm to poultry farm via direct and indirect contact with infected poultry. There is no evidence available suggesting that farm-to-farm or country-to-country spread of LPAI has ever occurred in relation to trade in poultry meat or table eggs, despite the absence of any specific precaution or trade restriction so far adopted in relation to the potential risks posed by these products.

So far, direct exposure to infected birds has been the only recognised way of transmission of AI viruses from birds to humans, whilst no danger has ever emerged by the consumption of eggs or poultry meat.

Possible risks for human or animal health related to any occurrence of AI viruses in poultry meat or eggs are most likely minimised by the following factors:

- infection of humans with AI viruses probably requires a high virus load,
- AI viruses are rather sensible to acid pH and therefore they are most likely quite rapidly inactivated during meat maturation and in the stomach,
- AI viruses are heat labile and do not survive cooking,
- feeding of poultry with catering waste is not practised in intensive poultry farms (in the EU it is totally forbidden).

The above data therefore suggest that the risk of transmission of LPAI viruses via products such as poultry meat or table eggs is extremely low, perhaps negligible.

In this context the risk posed by international trade in poultry meat and eggs for human consumption and the measures to be adopted in relation to this risk should be properly assessed.

In the absence of any scientific evidence that these commodities may actually pose any serious risks to animal or public health in relation to LPAI, it seems not appropriate to envisage special trade requirements as regards the disease status of the farm of origin of these products, if the general surveillance and control policy implemented by the exporting country (see paragraph below) ensures that:

i) the introduction of LPAI viruses in poultry farms and areas at-risk is rapidly detected,

ii) an adequate control policy is adopted in the infected farms,

and, as a consequence of both i) and ii),

iii) the overall risk of undetected spread of LPAI infection to other poultry farms is thus minimised.

As a precautionary measure, however, slaughter and trade in poultry meat and table eggs from farms recognised as LPAI infected should be accompanied by the implementation of strict bio-safety protocols and appropriate precautions to prevent any spread of infection due to faecal contamination of meat, egg shells, packaging materials, etc.

A more cautious approach seems to be appropriate in case of trade in meat and table eggs from farms at risk for HPAI, taking into account both the pathogenesis of infection in poultry and the higher risks for human health, which have been described in chapter 1.4.[6]

Conversely, the risk that that LPAI is transmitted via trade in live poultry cannot be considered inferior to that posed by HPAI, as in most circumstances LPAI does not cause clinical disease in the infected poultry. For these reasons, trade in live poultry should be subjected to more stringent surveillance than trade in meat or table eggs, taking also into account that there is a much higher risk of further spread of infection in case of movements or trade in live infected birds than in their products.

3.3. Surveillance for LPAI

LPAI viruses are common in the wild birds throughout the world. The risk for introduction of LPAI from wild birds to poultry farms cannot be excluded "*a priori*" by any country. Differently from HPAI, LPAI infection does not necessarily cause clinical signs in the affected poultry.

[6] A more cautious approach is also suggested by the findings of AI antibodies in pigs kept in mixed pigs/poultry farms in the NL during the 2003 HPAI epidemic, which had been fed with eggs from HPAI infected hens.

For these reasons "active" on-going surveillance is an essential step to ensure early detection of LPAI, rapid adoption of appropriate measures for disease control and prevention of further spread of infection via trade or any other way.

Following the advice of the Scientific Committee, a serological and virological survey for LPAI has been carried out in the EU in 2003. The first results of this survey indicate that a risk for introduction of LPAI into poultry farms has been identified in certain areas of the EU. LPAI infection in most of the poultry farms where LPAI virus or AI antibodies have been found would have not been identified without the survey.[7]

It appears appropriate that surveillance is based on a risk analysis and focuses on:

- areas where LPAI virus strains have been more often detected in the previous years;
- areas located along the pathways of wild migratory birds;
- areas with a high density of poultry;
- commercial holdings where certain species and categories of birds more susceptible to LPAI are kept (ducks, geese, turkeys, laying hens),
- management practices, such as free ranging,
- poultry holdings at the beginning of the pyramid of production and/or specialised in the production of breeding poultry and hatching eggs.

