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Object: Meeting of the International Terrestrial Animal Health Code commission – March 2007

Dear Bernard,

Please find attached as an annex to this letter the Community comments on the report of the meeting of Code Commission between 2 to 13 October 2006 with reference to certain Chapters in the OIE Terrestrial Animal Health Code. In order to facilitate the examination of the comments of the Community, 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 Report.

Thank you for the continued excellent collaboration and trust you will find our comments constructive and useful.

Werner Zwingmann
CVO of Germany

Paola TESTORI
Deputy Director General

Enclosures: 1

Copy: All CVOs Member States, Croatia, Iceland, Norway, Turkey and Switzerland

Dr. B. Vallat
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ANNEX

Original: English

October 2006

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

Paris, 2-13 October 2006

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The OIE Terrestrial Animal Health Standards Commission (hereafter referred to as the Terrestrial Code Commission) met at the OIE Headquarters in Paris from 2 to 13 October 2006.

The members of the Terrestrial Code Commission are listed in Appendix I. The agenda adopted is given in Appendix II.

The Terrestrial Code Commission examined various OIE *Terrestrial Animal Health Code* (hereinafter referred to as the *Terrestrial Code*) texts in response to Member Countries' comments received by the end of August, as well as outstanding comments from the previous meeting and the General Session. During this meeting, the Terrestrial Code Commission again experienced difficulty in examining some of the comments because of the lack of explicit rationale.

The outcome of the Terrestrial Code Commission's work is presented as appendices to this report. Amendments made to existing chapters and previously circulated drafts are shown as double underlined text, with deleted text in strikeout.

Member Countries should note that, unless stated otherwise, all texts submitted for comment in this report (Part A) may be proposed for adoption at the 75th General Session. Depending on the nature of the comments received on each text, the Terrestrial Code Commission will indicate in its March 2007 meeting report whether a particular text will be proposed for adoption or held for further work.

The Terrestrial Code Commission strongly encourages Member Countries to participate in the development of the OIE's international standards by sending comments on this report. The Terrestrial Code Commission reiterates that it would be very helpful if comments were submitted as specific proposed text changes, supported by a scientific rationale.

Comments on this report need to reach the OIE Headquarters by **10 February 2007** in order to be considered at the next meeting of the Terrestrial Code Commission in March 2007. Comments should be sent to the International Trade Department at: trade.dept@oie.int.

The Director General, Dr B. Vallat, welcomed the members and thanked them for their willingness to participate in this important work. He noted the need of further close

communication and cooperation among Specialist Commissions, in particular between the Terrestrial Code Commission and the Scientific Commission for Animal Diseases (hereafter referred to as the Scientific Commission) for developing and revising chapters and appendices of the *Terrestrial Code*, and between the Terrestrial Code Commission and Aquatic Animal Health Standards Commission (hereinafter referred to a the Aquatic Animals Commission) for harmonisation of the two Codes.

Dr Vallat briefed the Terrestrial Code Commission on the recent meeting he held with Presidents of Specialist Commissions and the directors of Scientific and Technical Department and the International Trade Department. The purpose of that meeting was to review the terms of reference of the Commissions and to improve coordination between Commissions and Departments. Arrangements were made to improve the exchange of information including documents.

The Terrestrial Code Commission had detailed discussions with Dr Vallat on: BSE Chapter and Appendix on BSE risk assessment; the future of draft guidelines of traceability; the review of the *Performance, Vision and Strategy* [PVS] *Instrument* and the development of indicators and manual for evaluators; the terms of reference for the *ad hoc* Group on certification; the definition of animal handler as recommended by the Working Group on Animal Welfare; the urgently needed review of the Chapter on rinderpest; the review of the Chapter on zoning and compartmentalisation; and modification of the Chapter on avian influenza.

The Terrestrial Code Commission thanked the following Member Countries for providing written comments: Argentina, Australia, Canada, Chile, the European Union (EU), Japan, New Zealand, South Africa, Sudan, Switzerland, Taipei China and the United States of America (USA).

A. TEXTS WHICH ARE SUBMITTED FOR MEMBER COUNTRY COMMENT

1. General definitions (Chapter 1.1.1.)

Community comments:

The Community can support the proposed amendments to this Chapter in Appendix III but would like the comments given in the Appendix taken into account.

After considering many Member Countries' concerns about the definition of "animal handler", including the proposed requirement for certification of competency, the Terrestrial Code Commission modified the text in the general definitions. An explanation for this decision may be found under Item 19 Animal Welfare below.

Comments received from countries on the definitions of "slaughter" and "stunning" will be forwarded to the Working Group on Animal Welfare for further examination.

Noting that there are two different definitions for "surveillance", one in Chapter 1.1.1. and the other in Appendix 3.8.1., the Terrestrial Code Commission decided to seek

advice from the Scientific Commission, for a single definition of surveillance, including examination of the closely-related definition of "monitoring".

The Terrestrial Code Commission reviewed the definitions adopted for 'veterinary services', 'veterinary authority' and 'veterinary administration' and the usage of these terms in the *Terrestrial Code*. The Terrestrial Code Commission agreed that, in principle, definitions for the terms 'competent authority', 'veterinary authority' and 'veterinary services' should be clarified and steps taken to ensure that these terms are used consistently throughout the *Terrestrial Code*. The Terrestrial Code Commission proposes to eliminate the term 'veterinary administration' and instead use one of the other terms (as appropriate). Only after the definitions have been finalised can the use of the various terms throughout the *Terrestrial Code* be reviewed and modified as appropriate.

The revised chapter, which is presented at Appendix III, is circulated among Member Countries for comment.

2. Evaluation of Veterinary Services

Community comments:

The Community can support this work and the clearly separate publication of "The PVS Instrument, the Handbook and the Indicators"

a) Evaluation of Veterinary Services (Chapter 1.3.3.)

b) *Performance, Vision and Strategy Instrument*

The Terrestrial Code Commission discussed with Dr Vallat the future development of the *Performance, Vision and Strategy* [PVS] *Instrument* and next steps in the development of a Handbook and Indicators for conducting evaluations. The Terrestrial Code Commission noted the work under way and the planned meeting of the *ad hoc* Group on the Evaluation of Veterinary Services, which will take place from 31 October to 2 November. The Terrestrial Code Commission anticipates reviewing the work of the *ad hoc* Group at its March meeting. The PVS Instrument, the Handbook and the Indicators will not form part of the *Terrestrial Code*. Rather, they will be published by the OIE as an official tool for use in the evaluation of Veterinary Services, in accordance with Chapters 1.3.3. and 1.3.4.

3. Zoning and compartmentalisation

Community comments:

The Community can support the proposed amendments to Chapter 1.3.5 in Appendix IV but would like the comments given in the Appendix taken into account, and would point out that there are still some discrepancies between this Code and the Aquatic Code chapters which could be adjusted to better harmonise

both texts. It supports the work being done on preparing practical guidelines on compartmentalisation for avian influenza, and stays at the disposition of the OIE to help in the matter.

Moreover, while supporting the concept of compartmentalisation being developed and included in the various diseases Chapters, of which some have not yet been amended but should be, such as the Swine Vesicular Disease, it needs that clear and effective guidelines for its operation in each case are agreed before the strategy is operational.

The Terrestrial Code Commission has requested that the Scientific Commission evaluate the incorporation of the concept of compartmentalisation into specific disease chapters where applicable.

a) Zoning and compartmentalisation (Chapter 1.3.5.)

An expert was asked to review the chapter and incorporate Member Countries' comments, taking into account the input from the Scientific Commission's concept paper published in the OIE *Bulletin* (No. 2006 – 2). On the basis of further discussion, the Terrestrial Code Commission drafted the revision of Chapter 1.3.5. shown in Appendix IV. The draft chapter is circulated among Member Countries for comment.

b) Practical guidelines on compartmentalisation for avian influenza

Experts have been commissioned to develop practical guidelines on the application of the compartmentalisation concept to avian influenza. There is a possibility of applying these guidelines simultaneously to Newcastle disease. The Terrestrial Code Commission examined an early draft text and provided feedback to the experts to assist in this work. The Terrestrial Code Commission expects to produce a draft for circulation as part of the March 2007 report.

4. International transfer of pathogens (Chapter 1.4.5.)

Community comments:

The Community can support this work.

The Terrestrial Code Commission considered comments received from Member Countries. Reassurance was sought that material removed from the revised chapter would be retained in the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (hereinafter referred to as the *Terrestrial Manual*). This was endorsed by the Biological Standards Commission (hereinafter referred to as the Laboratories Commission) at its 13-15 September meeting. A new edition of the *Terrestrial Manual* will be developed in 2007. Chapter 1.4.5. will not be removed from the *Terrestrial Code*. The amendments in

the *Terrestrial Code* will be harmonised with amendments in the *Terrestrial Manual* and will be made at the same time.

5. Rabies (Chapter 2.2.5.)

Community comments:

The Community can support the proposed amendments to this Chapter in Appendix V but would like the comments given in the Appendix taken into account.

The Terrestrial Code Commission followed advice from the Laboratories Commission and updated this chapter in relation to the use of recombinant vaccines in a live virus vector.

The revised chapter, which is presented at Appendix V, is circulated among Member Countries for comment.

6. Paratuberculosis (Chapter 2.2.6)

Community comments:

The Community can support this work.

The Terrestrial Code Commission had decided at its March meeting that it could not proceed with revision of the Paratuberculosis Chapter without consulting the Biological Standards Commission on diagnostic methods.

The Biological Standards Commission has undertaken to consult experts for advice on diagnostic methods. Once this information is received and assessed, the Biological Standards Commission will make recommendation to the Terrestrial Code Commission.

The Terrestrial Code Commission considered that there would be merit in forwarding to such experts the text circulated among Member Countries as Appendix XXXVII to the meeting report of September 2005 together with the comments subsequently received from Member Countries.

7. Foot and mouth disease

Community comments:

The Community can possibly support the proposed amendments to this Chapter in Appendix III but it would need that the general and specific comments given in the Appendix are taken into account.

It can support the initiative to evaluate the feasibility of incorporating the concept of compartmentalisation into the FMD surveillance appendix as long as clear and effective guidelines for its operation are agreed before the strategy is operational.

a) Foot and mouth disease (Chapter 2.2.10.)

The comments received from Member Countries on the chapter were submitted to the Scientific Commission for consideration. Recommendations from the Scientific Commission were incorporated by the Terrestrial Code Commission.

As requested in Resolution No. XXX of the 74th General Session, an *ad hoc* Group was convened to consider the establishment of a procedure to expedite the recovery of status in the event of a limited outbreak in a previously FMD free country or zone. The recommendations of the *ad hoc* Group were endorsed by the Scientific Commission and the new article 2.2.10.6.(bis) and a definition for a containment zone were submitted to the Terrestrial Code Commission for consideration. The recommendations were adapted for inclusion in the chapter.

Suggested changes to the chapter, which are at Appendix VI, are circulated among Member Countries for comment.

b) Guidelines for surveillance of foot and mouth disease (Appendix 3.8.4.)

The Terrestrial Code Commission has requested that the Scientific Commission evaluate the feasibility of incorporating the concept of compartmentalisation into the FMD surveillance appendix (Appendix 3.8.4.).

8. Bluetongue

Community comments:

The Community will have difficulties to support the proposed amendments to this Chapter at Appendix VII if the comments given in the Appendix are not taken into account.

However it can support the proposal at Appendix VIII but would like the comments made in this Appendix taken into account.

The Terrestrial Code Commission reviewed comments received from Member Countries and the recommendations from the Scientific Commission. The discussion by an emergency *ad hoc* Group on bluetongue held immediately after the meeting of the Terrestrial Code Commission was also taken into consideration. The texts of the Chapter and of the Appendix on surveillance were modified accordingly. These texts, which are presented at Appendices VII and VIII, are circulated among Member Countries for comment.

a) Bluetongue (Chapter 2.2.13.)

Considering recent outbreaks in Europe and the understanding that bluetongue is increasing its geographical distribution in this region, the Terrestrial Code

Commission modified the northern latitude boundary in Articles 2.2.13.1. and 2.2.13.2.

Article 5 was deleted as per the Scientific Commission's recommendation. The Terrestrial Code Commission considers that the risks associated with importation from a bluetongue infected country are adequately addressed in the commodity articles.

The request to reassess the possibility of allowing importation of semen/embryos/oocytes from vaccinated donors was considered by the Terrestrial Code Commission. It was determined that this is already covered by relevant articles in the chapter.

b) Bluetongue surveillance guidelines

Comments received from Member Countries on the first draft of the guidelines on surveillance for bluetongue were reviewed by the Scientific Commission and appropriate changes to the text were made. The Terrestrial Code Commission noted the incorporation of the concept of compartmentalisation in these surveillance guidelines and questioned how this could be applied, in practice, to anything more than an individual holding, such as artificial insemination centres and quarantine stations. The principle of vector free premises is already well established in the *Terrestrial Code* without the need to consider the application of compartmentalisation. The Terrestrial Code Commission will further consider incorporating the concept of compartmentalisation in the bluetongue chapter in light of future comments from Member Countries.

9. Bovine brucellosis (Chapter 2.3.1.)

Significant comments were received from several Member Countries. The comments were reviewed by the Scientific Commission, which determined that the complex technical nature of the comments required consultation and that an *ad hoc* Group would be convened in February 2007.

Community comments:

The Community can support this work.

10. Bovine spongiform encephalopathy

a) Risk assessment recommendations (Appendix 3.8.5.)

Among a substantial number of comments suggesting modifications and better linkage to Chapter 2.3.13., the Terrestrial Code Commission recognised it should first address a comment from New Zealand requesting clarification of the purpose of this Appendix in relation to a set of guidelines titled "BSE Questionnaire for country status recognition" prepared by the Scientific Commission. The OIE has agreed to

conduct procedures to recognise the BSE status of Member Countries. In view of this, the Terrestrial Code Commission was of the opinion that Appendix 3.8.5. on factors to consider in conducting BSE risk assessment should be incorporated, without further review by the Terrestrial Code Commission, into the documents used for the official OIE categorisation of Member Countries.

Once such guidelines become available to Member Countries on the OIE website or otherwise, the Terrestrial Code Commission will propose to Member Countries that current Appendix 3.8.5. be dropped from the *Terrestrial Code*. It was agreed that any detailed and very prescriptive documents should not be part of the *Terrestrial Code*.

b) Bovine spongiform encephalopathy (Chapter 2.3.13.)

Community comments:

The Community welcomes the work done by the Code Commission but strongly opposes to the modification made related to the production of gelatine and ask the OIE Code Commission to reconsider its position prior to the General Session in May 2007.

In addition the Community would welcome the OIE Code Commission to consider the other comments made on the Chapter 2.3.13. of the Terrestrial Animal Health Code.

Some Member Countries requested clarification of the term "imported" appearing in Article 2.3.13.2. point a) Release assessment. The Terrestrial Code Commission was of the view that this should be addressed in Chapter 1.3.5. as it is a general consideration in implementation of zone and compartment.

The Terrestrial Code Commission examined outstanding concerns raised by the EU and Japan regarding the risk of potentially infected animals present in the age cohorts born before the risk management measures were enforced. As a result, Articles 2.3.13.6., 2.3.13.7. and 2.3.13.12. were modified.

The Terrestrial Code Commission was informed by the EU that an article from French scientists (D. Calavas, V. Supervie, E. Morignat, D. Costagliola & C. Ducrot) has been accepted for publication in the Journal on Risk Analysis and will be published very soon. This document will provide the scientific rationale for changes made to the compliance period (i.e. the period of 7 years from the reporting of the case changed to 11 years from the birth of the case - Article 2.3.13.3. paragraph 3 b).

A Member Country requested to exclude the transverse processes of the thoracic and lumbar vertebrae and the wings of the sacrum from the definition of the vertebral column in point 2 of Article 2.3.13.13. The Terrestrial Code Commission did not adopt this recommendation because it doubted if the proposed definitions would be universally practicable or enforceable.

The Terrestrial Code Commission examined comments from a Member Country regarding the safety of gelatine irrespective of the origin of source material due to the safety of the production process. Based on the supporting document and a risk

assessment recently published by the New Zealand Food Safety Authority (NZFSA, 2005, Wellington) and entitled "Officials' Review of New Zealand's BSE Country-Categorisation Measure" (http://www.nzfsa.govt.nz/imported-food/bse-categorisation/report/index.htm), the Terrestrial Code Commission decided to revise Article 2.3.13.14. to allow all cattle bones to be used as a source material for the production of gelatine, provided the cattle have passed ante-mortem and post-mortem inspections.

The revised chapter, which is presented at Appendix IX, is circulated among Member Countries for comment.

c) Surveillance for bovine spongiform encephalopathy (Appendix 3.8.4.)

The Terrestrial Code Commission examined comments received from Member Countries on this Appendix. Noting that some questions remain on the usage of the full BSurvE model instead of Appendix 3.8.4., the Terrestrial Code Commission reiterated its intention as follows: Appendix 3.8.4. was developed using a modified version of the BSurvE model so that it would be easily applicable to any Member Country. However, the Terrestrial Code Commission does not see any problem in a Member Country choosing to use the full BSurvE model to estimate its BSE presence/prevalence. The reason why Appendix 3.8.4. does not make any reference to the BSurvE model as an alternative method is that the concept of equivalence underpins all chapters of the *Terrestrial Code*.

The Terrestrial Code Commission did not adopt country recommendations to modify descriptions of cattle sub-populations, as those used in the Appendix are consistent with commonly used terminology. The Terrestrial Code Commission did not adopt a request to expand Table 1 (Appendix 3.8.4.) to provide a more detailed breakdown of cattle sub-populations because it considered that additional detail and complexity would not be helpful. Member Countries wishing to apply a more expanded version for BSE surveillance can use the BSurvE model.

d) Supporting document

The Terrestrial Code Commission received a fully revised supporting document on BSE prepared by a group of experts. The document was commissioned to provide supporting scientific evidence for recent changes made to the chapter on BSE. All Commission members expressed their sincere appreciation to the experts who contributed to the drafting of the report.

The supporting document, which is presented at Appendix XXVIII, is circulated among Member Countries for information.

11. Equine influenza (Chapter 2.5.5.)

Community comments:

The Community can support the proposed amendments to this Chapter in Appendix but the comments given in the Appendix should be taken into account.

The Terrestrial Code Commission reviewed country comments on the draft chapter, which was circulated as part of its meeting report in March 2006. The chapter was revised taking these comments into consideration. Most significantly, the chapter was modified to be consistent with the format and the purpose of the *Terrestrial Code*. Articles were modified to meet the requirements for safe trade, rather than identifying the status of importing country.

Submissions suggesting all trade in horses would require excessive quarantine period, including when imported into countries not free of disease, are not justified. Consistent with the approach of the *Terrestrial Code*, only countries or zones that are free or have adopted official control for the disease should require the application of measures recommended in the chapter. Countries that are not free and do not have a control programme should only require measures equivalent to those applied within the country.

The Terrestrial Code Commission received an enquiry about the scientific basis for recommending that no measures be applied in regard to trade in equine semen and embryos (see Article 2.5.5.5. in the working draft). The Terrestrial Code Commission sought additional advice from experts and will revisit this issue at its March meeting. In the meantime, this article is placed 'under study'.

In response to an enquiry about the scientific rationale for adopting a period of 30 days (see Article 2.5.5.10.) as opposed to 21 days (used elsewhere in the draft chapter), the Terrestrial Code Commission requested clarification from the members of the *ad hoc* Group on Equine Influenza. In the absence of definitive advice on this point, the Terrestrial Code Commission decided to adopt a period of 21 days throughout the chapter.

The revised chapter, which is presented at Appendix X, is circulated among Member Countries for comment.

12. Equine diseases (other than equine influenza)

a) Equine infectious anaemia (Chapter 2.5.4.)

Community comments:

The Community can support the proposed amendments to this in Appendix XI.

b) Equine piroplasmosis (Chapter 2.5.6.)

Community comments:

The Community can support the proposed amendments to this in Appendix XII.

c) Equine rhinopneumonitis (Chapter 2.5.7.)

Community comments:

The Community can support the proposed amendments to this in Appendix XIII.

The Terrestrial Code Commission examined further comments received on Chapters 2.5.4., 2.5.6. and 2.5.7. As for equine infectious anaemia, country comments on point 3 of Article 2.5.4.2. were accepted to cover equines imported on a temporary basis. As for equine piroplasmosis, point 3 of Article 2.5.6.2. was modified to give clear guidance. In response to Member Country requests, "equine herpes virus infection" was adopted in Article 2.5.7.2. and added to the chapter title in parentheses. The reference to equine rhinopneumonitis cannot be deleted as this is the name used in the *Terrestrial Manual*.

The revised chapters, which are presented at Appendix XI, XII and XIII, are circulated among Member Countries for comment.

d) Glanders (Chapter 2.5.8.)

Community comments:

The Community can support the proposed amendments to this Chapter in Appendix XIV.

The Terrestrial Code Commission examined newly-received comments on glanders in addition to those received for its March meeting. Recognising the use of surveillance programmes, Article 2.5.8.2. was modified based on a comment from Member Countries. Point 3 of Article 2.5.8.3. was deleted, as testing is considered unnecessary for equines from glanders free countries. Point 3 of Article 2.5.8.4. was modified from 15 to 30 days based on a proposal from a Member Country for reasons of practicality in line with other disease test periods. Article 2.5.8.5. was deleted, as the Terrestrial Code Commission agreed with Member Countries' concerns about exemption from testing for equines, even for immediate slaughter, taking into account the zoonotic potential of *B. malleus*.

The revised chapter, which is presented at Appendix XIV, is circulated among Member Countries for comment. In this Appendix, modifications made during this meeting on the text from the September 2005 report are indicated with a coloured background to distinguish the two groups of proposal.

e) Equine viral arteritis (Chapter 2.5.10.)

Community comments:

The Community cannot support the proposal to amend this Chapter in Appendix XV unless the comments in the Appendix are taken into account.

The Terrestrial Code Commission examined comments received from Member Countries and made appropriate changes.

The main change in Article 2.5.10.2. relates to young horses with maternal antibodies. Articles 2.5.10.4. and 2.5.10.5. relating to fresh and frozen semen were combined.

The revised chapter, which is presented at Appendix XV, is circulated among Member Countries for comment. In this Appendix, modifications made during this meeting on the text from the September 2005 report are indicated with a coloured background to distinguish the two groups of proposal.

13. Classical swine fever (Chapter 2.6.7.)

Community comments:

The Community supports the proposal on the classical swine fever chapter 2.6.7 at Appendix XVI but would like the comments in Appendix taken into account.

It especially welcomes the introduction of the concept of compartmentalisation and the use of marker vaccination against classical swine fever. The present text has been improved and became more clear and coherent. However it is still believed that Article 2.6.7.6. should be deleted and some of the provisions added to those to Article 2.6.7.3.

The Community agrees with the approach of the TACC to seek advice on the inconsistencies as regards the conflicting periods of recovery of a free status and the residency of animals in a free country, zone or compartment.

The Terrestrial Code Commission reviewed Chapter 2.6.7., which was largely restructured and adopted in last General Session, and recognised that certain articles may still need revision. To avoid possible confusion between point 2 of Article 2.6.7.3. and Article 2.6.7.5., titles of sub-article in Article 2.6.7.3. were modified to clarify that this article concerns the initial attainment of free status, while the word "previously" was inserted in Article 2.6.7.5. to clarify that this article concerns recovery of free status. In light of Member Countries' comments, the title of Article 2.6.7.4. was modified to clarify the difference between Articles 2.6.7.3. and 2.6.7.4. (being with/without infection in the wild pig population). Point 2 of Article 2.6.7.4. was modified to clarify the intent of these articles.

As for Member Countries' comments about harmonising time periods that animals must be kept in free countries/zones or compartments to obtain free status (30 days per Article 2.6.7.5.; 3 months per Article 2.6.7.7. and subsequent articles), the Terrestrial Code Commission decided to seek advice from the Scientific Commission.

Suggested changes to the chapter, which are presented at Appendix XVI, are circulated among Member Countries for comment.

14. Avian influenza

a) Avian influenza (Chapter 2.7.12.)

Community comments:

The Community can support the proposed amendments to this Chapter in Appendix XVII but would like the comments given in the Appendix taken into account.

Although few comments were received on this revised chapter from Member Countries, the Terrestrial Code Commission noted that the Central Bureau has been receiving many inquiries, from Member Countries and industry representatives, about the health status of particular countries following occurrences of HPNAI infection in various birds including wild birds and zoo birds. The Terrestrial Commission therefore clarified the definition of poultry (see point 2 of Article 2.7.12.1).

Considering the ongoing difficulty of Member Countries in applying the measures in the *Terrestrial Code*, which has resulted in trade bans being imposed following the reporting of any findings, including reports in birds other than poultry, a new point 4 clarifying the obligations of countries was added to Article 2.7.12.1.

The Terrestrial Code Commission also provided a clarification in regard to the detection of antibodies in the absence of virus. Further investigation should be conducted to identify the source of the antibodies. This should not be considered as an occurrence of infection if further investigation fails to isolate the virus or to detect viral RNA.

Suggested changes to the chapter, which are presented at Appendix XVII, are circulated among Member Countries for comment.

b) Guidelines for the surveillance of avian influenza (Appendices 3.8.9.)

Community comments:

The Community can support the proposed amendments to this Appendix on surveillance but would like the comments given in Appendix XVIII taken into account.

After reviewing countries' comments, the Terrestrial Code Commission revised the title of Article 3.8.9.5. to clarify that it refers to countries declaring that they have regained freedom.

Suggested changes to the Appendix, which are presented at Appendix XVIII, are circulated among Member Countries for comment.

c) Guidelines for the inactivation of avian influenza virus (Appendix 3.6.5.)

The Terrestrial Code Commission reviewed a research paper titled "Thermal Inactivation of H5N1 High Pathogenicity Avian Influenza Virus in Chicken Meat" published by Drs C. Thomas and D. Swayne (Research report to the USDA, 2006 April 25), which was sent by a Member Country for the purpose of reconsidering the conditions stipulated in Article 3.6.5.2. The Commission used this paper as a basis to modify the recommendations on the thermal inactivation of avian influenza virus in poultry meat. Article 3.6.5.1. was modified based on a communication from Dr Swayne regarding his review of his research findings on egg products.

Suggested changes to the Appendix, which are presented at Appendix XIX, are circulated among Member Countries for comment.

15. Bovine and small ruminant semen (Appendix 3.2.1.)

Community comments:

The Community can support this work.

The Terrestrial Code Commission examined comments received from Member Countries on the Appendix. A comment on point 2 a) in Article 3.2.1.5. recommending to remove the requirement for a serological test in the case of animals from brucellosis free countries was not adopted, as the current definition of 'free country' does not assume that all animals are free of infection.

A suggestion on Article 3.2.1.5 point 3 to use RT-PCR as a suitable testing method was forwarded to the Laboratories Commission for review. An inquiry on the possibility of transmission of border disease via semen was forwarded to an expert for advice.

16. Animal identification and traceability

The Terrestrial Code Commission noted the report of the third meeting of the *ad hoc* Group on Identification and Traceability of Live Animals, which is at Appendix XXV for Member Countries' information.

a) General principles for animal identification and traceability (Appendix 3.5.1.)

Community comments:

The Community can support the proposed amendments to Appendix XX.

The Terrestrial Code Commission addressed the recommendations of the *ad hoc* Group and of the Animal Production Food Safety Working Group in revising

the principles. The revised Appendix, which is presented at Appendix XX, is circulated among Member Countries for comment.

b) Guidelines for animal identification and traceability

Community comments:

The Community can support this work.

The Terrestrial Code Commission noted the progress made by the *ad hoc* Group on the guidelines for animal identification and traceability. It noted questions from Member Countries about the intended future status of the guidelines and the need to retain a focus on outcomes rather than to develop prescriptive guidance based on system design elements. The Terrestrial Code Commission clarified that the guidelines were intended as an Appendix to the *Terrestrial Code* and that the guidelines would indeed set out principles and general approaches rather than prescribing specific standards. The comments of Member Countries and the Terrestrial Code Commission will be sent back to the Animal Production Food Safety Working Group to consider at its November 2006 meeting.

17. Disposal of dead animals (Appendix 3.6.6.)

Community comments:

The Community can support the proposed amendments to this Appendix on disposal of dead animals but would like the comments given in Appendix XXI taken into account.

The Terrestrial Code Commission reviewed detailed recommendations received from a Member Country on Appendix 3.6.6. The Terrestrial Code Commission considered that these recommendations enhanced the newly-developed guidelines.

Suggested changes to the Appendix, which are presented at Appendix XXI, are circulated among Member Countries for comment.

18. Ante-mortem and post-mortem inspections (Appendix 3.10.1.)

Community comments:

The Community can support this work.

The Terrestrial Code Commission addressed the comments received on Appendix 3.10.1. and considered that no immediate amendments were necessary since the text already addressed these issues. It forwarded to the Animal Production Food Safety Working Group the comments raised by Delegates at the 74th General Session.

19. *Ad hoc* Group on the Revision of the OIE Model Certificates

Community comments:

The Community can support this work.

The Terrestrial Code Commission reviewed the report of the electronic meeting of the *ad hoc* Group on the revision of the OIE model certificates which is at Appendix XXVI for the information of Member Countries. The Terrestrial Code Commission noted the recommendation from the recent OIE Regional Conference for Europe concerning methods to combat fraudulent certification in international trade and recommended that this be considered by the *ad hoc* Group in its work.

The Terrestrial Code Commission reviewed the terms of reference for updating the current texts on certification in the *Terrestrial Code* and recommended that the *ad hoc* Group, with membership as proposed, be convened to do this work.

20. Animal welfare

After considering many Member Countries' concerns about the definition of "animal handler", including the proposed requirement of certification of competency, the Terrestrial Code Commission modified the text in the general definitions. The Terrestrial Code Commission supported the principle that animal handlers should be experienced and knowledgeable and that Veterinary Services should have a role in ensuring that competent people work as animal handlers, but considered that it is the responsibility of Member Countries to determine how the competence of animal handlers should be demonstrated. Also, the Terrestrial Code Commission was of the view that formal certification systems for animal handlers may not be practical or feasible for many Member Countries at this time. Consequently, the recommendation by the Working Group on Animal Welfare for the certification of competence of animal handlers was not adopted. The modified definition adopted by the Terrestrial Code Commission appears in General Definitions (Chapter 1.1.1.) and, to facilitate consultation with Member Countries, in the relevant Guidelines. Once adopted the definition would be removed from the Guidelines.

a) Guidelines for the transport of animals by sea and land (Appendices 3.7.2. and 3.7.3.)

Community comments: The Community can support the proposed amendments but would like the comments given in Appendix XXII and XXIII taken into account.

The Terrestrial Code Commission examined the comments of countries and the work done by the Animal Welfare Working Group to refine the draft guidelines for the transport of animals by sea and land including substantial modification to the presentation. The Terrestrial Code Commission noted a recommendation from a Member Country to develop more specific guidance on the transport of poultry and agreed that such work could be undertaken in future. However, this would depend on the priority afforded to other tasks currently before the OIE and the availability of resources to carry out the high priority work items.

The revised Appendices, which are presented at Appendices XXII and XXIII, are circulated among Member Countries for comment.

b) Report of the OIE Working Group on Animal Welfare

Community comments: The Community can support this work.

The Terrestrial Code Commission noted the report of the Working Group on Animal Welfare, including some outstanding work in the guidelines on animal slaughter and killing for disease control purposes. The Terrestrial Code Commission endorsed the priorities identified by the Working Group including on the development of guidelines on the humane management of stray dogs, the use of laboratory animals in research and on animal production, housing and management. The report of the fifth meeting of the Working Group on Animal Welfare is presented at Appendix XXVII for information.

21. Revision of the structure of the *Terrestrial Code*

Community comments:

The Community can support the proposed amendments to the structure of the Terrestrial Code.

The Terrestrial Code Commission agreed to a recommendation from the International Trade Department that, based on the quantity of material and technical considerations, the printed version of the *Terrestrial Code* should be divided into two separate volumes. The International Trade Department recommended that one volume contain horizontal chapters (i.e. all of Part 1 plus some information from Parts 3 and 4, including guidelines on animal welfare). The International Trade Department recommended that the second volume contain specific disease chapters together with appendices relevant to specific diseases (including guidelines on surveillance, inactivation of specified pathogens, risk analysis for specified diseases). A table showing the proposed distribution of current *Terrestrial Code* chapters and appendices in the proposed new format appears in Appendix XXIX for the information of Member Countries.

22. Meeting with the Aquatic Animal Health Standards Commission

Community comments:

The Community can support this work.

The Terrestrial Code Commission held a short meeting with the Aquatic Animals Commission to discuss issues of mutual interest, including: the future structure of the *Terrestrial Code* (the need to divide the *Terrestrial Code* into two volumes and the possibility of combining horizontal chapters of the *Terrestrial* and *Aquatic Codes*),

harmonisation of terms and horizontal themes, animal welfare recommendations and exchange of information, including documents.

23. Future Work Programme

Community comments:

The Community can support the proposed amendments to the future work programme but would like the comments given in Appendix XXIV taken into account.

The Terrestrial Code Commission expressed its satisfaction with the proposal by the Scientific Commission to convene an *ad hoc* Group to review new scientific information and experience of managing rinderpest in the field in order to update the chapter. The Terrestrial Code Commission considered this information to be of urgent priority to modify the OIE pathway to eradicate this disease. On receipt of the report of the Scientific Commission, the Terrestrial Code Commission anticipates being able to review the chapter at its March meeting.

The Terrestrial Code Commission reviewed progress on the work programme agreed at its September 2005 meeting, including comments received from Member Countries on the work programme.

The Terrestrial Code Commission discussed the repeated request from Member Countries to establish a *Terrestrial Code* chapter on the small hive beetle. A draft chapter and supporting documents are currently with the Scientific Commission awaiting review. The Terrestrial Code Commission agreed to expedite work on this request as soon as it receives advice from the Scientific Commission.

A Member Country suggested that, further to planned work on the inactivation of *B. anthracis*, the OIE should develop guidelines on methods for the inactivation of agents of important zoonotic diseases, such as toxoplasmosis, brucellosis and leptospirosis. The Terrestrial Code Commission referred this request to the Working Group on Animal Production Food Safety.

Some other Member Countries' comments that related to disease reporting arrangements were referred to the Information Department.

The updated work programme is shown in Appendix XXIV for the comments of Member Countries.

24. Others

The next meeting of the Terrestrial Code Commission is scheduled for 12 to 16 March 2007.

B. REPORTS OF WORKING GROUPS AND *AD HOC* GROUPS

The following reports are presented to Member Countries for information:

– ***Ad hoc*** **Group on Identification and Traceability of Live Animals** (Appendix XXV)

– ***Ad hoc*** **Group on the Revision of the OIE Model Certificates** (Appendix XXVI)

– **Animal Welfare Working Group** (Appendix XXVII)

C. OTHER DOCUMENTS

The following documents are presented to Member Countries for information:

1. **Supporting document of the *Terrestrial Code* Chapter on BSE (edition 2006)** (Appendix XXVIII)
2. **Plan of the division of the *Terrestrial Code* into two volumes** (Appendix XXIX)

.../Appendices

Appendix I

MEETING OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 2-13 October 2006

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Appendix II

MEETING OF THE OIE TERRESTRIAL ANIMAL

HEALTH STANDARDS COMMISSION

Paris, 2-13 October 2006

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Adopted agenda

A. EXAMINATION OF MEMBER COUNTRIES' COMMENTS AND WORK OF RELEVANT EXPERT GROUPS

Item 1 General definitions (Chapter 1.1.1.)

Item 2 Evaluation of Veterinary Services

a) Evaluation of Veterinary Services (Chapter 1.3.3.)

b) *Performance, Vision and Strategy Instrument*

Item 3 Zoning and Compartmentalisation

a) Zoning and compartmentalisation (Chapter 1.3.5.)

b) Practical biosecurity guidelines for avian influenza

Item 4 International transfer of pathogens (Chapter 1.4.5.)

Item 5 Rabies (Chapter 2.2.5.)

Item 6 Paratuberculosis (Chapter 2.2.6.)

Item 7 Foot and mouth disease

a) Foot and mouth disease (Chapter 2.2.10.)

b) Guidelines for surveillance of foot and mouth disease (Appendix 3.8.4.)

Item 8 Bluetongue

a) Bluetongue (Chapter 2.2.13.)

b) Bluetongue surveillance

Item 9 Bovine brucellosis (Chapter 2.3.1.)

Item 10 Bovine spongiform encephalopathy

a) Risk assessment recommendations (Appendix 3.8.5.)

b) BSE (Chapter 2.3.13.)

c) Surveillance for BSE (Appendix 3.8.4.)

d) Supporting document

Item 11 Equine influenza (Chapter 2.5.5.)

Item 12 Equine diseases (other than equine influenza)

a) Equine infectious anaemia (Chapter 2.5.4.)

b) Equine piroplasmosis (Chapter 2.5.6.)

c) Equine rhinopneumonitis (Chapter 2.5.7.)

d) Glanders (Chapter 2.5.8.)

e) Equine viral arteritis (Chapter 2.5.10.)

Item 13 Classical swine fever (Chapter 2.6.7.)

Item 14 Avian influenza

a) Avian influenza (Chapter 2.7.12.)

b) Guidelines for the surveillance of avian influenza (Appendix 3.8.9.)

c) Guidelines for the inactivation of avian influenza virus (Appendix 3.6.5.)

Item 15 Bovine and small ruminant semen (Appendix 3.2.1.)

Item 16 Animal identification and traceability

a) Animal identification and traceability (Appendix 3.5.1.)

b) Guidelines for traceability

c) Animal identification and traceability *ad hoc* Group work

Item 17 Disposal of dead animals (Appendix 3.6.6.)

Item 18 Ante-mortem and post-mortem inspection (Appendix 3.10.1.)

Item 19 Ad hoc Group on the revision of the OIE Model Certificate

Item 20 Animal welfare

a) Guidelines for the transport of animals by sea and land

b) Report of the OIE Working Group on Animal Welfare

B. OTHER ISSUES

Item 21 Revision of the structure of the Terrestrial Code

Item 22 Meeting with the OIE Aquatic Animal Health Standards Commission

Item 23 Future work programme

Item 24 Others

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Appendix III

CHAPTER 1.1.1.

GENERAL DEFINITIONS

Community comments:

The Community supports these proposals but would like the comment below taken into account.

Animal handler

means a person with a knowledge of the behaviour and needs of *animals* who ~~which~~, with appropriate experience and a professional and positive response to an *animal*'s needs, ~~results in~~ can achieve effective management and good welfare. ~~Their competence should be demonstrated through independent assessment and certification from the Competent Authority or from an independent body accredited by the Competent Authority. (under study)~~ Competence should be gained through formal training and/or practical experience.

Community comments:

In the following definition of Competent Authority the words "animal health measures" should be changed to "animal health and welfare measures".

Justification: Although animal welfare is included in the words "and other standards and guidelines", this change will focus Competent Authorities on their obligations related to animal welfare, a matter closely linked to animal health.

Competent Authority

means the *Veterinary* ~~Services,~~ *Authority* or other Governmental Authority of a Member Country~~,~~ having the responsibility and competence for ensuring or supervising the implementation of ~~the~~ animal health measures ~~or~~ and other standards and guidelines in the *Terrestrial Code* in the entire territory of the country.

~~***Veterinary Administration***~~

~~means the governmental *Veterinary Service* having authority in the whole country for implementing the animal health measures and international veterinary certification process which the OIE recommends, and supervising or auditing their application.~~

Community comments:

For reason of clarity, the Community would like the other Chapters of the Code be swiftly modified in consideration to the changes of the definitions, and particularly the deletion of "*Veterinary Administration*", which could be kept between brackets until then.

Veterinary Authority

~~means a *Veterinary Service,* under the authority of the *Veterinary Administration,* which is directly responsible for the application of animal health measures in a specified area of the country. It may also have responsibility for the issuing or the supervision of the issuing of *international veterinary certificates* in that area.~~

means the Governmental Authority of a Member Country, comprising veterinarians, other professionals and para-professionals, having the responsibility and competence for ensuring or supervising the implementation of animal health measures and other standards and guidelines in the *Terrestrial Code* in the entire territory of the country.

Veterinary Service(s)

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

means the infrastructure comprising the governmental and non-governmental organisations that deliver animal health measures and other standards and guidelines in the *Terrestrial Code* in the entire territory of the country. The *Veterinary Services* are under the overall control and direction of the *Veterinary Authority*. Private sector organisations are normally accredited or approved to deliver functions by the *Veterinary Authority*.

Community Comments:

The word "infrastructure" should be replaced by the word "bodies";

The word "deliver" in the first sentence should be replaced by the word "implement" as veterinary services are responsible for implementation rather than delivery.

The accreditation or approval may be given to laboratories or other structures, which are not organisations sensu stricto, and also to private veterinarians, so the last sentence should read: "Non governmental organisations or structures and veterinarians can be accredited, authorized or approved to deliver functions by the *Veterinary Authority*".

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Appendix IV

CHAPTER 1.3.5.

ZONING AND COMPARTMENTALISATION

Community comments:

The Community in general supports these proposals but would like the comments below taken into account and would point out that are still some discrepancies between this Code and the Aquatic Code chapters which could be adjusted to better harmonise both texts.

(Definition) once adopted, this will move to Chapter 1.1.1.

Biosecurity plan

means a plan that identifies potential pathways for the introduction and spread of *disease* in a *zone* or *compartment*, and describes the measures which are being or will be applied to mitigate the *disease* risks in accordance, when applicable, with the recommendations in the *Terrestrial Code*. The plan also describes how these measures are audited to ensure that the risks are regularly re-assessed and the measures adjusted accordingly.

Community comment:

The Community proposes the addition of the words "and undertake appropriate surveillance" between the words "*disease* risks" and the words "in accordance".

Article 1.3.5.1.

Introduction

For the purposes of the *Terrestrial Code*, 'zoning' and 'regionalisation' have the same meaning.

Given the difficulty of establishing and maintaining a *disease* free status for an entire country, especially for *diseases* the entry of which is difficult to control through measures at national boundaries, there may be benefits to a Member Country~~ies~~ in establishing and maintaining a *subpopulation* with a ~~different~~ distinct *animal health status* within ~~national boundaries~~ its territory. *Subpopulations* may be separated by natural or artificial geographical barriers or, in certain situations, ~~animal~~ ~~industries~~ by the application of appropriate management systems~~, including biosecurity management~~.

Zoning and compartmentalisation are procedures implemented by a country under the provisions of this chapter with a view to defining *subpopulations* of ~~different~~ distinct *animal health status* within its territory for the purpose of *disease* control and/or *international trade*. Compartmentalisation applies to a *subpopulation* when management practices ~~systems~~ related to biosecurity are the defining factors ~~applied~~, while zoning applies when a *subpopulation* is defined on a geographical basis. In practice, spatial considerations and good management play important roles in the application of both concepts.

Community comment:

The Community proposes the following wording of the last sentence:

In practice, spatial considerations, good management and the implementation of a robust biosecurity plan play important roles in the application of both concepts.

This chapter is to assist OIE Member Countries wishing to establish and maintain different *subpopulations* within their national borders using the principles of compartmentalisation and zoning. These principles should be applied in accordance with the measures recommended in the relevant *disease* chapter(s). ~~It~~ This chapter also outlines a process through which ~~for~~ trading partners ~~to follow in achieving recognition of~~ may recognise such *subpopulations*. ~~These procedures are~~ This process is best implemented by trading partners through establishing parameters and gaining agreement on the necessary measures prior to *disease outbreaks*.

Before trade in *animals* or their products may occur, an *importing country* needs to be satisfied that its *animal health status* will be appropriately protected. In most cases, the import regulations developed will rely in part on judgements made about the effectiveness of sanitary procedures undertaken by the *exporting country*, both at its borders and within its territory.

~~The benefits of~~ As well as contributing to the safety of *international trade*, zoning and compartmentalisation may ~~include a contribution to~~ assist *disease* control or eradication within Member Countries~~, and to the safety of *international trade*~~. Zoning may encourage the more efficient use of resources within certain parts of a country ~~to allow trade in certain *commodities* from that *zone* in accordance with the *Terrestrial Code*.~~ and compartmentalisation may allow ~~safe trade due to~~ the functional separation of a *subpopulation* from other domestic or wild animals through biosecurity measures, which a *zone* (through geographical separation) would not achieve. Following a *disease outbreak*, compartmentalisation may be able to take advantage of epidemiological links among *subpopulations* or common practices relating to biosecurity, despite diverse geographical locations, to facilitate *disease* control and/or the resumption of trade.

Community comment:

The words "epidemiological links among subpopulations" are introduced. The intention (well defined or "closed" populations) is very positive, however the wording could be improved/clarified. Maybe "epidemiologically *defined* subpopulations" would be preferable. In addition the intention is that trade from a compartment is not stopped if there is a disease outbreak outside the compartment so the word "resumption" is not correct and should be replaced by "continuation".

The Community suggests the following wording to replace the last sentence above:
"Following a *disease outbreak*, compartmentalisation may be able to take advantage of epidemiological links among defined or restricted *subpopulations* or common practices relating to biosecurity, despite diverse geographical locations, to facilitate *disease* control and/or the continuation of trade".

Zoning and compartmentalisation cannot be applied to all *diseases* but separate requirements will be developed for each *disease* for which the application of zoning or compartmentalisation is considered appropriate.

To regain free status following a *disease outbreak* in a *zone* or *compartment*, Member Countries should follow

the recommendations in the relevant *disease* chapter in the *Terrestrial Code.*

Article 1.3.5.2.

General considerations

The *Veterinary Services* of an *exporting country* which is establishing a *zone* or *compartment* within its territory for *international trade* purposes should clearly define the *subpopulation* in accordance with the ~~measures stipulated~~ recommendations in the relevant chapters in the *Terrestrial Code*, including those on surveillance, and the identification and traceability of live animals. The *Veterinary Services* of an *exporting country* ~~and~~ should be able to explain to the *Veterinary Services* of an *importing country* the basis for its claim of a distinct *animal health status* for the *zone* or *compartment* in such terms.

The procedures used to establish and maintain the distinct *animal health status* of a *zone* or *compartment* should be appropriate to the particular circumstances, and will depend on the epidemiology of the *disease*, environmental factors and applicable biosecurity measures ~~(including movement controls, use of natural and artificial boundaries, commercial management and husbandry practices), and surveillance and monitoring.~~

The authority, organisation and infrastructure of the *Veterinary Services*, including laboratories, must be clearly documented in accordance with the chapter on the evaluation of *Veterinary Services* of the *Terrestrial Code*, to provide confidence in the integrity of the *zone* or *compartment*. The final authority of the *zone* or *compartment*, for the purposes of domestic and international trade, lies within the *Veterinary Administration.*

The *exporting country* should be able to demonstrate, through detailed documentation published through official channels, that it has implemented the ~~measures stipulated~~ recommendations in the *Terrestrial Code* for establishing and maintaining such a *zone* or *compartment*.

An *importing country* should recognise the existence of this *zone* or *compartment* when the appropriate measures recommended in the *Terrestrial Code* are applied and the *Veterinary Administration* of the *exporting country* certifies that this is the case.

The *exporting country* should conduct an assessment of the resources needed and available to establish and maintain a *zone* or *compartment* for *international trade* purposes. These include the human and financial resources, and the technical capability of the *Veterinary Services* (and of the relevant industry, in the case of a *compartment*) including *disease* surveillance and diagnosis.

Biosecurity and surveillance are essential components of zoning and compartmentalization and the arrangements should be developed through cooperation of industry and *Veterinary Services.*

Industry's responsibilities in most cases include the application of biosecurity measures, quality assurance schemes, monitoring the efficacy of the measures, documenting corrective actions, conducting surveillance, rapid reporting and maintenance of records in a readily accessible form.

The *Veterinary Services* should provide movement certification, periodic inspections of facilities, biosecurity measures, records and surveillance procedures. *Veterinary Services* should audit surveillance and reporting and conduct or oversee laboratory diagnostic examinations.

Community comment:

In the last paragraph above, a requirement as regards the continuous documentation and risk assessment of the disease situation in the vicinity of a compartment as well as a clear reference to the biosecurity plan should be added. Such an assessment is of utmost importance in particular in a situation when trade is foreseen from a compartment in a Country/zone where a certain disease is endemic or recent outbreaks are suspected or confirmed in the area. Moreover, the first sentence is not clear and should be reworded.

Therefore the Community proposes the following wording:

"Industry's responsibilities, in particular concerning compartmentalization, include the application of biosecurity measures, documenting and recording movements of animals and personnel, quality assurance schemes, monitoring the efficacy of the measures, documenting corrective actions, conducting surveillance, rapid reporting and maintenance of records in a readily accessible form.

The Veterinary Services should carry out audit of the biosecurity plan including surveillance and reporting; conduct or oversee laboratory diagnostic examinations; check animal movement records and continuously check both documents and risk assessment of the disease situation in the vicinity of the compartment. They should be able to provide documentation on all these aspects as well information on the movements of animals."

~~Article 1.3.5.3.~~

~~**Prerequisite considerations in defining a zone or compartment**~~

~~The *exporting country* should conduct an assessment of the resources needed and available to establish and maintain a *zone* or *compartment* for *international trade* purposes. These include the human and financial resources, and the technical capability of the *Veterinary Services* (and of the relevant industry, in the case of a *compartment*).~~

Article 1.3.5.4.

Community comment:

The Community proposes the renumbering of the Articles following the deletion of Article 1.3.5.3.

Principles for defining a zone or compartment

In conjunction with the above considerations, the following principles should apply when Member Countries define~~ing~~ a *zone* or a *compartment* ~~should be based on the application of the following principles.~~:

1. The extent of a *zone* and its geographical limits should be established by the *Veterinary Administration* on the basis of natural, artificial and/or legal boundaries, and made public through official channels.

2. The ~~requirements regarding~~ factors defining a *compartment* should be established by the *Veterinary Administration* on the basis of relevant criteria such as ~~biosecurity~~ management and husbandry practices related to biosecurity, and made public through official channels.