Taking into account the risk factors related to the introduction of LPAI into poultry farms and the potential for its subsequent spread, targeted surveillance for AI viruses should therefore be considered as a fundamental requirement for international trade in poultry and poultry products.

In relation to trade, more stringent surveillance requirements should be established as regards trade in live poultry than as regards meat or table eggs, taking into account the different level of risks posed by these commodities.

It is essential, however, that guidelines on surveillance are established at international level, to ensure from one side that safety of international trade is guaranteed by an appropriate level of surveillance and from the other side that unnecessary surveillance is not required by importing countries.

For transparency purposes, results of AI surveys should be made public by OIE Member countries.

3.4. Compartmentalisation

The introduction of the concept of compartmentalisation could be introduced to identify individual poultry population for disease surveillance and control purposes and for the recognition of disease status.

To ensure that the concept of compartmentalisation is fully recognised at international level and successfully applied as regards LPAI it is however necessary that the current

[7] the results of the EU survey are currently being gathered and analysed.

definition and concept of compartment is further developed. In particular, compartments should be identified on the bases of both geographical and management considerations.

Given that HPAI is extremely contagious, however, it seems unlikely that this concept can be successfully applied in relation to HPAI. In this case, "regionalization" seems more appropriate.

3.5. The definition of AI

The following new definition could be used as a base for the establishment of international trade standards and disease control measures:

> "Notifiable avian Influenza (NAI) is an infection of poultry caused by any Influenza A virus of the H5 or H7 subtypes or by any AI virus with an IVPI greater than 1.2. Notifiable avian Influenza viruses can be divided into "Notifiable Highly Pathogenic Avian Influenza" (NHPAI) and "Notifiable Low Pathogenicity Avian Influenza (NLPAI)". NHPAI viruses have an IVPI in 6-week-old chickens greater than 1.2 or multiple basic amino acids at the cleavage site of the haemagglutinin molecule. NLPAI are all Influenza A viruses of H5 and H7 subtype that are not NHPAI viruses"

This definition would be consistent with the recommendation of the EU Scientific Committee of 2000 to consider both LPAI and HPAI virus subtypes as subjected to Community harmonised control measures. However, it would differentiate between the two conditions, to ensure that the most appropriate and proportioned surveillance and control measures and trade standards are adopted in relation to the different risks posed by LPAI and HPAI.

ANNEX I

Most important ways of farm-to-farm transmission of HPAI in Italy in 1999-2000

Way of transmission	**% of outbreaks caused**
- Proximity of farms (1000 m)	24.4%
- Movement of vehicles (e.g. transporting feed)	20.4%
- People entering farms to load animals to be slaughtered	9.1%
- Other indirect contacts	10.7%
- Introduction of infected poultry (movements of birds incubating the disease[8])	0.5%

[8] Only local movements were allowed, subjected to rigorous restrictions

ANNEX II

HPAI 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/02 (H7N3)
20. A/chicken/Netherlands/03 (H7N7)

*Where outbreaks were widespread and affecting more than one species, the isolate
from the first outbreak identified is listed.

ANNEX III

Avian influenza viruses and influenza in humans.

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Abstract

Influenza A viruses cause natural infections of humans, some other mammals and birds. Few of the 15 haemagglutinin and 9 neuraminidase subtype combinations have been isolated from mammals, but all subtypes have been isolated from birds. There are enormous pools of influenza A viruses in wild birds, especially migratory waterfowl.

In the 20th Century there were 4 pandemics of influenza due to the emergence of antigenically different strains in humans: 1918 (H1N1), 1957 (H2N2), 1968 (H3N2) and 1977 (H1N1). The RNA of influenza A viruses is segmented into 8 distinct genes and as a result genetic reassortment can occur in mixed infections with different viruses. The 1957 and 1968 pandemic viruses differed from the preceding viruses in humans by the substitution of some genes that came from avian viruses. Indicating that pandemic viruses may arise by genetic reassortment of viruses of human and avian origin.