3. Animals and herds belonging to such *subpopulations* need to be ~~clearly~~ recognisable as such through a clear epidemiological separation from other animals and all things presenting a *disease* risk. For a *zone*

or *compartment*, the *Veterinary Administration* ~~must~~ should document in detail the measures taken to ensure the identification of the *subpopulation* and the ~~recognition~~ establishment and maintenance of its *animal health status* through a *biosecurity plan*. The ~~procedures~~ measures used to establish and maintain the distinct *animal health status* of a *zone* or *compartment* should be appropriate to the particular circumstances, and will depend on the epidemiology of the *disease*, environmental factors, the *animal health status* of animals in adjacent areas, applicable biosecurity measures (including movement controls, use of natural and artificial boundaries, the spatial separation of animals, and commercial management and husbandry practices), and surveillance.

4. The existence of a valid animal traceability system is a prerequisite to assess the integrity of the *zone* or *compartment*. Animals within the *zone* or *compartment* should be identified in such a way that their history can be audited. Depending on the system of production, identification may be done at the herd, flock lot or individual animal level. All animal movements into and out of the *zone* or *compartment* should be well documented, controlled and supervised.

Community comment:

The Community proposes the following replacement paragraph:

"The existence of a valid animal traceability system is a prerequisite to assess the integrity of the *zone* or *compartment*. Animals within the *zone* or *compartment* should be identified and their movements documented in such a way that their history can be audited. Depending on the system of production, identification and documentation may be done at the herd, flock lot or individual animal level. All animal movements into and out of the *zone* or *compartment* should be well documented, controlled and supervised."

5. For a *compartment*, the *biosecurity plan* should describe the partnership between the relevant enterprise/industry and the *Veterinary Administration,* and their respective responsibilities. It should also describe the routine operating procedures to provide clear evidence that the surveillance conducted, the live animal identification and traceability system, and the management practices are adequate to meet the definition of the *compartment*. In addition to information on animal movement controls, the plan should include herd or flock production records, feed sources, surveillance results, birth and death records, visitor logbook, morbidity and mortality history, medications, vaccinations, documentation of training and any other criteria necessary for evaluation of risk mitigation. The information required may vary according to the species and *disease(s)* under consideration. The *biosecurity plan* should also describe how the measures will be audited to ensure that the risks are regularly re-assessed and the measures adjusted accordingly.

6. ~~Thus defined, the *zones* and *compartments* constitute the relevant *subpopulations* for the application of the recommendations in Part 2 of the *Terrestrial Code*.~~

Article 1.3.5.5.

Sequence of steps to be taken in ~~defining~~ establishing a zone/compartment and having it recognised for international trade purposes

There is no single sequence of steps which ~~must~~ should be followed in ~~defining~~ establishing a *zone* or a *compartment*. The steps that the *Veterinary Services* of the *importing country* and the *exporting country* choose and

implement will generally depend on the circumstances existing within ~~a~~ the countries ~~y~~ and at ~~its~~ their borders, and their trading history. The recommended steps are:

1. For zoning

   a) The *exporting country* identifies a geographical area within its territory, which it considers to contain an animal *subpopulation* with a distinct *health status* with respect to a specific *disease*/specific *diseases*, based on surveillance ~~and monitoring~~.

   b) The *exporting country* ~~identifies~~ describes in the *biosecurity plan* for the *zone* the ~~procedures~~ measures which are being, or ~~could~~ will be~~, employed~~ applied to distinguish such an area epidemiologically from other parts of its territory, in accordance with the ~~measures stipulated~~ recommendations in the *Terrestrial Code*.

   c) The *exporting country* provides the above information ~~above~~ to the *importing country*, ~~and explains that~~ with an explanation of why the area can be treated as an epidemiologically separate~~d~~ zone for *international trade* purposes.

   d) The *importing country* determines whether it ~~may~~ accepts such an area as a *zone* for the importation of *animals* and animal products, taking into account:

      i) an evaluation of the *exporting country*'s *Veterinary Services*;

      ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;

      iii) its own animal health situation with respect to the *disease(s)* concerned; and

      iv) other relevant OIE standards.

   e) The *importing country* notifies the *exporting country* of the result of its determination and the underlying reasons, within a reasonable period of time, being ~~either~~:

      i) recognition of the *zone*; or

      ii) request for further information; or

      iii) rejection of the area as a *zone* for *international trade* purposes.

   f) An attempt should be made to resolve any differences over the definition of the *zone*, either in the interim or finally, by using an agreed mechanism to reach consensus ~~(~~such as the OIE in-house procedure for settlement of disputes (Article 1.3.1.3.) ~~settlement mechanism)~~.

   g) The *Veterinary Administrations* of the *importing country* and the *exporting country* ~~may~~ should enter into a formal agreement ~~defining~~ recognizing the *zone*.

2. For compartmentalisation

   a) Based on discussions with the relevant enterprise/industry, the *exporting country* identifies within its territory a *compartment* of one or more *establishments* or other premises owned by an

enterprise(s) which operates under ~~a~~ common ~~biosecurity~~ management ~~system~~ practices related to biosecurity, and which ~~it considers~~ contains an identifiable animal *subpopulation* with a distinct *animal health status* with respect to a specific *disease*/specific *diseases*; ~~and~~ the *exporting country* describes how ~~that~~ this status is maintained through a partnership between the relevant enterprise/industry and the *Veterinary Services* of the *exporting country*.

b) The *exporting country* examines the *compartment*'s ~~'~~*biosecurity plan* ~~management manual' produced by the enterprise/industry for such establishment(s),~~ and confirms through an audit that:

   i) ~~such establishment(s)~~ the *compartment* is~~(are)~~ epidemiologically closed throughout its routine operating procedures as a result of effective implementation of its ~~'~~*biosecurity plan* ~~management manual'~~; and

   ii) the surveillance and monitoring programme in place is appropriate to verify the ~~free~~ status of such *establishment(s)* with respect to such *disease(s)*.

c) The *exporting country* ~~identifies~~ describes the ~~such an enterprise to be a *free* compartment~~, in accordance with the ~~measures stipulated~~ recommendations in the *Terrestrial Code*.

d) The exporting country provides the above information ~~above~~ to the *importing country*, ~~and explains that~~ with an explanation of why such an enterprise can be treated as an epidemiologically separate~~d~~ *compartment* for international trade purposes.

e) The *importing country* determines whether it ~~may~~ accepts such an enterprise as a *compartment* for the importation of *animals* and animal products, taking into account:

   i) an evaluation of the *exporting country's Veterinary Services*;

   ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;

   iii) its own animal health situation with respect to the *disease(s)* concerned; and

   iv) other relevant OIE standards.

f) The *importing country* notifies the *exporting country* of the result of its examination and the underlying reasons, within a reasonable period of time, being ~~either~~:

   i) recognition of the *compartment*; or

   ii) request for further information; or

   iii) rejection of such an enterprise as a *compartment* for international trade purposes.

g) An attempt should be made to resolve any differences over the definition of the *compartment*, either in the interim or finally, by using an agreed mechanism to reach consensus ~~(~~such as the OIE in-house procedure for settlement of disputes (Article 1.3.1.3.) ~~settlement mechanism)~~.

h) The *Veterinary Administrations* of the *importing country* and the *exporting country* ~~may~~ should enter into a formal agreement ~~defining~~ recognizing the *compartment*.

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– text deleted

Appendix V

CHAPTER 2.2.5.

RABIES

Community comments:

The Community supports these proposals but would like the comments below be taken into account.

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 or with a recombinant vaccine expressing the rabies virus protein;

Community comment:

The Community proposes the following wording:

"b) not more than one year prior to shipment or according to the manufacturer's instructions in the case of a booster vaccination;

c) with an inactivated virus vaccine or with a live recombinant vaccine expressing the rabies virus glycoprotein."

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 prescribed in the *Terrestrial Manual* with a positive result equivalent to at least 0.5 IU/ml;

OR

5. have not been vaccinated against rabies or do not meet all the conditions set out in points 1), 2), 3) and 4) above; in such cases, the *importing country* may require the placing of the animals in a *quarantine station* located on its territory, in conformity with the conditions stipulated in its animal health legislation.

Article 2.2.5.6.

When importing from countries considered infected with rabies, *Veterinary Administrations* should require:

for domestic ruminants, equines and pigs

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

1. showed no clinical sign of rabies on the day of shipment;

2. were kept for the 6 months prior to shipment in an *establishment* where separation from wild and feral animals was maintained and where no *case* of rabies was reported for at least 12 months prior to shipment.

Article 2.2.5.7.

When importing from countries considered infected with rabies, *Veterinary Administrations* should require:

for laboratory reared rodents and lagomorphs, and lagomorphs or wild mammals (other than non-human primates) reared under confined conditions

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.

Appendix VI

CHAPTER 2.2.10.

FOOT AND MOUTH DISEASE

Community comments:

The Community could support these proposals but the comments below would have to be taken into account.

The Community supports the concept of regionalization that can apply differently depending on specific situations.

If this definition of *containment zone* was to be accepted, it would then be useful to further expand the Chapter 1.3.5. on Zoning and compartmentalisation. Thus the 2 types of zoning, i.e. one defining a free zone in a previously infected country or zone and the other delimiting an infected zone after an outbreak in a previously free country or zone, could be clearly distinguished for the sake of clarification and better understanding. Furthermore, the possibility and opportunities to apply such a concept to other chapters should be quickly considered.

However the Community would have preferred the concept be further developed before applying it to FMD, one of the most contagious disease.

If applied to this disease, the Community considers at least that geographical and time criteria should be required for the establishment of a containment zone (see proposed wording below in proposed article 2.2.10.6 bis).

It also considers that a containment zone could not be established where vaccination is practiced without causing additional risk. The validity of the subsequent shortening of the time period necessary to recover the free status in the area outside the containment zone is not supported by epidemiological data coming from countries where vaccination is practiced. In this case it would be necessary to consider further risk mitigation measures such as deboning and maturation of traded meat (see proposed wording below in proposed article 2.2.10.20).

(Definition) once adopted, this will move to Chapter 1.1.1.

Containment zone

means a defined zone around and including suspected or infected *establishments*, taking into account the epidemiological factors and results of investigations, where control measures to prevent the spread of the infection are applied.

Article 2.2.10.1.

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

days.

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

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

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

The following defines the occurrence of FMDV infection:

1. FMDV has been isolated and identified as such from an animal or a product derived from that animal; or

2. viral antigen or viral RNA specific to one or more of the serotypes of FMDV has been identified in samples from one or more animals showing clinical signs consistent with FMD, or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV; or

3. antibodies to structural or non structural proteins of FMDV that are not a consequence of vaccination, have been identified in 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.

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

Article 2.2.10.2.

FMD free country where vaccination is not practised

Susceptible animals in the FMD free country should be separated 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 should be implemented.

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;

   d) no vaccinated animal has been introduced since the cessation of vaccination;

~~and~~

3. supply documented evidence that:

a) surveillance for both FMD and FMDV infection in accordance with Appendix 3.8.7. is in operation~~, and that~~

b) 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.

The information required in points 2 and 3a) above, should be submitted annually to the OIE.

Article 2.2.10.3.

FMD free country where vaccination is practised

Susceptible animals in the FMD free country where vaccination is practiced should be separated 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 should be implemented.

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 circulation for the past 12 months, with documented evidence that:

a) surveillance for FMD and FMDV circulation in accordance with Appendix 3.8.7. 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.

The information required in point 2 above, should be submitted annually to 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 then notify the OIE and provide evidence showing that FMDV circulation has not occurred during that period.

Article 2.2.10.4.

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 infected. In defining such zones the principles of Chapter 1.3.5. should be followed. Susceptible animals in the FMD free zone should be separated from the rest of the country ~~if infected,~~ and from neighbouring ~~infected~~ countries, if of a

different health status, by a *buffer zone*, or physical or geographical barriers, and ~~A~~animal health measures that effectively prevent the entry of the virus should 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 within the proposed FMD free zone:

   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 2.2.10.8.;

Community comment:

It is proposed to align the text with Article 2.2.10.5. and to delete paragraph 3.

3. supply documented evidence that surveillance for both FMD and FMDV infection in accordance with Appendix 3.8.7. is in operation in the proposed 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 proposed FMD free zone and, if applicable, the *buffer zone* or physical or geographical barriers,

   c) the system for preventing the entry of the virus (including the control of the movement of susceptible animals) into the proposed FMDV free zone (in particular if the procedure described in Article 2.2.10.8. is implemented),

   and supply documented evidence that these are properly implemented and supervised.

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

The information required in points 2, 3 and 4 c) above should be submitted annually as well as any relevant changes under points 4 a) and b).

Article 2.2.10.5.

FMD free zone where vaccination is practised

An FMD free zone where vaccination is practised can be established in either an FMD free country where vaccination is not practised or in a country of which parts are infected. In defining such zones the principles of Chapter 1.3.5. should be followed. Susceptible animals in the FMD free zone where

vaccination is practiced should be separated from the rest of the country~~, if infected,~~ and from neighbouring ~~infected~~ countries, if of a different health status, by a *buffer zone*, or physical or geographical barriers, and ~~A~~animal health measures that effectively prevent the entry of the virus should be implemented.

A country in which an FMD free zone where vaccination is practised is to be established should:

1. have a record of regular and prompt animal disease reporting;

2. send a declaration to the OIE that it wishes to establish an FMD free zone where vaccination is practised, where there has been no *outbreak* of FMD for the past 2 years and no evidence of FMDV circulation for the past 12 months, with documented evidence that surveillance for FMD and FMDV circulation in accordance with Appendix 3.8.7. is in operation in the proposed FMD free zone;

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 circulation,

   b) the boundaries of the proposed FMD free zone where vaccination is practised and, if applicable, the *buffer zone* or physical or geographical barriers,

   c) the system for preventing the entry of the virus into the proposed FMD free zone (in particular if the procedure described in Article 2.2.10.8. is implemented),

   and supply evidence that these are properly implemented and supervised;

~~5. supply documented evidence that it has a system of intensive and frequent surveillance for FMD in the FMD free zone where vaccination is practised.~~

The proposed 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. The information required in points 2, 3 and 4 c) above should be submitted annually as well as any relevant changes under points 4 a) and b).

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 is required and evidence must be provided showing that FMDV infection has not occurred in the said zone during that period

Article 2.2.10.6.

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 2.2.10.6 (bis) (under study)

Establishment of a containment zone within an FMD free country or zone

Community comment:

The Community supports the intention behind the draft put forward but, in line with the general comments, believes the wording needs to be further clarified.

It is suggested to replace the text of this Article by the following wording:

"Establishment of a containment zone within an FMD free country or zone

In the event of a limited outbreak within an FMD free country or zone with or without vaccination, a *containment zone* can be established for the purpose of minimizing the impact on the entire country or *zone* FMD free with or without vaccination. For this to be achieved, the *Veterinary Administration* should provide documented evidence that:

1. the outbreak is limited based on the following factors:

a) immediately on suspicion, a rapid response has been made as follows:

(i) notification has been made timely to the authorities

(ii) standstill of animal movements has at least been imposed on the suspect holding and any known or suspected contacts ;

(iii) epidemiological investigation (trace-back, trace-forward) has been commenced;

b) following confirmation

(i) a single "*containment zone*" has been defined of at least 10 km around each outbreak;

(ii) standstill of animal movements has been imposed for an appropriate time and in an appropriate area of the country or zone, at least including the whole containment zone;

(iii) all cases (and outbreaks) have been shown to be epidemiologically linked and are within the "*containment zone*", based on the epidemiological investigation (trace-back, trace-forward);

(iv) a *stamping-out policy* has been applied;

2. increased passive and targeted surveillance in accordance with Appendix 3.8.7. in the rest of the country or zone is carried to detect any evidence of infection or absence of virus circulation in case of vaccination;

3. measures to prevent spread of the infection from the *containment zone* to the rest of the country or zone, including ongoing surveillance in the *containment zone*, are in place, where necessary by establishing a *buffer zone*.

Irrespective of the provisions of Article 2.2.10.7., the free status of the areas outside the *containment zone* would be suspended until at least one incubation period has elapsed following the establishment of the containment zone and the following conditions are complied with:

1. the containment zone is clearly established, by complying with points 1 to 3 above;

2. surveillance, in accordance with Appendix 3.8.7., demonstrates that there are no undetected cases in the "containment zone";

3. increased surveillance in accordance with Appendix 3.8.7. in the rest of the country or zone has been carried out and has not detected any evidence of infection;

The recovery of the FMD free status of the *containment zone* should follow the provisions of Article 2.2.10.7."

In the event of a limited outbreak within an FMD free country or zone with or without vaccination, a *containment zone* can be established for the purpose of minimizing the impact on the entire country or *zone*. For this to be achieved, the *Veterinary Administration* should provide documented evidence that:

1. the outbreak is limited based on the following factors:
   a) immediately on suspicion, a rapid response including notification has been made;
   b) standstill of animal movements has been imposed;
   c) epidemiological investigation (trace-back, trace-forward) has been completed;
   d) a single "containment zone" has been defined;
   e) the infection has been confirmed;
   f) the primary case and its source have been identified;
   g) all cases have been shown to be epidemiologically linked and are within the "containment zone";
2. surveillance, in accordance with Appendix 3.8.7., demonstrates that there are no undetected cases in the "containment zone";
3. a *stamping-out policy* has been applied;
4. increased passive and targeted surveillance in accordance with Appendix 3.8.7. in the rest of the country or zone has been carried out and has not detected any evidence of infection;
5. measures to prevent spread of the infection from the *containment zone* to the rest of the country or zone, including ongoing surveillance in the *containment zone*, are in place.

The free status of the areas outside the *containment zone* would be suspended pending the establishment of the *containment zone*. The suspension of free status of these areas could be lifted irrespective of the provisions of Article 2.2.10.7., once the containment zone is clearly established, by complying with points 1 to 5 above.

The recovery of the FMD free status of the *containment zone* should follow the provisions of Article 2.2.10.7.

Article 2.2.10.7.

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 3.8.7.; 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 3.8.7.; 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 3.8.7., 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.

    Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 2.2.10.2. or 2.2.10.4. applies.

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 3.8.7. are applied, provided that the serological surveillance based on the detection of antibodies to non structural proteins of FMDV demonstrates the absence of virus circulation; or

    b) 18 months after the last *case* where a *stamping-out policy* is not applied, but emergency vaccination and serological surveillance in accordance with Appendix 3.8.7. are applied, provided that the serological surveillance based on the detection of antibodies to non structural proteins of FMDV demonstrates the absence of virus circulation.

Article 2.2.10.8.

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

FMD susceptible animals should only leave the infected zone if moved by mechanised transport to the nearest designated *abattoir* located in the *buffer zone* directly to slaughter.

In the absence of an *abattoir* in the *buffer zone*, live FMD susceptible animals can be transported to the nearest abattoir in a free zone directly to 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* during the time it is handling the meat of animals from the infected zone;

6. *vehicles* and the *abattoir* must be subjected to thorough cleansing and *disinfection* immediately after use.

All products obtained from the animals and any products coming 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.

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 2.2.10.11.

Article 2.2.10.9.

When importing from FMD free countries where vaccination is not practised or FMD free 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.

3. have not been vaccinated.

Article 2.2.10.10.

When importing from FMD free countries where vaccination is practised or from FMD free 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 or zone 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 2.2.10.11.

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 ten-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, 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 ten-kilometer 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 ten-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 2.2.10.12.

When importing from FMD free countries where vaccination is not practised or FMD free 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. or Appendix 3.2.2., as relevant.

Article 2.2.10.13.

When importing from FMD free countries where vaccination is not practised or FMD free 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. or Appendix 3.2.2., as relevant.

Article 2.2.10.14.

When importing from FMD free countries where vaccination is practised or from FMD free 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. or Appendix 3.2.2., as relevant;

    b) was stored in the country of origin for a period of at least one month following collection, and during this period no animal on the *establishment* where the donor animals were kept showed any sign of FMD.

Article 2.2.10.15.

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. or Appendix 3.2.2., 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, and during this period no animal on the *establishment* where the donor animals were kept showed any sign of FMD.

Article 2.2.10.16.

Irrespective of the FMD status of the *exporting country* or *zone*, *Veterinary Administrations* should authorise without restriction on account of FMD the import or transit through their territory of *in vivo* derived embryos of cattle subject to the presentation of an *international veterinary certificate* attesting that 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 2.2.10.17.

When importing from FMD free countries where vaccination is not practised or FMD free 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;

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 2.2.10.12., 2.2.10.13., 2.2.10.14. or 2.2.10.15., as relevant;

3. the oocytes 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 2.2.10.18.

When importing from FMD free countries where vaccination is practised or from FMD free 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;

   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 2.2.10.12., 2.2.10.13., 2.2.10.14. or 2.2.10.15., as relevant;

4. the oocytes 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 2.2.10.19.

When importing from FMD free countries where vaccination is not practised or FMD free 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 2.2.10.9., Article 2.2.10.10. or Article 2.2.10.11.;

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 2.2.10.20.

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

for *fresh meat* of cattle and buffalo (*Bubalus bubalis*) (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 2.2.10.9., Article 2.2.10.10. or Article 2.2.10.11.;

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 comment:

In line with the general comments and the specific comment in the article 2.2.10.6 bis (under study), the Community suggests to add the following point:

3. (under study) in case of the presence of a *containment zone* within the free country or zone where vaccination is practised and until the recovery of the FMD free status of the *containment zone*, the meat comes from deboned carcasses:
a) from which the major lymphatic nodes have been removed;
b) which, prior to deboning, have been submitted to maturation at a temperature above +°2°C for a minimum period of 24 hours following slaughter and in which the pH value was below 6.0 when tested in the middle of both the longissimus dorsi.

Article 2.2.10.21.

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

for *fresh meat* or *meat products* of pigs and ruminants other than cattle and buffalo

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 2.2.10.9., Article 2.2.10.10. or Article 2.2.10.11.;

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 2.2.10.22.

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 cattle and buffalo (*Bubalus bubalis*) (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 a ten-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 nodes have been removed;

    b) which, prior to deboning, have been submitted to maturation at a temperature above + 2°C for a minimum period of 24 hours following slaughter and in which the pH value was below 6.0 when tested in the middle of both the longissimus dorsi.

Article 2.2.10.23.

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 2.2.10.24.

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 2.2.10.9., Article 2.2.10.10. or Article 2.2.10.11.

Article 2.2.10.25.

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

for *milk*, cream, milk powder and *milk products*

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

1. these products:

    a) originate from herds or flocks which were not infected or suspected of being infected with 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 2.2.10.26.

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 2.2.10.27.

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 Article 3.6.2.2., Article 3.6.2.3. and Article 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 2.2.10.28.

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 2.2.10.29.

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 FMD susceptible wild animals

the presentation of an *international veterinary certificate* attesting that these products are derived from animals that have been killed ~~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 2.2.10.30.

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

for skins and trophies derived from FMD susceptible wild animals

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.

Appendix VII

CHAPTER 2.2.13.

BLUETONGUE

Community comments:

The Community will have difficulties to support these proposals if the points noted below are not taken into account.

Article 2.2.13.1.

For the purposes of the *Terrestrial Code,* the *infective period* for bluetongue virus (BTV) shall be 60 days.

The global BTV distribution is currently between latitudes of approximately 5~~0~~3°N and 34°S but is known to be expanding in the northern hemisphere.

In the absence of clinical disease in a country or *zone* within this part of the world, its BTV status should be determined by an ongoing surveillance programme (in accordance with Appendix 3.8.X.). The programme may need to be adapted to target parts of the country or *zone* at a higher risk due to historical, geographical and climatic factors, ruminant population data and *Culicoides* ecology, or proximity to enzootic or incursional zones as described in Appendix 3.8.X.

All countries or *zones* adjacent to a country or *zone* not having free status should be subjected to similar surveillance. The surveillance should be carried out over a distance of at least 100 kilometres from the border with that country or *zone,* but a lesser distance could be acceptable if there are relevant ecological or geographical features likely to interrupt the transmission of BTV or a bluetongue surveillance programme (in accordance with Appendix 3.8.X.) in the country or *zone* not having free status supports a lesser distance.

Community comment:

It is important for international trade that countries are reminded that e.g. meat and milk cannot transmit the disease.

Therefore the Community proposes that the following sentence is inserted in article 2.2.13.1 if the deletion proposed at 2.2.13.5 is agreed.

"Commodities not referred to in this chapter should be considered as not having the potential to spread BTV when they are the subject of international trade".

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

Article 2.2.13.2.

BTV free country or zone

1. A country or a *zone* may be considered free from BTV when bluetongue is notifiable in the whole country and either:

    1. the country or *zone* lies wholly north of 5~~0~~3°N or south of 34°S, and is not adjacent to a country or *zone* not having a free status; or

    2. a surveillance programme in accordance with Appendix 3.8.X. has demonstrated no evidence of BTV in the country or *zone* during the past 2 years; or

    3. a surveillance programme has demonstrated no evidence of *Culicoides* likely to be competent BTV vectors in the country or *zone*.

2. A BTV free country or zone in which surveillance has found no evidence that *Culicoides* likely to be competent BTV vectors are present will not lose its free status through the importation of vaccinated, seropositive or infective animals, or semen or embryos/ova from infected countries or zones.

3. A BTV free country or zone in which surveillance has found evidence that *Culicoides* likely to be competent BTV vectors are present will not lose its free status through the importation of vaccinated or seropositive animals from infected countries or zones, provided:

    a) the animals have been vaccinated in accordance with the *Terrestrial Manual at* least 60 days prior to dispatch with a vaccine which covers all serotypes whose presence in the source population has been demonstrated through a surveillance programme in accordance with Appendix 3.8.X., and that the animals are identified in the accompanying certification as having been vaccinated; or

    b) the animals are not vaccinated, and a surveillance programme in accordance with Appendix 3.8.X. has been in place in the source population for a period of 60 days immediately prior to dispatch, and no evidence of BTV transmission has been detected.

4. A BTV free country or zone adjacent to an infected country or zone should include a *zone* as described in Article 2.2.13.1. in which surveillance is conducted in accordance with Appendix 3.8.X. Animals within this *zone* must be subjected to continuing surveillance. The boundaries of this *zone* must be clearly defined, and must take account of geographical and epidemiological factors that are relevant to BTV transmission.

Article 2.2.13.3.

BTV seasonally free zone

A BTV seasonally free zone is a part of an infected country or zone for which for part of a year, surveillance demonstrates no evidence either of BTV transmission or of adult *Culicoides* likely to be competent BTV vectors.

For the application of Articles 2.2.13.7., 2.2.13.10. and 2.2.13.14., the seasonally free period is taken to commence the day following the last evidence of BTV transmission (as demonstrated by the surveillance programme), or of the cessation of activity of adult *Culicoides likely* to be competent BTV vectors.

For the application of Articles 2.2.13.7., 2.2.13.10. and 2.2.13.14., the seasonally free period is taken to conclude either:

1. at least 28 days before the earliest date that historical data show bluetongue virus activity has recommenced; or

2. immediately if current climatic data or data from a surveillance programme indicate an earlier resurgence of activity of adult *Culicoides* likely to be competent BTV vectors.

A BTV seasonally free zone in which surveillance has found no evidence that *Culicoides* likely to be competent BTV vectors are present will not lose its free status through the importation of vaccinated, seropositive or infective animals, or semen or embryos/ova from infected countries or zones.

Article 2.2.13.4.

BTV infected country or zone

A BTV infected country or zone is a clearly defined area where evidence of BTV has been reported during the past 2 years.

~~Article 2.2.13.5.~~

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

~~1. ruminants and other BTV susceptible herbivores;~~

~~2. semen of these species;~~

~~3. embryos/ova of these species;~~

~~4. *pathologicalmaterial*and biological products (from these species) (see Chapter 1.4.5. and Section 1.5.).~~

~~Other *commodities* should be considered as not having the potential to spread BTV when they are the subject of *international trade.*~~

Community comment:

The wording of the last sentence is not captured elsewhere and needs to be retained in order that it is clear to all countries that only live ruminants and other susceptible herbivores, semen and embryos/ova from these species and pathological materials are the only commodities considered as having the potential to spread BTV when they are

the subject of international trade. It is important for international trade that countries are reminded that e.g. meat and milk cannot transmit the disease.

Therefore the Community proposes that this is clearly stated in article 2.2.13.1.

Article 2.2.13.~~6.~~5.

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

for ruminants and other BTV susceptible herbivores

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

1. the animals were kept in a BTV free country or zone since birth or for at least 60 days prior to shipment; or

2. the animals were kept in a BTV free country or zone for at least 28 days, then were subjected, with negative results, to a serological test to detect antibody to the BTV group according to the *Terrestrial Manual* and remained in the BTV free country or zone until shipment; or

3. the animals were kept in a BTV free country or zone for at least 7 days, then were subjected, with negative results, to an agent identification test according to the *Terrestrial Manual,* and remained in the BTV free country or zone until shipment; or

4. the animals:

   a) were kept in a BTV free country or zone for at least 7 days;

   b) were vaccinated in accordance with the *Terrestrial Manual* 60 days before the introduction into the free country or zone against all serotypes whose presence in the source population has been demonstrated through a surveillance programme as described in Appendix 3.8.X;

   c) were identified as having been vaccinated; and

   d) remained in the BTV free country or zone until shipment;

AND

5. if the animals were exported from a free zone, either:

   a) did not transit through an infected zone during transportation to *the place of shipment*; or

   b) were protected from attack from *Culicoides* likely to be competent BTV vectors at all times when transiting through an infected zone; or

c) had been vaccinated in accordance with point 4 above.

Article 2.2.13.~~7.~~6.

When importing from BTV seasonally free zones, *Veterinary Administrations* should require:

for ruminants and other BTV susceptible herbivores

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

1. were kept during the seasonally free period in a BTV seasonally free zone for at least 60 days prior to shipment; or

This point means that animals less than 60 days of age, like calves and lambs, cannot be traded from a seasonally free zone, though these animals, if born after the beginning of the seasonally free period, represent no risk. The Community thus proposes to the following for point 1:

"were kept during the seasonally free period in a BTV seasonally free zone since birth or for at least 60 days prior to shipment; or"

2. were kept during the BTV seasonally free period in a BTV seasonally free zone for at least 28 days prior to shipment, and were subjected during the residence period in the zone to a serological test to detect antibody to the BTV group according to the *Terrestrial Manual,* with negative results, carried out at least 28 days after the commencement of the residence period; or

3. were kept during the BTV seasonally free period in a BTV seasonally free zone for at least 14 days prior to shipment, and were subjected during the residence period in the zone to an agent identification test according to the *Terrestrial Manual,* with negative results, carried out at least 14 days after the commencement of the residence period; or

4. were kept during the seasonally free period in a BTV seasonally free zone, and were vaccinated in accordance with the *Terrestrial Manual* 60 days before the introduction into the free country or zone against all serotypes whose presence in the source population has been demonstrated through a surveillance programme in accordance with Appendix 3.8.X.~~,~~ and were identified as having been vaccinated and remained in the BTV free country or zone until shipment;

AND

5. if the animals were exported from a free zone, either:

   a) did not transit through an infected zone during transportation to the *place of shipment*; or

   b) were protected from attack from *Culicoides* likely to be competent BTV vectors at all times when transiting through an infected zone; or

c) were vaccinated in accordance with point 4 above.

Article 2.2.13.~~8.~~7.

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

for ruminants and other BTV susceptible herbivores

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

1. were protected from attack from *Culicoides* likely to be competent BTV vectors for at least 60 days prior to shipment; or

2. were protected from attack from *Culicoides* likely to be competent BTV vectors for at least 28 days prior to shipment, and were subjected during that period to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, with negative results, carried out at least 28 days after introduction into the *quarantine station*; or

3. were protected from attack from *Culicoides* likely to be competent BTV vectors for at least 14 days prior to shipment, and were subjected during that period to an agent identification test according to the *Terrestrial Manual,* with negative results, carried out at least 14 days after introduction into the *quarantine station*; or

4. were vaccinated in accordance with the *Terrestrial Manual* at least 60 days before shipment, against all serotypes whose presence in the source population has been demonstrated through a surveillance programme in accordance with Appendix 3.8.X., and were identified in the accompanying certification as having been vaccinated; or

5. are not vaccinated, a surveillance programme in accordance with Appendix 3.8.X. has been in place in the source population for a period of 60 days immediately prior to shipment, and no evidence of BTV transmission has been detected;

AND

6. were protected from attack from *Culicoides* likely to be competent BTV vectors during transportation to the *place of shipment*; or

7. were vaccinated in accordance with the *Terrestrial Manual* 60 days before shipment or had antibodies against all serotypes whose presence in the zones of transit has been demonstrated through a surveillance programme in accordance with Appendix 3.8.X.

Article 2.2.13.~~9.~~8.

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

for semen of ruminants and other BTV susceptible herbivores

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

1. the donor animals:

    a) were kept in a BTV free country or zone for at least 60 days before commencement of, and during, collection of the semen; or

    b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after the last collection for this consignment, with negative results; or

    c) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

2. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.1.

Article 2.2.13.~~10.~~9.

When importing from BTV seasonally free zones, *Veterinary Administrations* should require:

for semen of ruminants and other BTV susceptible herbivores

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

1. the donor animals:

    a) were kept during the BTV seasonally free period in a seasonally free zone for at least 60 days before commencement of, and during, collection of the semen; or

    b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment; or

    c) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

2. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.1.

Article 2.2.13.~~11.~~10.

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

for semen of ruminants and other BTV susceptible herbivores

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

1. the donor animals:

   a) were protected from attack from *Culicoides* likely to be competent BTV vectors for at least 60 days before commencement of, and during, collection of the semen; or

   b) were subjected to a serological test according to the *Terrestrial Manual to* detect antibody to the BTV group, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment; or

   c) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolationtest) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

2. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.1.

Article 2.2.13.~~12.~~11.

Regardless of the bluetongue status of the *exporting country*, *Veterinary Administrations* of *importing countries* should require:

for *in vivo* derived bovine embryos /oocytes

the presentation of an *international veterinary certificate* attesting that the embryos/oocytes were collected, processed and stored in conformity with the provisions of Appendix 3.3.1. or Appendix 3.3.3., as relevant.

Article 2.2.13.~~13.~~12.

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

for *in vivo* derived embryos of ruminants (other than bovines) and other BTV susceptible herbivores

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

1. the donor females:

   a) were kept in a BTV free country or zone for at least the 60 days prior to, and at the time of, collection of the embryos; or

   b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after collection, with negative results; or

   c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;

2. the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.2.13.~~14.~~13.

When importing from BTV seasonally free zones, *Veterinary Administrations* should require:

for *in vivo* derived embryos/oocytes of ruminants (other than bovines) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

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

1. the donor females:

   a) were kept during the seasonally free period in a seasonally free zone for at least 60 days before commencement of, and during, collection of the embryos/oocytes; or

   b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after collection, with negative results; or

   c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;

2. the embryos/oocytes were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.2.13.~~15.~~14.

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

for *in vivo* derived embryos/oocytes of ruminants (other than bovines) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

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

1. the donor females:

   a) were protected from attack from *Culicoides* likely to be competent BTV vectors for at least 60 days before commencement of, and during, collection of the embryos/oocytes; or

   b) were subjected to a serological test according to the *Terrestrial Manual to* detect antibody to the BTV group, between 21 and 60 days after collection, with negative results; or

   c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;

2. the embryos/oocytes were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.2.13.~~16.~~15.

Protecting animals from Culicoides attack

When transporting animals through BTV infected countries or zones, *Veterinary Administrations* should require strategies to protect animals from attack from *Culicoides* likely to be competent BTV vectors during transport, taking into account the local ecology of the vector.

Potential risk management strategies include:

1. treating animals with chemical repellents prior to and during transportation;
2. *loading,* transporting and *unloading* animals at times of low vector activity (i.e. bright sunshine, low temperature);
3. ensuring *vehicles* do not stop en route during dawn or dusk, or overnight, unless the animals are held behind insect proof netting;
4. darkening the interior of the *vehicle,* for example by covering the roof and/or sides of *vehicles* with shadecloth;
5. surveillance for vectors at common stopping and offloading points to gain information on seasonal

variations;

6. using historical, ongoing and/or BTV modelling information to identify low risk ports and transport routes.

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APPENDIX 3.X.X.

GUIDELINES FOR THE SURVEILLANCE OF BLUETONGUE

Community comments:

The Community supports these proposals, except for the comment below.

Article 3.X.X.1.

Introduction

This Appendix defines the principles and provides a guide for the surveillance of bluetongue (BT) in accordance with Appendix 3.8.1., applicable to countries seeking recognition for a declared BT status, with or without the use of vaccination. This may be for the entire country, *zone* or *compartment*. Guidance for countries seeking free status following an *outbreak* and for the maintenance of BT status is also provided. This Appendix complements Chapter 2.2.13.

BT is a vector-borne infection transmitted by different species of *Culicoides* insects in a range of ecosystems. An important component of BT epidemiology is vectorial capacity which provides a measure of disease risk that incorporates vector competence, abundance, biting rates, survival rates and extrinsic incubation period. However, methods and tools for measuring some of these vector factors remain to be developed, particularly in a field context. Therefore, surveillance for BT should focus on transmission in domestic ruminants.

Susceptible wild ruminant populations should be included in surveillance ~~only if necessary~~ when these animals are intended for trade.

The impact and epidemiology of BT differ widely in different regions of the world and therefore it is impossible to provide specific guidelines for all situations. It is incumbent upon Member Countries to provide scientific data that explain the epidemiology of BT in the region concerned and adapt the surveillance strategies for defining their infection status (~~free, endemic or area of potential spread~~ free, seasonally free, infected or endemic country/zone) to the local conditions. There is considerable latitude available to Member Countries to justify their infection status at an acceptable level of confidence.

Community comment:

This is the first reference to the concept of "endemic country" both in the Chapter and the guidelines for surveillance. It has no defined meaning and should be deleted.

Surveillance for BT should be in the form of a continuing programme.

Article 3.X.X.2.

Case definition

For the purposes of surveillance, a *case* refers to an animal infected with BT virus (BTV).

For the purposes of *international trade*, a ~~difference~~ distinction must be made between a case as defined below and an animal that is potentially infectious to vectors. The conditions for trade are defined in Chapter 2.2.13 of the *Terrestrial Code*.

The purpose of surveillance is the detection of virus circulation in a country or *zone* and not determination of the status of an individual animal or herds. Surveillance deals not only with the occurrence of clinical signs caused by BTV, but also with the ~~presence~~ evidence of infection with BTV in the absence of clinical signs.

The following defines the occurrence of BTV infection:

1. BTV 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 BTV has been identified in samples from one or more animals showing clinical signs consistent with BT, or epidemiologically linked to a confirmed or suspected *case*, or giving cause for suspicion of previous association or contact with BTV, or

3. antibodies to structural or nonstructural proteins of BTV that are not a consequence of vaccination have been identified in one or more animals that either show~~ing~~ clinical signs consistent with BT, or epidemiologically linked to a confirmed or suspected *case*, or give~~ing~~ cause for suspicion of previous association or contact with BTV.

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

Article 3.X.X.3.

General conditions and methods

1. A surveillance system in accordance with Appendix 3.8.1. should be under the responsibility of the *Veterinary Administration*. In particular:

   a) a formal and ongoing system for detecting and investigating *outbreaks of disease* should be in place;

   b) a procedure should be in place for the rapid collection and transport of samples from suspect cases of BT to a laboratory for BT diagnosis as described in the *Terrestrial Manual*;

   c) a system for recording, managing and analysing diagnostic and surveillance data should be in place.

2. The BT surveillance programme should:

   a) in a country/zone free or seasonally free, include an early warning system for reporting suspicious cases. Farmers and workers, who have day-to-day contact with domestic ruminants, as well as diagnosticians, should report promptly any suspicion of BT to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Administration*. 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 BTV. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. All suspected cases of BT should be investigated immediately and 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;

b) conduct random or targeted serological and virological surveillance appropriate to the infection status of the country or *zone*.

With regards to BT, *compartment* refers to *establishments* where animals are kept in a confirmed vector free environment to prevent BTV infection. Generally, the conditions to prevent exposure of susceptible animals to BTV infected vectors will be difficult to apply. However, under specific situations like *artificial insemination centres* or *quarantine stations* such conditions may be met. The testing requirements for animals kept in these facilities are described in Articles 2.2.13.11 and 2.2.13.15.

Article 3.X.X.4.

Surveillance strategies

The target population for surveillance aimed at identification of *disease* and/or *infection* should cover susceptible domestic ruminants within the country, *zone* or *compartment*. Active and passive surveillance for BTV infection should be ongoing. Surveillance should be composed of random or targeted approaches using virological, serological and clinical methods appropriate for the infection status of the country or *zone*.

The strategy employed may be based on randomised ~~sampling~~ surveillance requiring ~~surveillance~~ sampling consistent with demonstrating the absence of BTV infection at an acceptable level of confidence. The frequency of sampling should be dependent on the epidemiological situation. Random surveillance is conducted using serological tests described in the *Terrestrial Manual*. Positive serological results may be followed up with virological methods as appropriate.

Targeted surveillance (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. Virological and serological methods may be used concurrently to define the BTV status of targeted populations.

A country should justify the surveillance strategy chosen as being adequate to detect the presence of BTV infection in accordance with Appendix 3.8.1. and the prevailing epidemiological situation. It may, for example, be appropriate to target clinical surveillance at particular species likely to exhibit clinical signs (e.g. sheep). Similarly, virological and serological testing may be targeted to species that rarely show clinical signs (e.g. cattle).

In vaccinated populations, serological and virological surveillance is necessary to detect the BTV types circulating to ensure that all circulating types are included in the vaccination programme.

If a Member Country wishes to declare freedom from BTV infection in a specific *zone*, the design of the surveillance strategy would need to be aimed at the population within the *zone*.

For random surveys, the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect evidence of *infection* if it were to occur at a predetermined minimum rate. The sample size and expected prevalence determine the level of confidence in the results of the survey. The applicant country must justify the choice of design prevalence and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Appendix 3.8.1. Selection of the design prevalence in particular needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/infection history and the different species in the target population.

Irrespective of the testing system employed, surveillance system design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of infection or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as those which may be epidemiologically linked to it.

The principles involved in surveillance for *disease/infection* are technically well defined. The design of surveillance programmes to prove the absence of BTV infection/circulation needs to be carefully followed 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 surveillance programme, therefore, requires inputs from professionals competent and experienced in this field.

1. Clinical surveillance

   Clinical surveillance aims at the detection of clinical signs of BT at the flock/herd level. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, surveillance based on clinical inspection should not be underrated, particularly during a newly introduced infection. In sheep and occasionally goats, clinical signs may include oedema, hyperaemia of mucosal membranes, coronitis and cyanotic tongue.

   BT suspects detected by clinical surveillance should always be confirmed by laboratory testing.

2. Serological surveillance

   An active programme of surveillance of host populations to detect evidence of BTV transmission is essential to establish BTV status in a country or *zone*. Serological testing of ruminants is one of the most effective methods of detecting the presence of BTV. The species tested depends on the epidemiology of BTV infection, and the species available, in the local area. Cattle are usually the most sensitive indicator species. Management variables that may influence likelihood of infection, such as the use of insecticides and animal housing, should be considered.

   Surveillance may include serological surveys, for example abattoir surveys, the use of cattle as sentinel animals (which must be individually identifiable), or a combination of methods.

   The objective of serological surveillance is to detect evidence of BTV circulation. Samples should be examined for antibodies against BTV using tests prescribed in the *Terrestrial Manual*. Positive BTV antibody tests results can have four possible causes:

   a) natural infection with BTV,

   b) vaccination against BTV,

   c) maternal antibodies,

   d) positive results due to the lack of specificity of the test.

   It may be possible to use sera collected for other survey purposes for BTV surveillance. However, the principles of survey design described in these guidelines and the requirements for a statistically

valid survey for the presence of BTV infection should not be compromised.

The results of random or targeted serological surveys are important in providing reliable evidence that no BTV infection is present in a *country*, *zone* or *compartment*. It is, therefore, essential that the survey is thoroughly documented. It is critical to interpret the results in light of the movement history of the animals being sampled.

Serological surveillance in a free *zone* should target those areas that are at highest risk of BTV transmission, based on the results of previous surveillance and other information. This will usually be towards the boundaries of the free *zone*. In view of the epidemiology of BTV infection, either random or targeted sampling is suitable to select herds and/or animals for testing.

A surveillance *zone* within a free country or *zone* should separate it from a potentially infected country or *zone*. Serological surveillance in a free country or *zone* should be carried out over an appropriate distance from the border with a potentially infected country or *zone*, based upon geography, climate, history of infection and other relevant factors.

Serological surveillance in infected *zones* will identify changes in the boundary of the *zone*, and can also be used to identify the BTV types circulating. In view of the epidemiology of BTV infection, either random or targeted sampling is suitable.

3. Virological surveillance

Isolation and genetic analysis ~~of samples~~ of BTV from a proportion of infected animals is beneficial in terms of providing information on serotype and genetic characteristics of the viruses concerned.

Virological surveillance using tests described in the *Terrestrial Manual* can be conducted:

a) to identify virus circulation in at risk populations,

b) to confirm clinically suspect cases,

c) to follow up positive serological results,

d) to better characterize the genotype of circulating virus in a country or *zone*.

4. Sentinel ~~herds~~ animals

Sentinel ~~herds~~ animals are a form of targeted surveillance with a prospective study design. They are the preferred strategy for BTV surveillance. They comprise groups of unexposed animals managed at fixed locations and sampled regularly to detect new BTV infections.

The primary purpose of a sentinel ~~herd~~ animal programme is to detect BTV infections occurring at a particular place, for instance sentinel groups may be located on the usual boundaries of infected *zones* to detect changes in distribution of BTV. In addition, sentinel ~~herd~~ animal programmes allow ~~incidence rates to be determined and~~ the timing and dynamics of infections to be observed.

A sentinel ~~herd~~ animal programme should use animals of known source and history of exposure, control management variables such as use of insecticides and animal housing (depending on the epidemiology of BTV in the area under consideration), and be flexible in its design in terms of sampling frequency and choice of tests.

Care is necessary in choosing the sites for the sentinel groups. The aim is to maximise the chance of

detecting BTV activity at the geographical location for which the sentinel site acts as a sampling point. The effect of secondary factors that may influence events at each location, such as climate, may also be analysed. To avoid confounding factors, sentinel groups should comprise animals selected to be of similar age and susceptibility to BTV infection. Cattle are the most appropriate sentinels but other domestic ruminant species may be used. The only feature distinguishing groups of sentinels should be their geographical location.

Sera from sentinel ~~herd~~ animal programmes should be stored methodically in a serum bank to allow retrospective studies to be conducted in the event of new serotypes being isolated.

The frequency of sampling will depend on the reason for choosing the sampling site. In endemic areas, virus isolation will allow monitoring of the serotypes and genotypes of BTV circulating during each time period. The borders between infected and non infected areas can be defined by serological detection of infection. Monthly sampling intervals are frequently used. Sentinels in declared free *zones* add to confidence that BTV infections are not occurring unobserved. In such cases, sampling prior to and after the possible period of transmission is sufficient.

~~The definitive measure of a country or *zone*'s BTV infection status is detection~~ Definitive information on BTVs circulating in a country or zone is provided by isolation and identification of the viruses. If virus isolation is required, sentinels should be sampled at sufficiently frequent intervals to ensure that samples are collected during the period of viraemia.

5. Vector surveillance

BTV is transmitted between ruminant hosts by ~~vector~~ species of *Culicoides* which vary across the world. It is therefore important to be able to identify potential vector species accurately although many such species are closely related and difficult to differentiate with certainty.

The main purpose of vector surveillance is to define high, medium and low-risk areas and local details of seasonality by determining the various species present in an area, their respective seasonal ~~incidence and profile~~ occurrence, and ~~their~~ abundance. Vector surveillance has particular relevance to potential areas of spread. Long term surveillance can also be used to assess vector abatement measures.

The most effective way of gathering this information should take account of the biology and behavioural characteristics of the local vector species of *Culicoides* and may include the use of Onderstepoort-type light traps or similar, operated from dusk to dawn in locations adjacent to domestic ruminants, or the use of drop traps over ruminant animals.

Vector surveillance should be based on scientific sampling techniques. The choice of t~~T~~he number and type of traps to be used in ~~a~~ vector surveillance ~~system~~ and the frequency of their use ~~will depend on~~ should take into account ~~the availability of resources but is also dependent upon~~ the size ~~or~~ and ecological characteristics of the area to be surveyed.

The operation of vector surveillance sites at the same locations as sentinel ~~herds~~ animals is advisable.

The use of a vector surveillance system to detect the presence of circulating virus is not recommended as a routine procedure as the typically low vector infection rates mean that such detections can be rare. Other surveillance strategies (e.g. the use of sentinel ~~herds~~ animals of domestic ruminants) are preferred to detect virus circulation.

Article 3.X.X.5.

Documentation of BTV infection free status

1. Countries declaring freedom from BTV infection for the country, zone or compartment

In addition to the general conditions described in Chapter 2.2.13. of the *Terrestrial Code*, a Member Country declaring freedom from BTV infection for the entire country, or a *zone* or a *compartment* 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 and should be planned and implemented according to general conditions and methods described in this Appendix, to demonstrate absence of BTV infection during the preceding 24 months in susceptible domestic ruminant populations. This requires the support of a laboratory able to undertake identification of BTV infection through virus detection and antibody tests described in the *Terrestrial Manual*. This surveillance should be targeted to non-vaccinated animals. Clinical surveillance may be effective in sheep while serological surveillance is more appropriate in cattle.

2. Additional requirements for countries, zones or compartments that practise vaccination

Vaccination to prevent the transmission of BTV may be part of a disease control programme. The level of flock or herd immunity required to prevent transmission will depend on the flock or herd size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive. The vaccine must also comply with the provisions stipulated for BTV vaccines in the *Terrestrial Manual*. Based on the epidemiology of BTV infection in the country, *zone* or *compartment*, it may be that a decision is reached to vaccinate only certain species or other subpopulations.

In countries~~, or~~ *zones* or *compartments* that practise vaccination, there is a need to perform virological and serological tests to ensure the absence of virus circulation. These tests should be performed on non-vaccinated subpopulations or on sentinels. The tests have to be repeated at appropriate intervals according to the purpose of the surveillance programme. For example, longer intervals may be adequate to confirm endemicity, while shorter intervals may allow on-going demonstration of absence of transmission.

Article 3.X.X.6.