In poultry some influenza A viruses cause highly pathogenic avian influenza [HPAI], with 100% mortality in infected flocks. The virulence of HPAI viruses is related to the presence of multiple basic amino acids at the precursor HA0 cleavage site, which enables it to be cleaved, and the virus rendered infectious, by a ubiquitous protease [e.g. furin], causing a systemic infection, instead of being restricted to cleavage by trypsin-like proteases. Humans also have furin, but none of the pandemic viruses have had HA0 cleavage sites with multiple basic amino acids.

Up to 1995 there had been only three reports of avian influenza viruses infecting humans, in 1959, 1977 and 1981. All three viruses were H7N7 and two of these infections were the result of laboratory accidents. However, since 1996 there have been regular reports of natural infections of humans with avian influenza viruses. Isolations of avian influenza viruses from humans in England in 1996 [H7N7], Hong Kong in 1997 [H5N1] and 1999 [H9N2] caused concern that a new influenza pandemic could begin. The H5N1 virus was especially alarming, as it possessed multiple basic amino acids at the HA0 cleavage site and 6/18 of the people infected died. In 2003 further human infections with H5N1 virus were reported in Hong Kong with two associated deaths and in The Netherlands a total of 82 people were confirmed as infected with the H7N7 virus responsible for a series of HPAI outbreaks in poultry, one death was reported. Although these infections seem to have been limiting, with very little human to human transmission, they are a cause for alarm since if people infected with an "avian" virus were infected simultaneously with a "human" influenza virus 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.

Keywords

Avian influenza, human influenza, interspecies transmission, pandemics, reassortment, zoonosis.

Introduction

Influenza is a highly contagious, acute illness in humans for which there are recognisable accounts of epidemics dating back to ancient times. Influenza viruses have negative sense RNA genomes and are placed in the *Orthomyxoviridae* family; they are grouped into types A, B and C on the basis of the antigenic nature of the internal nucleocapsid or the matrix protein, these types are now recognised as genera. Influenza A viruses infect a large variety of animal species including humans, pigs, horses, sea mammals and birds, occasionally producing devastating pandemics in humans. The two surface glycoproteins of the virus, haemagglutinin (HA) and neuraminidase (NA), are the most important antigens for inducing protective immunity in the host and therefore show the greatest variation. For influenza A viruses 15 antigenically distinct HA [H1-H15] and 9 NA [N1-N9] subtypes are recognised at present; a virus possesses one HA and one NA subtype, apparently in any combination. Although viruses of relatively few subtype combinations have been isolated from mammalian species, all subtypes, in most combinations, have been isolated from birds.

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 (Nguyen-Van-Tam & Hampson, 2003). In 1957 and 1968 the new viruses completely replaced the previous virus in the human population, but in 1977 this did not occur and currently H3N2 and H1N1 viruses both circulate.

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 inter-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. Occasionally the degree of antigenic drift is sufficient that a very large proportion of the population is susceptible and severe epidemics occur with world-wide spread.

By far the worst influenza pandemic for which there are accurate records was the one beginning in 1918. It has been estimated that during the pandemic more than 40 million people died (Nguyen-Van-Tam & Hampson, 2003). In well developed countries such as the USA about 0.5% of the population died, but in some communities in Alaska and the Pacific islands half the population perished. Since 1918 the central theme in the study of human influenza has been to understand how antigenic shift occurs and to predict when and how it will next occur.