The use and interpretation of serological and virus detection tests

1. Serological testing

Ruminants infected with BTV produce antibodies to structural and non-structural viral proteins, as do animals vaccinated with current modified live virus vaccines. Antibodies to the BTV serogroup antigen are detected with high sensitivity and specificity by competitive ELISA (c-ELISA) and to a lesser extent by AGID as described in the *Terrestrial Manual*. Positive c-ELISA results can be confirmed by neutralization assay to identify the infecting serotype(s); however, BTV infected ruminants can produce neutralizing antibodies to serotypes of BTV other than those to which they were exposed (false positive results), especially if they have been infected with multiple serotypes.

2. Virus detection

The presence of BTV in ruminant blood and tissues can be detected by virus isolation or polymerase chain reaction (PCR) as described in the *Terrestrial Manual*.

Interpretation of positive and negative results (both true and false) differs markedly between these tests because they detect different aspects of BTV infection, specifically (1) infectious BTV (virus isolation) and (2) nucleic acid (PCR). The following are especially relevant to interpretation of PCR assays:

a) The nested PCR assay detects BTV nucleic acid in ruminants long after the clearance of infectious virus. Thus positive PCR results do not necessarily coincide with active infection of ruminants. Furthermore, the nested PCR assay is especially prone to template contamination, thus there is considerable risk of false positive results.

b) PCR procedures other than real time PCR allow sequence analysis of viral amplicons from ruminant tissues, insect vectors or virus isolates. These sequence data are useful for creating data bases to facilitate important epidemiological studies, including the possible distinction of field and vaccine virus strains of BTV, genotype characterization of field strains of BTV, and potential genetic divergence of BTV relevant to vaccine and diagnostic testing strategies.

It is essential that BTV isolates are sent regularly to the OIE Reference Laboratories for genetic and antigenic characterization.

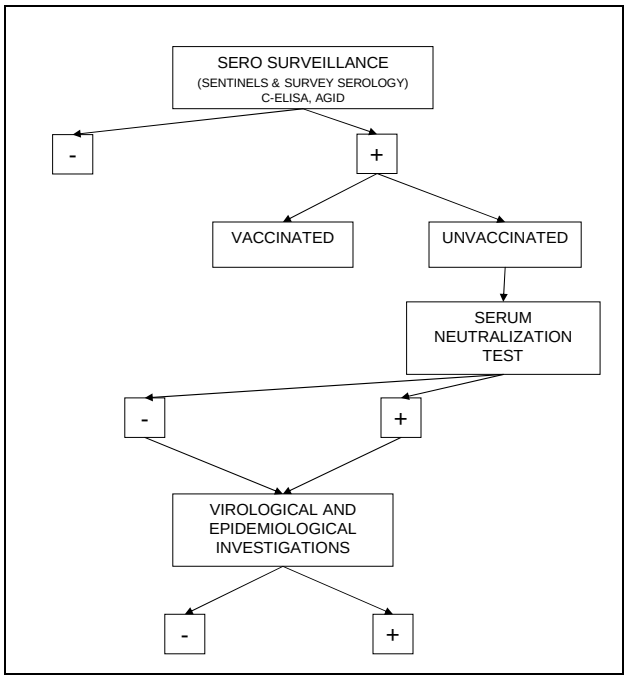

Figure 1

Application of laboratory tests in serological surveillance

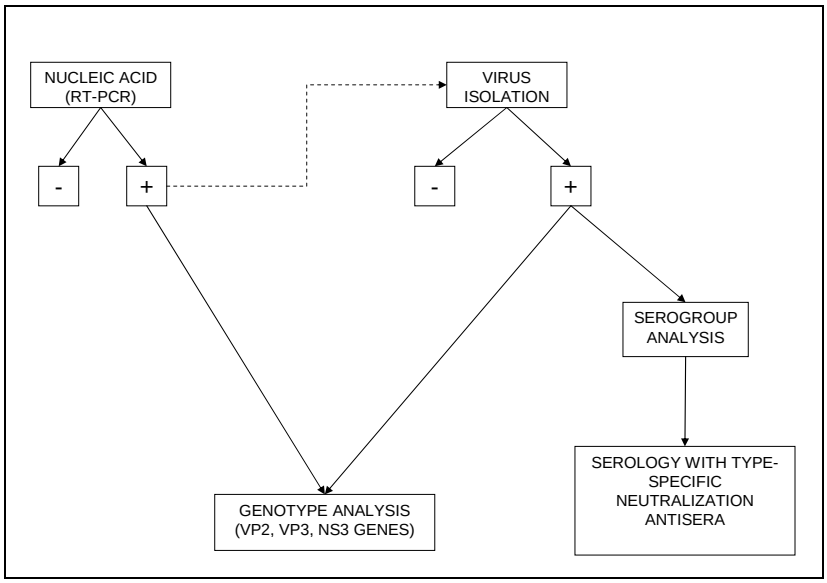

Figure 2

Application of laboratory tests in virological surveillance

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CHAPTER 2.3.13.

BOVINE SPONGIFORM ENCEPHALOPATHY

Community Comments:

The Community welcomes the work done by the Code Commission. However the Community strongly opposes to the modification made related to the production of gelatine. In addition the Community restates its previous comments and asks the Code Commission to consider those comments prior to the General Session in May 2007.

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.

1. When authorising import or transit of the following *commodities* and any products made from these *commodities* and containing no other tissues from cattle, *Veterinary Administrations* should not require any BSE related conditions, regardless of the BSE risk status of the cattle population of the *exporting country, zone* or *compartment*:

   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;

   d) gelatine and collagen prepared exclusively from hides and skins;

   e) protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;

The Community would like to remind the Code Commission of its previous opinion on this point and to restate its position.

Based on the outcome of the Quantitative risk assessment and the subsequent update of the European Food Safety Authority (EFSA) of the scientific opinions on tallow, the Community can only support the inclusion of protein-free tallow with a maximal 0,15% insoluble impurities to the list under Article 2.3.13.1, point 1) if no SRM is used for the

production of tallow and that the animals of which the raw material has been derived, have passed ante- and post mortem inspection.

f) dicalcium phosphate (with no trace of protein or fat);

g) deboned skeletal muscle meat (excluding mechanically separated meat) from cattle 30 months of age or less, which 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, and which passed ante-mortem and post-mortem inspections and which has been prepared in a manner to avoid contamination with tissues listed in Article 2.3.13.13.;

Community Comment:

The definition of deboned skeletal muscle meat should be clearly defined.

The Community welcomes the decision to keep the age limit awaiting the outcome of ongoing research and pathogenesis studies before assessing the modification of the current age criteria for deboned skeletal muscle meat of cattle as defined in Article 2.3.13.1, point g).

h) blood and blood by-products, from cattle which 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.

2. When authorising import or transit of other *commodities* listed in this Chapter, *Veterinary Administrations* should require the conditions prescribed in this Chapter relevant to the BSE risk status of the cattle population of the *exporting country, zone* or *compartment.*

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, *zone* or *compartment* should be determined on the basis of the following criteria:

1. the outcome of a *risk assessment,* based on Section 1.3., identifying all potential factors for BSE occurrence and their historic perspective. Countries should review the risk assessment annually to determine whether the situation has changed.

Community Comment:

In case the situation changes over the year the member countries should review but also be obliged to provide this documentation and its conclusion. This should be part of the annual report which should also include the specific details of the annual surveillance programme. These details should be provided in the format of table under section 3.6 of the questionnaire on recognition of BSE status.

a) Release assessment

Release assessment consists of assessing, through consideration of the following, the likelihood that the BSE agent has either been introduced into the country, *zone* or *compartment* via *commodities* potentially contaminated with it, or is already present in the country, *zone* or *compartment*.

i) the presence or absence of the BSE agent in the indigenous ruminant population of the country, *zone* or *compartment* and, if present, evidence regarding its prevalence;

ii) production of *meat-and-bone meal* or *greaves* from the indigenous ruminant population;

iii) imported *meat-and-bone meal* or *greaves;*

iv) imported cattle, sheep and goats;

v) imported animal feed and feed ingredients;

vi) imported products of ruminant origin for human consumption, which may have contained tissues listed in Article 2.3.13.13. and may have been fed to cattle;

vii) imported products of ruminant origin intended for *in vivo* use in cattle.

The results of any epidemiological investigation into the disposition of the *commodities* identified above should be taken into account in carrying out the assessment.

The Community would like to remind the Code Commission of its previous opinion on this point and to restate its position.

When using the concept of zone or compartment in addition to a country, it is also important to assess the flow of animals and other potentially contaminated commodities between zones in the country, it is not totally clear if the term "imported" in a) iii), iv), v), vi) and vii) also includes trade or movements within a country from another zone. The EU welcomed clarification if this point is addressed in Chapter 1.3.5. of the Terrestrial Animal health Code.

b) Exposure assessment

If the release assessment identifies a *risk* factor, an exposure assessment should be conducted, consisting of assessing the likelihood of cattle being exposed to the BSE agent, through a consideration of the following:

i) 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;

ii) the use of ruminant carcasses (including from fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;

iii) the feeding or not of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants, including measures to prevent cross-contamination of animal feed;

iv) the level of surveillance for BSE conducted on the cattle population up to that time and the results of that surveillance;

2. on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle to encourage reporting of all *cases* showing clinical signs consistent with BSE in target sub-populations as defined in Appendix 3.8.4.;

3. the compulsory notification and investigation of all cattle showing clinical signs consistent with BSE;

4. the examination in an *approved laboratory* of brain or other tissues collected within the framework of the aforementioned surveillance and monitoring system.

The Community would like to remind the Code Commission of its previous opinion on this point and to restate its position:

Apart from the approval of the laboratory the test methodology should also be approved.

The Community proposes under point 4) of Article 2.3.13.2 to replace "approved laboratories" by "approved laboratories and approved methods".

When the *risk assessment* demonstrates negligible risk, the country should conduct Type B surveillance in accordance with Appendix 3.8.4.

When the *risk assessment* fails to demonstrate negligible risk, the country should conduct Type A surveillance in accordance with Appendix 3.8.4.

Article 2.3.13.3.

Negligible BSE risk

Commodities from the cattle population of a country, *zone* or *compartment* pose a negligible risk of transmitting the BSE agent if the following conditions are met:

1. a *risk assessment,* as described in point 1 of Article 2.3.13.2., has been conducted in order to identify the historical and existing risk factors, and the country has demonstrated that appropriate specific measures have been taken for the relevant period of time defined below to manage each identified risk;

2. the country has demonstrated that Type B surveillance in accordance with Appendix 3.8.4. is in place and the relevant points target, in accordance with Table 1, has been met;

Community Comment:

The Community would welcome improved wording which would clarify what surveillance efforts will be required when the relevant target points have been met for countries with a negligible BSE risk.

3. EITHER:

a) there has been no *case* of BSE or, if there has been a *case,* every *case* of BSE has been demonstrated to have been imported and has been completely destroyed, and

i) the criteria in points 2 to 4 of Article 2.3.13.2. have been complied with for at least 7 years; and

ii) it has been demonstrated through an appropriate level of control and audit that for at least 8 years neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants;

The Community would like to remind the Code Commission of its previous opinion on this point and to restate its position:

Experience within the European Community pointed out the risk of cross-contamination when applying a restricted ruminant to ruminant feed ban. The Community proposes to modify Article 2.3.13.3., point 3 a) ii) and 3 b) ii) as follows:

"ii) it has been demonstrated, through an appropriate level of control and audit, that for at least 8 years neither meat-and-bone meal nor greaves derived from mammals has been fed to ruminants;"

OR

b) if there has been an indigenous *case,* every indigenous *case* was born more than 11 years ago; and

i) the criteria in points 2 to 4 of Article 2.3.13.2. have been complied with for at least 7 years; and

ii) it has been demonstrated through an appropriate level of control and audit that for at least 8 years neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants; and

iii) all BSE cases, as well as:

- all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or

- if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases,*

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

Article 2.3.13.4.

Controlled BSE risk

Community Comment:

In the TAHSC report of March 2006 it was stated that: "The Terrestrial Code Commission noted that some concerns had been raised in relation to the need to further clarify the BSE status of countries in the process of upgrading their status from 'controlled risk' to 'negligible risk'. It was considered self-evident that, if a country had qualified for 'controlled risk' but had not yet met the criteria for a country with 'negligible risk', the country would retain its 'controlled risk' status and would not regress into the status of a country with 'undetermined risk'."

Where this covers the situation of countries on the way of being "promoted" to a more favourable category, the Community would like to have a clarification to the current wording in the case of countries requesting to be categorised.

The current wording could imply that a country which has had an indigenous case of BSE less than 11 years old but has complied with the criteria in points 2 to 4 of Article 2.3.13.2 for at least 7 years and can demonstrate that controls over the feeding of meat-and-bone meal and greaves derived from ruminants to ruminants have been in place for at least 8 years, could nevertheless be placed in the "Undetermined BSE risk" category since the country does not yet comply with all the conditions of the negligible risk category, nor to the controlled risk category applying very rigorously the current wording of the TAHC.

It would be not logical in the latter case that this country would be awarded an "Undetermined BSE risk" categorisation where their controls are demonstrated to actually go beyond what is required to be categorised as "Controlled risk".

In order to clarify this, the Community ask the OIE to confirm that in the latter case the country would be categorised in the controlled risk until it fully qualifies for the negligible BSE risk status or to amend the wording in the first paragraph of Article 2.3.13.4. as follows:

"*Commodities* from the cattle population of a country, zone or compartment pose a controlled risk of transmitting the BSE agent if the following conditions are met, or exceeded and the country does not yet comply with the conditions referred to in Article 2.3.13.3".

Commodities from the cattle population of a country, *zone* or *compartment* pose a controlled risk of transmitting the BSE agent if the following conditions are met:

1. a *risk assessment,* as described in point 1 of Article 2.3.13.2., has been conducted in order to identify the historical and existing risk factors, and the country has demonstrated that appropriate measures are being taken to manage all identified risks, but these measures have not been taken for the relevant

period of time;

2. the country has demonstrated that Type A surveillance in accordance with Appendix 3.8.4. has been carried out and the relevant points target, in accordance with Table 1, has been met; Type B surveillance may replace Type A surveillance once the relevant points target is met;

3. EITHER:

   a) there has been no *case* of BSE or, if there has been a *case,* every *case* of BSE has been demonstrated to have been imported and has been completely destroyed, the criteria in points 2 to 4 of Article 2.3.13.2. are complied with, and it can be demonstrated through an appropriate level of control and audit that neither *meat-and-bone meal nor greaves* derived from ruminants has been fed to ruminants, but at least one of the following two conditions applies:

      i) the criteria in points 2 to 4 of Article 2.3.13.2. have not been complied with for 7 years;

      ii) it cannot be demonstrated that controls over the feeding of *meat-and-bone meal* or *greaves* derived from ruminants to ruminants have been in place for 8 years;

   OR

   b) there has been an indigenous *case* of BSE, the criteria in points 2 to 4 of Article 2.3.13.2. are complied with, and it can be demonstrated through an appropriate level of control and audit that neither meat-and-bone meal nor greaves derived from ruminants has been fed to ruminants, but at least one of the following two conditions applies:

      i) the criteria in points 2 to 4 of Article 2.3.13.2. have not been complied with for 7 years;

      ii) it cannot be demonstrated that controls over the feeding of *meat-and-bone meal* and greaves derived from ruminants to ruminants have been in place for 8 years;

      AND

      iii) all BSE *cases,* as well as:

         - all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or

         - if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases,*

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

Article 2.3.13.5.

Undetermined BSE risk

The cattle population of a country, *zone* or *compartment* poses an undetermined BSE risk if it cannot be demonstrated that it meets the requirements of another category.

Article 2.3.13.6.

When importing from a country, *zone* or *compartment* posing a negligible BSE risk, *Veterinary Administrations* should require:

for all *commodities* from cattle not listed in point 1 of Article 2.3.13.1.

the presentation of an *international veterinary certificate* attesting that the country, *zone* or *compartment* complies with the conditions in Article 2.3.13.3.

Article 2.3.13.6.a

When importing from a country, *zone* or *compartment* posing a negligible BSE risk, *Veterinary Administrations* should require:

for cattle selected for export

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

a) 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 3) b) iii) of Article 2.3.13.3.;

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 had been effectively enforced.

Community Comment:

The Community welcome the proposal to take into account that within the cattle population of a country with a negligible risk status with indigenous cases in the past, potential infected animals may be present in the age cohorts before the risk management measures were taken. However the possibility of cases born just after the implementation of the feed ban should also be considered and should not always, based on the situation and an assessment, constitute a reason to question the negligible risk status.

The Community proposes the following:

"For cattle from countries with a negligible BSE risk where any indigenous case of BSE was detected, the presentation of an international veterinary certificate attesting that:

1. the country, zone or compartment complies with the conditions in Article 2.3.13.3.;

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 3) b) iii) of Article 2.3.13.3.;

3. cattle selected for export were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from mammals (see comment under Article 2.3.13.3, point 3(a)(ii) had been effectively enforced or after the date of birth of the last indigenous case if that indigenous case was born after the date of the feed ban ."

Article 2.3.13.7.

When importing from a country, *zone* or *compartment* posing a controlled BSE risk, *Veterinary Administrations* should require:

for cattle

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

1. the country, *zone* or *compartment* complies with the conditions referred to in Article 2.3.13 .4.;

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 3b)iii) of Article 2.3.13.4.;

3. ~~in the case of a country, *zone* or *compartment* where there has been an indigenous *case,*~~ cattle selected for export were born 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.

Community Comment:

The Community welcomes that the previous comment was taken on board. However the possibility of cases born just after the implementation of the feed ban should be considered. The Community proposes to clarify as follows:

"3) Cattle selected for export were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from mammals (see comment under Article 2.3.13.3, point 3(a)(ii)) had been effectively enforced or after the date of birth of the last indigenous case if that indigenous case was born after the date of the feed ban .."

Article 2.3.13.8.

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

for cattle

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

1. the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;

2. all BSE *cases,* as well as:

   a) all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and, which investigation showed consumed the same potentially contaminated feed

during that period, or

b) if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,

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

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;

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 2.3.13.9.

When importing from a country, *zone* or *compartment* posing a negligible BSE risk, *Veterinary Administrations* should require:

for *fresh meat* and *meat products* from cattle (other than those listed in point 1 of Article 2.3.13.1.)

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

1. the country, *zone* or *compartment* complies with the conditions in Article 2.3.13.3.;

2. the cattle from which the fresh meat and meat products were derived passed ante-mortem and post-mortem inspections.

Community Comment:

Taking into account that within the cattle population of a country with a negligible risk status with indigenous cases in the past, potential infected animals may be present that were born before the risk management measures were taken, assurances should be given to exclude those animals and products derived from trade. The Community took note of the intention of the TAHSC to look into this issue further.

The Community proposes to amend Article 2.3.13.9, point 2) as follows:

"point 2: In countries with negligible BSE risk where there have been indigenous cases, the cattle from which the fresh meat and meat products were derived passed ante-mortem and post-mortem inspections, and were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from mammals (see comment under Article 2.3.13.3, point 3(a)(ii) had been enforced."

Article 2.3.13.10.

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

Community Comment:

First sentence should read:

"When importing from a country, zone or compartment with a <u>controlled</u> BSE risk, Veterinary Administrations should require"

<u>for *fresh meat* and *meat products* from cattle (other than those listed in point 1 of Article 2.3.13.1.)</u>

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

1. the country, *zone* or *compartment* complies with the conditions referred to in Article 2.3.13.4.;

2. the cattle from which the *fresh meat* and *meat products* were derived passed ante-mortem and post-mortem inspections;

3. cattle from which *the fresh meat* and *meat products* destined for export were derived 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;

4. the *fresh meat* and *meat products* were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:

   a) the tissues listed in points 1 and 2 of Article 2.3.13.13.,

   b) mechanically separated meat from the skull and vertebral column from cattle over 30 months of age.

The Community would like to remind the Code Commission of its previous opinion on this point and to restate its position:

The Community feels that for control reasons the harvesting of mechanically recovered meat should not only be extended to the skull or vertebral column of bovine animals of any age but should also be extended to all bovine bones.

In view of this the Community suggest replacing article 2.3.13.10 point 4 b) with:

'4) b) mechanically separated meat from all bones from cattle of all ages,'

Article 2.3.13.11.

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

<u>for *fresh meat* and *meat products* from cattle (other than those listed in point 1 of Article 2.3.13.1.)</u>

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

1. the cattle from which *the fresh meat* and *meat products* originate:

   a) have not been fed *meat-and-bone meal* or *greaves* derived from ruminants;

   b) passed ante-mortem and post-mortem inspections;

   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;

2. the *fresh meat* and *meat products* were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:

   a) the tissues listed in points 1 and 3 of Article 2.3.13.13.,

   b) nervous and lymphatic tissues exposed during the deboning process,

   c) mechanically separated meat from the skull and vertebral column from cattle over 12 months of age.

The Community would like to remind the Code Commission of its previous opinion on this point and to restate its position:

The Community feels that for control reasons the harvesting of mechanically recovered meat should not only be extended to the skull or vertebral column of bovine animals of any age but should also be extended to all bovine bones.

In view of this the Community suggest replacing article 2.3.13.11 point 2 c) with:

'4) b) mechanically separated meat from all bones from cattle of all ages,'

Article 2.3.13.12.

1. Ruminant-derived *meat-and-bone meal* or *greaves,* or any *commodities* containing such products, which originate from a country, *zone* or *compartment* defined in Article 2.3.13.3. should not be traded if such products were derived from cattle born before the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants had been enforced.

~~1.~~2. Ruminant-derived *meat-and-bone meal* or *greaves,* or any *commodities* containing such products, which originate from a country, *zone* or *compartment* defined in Articles 2.3.13.4. and 2.3.13.5. should not be traded between countries.

Community Comment:

The Community welcome that the EU comment has been taken on board.

Article 2.3.13.13.

1. From cattle of any age originating from a country, *zone* or *compartment* defined in Articles 2.3.13.4. and 2.3.13.5., 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 distal ileum. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this Chapter) should also not be traded.

Comments of the Community:

In its opinion of 29 June 2001 on adipose tissue associated with the digestive tract of cattle, sheep and goats, the Scientific Steering Committee pointed out that potential infectivity could be found in the mesenteric nerves and the mesenteric lymph nodes situated near the arteria mesenterica in bovine animals. As control of the removal of this specific area alone is unlikely to be feasible, the whole mesentery from bovine animals should therefore be regarded as SRM.

Furthermore, the Community would welcome any updated scientific basis to define only the distal ileum as specified risk material instead of the whole intestine.

2. From cattle that were at the time of slaughter over 30 months of age originating from a country, *zone* or *compartment* defined in Article 2.3.13.4., 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, skull and vertebral column. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this Chapter) should also not be traded.

The Community would like to remind the Code commission of its previous opinion on this point and to restate its position:

In the opinions of the former Scientific Steering Committee it was considered that the intestines and tonsils of bovine animals should be considered a risk at any age and therefore be removed in all cattle. For the rest of SRM the SSC took, according to the opinion, an extremely cautious approach and although it was considered extremely unlikely to have detectable infectivity below an age of 30 months being the half of the mean incubation period in field BSE cases (60 months), the exceptional finding of BSE cases in younger animals lead to an age limit of 12 months. This age limit was considered by the SSC as a considerable reassurance of non-infectivity.

The recent conclusions from the recent EFSA opinion on SRM, published in May 2005, stated that following a cautious approach and taking into account the appearance of infectivity in central nervous system (CNS) at ¾ of the incubation period and the age of BSE cases in young animals (less than 35 months old, 0.06 % of total of BSE cases), a cut-off at 21 months would give the highest safety margin. If the rare BSE cases found in very young animals (4 cases in 40 Million tested since 2001) are not taken into account, a cut-off at 30 months would represent a "considerable but not an absolute safety margin

with respect to detectable infectivity". There is no scientific basis to raise the age limit for removal of tonsils and intestines. In addition EFSA recommends further work on the epidemiological data to evaluate the likelihood of infectivity in SRM derived from young animals.

The Community reserves its position on the 30 month age limit pending the further work by the EFSA.

3. From cattle that were at the time of slaughter over 12 months of age originating from a country, *zone* or *compartment* defined in Article 2.3.13.5., 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, skull and vertebral column. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this Chapter) should also not be traded.

Article 2.3.13.14.

Veterinary Administrations of *importing countries* should require:

for gelatine 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:

1. the *commodities* came from a country, *zone* or *compartment* posing a negligible BSE risk;

Community Comment

Taken into account the international trade and product flows, it would be far more rational to certify on the origin of the raw material that have been used to elaborate the commodities, rather than the country of origin of the commodities.

In view of this the Community suggests replacing article 2.3.13.14 point 1 with:

"The commodities have been processed with bones from bovines born and reared according to the conditions defined by article 2.3.13.3."

The same comment applies for Article 2.3.13.14 point 2) in case of controlled risk and point 3) in case of undetermined risk.

OR

2. they originate from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk and are derived from cattle which have passed ante-mortem and post-mortem inspections; and that

Community Comment:

On 18 January 2006 the European Food Safety Authority adopted an opinion on the "Quantitative assessment of the human BSE risk posed by gelatine with respect to

residual BSE risk". Previous scientific advice recommended that for countries with a BSE risk in addition to appropriate sourcing of bones, and pending the outcome of QRA, the skull and vertebrae from bovine animals older than 12 months should not be used in the production of gelatine. In this context, the QRA of residual BSE risk in vertebral column derived gelatine provides no support for this recommendation as the relevant exposures are regarded as very small. In view of the anticipated problems associated with the practical implementation of the removal of the brain from the skull and the unavoidable contamination of skull bone with brain material, the Community cannot support to include skull bones a raw material for the production of gelatine in controlled nor undetermined risk countries.

Furthermore for countries with an undetermined risk the QRA illustrated that the residual BSE infectivity in gelatine produced from bones in a country with a controlled risk compared to an undetermined risk (worst case scenario) is a factor 100 to 10,000. Therefore the Community cannot accept the production of gelatine using skull and vertebral column in a country with an undetermined risk.

Furthermore inconsistency is noted since, as stipulated in Article 2.3.13.13, the trade of specified risk materials is prohibited while the trade of gelatine derived from specified risk material is allowed.

Based on the above-mentioned rationale, the Community is strongly opposed to the proposed modifications to Article 2.3.13.14.

~~a)~~ ~~skulls from cattle over 30 months of age at the time of slaughter have been excluded ;~~

~~b)~~a) the bones have been subjected to a process which includes all of the following steps:

i) pressure washing (degreasing),

ii) acid demineralisation,

iii) acid or alkaline treatment,

iv) filtration,

v) sterilisation at >138°C for a minimum of 4 seconds,

or to an equivalent or better process in terms of infectivity reduction (such as high pressure heating)~~;~~.

~~OR~~

~~3. they originate from a country, *zone* or *compartment* posing an undetermined BSE risk and are derived from cattle which have passed ante-mortem and post-mortem inspections; and that~~

~~a) skulls and vertebrae (except tail vertebrae) from cattle over 12 months of age at the time of slaughter have been excluded;~~

~~b) the bones have been subjected to a process which includes all of the following steps:~~

~~i) pressure washing (degreasing),~~

~~ii) acid demineralisation,~~

~~iii) acid or alkaline treatment,~~

~~iv) filtration,~~

~~v) sterilisation at >138°C for a minimum of 4 seconds,~~

~~or to an equivalent or better process in terms of infectivity reduction (such as high pressure heating).~~

Article 2.3.13.15.

Veterinary Administrations of *importing countries* should require:

for tallow and dicalcium phosphate (other than as defined in Article 2.3.13.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

1. the *commodities* came from a country, *zone* or *compartment* posing a negligible BSE risk; or

2. they originate from a country, *zone* or *compartment* posing a controlled BSE risk, are derived from cattle which have passed ante-mortem and post-mortem inspections, and have not been prepared using the tissues listed in points 1 and 2 of Article 2.3.13.13.

Article 2.3.13.16.

Veterinary Administrations of *importing countries* should require:

for tallow derivatives (other than those made from protein-free tallow as defined in Article 2.3.13.1.) 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 country, *zone* or *compartment* posing a negligible BSE risk; or

2. they are derived from tallow meeting the conditions referred to in Article 2.3.13.15.; or

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

Appendix X

CHAPTER 2.5.5.

EQUINE INFLUENZA

Community comments:

The Community supports these proposals; however the comments below should be taken into account.

Article 2.5.5.1.

For the purposes of the *Terrestrial Code*, equine influenza (EI) is defined as an infection of domestic horses, ~~which shall include~~ donkeys and mules.

For the purposes of *international trade*, this Chapter deals not only with the occurrence of clinical signs caused by equine influenza virus (EIV), but also with the presence of infection with EIV in the absence of clinical signs.

For the purposes of this chapter, isolation is defined as 'the separation of horses from horses of a different equine influenza health status, utilising appropriate biosecurity measures, with the purpose of preventing the transmission of infection'.

For the purposes of the *Terrestrial Code*, the *infective period* for equine influenza is 21 days.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*. ~~For the purposes of this chapter, a primary vaccination course for an inactivated vaccine comprises two vaccine doses given at an interval specified by the manufacturer; in the case of a live vaccine, one dose constitutes the primary course. Subsequent doses are classified as booster doses.~~

Article 2.5.5.2.

The EI status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

1. the outcome of a *risk assessment* identifying all potential factors for EI occurrence and their historic perspective;

2. whether EI is notifiable in the whole country, an on-going EI awareness programme is in place, and all notified suspect occurrences of EI 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 horses~~; this may be achieved through an EI surveillance programme.~~

Article 2.5.5.3.

Equine influenza free country, zone or compartment

A country or *zone* or *compartment* may be considered free from EI provided it shows evidence of an effective surveillance programme, planned and implemented according to the general principles in

Appendix 3.8.1. The surveillance may need to be adapted to parts of the country, *zone* or *compartment* depending on historical or geographical factors, industry structure, population data, movements of equids into the country, *zone* or *compartment*, wild equid populations or proximity to recent *outbreaks*.

~~For a country, *zone* or *compartment* in which vaccination is not practised or is practised at a moderate to low level, the absence of clinical equine influenza in the country, *zone* or *compartment* for the past 12 months should be demonstrated.~~

A country, *zone* or *compartment* seeking freedom from EI, in which vaccination is practised ~~at a high level~~, should also demonstrate that EIV has not been circulating in the domestic horse population during the past 12 months, through surveillance at a level sufficient to provide at least a 95% level of confidence of detecting infection if it is present at a prevalence rate exceeding 1%. ~~The level of population immunity required to prevent transmission will depend on the size, composition and density of the susceptible population, but the aim should be to vaccinate at least 80% of the susceptible population. Based on the epidemiology of EI in the country, *zone* or *compartment*, a decision may be reached to vaccinate only certain subsets of the total susceptible horse population.~~ In a country in which vaccination is not practised surveillance could be conducted using serological testing. In countries where vaccination is practiced, the surveillance should include methods of virus detection.

If an outbreak of clinical equine influenza occurs in a previously free country, *zone* or *compartment*, free status can be regained 12 months after the last clinical case, providing that surveillance for evidence of infection has been carried out during that 12-month period at a level sufficient to provide at least a 95% level of confidence of detecting infection if it is present at a prevalence rate exceeding 1%.

Article 2.5.5.4.

Country, zone or compartment not free ~~of undetermined~~ from equine influenza ~~status~~

A country, *zone* or *compartment* may be considered not free from equine influenza ~~of undetermined status~~ when it does not meet the conditions for free status.

Community comment:

This article should be deleted as redundant and the rest of the chapter renumbered accordingly.

Article 2.5.5.5. (under study)

Community comment:

This Article should become Article 2.5.5.8 to be consistent with other Chapters of the Code (live animals – semen/ova/embryos - meat)

Regardless of the EI status of the *exporting country*, *zone* or *compartment*, the *Veterinary Administration* of a country, *zone* or *compartment* should authorise without restriction on account of EI the importation into their *territory* of the following *commodities*:

a) semen;

b) *in vivo* derived equine embryos collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.5.5.6.

Community comment:

This Article should become Article 2.5.5.7.

When importing horses for immediate slaughter, the *Veterinary Administrations* ~~of an EI free country, *zone* or *compartment*~~ should require:

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

1. came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days; or

2. came from a country, *zone* or *compartment* not known ~~of undetermined~~ to be EI free ~~status~~ and had been subjected to pre-export isolation for 21 days, and showed no clinical sign of EI during isolation nor on the day of shipment.

~~Article 2.5.5.7.~~

~~When importing horses for immediate slaughter, the *Veterinary Administration* of a country, *zone* or *compartment* of undetermined EI status should require:~~

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

~~1. came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days; or~~

~~2. came from a country, *zone* or *compartment* of undetermined EI status and showed no clinical sign of EI on the day of shipment.~~

Article 2.5.5.~~8.~~7.

Community comment:

This Article should become Article 2.5.5.5.

When importing horses for unrestricted movement, ~~the~~ *Veterinary Administrations* ~~of an EI free country, *zone* or *compartment*~~ should require:

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

1. came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days; in the case of a vaccinated horse, information on its vaccination status should be included in the veterinary certificate;

OR

2. came from a country, *zone* or *compartment* not known to be free from ~~of undetermined~~ EI ~~status~~, were subjected to pre-export isolation for 21 days and showed no clinical sign of EI during isolation nor on the day of shipment; and

3. were vaccinated according to the manufacturer's instructions. ~~between 14 and 90 days before shipment either with a primary course or a booster.~~

Community comment:

Point 3. should read: "3. were validly vaccinated according to the manufacturer's instructions."

Article 2.5.5.~~9.~~8.

~~When importing horses for unrestricted movement, the *Veterinary Administration* of a country, *zone* or *compartment* of undetermined EI status should require:~~

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

~~1. came from an EI free country, zone or compartment in which they had been resident for at least 21 days; in the case of a vaccinated horse, information on its vaccination status should be included in the veterinary certificate;~~

~~OR~~

~~2. came from a country, *zone* or *compartment* of undetermined EI status and showed no clinical sign of EI on the day of shipment; and~~

~~3. were vaccinated between 14 and 180 days before shipment either with a primary course or a booster.~~

Article 2.5.5.~~10.~~9.

Community comment:

This Article should become Article 2.5.5.~~10~~.6.

When importing horses which will be kept in isolation, ~~the~~ *Veterinary Administrations* ~~of an EI free country, *zone* or *compartment*~~ should require:

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

1. came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days; in the case of a vaccinated horse, information on its vaccination status should be included in the veterinary certificate;

OR

2. showed no clinical sign of EI in any premises in which the horses had been resident for the ~~30~~ 21 days prior to shipment nor on the day of shipment; and

3. were vaccinated according to the manufacturer's instructions ~~between 14 and 180 days before shipment either with a primary course or a booster~~;

4. ~~(where applicable) had been kept in isolation except during competition.~~

~~Article 2.5.5.11.~~

~~When importing horses which will be kept in isolation, the *Veterinary Administration* of a country, *zone* or~~

~~*compartment* of undetermined EI status should require:~~

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

~~1. came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days; in the case of a vaccinated horse, information on its vaccination status should be included in the veterinary certificate;~~

~~OR~~

~~2. showed no clinical sign of EI in any premises in which the horses had been resident for the 30 days prior to shipment nor on the day of shipment; and~~

~~3. were vaccinated between 14 and 180 days before shipment either with a primary course or a booster;~~

~~4. (where applicable) had been kept in isolation except during competition.~~

Article 2.5.5.~~12.~~10.

Community comment:

1. Renumbering required, this Article should become Article 2.5.5.9

2. In all cases it should read "fresh meat of equines" or "fresh meat of equids" instead of "fresh horse meat".

When importing *fresh* horse *meat*, ~~the~~ *Veterinary Administrations* ~~of a country, *zone* or *compartment*~~ should require:

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

1. came from an EI free country, *zone* or *compartment* in which the horses from which the meat was derived had been resident for at least 21 days; or

2. came from horses which had been subjected to ante-mortem and post-mortem inspections as described in the Codex Alimentarius Code of Hygienic Practice for Meat ~~Hygiene~~.

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— text deleted

Appendix XI

CHAPTER 2.5.4.

EQUINE INFECTIOUS ANAEMIA

Community comments:

The Community can support the proposed amendments except for the following small editorial suggestion in the proposed modification of article 2.5.4.2:

"3. the animals … or if the animals are imported on a temporary basis, on blood samples collected during the 90 days prior to shipment".

Article 2.5.4.1.

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

Article 2.5.4.2.

Veterinary Administrations of *importing countries* should require:

for equines

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

1. the animals showed no clinical sign of equine infectious anaemia (EIA) on the day of shipment and during the 48 hours prior to shipment;

2. no *case* of EIA has been associated with any premises where the animals were kept during the 3 months prior to shipment;

3. the animals were subjected to a diagnostic test for EIA with negative results on blood samples collected during the 30 days prior to shipment or the animals are imported on a temporary basis and the blood samples were collected within 90 days of export.

Appendix XII

CHAPTER 2.5.6.

EQUINE PIROPLASMOSIS

Community comments:

The Community can support the proposed amendments.

Article 2.5.6.1.

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

Article 2.5.6.2.

Veterinary Administrations of *importing countries* should require:

for equines

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

1. showed no clinical sign of equine piroplasmosis on the day of shipment;
2. were subjected to diagnostic tests for equine piroplasmosis *(Theileria equi* and *Babesia caballi)* with negative results during the 30 days prior to shipment;
3. were maintained free from ticks, by treatment where necessary, during the 30 days prior to shipment.

Article 2.5.6.3.

Veterinary Administrations of *importing countries* should consider the possibility of importing competition horses on a temporary basis and which are positive to the testing procedure referred to in point 2 of Article 2.5.6.2. under the following safeguards:

1. the horses are accompanied by a passport in conformity with the model contained in Appendix 4.1.5.;
2. the *Veterinary Administrations* of *importing countries* require the presentation of an *international veterinary certificate* attesting that the animals:
   a) showed no clinical sign of equine piroplasmosis on the day of shipment;
   b) were treated against ticks within the 7 days prior to shipment;
3. the horses are kept in an area where necessary precautions are taken to control ticks and that is under the direct supervision of the *Veterinary Authority;*
4. the horses are regularly examined for the presence of ticks under the direct supervision of the *Veterinary Authority.*

Appendix XIII

CHAPTER 2.5.7.

EQUINE RHINOPNEUMONITIS
(Equine herpes virus infection)

Community comments:

The Community can support the proposed amendments.

Article 2.5.7.1.

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

Article 2.5.7.2.

Veterinary Administrations of *importing countries* should require:

for equines

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

1. showed no clinical sign of equine ~~rhinopneumonitis~~ herpes virus infection, on the day of shipment and during the 21 days prior to shipment;

2. were kept for the 21 days prior to shipment in an *establishment* where no *case* of equine ~~rhinopneumonitis~~ herpes virus infection, was reported during that period.

— text deleted

Appendix XIV

CHAPTER 2.5.8.
GLANDERS

Community comments:

The Community can support the proposed amendments.

Article 2.5.8.1.

For the purposes of this *Terrestrial Code*, the *incubation period* for glanders shall be 6 months.

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

Article 2.5.8.2.

Glanders free country

A country may be considered free from glanders when:

1. glanders is notifiable in the country;

2. no *case* of glanders has been reported during ~~confirmed for at least~~ the past 3 ~~last 2~~ years, or no *case* has been reported for a period of at least 6 months and a surveillance programme is in place demonstrating the absence of the disease in accordance with general guidelines for animal health surveillance (Appendix 3.8.1.).

~~When importing equines for immediate slaughter from an infected country (see Article 2.5.8.5.), a glanders free country will not be considered as infected if one of the imported equines is found infected.~~

~~The conditions for such imports will require direct transport of the animals from the place of disembarkation to a designated abattoir and completion of cleansing and *disinfection* of the means of transport, the lairages and the abattoir immediately after use. These conditions should be prescribed and enforced by the *Veterinary Administration*.~~

Article 2.5.8.3.

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

for equines

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

1. showed no clinical signs ~~evidence~~ of glanders on the day of shipment;

2. were kept ~~since birth, or~~ for the ~~past~~ 6 months prior to shipment, or since birth if less than 6 months of age, in the *exporting country*~~; or~~

~~3. were subjected to a test as prescribed in the *Terrestrial Manual* the mallein test and/or the complementfixation test for glanders with negative results, during the 15 days prior to shipment.~~

Article 2.5.8.4.

When importing from countries considered infected with glanders, *Veterinary Administrations* should require:

for equines

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

1. showed no clinical sign of glanders on the day of shipment;

2. were kept for the 6 months prior to shipment in an *establishment* where no *case* of glanders was ~~officially~~ reported during that period;

3. were subjected to a test as prescribed in the *Terrestrial Manual* ~~the mallein test and the complement fixation test~~ for glanders with negative results, during the ~~15~~ 30 days prior to shipment.

~~Article 2.5.8.5.~~

~~When importing from countries considered infected with glanders, *Veterinary Administrations* should require:~~

~~for equines for immediate slaughter~~

~~the presentation of an *international veterinary certificate* attesting that the animals showed no clinical sign of glanders on the day of shipment. (See also Article 2.5.8.2.)~~

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— text deleted

Appendix XV

CHAPTER 2.5.10.

EQUINE VIRAL ARTERITIS

Community comments:

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

Article 2.5.10.1.

The *infective period* for equine viral arteritis (EVA) shall be 28 days for ~~mares,~~ ~~and~~ ~~geldings, and~~ all categories of equine except uncastrated sexually immature equines. Because the infective period may be extended in the case of virus shedding in semen, t~~T~~he ~~health~~ status of seropositive stallions should be checked to ensure that they do not shed ~~equine arteritis~~ virus in their semen.

Community comment:

As uncastrated sexually immature equines may also transmit the virus through aerosol, the following text is suggested to replace Article 2.5.10.1.:

"The infective period for equine viral arteritis (EVA) shall be 28 days for all categories of equine. Because the infective period may be extended in the case of virus shedding in semen, the status of seropositive stallions should be checked to ensure that they do not shed virus in their semen."

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

Article 2.5.10.2.

Veterinary Administrations of *importing countries* should require:

for uncastrated male equines imported on a temporary basis for breeding or on a permanent basis

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

1. showed no clinical sign of EVA on the day of shipment and during the 28 days prior to shipment;
2. were subjected to two tests for EVA as prescribed in the *Terrestrial Manual* ~~diagnostic~~ on blood samples collected at least 14 days apart with negative results, during the 28 days prior to shipment; or

Community comment:

The Community agrees with the proposed modifications, however two negative tests on an equine are no better than a single one, therefore the burden of testing should be reduced and the repeat sampling and testing should be reserved for the non-negative

animals. So it is suggested the following:

"2. were subjected, to a test for EVA as prescribed in the Terrestrial Manual, carried out either

(a) on a blood sample collected during the 28 days prior to shipment with negative result, or

(b) on blood samples taken on two occasions at least 14 days apart within 28 days prior to shipment, which demonstrated stable or declining antibody titres; or"

3. ~~were subjected between 6 and 12 months of age to a diagnostic test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results, immediately vaccinated for EVA and regularly revaccinated; or~~

were subjected between 6 and 9 months of age to a test for EVA as prescribed in the *Terrestrial Manual* carried out on two blood samples collected at least 10 days apart with stable or decreasing titre, immediately vaccinated for EVA and regularly revaccinated according to the manufacturer's instructions; or

Community comment:

The period of sufficient seroconversion to be detected in available test systems should be identical throughout the text: in other places 14 days was required, so the following text is proposed:

3. were subjected between 6 and 9 months of age to a test for EVA as prescribed in the *Terrestrial Manual* carried out on two blood samples collected at least 14 days apart with stable or decreasing titre, immediately vaccinated for EVA and regularly revaccinated according to the manufacturer's instructions; or

4. were subjected to a test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results, immediately vaccinated for EVA, kept for 21 days following vaccination separated from other equidae and regularly revaccinated according to the manufacturer's instructions; or

~~4~~5. have been subjected to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with positive results and then: either

a) were subsequently test mated to two mares within 12 months prior to shipment which were subjected to two tests for EVA as prescribed in the *Terrestrial Manual* ~~diagnostic~~ with negative results on blood samples collected at the time of test mating and again 28 days after the mating; or

b) were subjected to a ~~virus isolation~~ test for ~~EVA~~ equine arteritis virus as prescribed in the *Terrestrial Manual* with negative results ~~(under study)~~, carried out on semen collected during the 28 days prior to shipment.

Community comment:

The following wording is suggested:

"5. have been subjected within 12 months prior to shipment to a diagnostic test for EVA as prescribed in the Terrestrial Manual on a blood sample with positive results and then: either

a) were subsequently test mated to two mares which were subjected to two tests for EVA as prescribed in the Terrestrial Manual diagnostic with negative results on blood samples collected at the time of test mating and again 28 days after the mating; or

b) were subjected to a virus isolation test for EVA equine arteritis virus as prescribed in the Terrestrial Manual with negative results (under study), carried out on semen collected during the 28 days prior to shipment."

Rationale:

The Community agrees that the non-shedder status of a seropositive stallion shall be valid for one year and should be reconfirmed annually.

If, however, the 12 months (double underlined above) would remain in point a) as proposed by OIE, it would assign a superiority to the test-mating against the laboratory test.

However, in the Manual the Virus isolation from semen is a prescribed test for international trade and must therefore be a safe test equal or at least not inferior to test-mating with subsequent serology in mares.

Article 2.5.10.3.

Veterinary Administrations of *importing countries* should require:

for uncastrated male equines imported on a temporary basis other than for breeding, and for equines other than uncastrated males

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

1. showed no clinical sign of EVA on the day of shipment and were kept in an *establishment* where no animals have shown any signs of EVA for ~~during~~ the 28 days prior to shipment;

2. were subjected, during the 28 days prior to shipment, to two ~~diagnostic~~ tests for EVA as prescribed in the *Terrestrial Manual* on blood samples collected at least 14 days apart, which demonstrated negative results or a stable or declining antibody titres;

3. were subjected, between 6 and 12 months of age, to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample, with negative results, and immediately vaccinated for EVA and regularly revaccinated.

Community comment:

The Community agrees with the proposed modifications, however suggests the following:

The Community does not agree that other equine animals than entire males are regulated for EVA as they do not pose a particular disease risk, therefore it is suggested to delete paragraphs 2 and 3, and to incorporate entire males for non-reproductive purposes in Article 2.5.10.2.

If a deletion of test requirements for equidae other than entire stallions cannot be agreed the wording of paragraphs 2 and 3 should be changed as follows:

"2. were subjected, to a test for EVA as prescribed in the *Terrestrial Manual* , carried out either

(a) on a blood sample collected during the 28 days prior to shipment with negative result, or

(b) on blood samples collected on two occasions at least 14 days apart within 28 days prior to shipment, which demonstrated stable or declining antibody titres; or

3. were subjected, between 6 and 9 months of age, to a diagnostic test for EVA as prescribed in the *Terrestrial Manual* carried out on two a blood samples collected at least 14 days apart, with negative results or stable or declining titre, and immediately vaccinated for EVA and regularly revaccinated."

Rationale:

Two negative tests on an equine are no better than a single one, therefore the burden of testing should be reduced and the repeat sampling and testing should be reserved for the non-negative animals.

The age limits for vaccination should be the same as in 2.5.10.2.(3).

Article 2.5.10.4.

Veterinary Administrations of *importing countries* should require:

for ~~fresh~~ semen

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

1. were kept for the 28 ~~30~~ days prior to semen collection in an *establishment* where no equine has shown any clinical sign of EVA during that period;

2. showed no clinical sign of EVA on the day of semen collection;

3. were subjected between 6 and ~~12~~ 9 months of age to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with ~~negative results,~~ stable or decreasing titre, ~~and~~ immediately vaccinated for EVA and regularly revaccinated according to the manufacturer's instructions; or

4. were subjected to a test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with

negative results, immediately vaccinated for EVA, kept for 21 days following vaccination separated from other equidae and regularly revaccinated according to the manufacturer's instructions; or

45. were subjected to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results within 14 days prior to semen collection, and had ~~not been used for natural breeding~~ been separated from other equidae from the time of the taking of the blood sample to the time of semen collection; or

56. have been ~~were~~ subjected to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with positive results and then: either

a) were subsequently test mated to two mares within 12 months ~~one year~~ prior to semen collection, ~~to two mares~~ which ~~showed negative results to two diagnostic tests~~ were subjected to two tests for EVA as prescribed in the *Terrestrial Manual* with negative results on blood samples collected at the time of test mating and again 28 days after the test mating, or

b) were subjected to a ~~virus isolation~~ test for equine arteritis virus as prescribed in the *Terrestrial Manual* with negative results ~~(under study)~~, carried out on semen collected within one year prior to collection of the semen to be exported.

Community comment:
See remarks under 2.5.10.2.

Rationale:

Equine semen for trade purposes must be free of EVA-virus, i.e. come from a non-shedder stallion. Consequently the description of the non-shedder status must be consistent throughout the text.

~~Article 2.5.10.5.~~

~~*Veterinary Administrations* of *importing countries* should require:~~

~~for frozen semen~~

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

~~1. showed no clinical sign of EVA on the day of semen collection;~~

~~2. were subjected to a diagnostic test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results not less than 14 days after semen collection; or~~

~~3. were subjected, between 6 and 12 months of age, to a diagnostic test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results, and immediately vaccinated for EVA and regularly revaccinated; or~~

~~4. were subjected to a diagnostic test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with positive results and then: either~~

~~a) were test mated, within 12 months one year prior to or as soon as possible after semen collection, to two mares which showed negative results to two diagnostic tests as prescribed in the *Terrestrial Manual* on blood samples collected at the time of test mating and again 28 days after the test mating, or~~

~~b) were subjected to a virus isolation test as prescribed in the *Terrestrial Manual*c with negative results (under study), carried out on semen collected within one year prior to collection of the semen to be exported.~~

Community comments:

Community believes Article 2.5.10.5. should be retained and replaced as follows:
"Veterinary Administrations of importing countries should require:
for frozen semen:
the presentation of an international veterinary certificate attesting that the donor animals:
1. showed no clinical sign of EVA on the day of semen collection;
2. were subjected to a test for EVA as prescribed in the Terrestrial Manual on a blood sample with negative results not less than 14 days after semen collection; or
3. were subjected to a test for EVA as prescribed in the Terrestrial Manual on a blood sample with positive results and then: either
a) were test mated, within 30 days after semen collection, to two mares which showed negative results to two tests as prescribed in the Terrestrial Manual on blood samples collected during a 28 days isolation at the time of test mating and again 28 days after the test mating, or
b) were subjected to a test as prescribed in the Terrestrial Manualc with negative results, carried out on semen collected within 30 days after collection of the semen to be exported."