Human/avian influenza link

The RNA of influenza viruses is segmented into 8 distinct genes, which 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; Gething, *et al.,* 1980; Kawaoka, *et al.,* 1989; Schlotissek, *et al.,* 1978). As a result systematic surveillance studies in to the presence of influenza viruses in avian species were undertaken. These revealed enormous pools of influenza A viruses in wild birds, especially migratory waterfowl. In a series of surveillance studies involving over 20,000 birds during 1973-1986, virus was isolated from about 10%, with an isolation rate of approximately 15% from ducks and geese and 2% from other birds (Alexander, 2000). In addition, unlike mammals, where the number of subtypes that have been established appears to be limited, all 15 H and 9 N subtypes recognised currently have been recorded in birds in most possible combinations.

This wealth of influenza viruses in the bird population brought into question the reassortment theory for the origins of pandemic virus, as transfer and reassortment would seem likely to occur much more frequently than subtype changes have appeared in the human population. However, volunteer experiments had shown that only transitory infections resulted when humans were infected with viruses of avian origin (Beare and Webster, 1991) and at that time few natural infections of humans with avian viruses had been reported (see below). 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 gene segments. Both human and avian viruses are known to infect pigs readily and it was 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 gene(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 naive. 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).

The emergence of pandemic virus may be even more complicated and two hypotheses have been proposed for the rhythm of occurrence of human influenza A viruses, which were termed by Shortridge (1992) as an influenza circle or cycle and an influenza spiral, respectively. The circulation theory suggests there is simply a recycling of H1, H2 and H3 subtypes. If this is so, the HA subtype of the next pandemic virus would be H2. The spiral theory presupposes that humans are

capable of being infected with all HA subtypes of influenza A viruses providing a specific constellation of the other genes is present and that it is a lottery as to which of the 15 recognised will emerge next by reassortment. The theories are not mutually exclusive and since the circulation theory does not state how it the next pandemic virus will arise, it could be by reassortment.

Avian influenza pathogenicity

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 cause a disease formerly known as fowl plague and now termed highly pathogenic avian influenza [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. 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.

The main functional glycoprotein the haemagglutinin, for influenza viruses is produced in a precursor form, HA0, which requires post translational cleavage by host proteases before the protein is functional and the virus particles are infectious. It has been demonstrated that the HA0 precursor proteins of avian influenza viruses of low virulence for poultry are limited to cleavage by host proteases such as trypsin and 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. In contrast virulent viruses appear to be cleavable by a ubiquitous protease[s], which remains to be fully identified but appears to be one or more proprotein-processing subtilisin-related endoproteases of which furin is the leading candidate (Stieneke-Grober et al., 1992), and this enables these viruses to replicate throughout the animal, damaging vital organs and tissues which brings about disease and death in the infected bird.

Comparisons of the amino acid sequences at the HA0 cleavage site of avian influenza viruses of high and low pathogenicity revealed that while viruses of low virulence have a single basic amino acid [arginine] at the site, all HPAI viruses possessed multiple basic amino acids [arginine and lysine] adjacent to the cleavage site either as a result of apparent insertion or apparent substitution (Senne et al., 1996, Vey et al., 1992, Wood et al., 1993). The additional basic amino acids resulting in a motif recognised and cleavable by the putative ubiquitous protease[s]. Mammals, including humans, also have furin-like proteases capable of cleaving at multiple basic amino acid motifs.

Human infections with avian influenza viruses (Table 1)

There were three reports of human infections with avian influenza virus in the literature prior to 1996. In 1959 a HPAI virus of was obtained from a patient with hepatitis (Campbell *et al.*, 1970). The second related to a laboratory worker in Australia who developed conjunctivitis after accidental exposure directly in the eye with a HPAI virus (Taylor & Turner, 1977). The third also related to conjunctivitis as the result of infection with an avian LPAI virus, which spread to an animal handler

from an infected seal (Webster *et al*., 1981). Interestingly all three of these viruses were of H7N7 subtype.

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. 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 HPAI. 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 had been reported in Germany, Italy, Ireland, South Africa, USA, Korea, China, the Middle East, Iran and Pakistan (Banks et al., 2000) and this virus continues to spread. 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.