Rationale: The unique instrument of post-collection sampling and testing must be maintained in case of frozen semen that may be stored of an extended period of time.

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— text deleted

CHAPTER 2.6.7.

CLASSICAL SWINE FEVER

Community comments:

The Community supports the proposal on the classical swine fever chapter 2.6.7. It welcomes especially the introduction of the concept of compartmentalisation and the use of marker vaccination against classical swine fever. The present text has been improved and became more clear and coherent. However it is still believed that Article 2.6.7.6. should be deleted and some of the provisions added to those to Article 2.6.7.3.

Further comments are made to the text at Articles concerned.

The Community agrees with the approach of the TACC to seek advice on the inconsistencies as regards the conflicting periods of recovery of a free status and the residency of animals in a free country, zone or compartment.

Article 2.6.7.1.

The pig is the only natural host for classical swine fever (CSF) virus. The definition of pig includes all varieties of *Sus scrofa,* both domestic breeds and wild boar. For the purposes of this chapter, a distinction is made between domestic pigs (permanently captive and owned free-range pigs) and wild pigs (including feral pigs).

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.*

Community comment:

The Community proposes to amend the text of the second paragraph as follows: "…, and are usually infective after day 5 of infection until death. Acutely diseased pigs may die within the first month of infection, but pigs with chronic infection may shed virus up to three months. Pigs which recover from the disease are usually infective between post-infection days 5 and 15."

Article 2.6.7.2.

The CSF status of a country, *zone* or *compartment* can only be determined after considering the following criteria in domestic and wild pigs, as applicable:

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 domestic pigs in the country, *zone* or *compartment*;

5. the *Veterinary Administration* should have current knowledge about the population and habitat of wild pigs in the country or *zone*.

Article 2.6.7.3.

CSF free country, zone or compartment

1. ~~CSF free status in the absence of an outbreak~~

~~a)~~ Historically free status

A country, *zone* or *compartment* may be considered free from the disease after conducting a *risk assessment* as referred to in Article 2.6.7.2. but without formally applying a specific surveillance programme, if the provisions of Article 3.8.1.6. are complied with.

~~b)~~

2. Free status as a result of a specific surveillance programme

A country, *zone* or *compartment* which does not meet the conditions of point 1 above may be considered free from CSF when a *risk assessment* as referred to in Article 2.6.7.2. has been conducted, surveillance in accordance with Appendix 3.8.8. has been in place for at least 12 months, and when no *outbreak* has been observed for at least 12 months.

3. ~~2. CSF free status following an outbreak~~ Free status as a result of an eradication programme

A country, *zone* or *compartment* which does not meet the conditions of point ~~a)~~ 1. or ~~b)~~ 2. above may be considered free from CSF if surveillance in accordance with Appendix 3.8.8. has been in place and after a *risk assessment* as referred to in Article 2.6.7.2. has been conducted, and

a) where a *stamping-out policy* without vaccination is practised and no *outbreak* has been observed in domestic pigs for at least 6 months;

OR

b) where a *stamping-out policy* with vaccination is practised, and either:

i) vaccinated pigs are slaughtered, and no *outbreak* has been observed in domestic pigs for at least 6 months after the last vaccinated pig was slaughtered; or

ii) where there are validated means of distinguishing between vaccinated and infected pigs, no *outbreak* has been observed in domestic pigs for at least 6 months;

OR

c) where a vaccination strategy is practised without a *stamping-out policy:*

i) vaccination has been banned in all domestic pigs in the country, *zone* or *compartment* for at least 12 months, unless there are validated means of distinguishing between vaccinated and infected pigs;

ii) if vaccination has been practised within the past 5 years, surveillance in accordance with Appendix 3.8.8. has been in place for at least 6 months to demonstrate the absence of infection within the population of domestic pigs 6 months to one year old; and

iii) no *outbreak* has been observed in domestic pigs for at least 12 months;

AND

in all cases, based on surveillance in accordance with Appendix 3.8.8., CSF infection is not known to occur in any wild pig population in the country or *zone.*

Community comment:

The Community acknowledges that Article 2.6.7.3. has become more clear and coherent. However it still believes that Article 2.6.7.6. should be deleted and some of its provisions be added to the last paragraph of Article 2.6.7.3.

The last paragraph beginning with 'AND' should be at the same level of point 1., 2. and 3. as this paragraph applies to all 3 cases.

The text would read as follows:

"AND

in all cases, surveillance in accordance with Appendix 3.8.8. has been in place to determine the CSF status of the wild pig population (if any) in the country, and in the country or zone:

i) there has been no virological evidence of CSF in wild pigs during the past 12 months;

ii) no seropositive wild pigs have been detected in the age class 6-12 months during the past 12 months;

iii) there has been no vaccination in wild pigs for the past 12 months.

Article 2.6.7.4.

Country or zone free of CSF in domestic pigs but with infection in the ~~a~~ wild pig population

Community comment:

The Community believes that in view of the present draft the title should be modified to read: "Country or zone free of CSF in domestic pigs but *where infection may be present* in the wild pig population".

Requirements in points ~~2~~3a to ~~2~~3c of Article 2.6.7.3., as relevant, are complied with. As CSF infection may be present in the wild pig population, the following additional conditions are complied with:

1. a programme for the management of CSF in wild pigs is in place, 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. ~~zoning or compartmentalisation is applied~~ the domestic pig population must be separated from the infected wild pig population through biosecurity measures to prevent transmission of CSF from wild pigs to domestic pigs.

Article 2.6.7.5.

Recovery of free status

Should a CSF *outbreak* occur in a previously free country, zone or compartment, the status of the country, *zone* or *compartment* may be restored not less than 30 days after completion of a *stamping-out policy* where surveillance in accordance with Appendix 3.8.8. has been carried out with negative results.

If emergency vaccination has been practised within the CSF domestic pig control area, recovery of the free status cannot occur before all the vaccinated pigs have been slaughtered, unless there are validated means of distinguishing between vaccinated and infected pigs.

Article 2.6.7.6.

Community comment:

The Community still believes that Article 2.6.7.6. does not have a meaning on its own and that its relevant provisions should be integrated into Article 2.6.7.3. The last paragraph of Article 2.6.7.3. namely requires that CSF infection is not known to occur in any wild pig population in the country or zone, while paragraph 1 of Article 2.6.7.6. requires that the domestic pig population in the country or zone is free from CSF infection. Therefore, a separate Article for a country or zone free of CSF in wild pigs does not make sense because it is one of the requirements to gain the status of a CSF free country, zone or compartment. Furthermore it is difficult to imagine the situation where a country or zone would wish to gain the status as country or zone free of CSF in wild pigs (only), when the country or zone could gain the status as CSF free country, zone or compartment instead.

As a consequence:

- paragraph 1. would become obsolete;

- paragraphs 2. and 3. would need to be added to the last paragraph of Article 2.6.7.3.

The words under paragraph 2, a) "no clinical evidence, nor virological evidence" should be replaced by "no virological evidence" because although clinical surveillance is essential, it is difficult to implement in wild populations. Clinical signs are also never conclusive, and any clinical suspicion should be followed by virological analysis. There is no need to refer to clinical evidence here, but only to the key criteria (ie virology).

Furthermore, in the light of the deletion of the former article 2.6.7.4.2.c) in the draft of May 2005 it would be reasonable to also delete paragraph 4 of article 2.6.7.6.

The requirement in paragraph 5 in article 2.6.7.6 seems to be unnecessary as it should be a fundamental principle of the Code.

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. surveillance in accordance with Appendix 3.8.8. 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 evidence, nor 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 the past 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.

Article 2.6.7.7.

When importing from countries, zones or compartments free of CSF, *Veterinary Administrations* should require:

for domestic pigs

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

1. showed no clinical sign of CSF on the day of shipment;

2. were kept in a country, zone or compartment free of CSF 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 2.6.7.8.

When importing from countries free of CSF in domestic pigs but with infection in the wild pig population, *Veterinary Administrations* should require:

Community comment:

The Community believes that in view of the present draft the introductory phrase above should be modified into: "When importing from countries free of CSF in domestic pigs but *where infection may be present* in the wild pig population, *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 a CSF free zone or compartment;

4. showed no clinical sign of CSF on the day of shipment.

Article 2.6.7.9.

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 a CSF free compartment;

3. showed no clinical sign of CSF on the day of shipment.

Article 2.6.7.10.

When importing from countries or zones free of CSF, *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;

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 2.6.7.11.

When importing from countries, zones or compartments free of CSF, *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, zone or compartment free of CSF since birth or for at least 3 months prior to collection;

   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 3.2.2.

Article 2.6.7.12.

When importing from countries free of CSF in domestic pigs but with infection in the wild pig population, *Veterinary Administrations* should require:

Community comment:

The Community believes that in view of the present draft the introductory phrase should be modified into: "When importing from countries free of CSF in domestic pigs but *where infection may be present* in the wild pig population, *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, zone or compartment free of CSF in domestic pigs since birth or for at least 3 months prior to collection;

   b) 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 3.2.2.

Article 2.6.7.13.

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) were kept in a compartment free of CSF in domestic pigs since birth or for at least 3 months prior to collection;

   b) showed no clinical sign of CSF on the day of collection of the semen and for the following 40 days;

   c) 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 3.2.2.

Article 2.6.7.14.

When importing from countries, zones or compartments free of CSF, *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 2.6.7.15.

When importing from countries free of CSF in domestic pigs but with infection in the wild pig population, *Veterinary Administrations* should require:

Community comment:

The Community believes that in view of the present draft the introductory phrase should be modified into: "When importing from countries free of CSF in domestic pigs but *where infection may be present* in the wild pig population, *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 in a country, zone or compartment free of CSF in domestic pigs since birth or for at least 3 months prior to collection;

   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 2.6.7.16.

When importing from countries or *zones* 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 in a compartment free of CSF in domestic pigs since birth or for at least 3 months prior to collection;

   b) showed no clinical sign of CSF on the day of collection of the embryos and for the following 40 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 2.6.7.1 7.

When importing from countries, zones or compartments free of CSF, *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, zone or compartment free of CSF 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 2.6.7.18.

When importing from countries or zones free of CSF in domestic pigs but with infection in the wild pig population, *Veterinary Administrations* should require:

Community comment:

The Community believes that in view of the present draft the introductory phrase should be modified into: "When importing from countries free of CSF in domestic pigs but *where infection may be present* in the wild pig population, *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, zone or compartment free of CSF in domestic 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 as described in the Codex Alimentarius Code of Hygienic Practice for Meat and have been found free of any sign suggestive of CSF.

Article 2.6.7.19.

When importing from countries or zones free of CSF, *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;

    b) have been subjected to a post-mortem inspection as described in the Codex Alimentarius Code of Hygienic Practice for Meat 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 2.6.7.20.

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 2.6.7.17., 2.6.7.18. or 2.6.7.19., as relevant;

    b) in a processing establishment:

        i) approved by the *Veterinary Administration* for export purposes;

ii) processing only meat meeting the conditions laid down in Articles 2.6.7.17., 2.6.7.18. or 2.6.7.19., as relevant;

OR

2. have been processed in an establishment approved by the *Veterinary Administration* for export purposes 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 2.6.7.21.

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 2.6.7.17., 2.6.7.18. or 2.6.7.19., as relevant;

b) in a processing establishment:

i) approved by the *Veterinary Administration* for export purposes;

ii) 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 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 2.6.7.22.

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, zone or compartment free of CSF; or

2. have been processed in an establishment approved by the *Veterinary Administration* for export purposes so as to ensure the destruction of the CSF virus.

Article 2.6.7.23.

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, zone or compartment free of CSF; or

2. have been processed in an establishment approved by the *Veterinary Administration* for export purposes so as to ensure the destruction of the CSF virus.

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— text deleted

CHAPTER 2.7.12.

AVIAN INFLUENZA

Community comments:

In the light of the proposed changes (and because of the changes made last year to chapter 2.1.1), the Community wants to point out that there are discrepancies between the definition for Avian influenza in the Code Chapter on AI and the rules for notification of diseases as described in Chapter 1.1.2. in conjunction with Chapter 2.1.1. The latter requires notifying HPAI in all species of birds, but this disease is only defined in poultry.

The Community believes that for transparency reasons and in view of surveillance activities in accordance to Appendix 3.8.9. it is important that HPAI in birds other than poultry is notified too in accordance with Chapter 1.1.2. A reference to the requirements for notification as laid down in Chapter 2.1.1 should be made as an introduction to this chapter and the comments below should be taken into account.

On the other hand it must be made clearer that infection in certain categories of birds, e.g. in 'birds kept in captivity' or wild birds shall not in itself lead to any trade restrictions in poultry and therefore a change is suggested to paragraph 4 below.

The change in relation to point 5 of Article 2.7.12.1. concerning detection of antibodies is very much welcomed, as it should improve transparency while limiting trade restrictions.

Article 2.7.12.1.

1. For the purposes of the *Terrestrial Code,* avian influenza in its notifiable form (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):

Community comment:

It is proposed to change 'For the purpose of the *Terrestrial Code* …' into 'For the purpose of *international trade*' to make clear that this article relates only to trade and not to other obligations under the Code.

a) HPNAI viruses have an IVPI in 6-week-old chickens greater than 1.2 or, as an alternative, cause at least 75% mortality in 4-to 8-week-old chickens infected intravenously. H5 and H7 viruses which do not have an IVPI of greater than 1.2 or cause less than 75% mortality in an intravenous lethality test should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0); if the amino acid motif is similar to that observed for other HPNAI isolates, the isolate being tested should be considered as HPNAI;

b) LPNAI are all influenza A viruses of H5 and H7 subtype that are not HPNAI viruses.

2. Poultry is defined as 'all domesticated birds, including backyard poultry, used 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, as well as fighting cocks used for any purpose'.

Birds that are kept in captivity for any reason other than those reasons referred to in point 2, including those that are kept for shows, races, exhibitions, competitions, breeding or selling, are not considered to be poultry.

3. 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.

4. For the purposes of *international trade,* a country should interpret an occurrence of infection with HPNAI virus in birds other than poultry according to the *Terrestrial Code* and should not impose immediate trade bans.

Community comment:

The sentence is not clear. According to point 1 above, HPNAI only exists in poultry. The Community proposes the following wording for paragraph 4:

"The occurrence of infection with HPAI virus in birds other than poultry according to the Terrestrial Code should not lead importing countries to impose trade bans unless on imports of that specific bird category, though information may be asked about the measures taken to prevent the spreads of infection to poultry."

5. Antibodies to H5 or H7 subtype of NAI virus, which have been detected in poultry and are not a consequence of vaccination, have to be further investigated. In the case of isolated serological positive results, NAI infection may be ruled out on the basis of a thorough epidemiological investigation that does not demonstrate further evidence of NAI infection.

~~4.~~6 The following defines the occurrence of infection with NAI virus:

a) HPNAI virus has been isolated and identified as such or viral RNA specific for HPNAI has been detected in poultry or a product derived from poultry; or

b) LPNAI virus has been isolated and identified as such or viral RNA specific for LPNAI has been

detected in poultry or a product derived from poultry~~;~~, ~~or~~

~~c) antibodies to H5 or H7 subtype of NAI virus that are not a consequence of vaccination have been detected in poultry. In the case of isolated serological positive results, NAI infection may be ruled out on the basis of a thorough epidemiological investigation that does not demonstrate further evidence of NAI infection.~~

For the purposes of the *Terrestrial Code,* 'NAI free establishment' means an *establishment* in which the poultry have shown no evidence of NAI infection, based on surveillance in accordance with Appendix 3.8.9.

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

Standards for diagnostic tests, including pathogenicity testing, are described in the *Terrestrial Manual.* Any vaccine used should comply with the standards described in the *Terrestrial Manual.*

Article 2.7.12.2.

The NAI status of a country, a *zone* or a *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 Appendix 3.8.9.

Article 2.7.12.3.

NAI free country, zone or compartment

A country, *zone* or *compartment* may be considered free from NAI when it has been shown that neither HPNAI nor LPNAI infection has been present in the country, *zone* or *compartment* for the past 12 months, based on surveillance in accordance with Appendix 3.8.9. The surveillance may need to be adapted to parts of the country or existing *zones* or *compartments* depending on historical or geographical factors, industry structure, population data, or proximity to recent outbreaks.

If infection has occurred in a previously free country, zone or compartment, NAI free status can be regained:

1. In the case of HPNAI infections, 3 months after a *stamping-out policy* (including *disinfection* of all affected *establishments)* is applied, providing that surveillance in accordance with Appendix 3.8.9. has been carried out during that three-month period.

2. In the case of LPNAI infections, poultry may be kept for slaughter for human consumption subject to conditions specified in Article 2.7.12.19. or 2.7.12.20. or a *stamping-out policy* may be applied; in either case, 3 months after the *disinfection* of all affected *establishments,* providing that surveillance in accordance with Appendix 3.8.9. has been carried out during that three-month period.

Article 2.7.12.4.

HPNAI free country, zone or compartment

A country, *zone* or *compartment* may be considered free from HPNAI when it has been shown that HPNAI infection has not been present in the country, *zone* or *compartment* for the past 12 months, although its LPNAI status may be unknown, or when, based on surveillance in accordance with Appendix 3.8.9., it does not meet the criteria for freedom from NAI but any NAI virus detected has not been identified as HPNAI virus. The surveillance may need to be adapted to parts of the country or existing *zones* or *compartments* depending on historical or geographical factors, industry structure, population data, or proximity to recent *outbreaks.*

If infection has occurred in a previously free country, *zone* or *compartment,* HPNAI free status can be regained 3 months after a *stamping-out policy* (including *disinfection* of all affected *establishments)* is applied, providing that surveillance in accordance with Appendix 3.8.9. has been carried out during that three-month period.

Article 2.7.12.5.

When importing from an NAI free country, zone or compartment, *Veterinary Administrations* should require:

for live poultry (other than day-old poultry)

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

1. the poultry showed no clinical sign of NAI on the day of shipment;

2. the poultry were kept in an NAI free country, zone or compartment since they were hatched or for at least the past 21 days;

3. the required surveillance has been carried out on the *establishment* within at least the past 21 days;

4. if vaccinated, the poultry have been vaccinated in accordance with Appendix 3.8.9., and the relevant information is attached.

Article 2.7.12.6.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Administrations* should require:

for live birds other than poultry

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

1. the birds showed no clinical sign of infection with a virus which would be considered NAI in poultry on the day of shipment;

2. the birds were kept in isolation approved by the *Veterinary Services* since they were hatched or for at least the 21 days prior to shipment and showed no clinical sign of infection with a virus which would be considered NAI in poultry during the isolation period;

3. the birds were subjected to a diagnostic test 7 to 14 days prior to shipment to demonstrate freedom from infection with a virus which would be considered NAI in poultry;

4. the birds are transported in new containers.

If the birds have been vaccinated, the relevant information should be attached to the certificate.

Article 2.7.12.7.

When importing from an NAI free country, zone or compartment, *Veterinary Administrations* should require:

for day-old live poultry

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

1. the poultry were kept in an NAI free country, zone or compartment since they were hatched;

2. the poultry were derived from parent flocks which had been kept in an NAI free country, zone or compartment for at least 21 days prior to and at the time of the collection of the eggs;

3. if the poultry or the parent flocks were vaccinated, vaccination was carried out in accordance with Appendix 3.8.9., and the relevant information is attached.

Article 2.7.12.8.

When importing from an HPNAI free country, zone or compartment, *Veterinary Administrations* should require:

for day-old live poultry

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

1. the poultry were kept in an HPNAI free country, zone or compartment since they were hatched;

2. the poultry were derived from parent flocks which had been kept in an NAI free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;

3. the poultry are transported in new containers;

4. if the poultry or the parent flocks were vaccinated, vaccination was carried out in accordance with Appendix 3.8.9., and the relevant information is attached.

Article 2.7.12.9.

When importing from an NAI free country, zone or compartment, *Veterinary Administrations* should require:

for *hatching eggs*

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

1. the eggs came from an NAI free country, zone or compartment;

2. the eggs were derived from parent flocks which had been kept in an NAI free country, zone or compartment for at least 21 days prior to and at the time of the collection of the eggs;

3. if the parent flocks were vaccinated, vaccination was carried out in accordance with Appendix 3.8.9., and the relevant information is attached.

Article 2.7.12.10.

When importing from an HPNAI free country, zone or compartment, *Veterinary Administrations* should require:

for *hatching eggs*

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

1. the eggs came from an HPNAI free country, zone or compartment;

2. the eggs were derived from parent flocks which had been kept in an NAI free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;

3. the eggs have had their surfaces sanitised (in accordance with Article 3.4.1.7) and are transported in new packing material;

4. if the parent flocks were vaccinated, vaccination was carried out in accordance with Appendix 3.8.9., and the relevant information is attached.

Article 2.7.12.11.

When importing from an NAI free country, zone or compartment, *Veterinary Administrations* should require:

for eggs for human consumption

the presentation of an *international veterinary certificate* attesting that the eggs come from an NAI free country, zone or compartment.

Article 2.7.12.12.

When importing from an HPNAI free country, zone or compartment, *Veterinary Administrations* should require:

for eggs for human consumption

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

1. come from an HPNAI free country, zone or compartment;

2. have had their surfaces sanitised (in accordance with Article 3.4.1.7) and are transported in new packing material.

Article 2.7.12.13.

When importing from an NAI free country, zone 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, zone or compartment.

Article 2.7.12.14.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Administrations* should require:

for egg products

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

1. the egg products are derived from eggs which meet the requirements of Articles 2.7.12.9., 2.7.12.10., 2.7.12.11. or 2.7.12.12.; or

2. the egg products were processed to ensure the destruction of NAI virus in accordance with Appendix 3.6.5.;

3. the necessary precautions were taken after processing to avoid contact of the *commodity* with any source of NAI virus.

Article 2.7.12.15.

When importing from an NAI free country, zone or compartment, *Veterinary Administrations* should require:

for poultry semen

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

1. showed no clinical sign of NAI on the day of semen collection;

2. were kept in an NAI free country, zone or compartment for at least the 21 days prior to and at the time of semen collection.

Article 2.7.12.16.

When importing from an HPNAI free country, zone or compartment, *Veterinary Administrations* should require:

for poultry semen

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

1. showed no clinical sign of HPNAI on the day of semen collection;

2. were kept in an HPNAI free country, zone or compartment for at least the 21 days prior to and at the time of semen collection.

Article 2.7.12.17.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Administrations* should require:

for 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* for at least the 21 days prior to semen collection;

2. showed no clinical sign of infection with a virus which would be considered NAI in poultry during the isolation period;

3. were tested between 7 and 14 days prior to semen collection and shown to be free of NAI infection.

Article 2.7.12.18.

When importing from an NAI free country, zone or compartment, *Veterinary Administrations* should require:

for fresh meat of poultry

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

1. which have been kept in an NAI free country, zone or compartment since they were hatched or for at least 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 2.7.12.19.

When importing from an HPNAI free country, zone or compartment, *Veterinary Administrations* should require:

for *fresh meat* of poultry

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

1. which have been kept in an HPNAI free country, zone or compartment since they were hatched or for at least 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 2.7.12.20.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Administrations* should require:

for *meat products* of poultry

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

1. the *commodity* is derived from *fresh meat* which meet the requirements of Articles 2.7.12.18. or 2.7.12.19.; or

2. the *commodity* has been processed to ensure the destruction of NAI virus in accordance with Appendix 3.6.5.;

Community comment:

In order to be coherent with the article 3.6.5.2 of the Appendix 3.6.5, it is proposed that the word NAI in point 2 above be replaced by the word HPNAI.

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 2.7.12.21.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *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:

1. these *commodities* come from poultry which have been kept in an NAI free country, zone or compartment since they were hatched or for at least the past 21 days; or
2. these *commodities* have been processed to ensure the destruction of NAI virus (under study);
3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 2.7.12.22.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Administrations* should require:

for feathers and down (from poultry)

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

1. these *commodities* come from poultry which have been kept in an NAI free country, zone or compartment since they were hatched or for at least the past 21 days; or
2. these *commodities have* been processed to ensure the destruction of NAI virus (under study);
3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 2.7.12.23.

Regardless of the NAI status of the country, *zone* or *compartment, 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 NAI virus (under study);
2. the necessary precautions were taken after processing to avoid contact of the *commodity* with any source of NAI virus.

APPENDIX 3.8.9.

GUIDELINES FOR THE SURVEILLANCE OF AVIAN INFLUENZA

Community comments:

The EC believes the current guidelines are generally appropriate and agrees with the suggested change in 3.8.9.5. However, it is proposed to take into account the occurrence of HPAI in birds other than poultry, including HPAI presence in wild birds when assessing the risks posed to poultry.

Article 3.8.9.1.