In 2003 an H5N1 virus was isolated from a father and son in Hong Kong who presented with respiratory illness after returning from the Chinese mainland, the father died. A daughter had become ill and died while visiting the Chinese mainland, it is not known if she was infected with H5N1virus. There were reported to be some genetic differences between the 1997 and the 2003 H5N1 viruses (WHO website: http://www.who.int/mediacentre/releases/2003/pr17/en/).

During the 2003 HPAI H7N7 outbreaks in The Netherlands of 260 people involved in some aspect of the outbreak and presenting with conjunctivitis and/or influenza-like illness 82 were confirmed as infected with H7 virus (Koopmans *et al*., 2003). There was also evidence of three cases of human to human transmission within families. Six people tested proved positive for H3N2 influenza, but none were also positive for H7N7. Following these cases all staff involved in the outbreaks were treated prophylacticly with antiviral drugs and subjected to vaccination against human influenza (to reduce the chance of reassortment between human and avian viruses). During this outbreak a human fatality also occurred. The victim was a 57-year-old veterinarian who had not received prophylactic antiviral drugs and had contact with infected birds during outbreak management. He was admitted to hospital with severe headache and fever, subsequently he developed a severe respiratory condition, kidney failure and died. H7 virus was recovered from a broncho-alveolar lavage collected 9 days after the onset of illness (Koopmans *et al*., 2003).

Five of the eight reports of avian influenza infections in humans have been with H7N7 subtype viruses. The significance of this is not known.

Conclusions

The high mortality, 6/18, amongst the people infected with the H5N1 virus in Hong Kong was worrying in case the virus was capable of systemic infection due to the presence of multiple basic amino acids at the HA0 cleavage site allowing cleavage to be mediated by a furin-like protease(s). However, evidence that this was the case is lacking. Generally, the 18 patients presented with severe respiratory symptoms and 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. Similarly the single death amongst those infected with the HPAI H7N7 virus in The Netherlands in 2003 was also the result of pneumonia. Infections of other mammals with avian influenza viruses also give few clues to the significance of multiple basic amino acids at the HA0 cleavage site. An infection of harbour seals during 1978-80 off the NE coast of the United States of America with H7N7 avian influenza resulted in death of an estimated >20% of the population. While this mortality rate is comparable to that occurring in humans in Hong Kong, the HA0 cleavage site of the H7N7 virus did not have a motif containing multiple basic amino acids (Webster et al., 1992). Conversely, H7N7 viruses responsible for equine influenza type 1, for which A/equine/Prague/56 is the type strain, does have multiple basic amino acids at the HA0 cleavage site and yet in infections of horses with this strain, virus replication is invariably restricted to the respiratory tract (Gibson et al., 1988).

The demonstration of direct natural infections of humans with avian viruses suggests that pandemic viruses could emerge as a result without an intermediate host. However, for the human population as a whole the main danger is probably not directly the viruses that have spread from avian species, but if the people infected with the avian influenza viruses had been infected simultaneously with a "human" influenza virus, reassortment could have occurred with the potential emergence of a virus fully capable of spread in the human population, but with H5, H7 or H9 HA, resulting in a true influenza pandemic.

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Table 1 Reports of human infections with avian influenza viruses

Year	Subtype	HPAI/LPAI[1]	Number of people infected	Symptoms
1959	H7N7	HPAI	1	hepatitis?
1977	H7N7	HPAI	1	conjunctivitis
1981	H7N7	LPAI	1	conjunctivitis
1996	H7N7	LPAI	1	conjunctivitis
1997	H5N1	HPAI	18	influenza-like illness 6 deaths
1998	H9N2	LPAI	2 (+5?)	influenza-like illness
2003	H5N1	?	2 (+1?)	influenza-like illness, 1 (+1?) death
2003	H7N7	HPAI	82	conjunctivitis, some cases of influenza-like illness, 1 death

[1]HPAI or LPAI in chickens. See text for source.