Introduction

This Appendix defines the principles and provides a guide for the surveillance of notifiable avian influenza (NAI) in accordance with Appendix 3.8.1., applicable to countries seeking recognition for a declared NAI status, with or without the use of vaccination. This may be for the entire country, *zone* or *compartment*. Guidance for countries seeking free status following an *outbreak* and for the maintenance of NAI status are provided. This Appendix complements Chapter 2.7.12.

The presence of avian influenza viruses in wild birds creates a particular problem. In essence, no country can declare itself free from avian influenza (AI) in wild birds. However, the definition of NAI in Chapter 2.7.12. refers to the infection in poultry only, and this Appendix was developed under this definition.

The impact and epidemiology of NAI differ widely in different regions of the world and therefore it is impossible to provide specific guidelines for all situations. It is axiomatic that the surveillance strategies employed for demonstrating freedom from NAI at an acceptable level of confidence will need to be adapted to the local situation. Variables such as the frequency of contacts of poultry with wild birds, different biosecurity levels and production systems and the commingling of different susceptible species including domestic waterfowl require specific surveillance strategies to address each specific situation. It is incumbent upon the country to provide scientific data that explains the epidemiology of NAI in the region concerned and also demonstrates how all the risk factors are managed. There is therefore considerable latitude available to Member Countries to provide a well-reasoned argument to prove that absence of NAI virus (NAIV) infection is assured at an acceptable level of confidence.

Surveillance for NAI should be in the form of a continuing programme designed to establish that the country, *zone* or *compartment,* for which application is made, is free from NAIV infection.

Article 3.8.9.2.

General conditions and methods

1. A surveillance system in accordance with Appendix 3.8.1. should be under the responsibility of the *Veterinary Administration*. In particular:

   a) a formal and ongoing system for detecting and investigating *outbreaks of disease* or NAI *infection* should be in place;

   b) a procedure should be in place for the rapid collection and transport of samples from suspect
   cases of NAI to a laboratory for NAI diagnosis as described in the *Terrestrial Manual;*

   c) a system for recording, managing and analysing diagnostic and surveillance data should be in place.

2. The NAI surveillance programme should:

   a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers, who have day-to-day contact with poultry, as well as diagnosticians, should report promptly any suspicion of NAI to the *Veterinary Authority.*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 suspected cases of NAI should be investigated immediately. As suspicion cannot be resolved by epidemiological and clinical investigation alone, 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 NAI diagnosis and control. In cases where potential public health implications are suspected, notification to the appropriate public health authorities is essential;

   b) implement, when relevant, regular and frequent clinical inspection, serological and virological testing of high-risk groups of animals, such as those adjacent to an NAI infected country, *zone* or *compartment,* places where birds and poultry of different origins are mixed, such as live bird markets, poultry in close proximity to waterfowl or other sources of NAIV.

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 NAIV. 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 NAIV 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.).

Article 3.8.9.3.

Surveillance strategies

1. Introduction

   The target population for surveillance aimed at identification of *disease* and *infection* should cover all the susceptible poultry species within the country, *zone* or *compartment.* Active and passive surveillance for NAI should be ongoing. The frequency of active surveillance should be at least every 6 months.

Surveillance should be composed of random and targeted approaches using virological, serological and clinical methods.

The strategy employed may be based on randomised sampling requiring surveillance consistent with demonstrating the absence of NAIV infection at an acceptable level of confidence. The frequency of sampling should be dependent on the epidemiological situation. Random surveillance is conducted using serological tests described in the *Terrestrial Manual*. Positive serological results should be followed up with virological methods.

Targeted surveillance (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. Virological and serological methods should be used concurrently to define the NAI status of high risk populations.

Community comment:

Occurrence of HPAI in birds kept in captivity or in wild birds should be taken into account when assessing high risk populations of poultry and be reflected in surveillance activities.

The Community proposes the following additional sentence to be added as a last sentence above:

"The occurrence of HPAI infections in birds other than poultry as defined in Article 2.7.12.1. point 3 and in wild birds should be taken into account when assessing high risk populations of poultry and be reflected in surveillance activities".

A country should justify the surveillance strategy chosen as adequate to detect the presence of NAIV infection in accordance with Appendix 3.8.1. and the prevailing epidemiological situation. It may, for example, be appropriate to target clinical surveillance at particular species likely to exhibit clear clinical signs (e.g. chickens). Similarly, virological and serological testing could be targeted to species that may not show clinical signs (e.g. ducks).

If a Member Country wishes to declare freedom from NAIV infection in a specific *zone* or *compartment,* the design of the survey and the basis for the sampling process would need to be aimed at the population within the *zone* or *compartment*.

For random surveys, the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalence. The sample size 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 results of the survey. The applicant country must justify the choice of design prevalence and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Appendix 3.8.1. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results

obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/infection history and the different species in the target population.

Irrespective of the testing system employed, surveillance system design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of infection or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as flocks which may be epidemiologically linked to it.

The principles involved in surveillance for *disease / infection* are technically well defined. The design of surveillance programmes to prove the absence of NAIV infection/circulation needs to be carefully followed to avoid producing results that are either insufficiently reliable, or excessively costly and logistically complicated. The design of any surveillance programme, therefore, requires inputs from professionals competent and experienced in this field.

2. Clinical surveillance

Clinical surveillance aims at the detection of clinical signs of NAI at the flock level. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, surveillance based on clinical inspection should not be underrated. Monitoring of production parameters, such as increased mortality, reduced feed and water consumption, presence of clinical signs of a respiratory disease or a drop in egg production, is important for the early detection of NAIV infection. In some cases, the only indication of LPNAIV infection may be a drop in feed consumption or egg production.

Clinical surveillance and laboratory testing should always be applied in series to clarify the status of NAI suspects detected by either of these complementary diagnostic approaches. Laboratory testing may confirm clinical suspicion, while clinical surveillance may contribute to confirmation of positive serology. Any sampling unit within which suspicious animals are detected should be classified as infected until evidence to the contrary is produced.

Identification of suspect flocks is vital to the identification of sources of NAIV and to enable the molecular, antigenic and other biological characteristics of the virus to be determined. It is essential that NAIV isolates are sent regularly to the regional Reference Laboratory for genetic and antigenic characterization.

3. Virological surveillance

Virological surveillance using tests described in the *Terrestrial Manual* should be conducted:

a) to monitor at risk populations;

b) to confirm clinically suspect cases;

c) to follow up positive serological results;

d) to test 'normal' daily mortality, to ensure early detection of infection in the face of vaccination or in *establishments* epidemiologically linked to an *outbreak*.

4. Serological surveillance

Serological surveillance aims at the detection of antibodies against NAIV. Positive NAIV antibody test results can have four possible causes:

a) natural infection with NAIV;

b) vaccination against NAI;

c) maternal antibodies derived from a vaccinated or infected parent flock are usually found in the
yolk and can persist in progeny for up to 4 weeks;

d) positive results due to the lack of specificity of the test.

It may be possible to use serum collected for other survey purposes for NAI surveillance. However, the principles of survey design described in these guidelines and the requirement for a statistically valid survey for the presence of NAIV should not be compromised.

The discovery of clusters of seropositive flocks may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or infection. As clustering may signal infection, the investigation of all instances must be incorporated in the survey design. Clustering of positive flocks is always epidemiologically significant and therefore should be investigated.

If vaccination cannot be excluded as the cause of positive serological reactions, diagnostic methods to differentiate antibodies due to infection or vaccination should be employed.

The results of random or targeted serological surveys are important in providing reliable evidence that no NAIV infection is present in a country, *zone* or *compartment*. It is therefore essential that the survey be thoroughly documented.

5. Virological and serological surveillance in vaccinated populations

The surveillance strategy is dependent on the type of vaccine used. The protection against AI is haemagglutinin subtype specific. Therefore, two broad vaccination strategies exist: 1) inactivated whole AI viruses, and 2) haemagglutinin expression-based vaccines.

In the case of vaccinated populations, the surveillance strategy should be based on virological and/or serological methods and clinical surveillance. It may be appropriate to use sentinel birds for this purpose. These birds should be unvaccinated, AI virus antibody free birds and clearly and permanently identified. The interpretation of serological results in the presence of vaccination is described in Article 3.8.9.7.

Article 3.8.9.4.

Documentation of NAI or HPNAI free status

1. Countries declaring freedom from NAI or HPNAI for the country, zone or compartment

In addition to the general conditions described in the *Terrestrial Code,* a Member Country declaring freedom from NAI or highly pathogenic notifiable avian influenza (HPNAI) for the entire country, or a *zone* or a *compartment* 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 and should be planned and implemented according to general conditions and methods described in this Appendix, to demonstrate absence of NAIV or HPNAIV infection, during the preceding 12 months in susceptible poultry populations (vaccinated and non-vaccinated). This requires the support of a laboratory able to undertake identification of NAIV or HPNAIV infection through virus detection and antibody tests described in the *Terrestrial Manual.* This surveillance may be targeted to poultry population at specific risks linked to the types of production, possible direct or indirect contact with wild birds, multi-age flocks, local trade patterns including live bird markets, use of possibly contaminated surface water, and the presence of more than one species on the holding and poor biosecurity measures in place.

2. Additional requirements for countries, zones or compartments that practise vaccination

Vaccination to prevent the transmission of HPNAI virus may be part of a disease control programme. The level of flock immunity required to prevent transmission will depend on the flock size, composition (e.g. species) and density of the susceptible poultry population. It is therefore impossible to be prescriptive. The vaccine must also comply with the provisions stipulated for NAI vaccines in the *Terrestrial Manual.* Based on the epidemiology of NAI in the country, *zone* or *compartment,* it may be that a decision is reached to vaccinate only certain species or other poultry subpopulations.

In all vaccinated flocks there is a need to perform virological and serological tests to ensure the absence of virus circulation. The use of sentinel poultry may provide further confidence of the absence of virus circulation. The tests have to be repeated at least every 6 months or at shorter intervals according to the risk in the country, *zone* or *compartment.*

Evidence to show the effectiveness of the vaccination programme should also be provided.

Article 3.8.9.5.

Countries, zones or compartments declaring that they have regained ~~regaining~~ freedom from NAI or HPNAI following an outbreak

In addition to the general conditions described in Chapter 2.7.12., a country declaring that it has regained ~~regaining~~ country, *zone* or *compartment* freedom from NAI or HPNAI virus infection should show evidence of an active surveillance programme depending on the epidemiological circumstances of the *outbreak* to demonstrate the absence of the infection. This will require surveillance incorporating virus detection and antibody tests described in the *Terrestrial Manual.* The use of sentinel birds may facilitate the interpretation of surveillance results.

A Member Country declaring freedom of country, *zone* or *compartment* after an *outbreak* of NAI or HPNAI (with or without vaccination) should report the results of an active surveillance programme in which the NAI or HPNAI susceptible poultry population undergoes regular clinical examination and active surveillance planned and implemented according to the general conditions and methods described in these guidelines. The surveillance should at least give the confidence that can be given by a randomized representative sample of the populations at risk.

Community comment:

The Community agrees with the suggested change in 3.8.9.5. as it improves the clarity of the text.

Article 3.8.9.6.

NAI free establishments within HPNAI free compartments

The declaration of NAI free *establishments* requires the demonstration of absence of NAIV infection. Birds in these *establishments* should be randomly tested using virus detection or isolation tests, and serological methods, following the general conditions of these guidelines. The frequency of testing should be based on the risk of infection and at a maximum interval of 21 days.

Article 3.8.9.7.

The use and interpretation of serological and virus detection tests

Poultry infected with NAI virus produce antibodies to haemagglutinin (HA), neuraminidase (NA), nonstructural proteins (NSPs), nucleoprotein/matrix (NP/M) and the polymerase complex proteins. Detection of antibodies against the polymerase complex proteins will not be covered in this Appendix. Tests for NP/M antibodies include direct and blocking ELISA, and agar gel immunodiffusion (AGID) tests. Tests for antibodies against NA include the neuraminidase inhibition (NI), indirect fluorescent antibody and direct ELISA tests. For the HA, antibodies are detected in haemagglutination inhibition (HI) and neutralization (SN) tests. The HI test is reliable in avian species but not in mammals. The SN test can be used to detect subtype specific antibodies to the haemagglutinin and is the preferred test for mammals and some avian species. The AGID test is reliable for detection of NP/M antibodies in chickens and turkeys, but not in other avian species. As an alternative, blocking ELISA tests have been developed to detect NP/M antibodies in all avian species.

The HI and NI tests can be used to subtype AI viruses into 16 haemagglutinin and 9 neuraminidase subtypes. Such information is helpful for epidemiological investigations and in categorization of AI viruses.

Poultry can be vaccinated with a variety of AI vaccines including inactivated whole AI virus vaccines, and haemagglutinin expression-based vaccines. Antibodies to the haemagglutinin confer subtype specific protection. Various strategies can be used to differentiate vaccinated from infected birds including serosurveillance in unvaccinated sentinel birds or specific serological tests in the vaccinated birds.

AI virus infection of unvaccinated birds including sentinels is detected by antibodies to the NP/M, subtype specific HA or NA proteins, or NSP. Poultry vaccinated with inactivated whole AI vaccines containing an influenza virus of the same H sub-type but with a different neuraminidase may be tested for field exposure by applying serological tests directed to the detection of antibodies to the NA of the field virus. For

example, birds vaccinated with H7N3 in the face of a H7N1 epidemic may be differentiated from infected birds (DIVA) by detection of subtype specific NA antibodies of the N1 protein of the field virus. Alternatively, in the absence of DIVA, inactivated vaccines may induce low titres of antibodies to NSP and the titre in infected birds would be markedly higher. Encouraging results have been obtained experimentally with this system, but it has not yet been validated in the field. In poultry vaccinated with haemagglutinin expression-based vaccines, antibodies are detected to the specific HA, but not any of the other AI viral proteins. Infection is evident by antibodies to the NP/M or NSP, or the specific NA protein of the field virus. Vaccines used should comply with the standards of the *Terrestrial Manual*.

All flocks with seropositive results should be investigated. Epidemiological and supplementary laboratory investigation results should document the status of NAI infection/circulation for each positive flock.

A confirmatory test should have a higher specificity than the screening test and sensitivity at least equivalent than that of the screening test.

Information should be provided on the performance characteristics and validation of tests used.

1. The follow-up procedure in case of positive test results if vaccination is used

In case of vaccinated populations, one has to exclude the likelihood that positive test results are indicative of virus circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from surveillance conducted on NAI-vaccinated poultry. The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated, and the results should be collated in the final report.

Knowledge of the type of vaccine used is crucial in developing a serological based strategy to differentiate infected from vaccinated animals.

a) Inactivated whole AI virus vaccines can use either homologous or heterologous neuraminidase subtypes between the vaccine and field strains. If poultry in the population have antibodies to NP/M and were vaccinated with inactivated whole AI virus vaccine, the following strategies should be applied:

i) sentinel birds should remain NP/M antibody negative. If positive for NP/M antibodies, indicating AI virus infection, specific HI tests should be performed to identify H5 or H7 AI virus infection;

ii) if vaccinated with inactivated whole AI virus vaccine containing homologous NA to field virus, the presence of antibodies to NSP could be indicative of infection. Sampling should be initiated to exclude the presence of NAIVby either virus isolation or detection of virus specific genomic material or proteins;

iii) if vaccinated with inactivated whole AI virus vaccine containing heterologous NA to field virus, presence of antibodies to the field virus NA or NSP would be indicative of infection. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins.

b) Haemagglutinin expression-based vaccines contain the HA protein or gene homologous to the HA of the field virus. Sentinel birds as described above can be used to detect AI infection. In vaccinated or sentinel birds, the presence of antibodies against NP/M, NSP or field virus NA is indicative of infection. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins.

2. The follow-up procedure in case of positive test results indicative of infection for determination of infection due to HPNAI or LPNAI virus

The detection of antibodies indicative of a NAI virus infection as indicated in point a)i) above will result in the initiation of epidemiological and virological investigations to determine if the infections are due to HPNAI or LPNAI viruses.

Virological testing should be initiated in all antibody-positive and at risk populations. The samples should be evaluated for the presence of AI virus, by virus isolation and identification, and/or detection of influenza A specific proteins or nucleic acids (Figure 2). Virus isolation is the gold standard for detecting infection by AI virus and the method is described in the *Terrestrial Manual*. All AI virus isolates should be tested to determine HA and NA subtypes, and *in vivo* tested in chickens and/or sequencing of HA proteolytic cleavage site of H5 and H7 subtypes for determination of classification as HPNAI, LPNAI or LPAI (not notifiable) viruses. As an alternative, nucleic acid detection tests have been developed and validated; these tests have the sensitivity of virus isolation, but with the advantage of providing results within a few hours. Samples with detection of H5 and H7 HA subtypes by nucleic acid detection methods should either be submitted for virus isolation, identification, and *in vivo* testing in chickens, or sequencing of nucleic acids for determination of proteolytic cleavage site as HPNAI or LPNAI viruses. The antigen detection systems, because of low sensitivity, are best suited for screening clinical field cases for infection by Type A influenza virus looking for NP/M proteins. NP/M positive samples should be submitted for virus isolation, identification and pathogenicity determination.

Laboratory results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:

a) characterization of the existing production systems;

b) results of clinical surveillance of the suspects and their cohorts;

c) quantification of vaccinations performed on the affected sites;

d) sanitary protocol and history of the affected *establishments;*

e) control of animal identification and movements;

f) other parameters of regional significance in historic NAIV transmission.

The entire investigative process should be documented as standard operating procedure within the epidemiological surveillance programme.

Fig. 1. ***Schematic representation of laboratory tests for determining evidence of NAI infection through or following serological surveys***

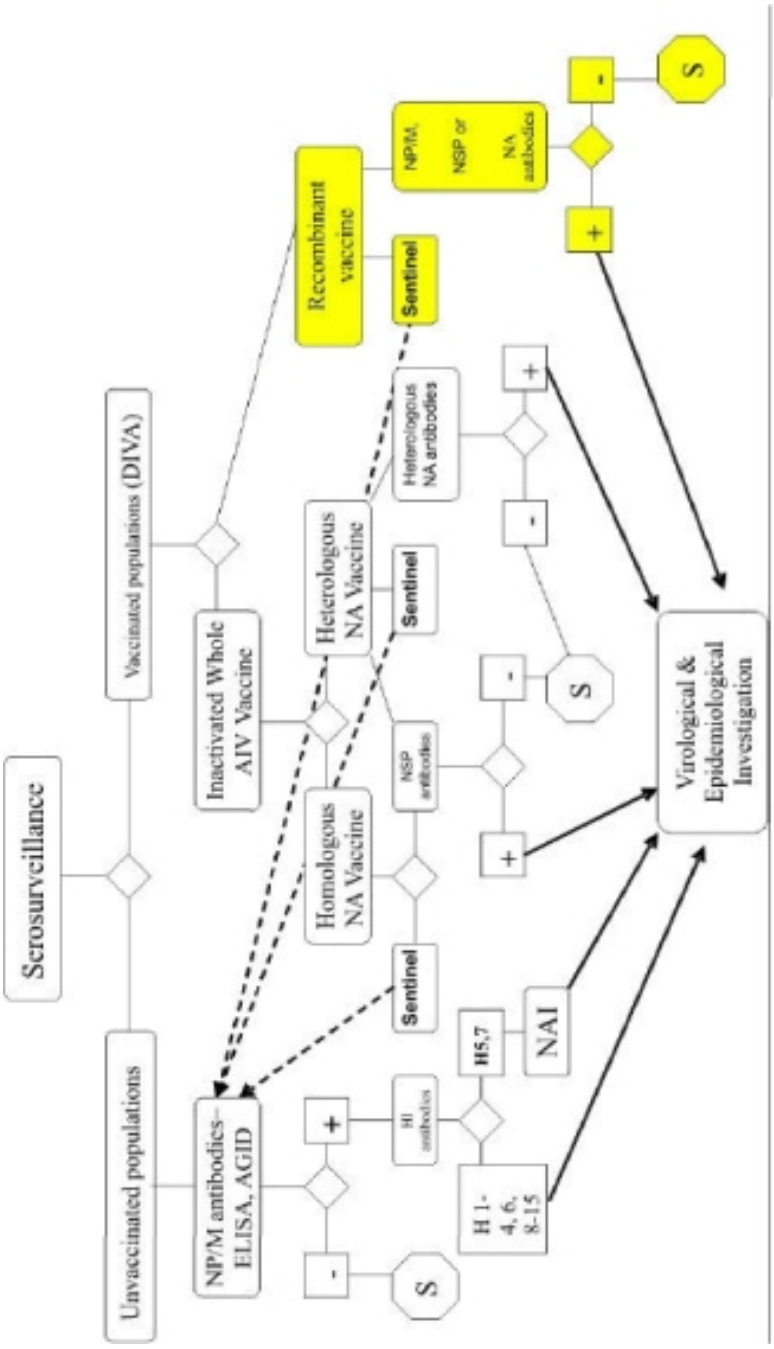
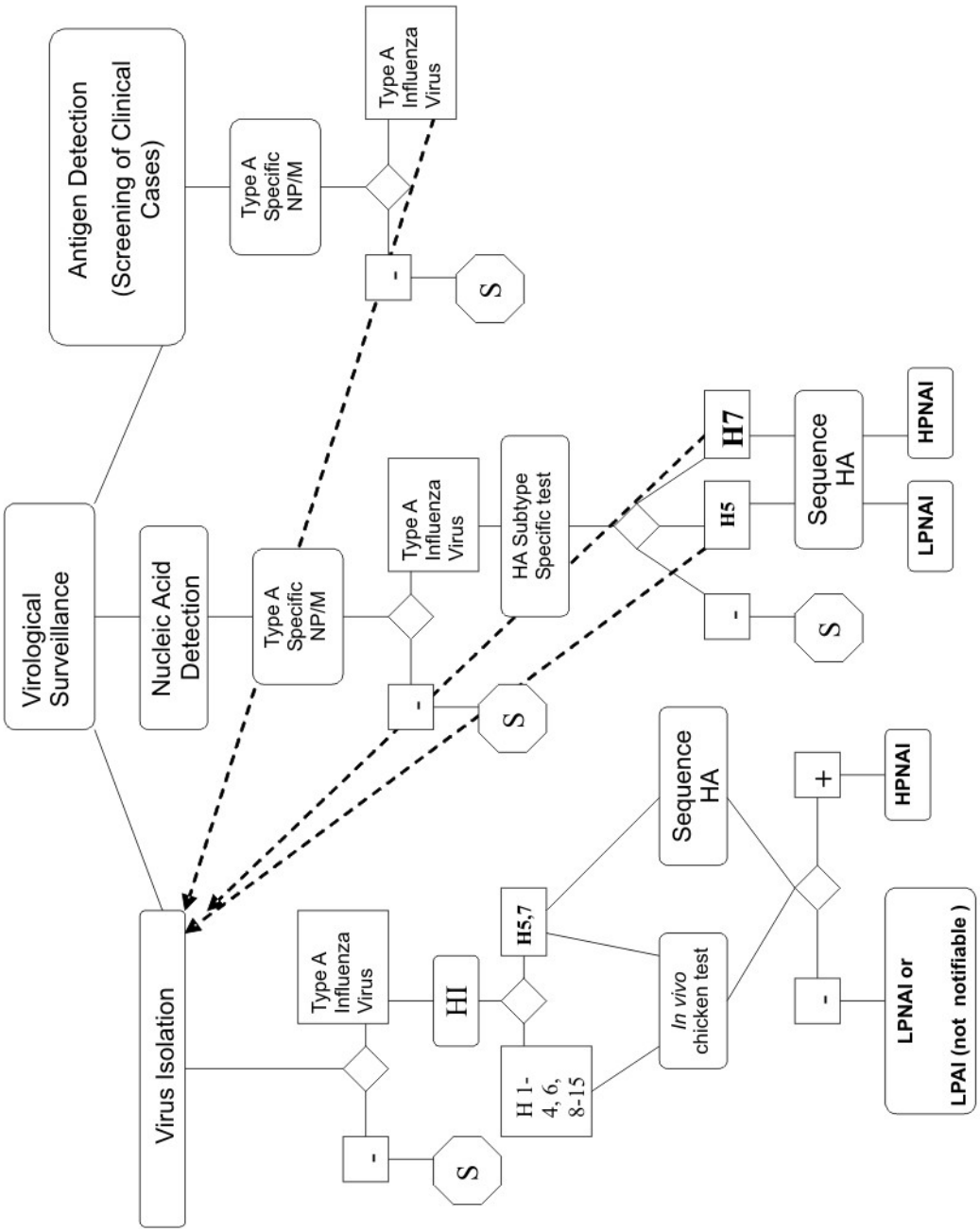


Figure 2. - ***Schematic representation of laboratory tests for determining evidence of NAI infection using virological methods***



Appendix XVIII

The above diagram indicates the tests which are recommended for use in the investigation of poultry flocks.

Key:

AGID	Agar gel immunodiffusion
DIVA	Differentiating infected from vaccinated animals
ELISA	Enzyme-linked immunosorbant assay
HA	Haemagglutinin
HI	Haemagglutination inhibition
NA	Neuraminidase
NP/M	Nucleoprotein and matrix protein
NSP	Nonstructural protein
S	No evidence of NAIV

Appendix XIX

APPENDIX 3.6.5.

GUIDELINES FOR THE INACTIVATION OF THE AVIAN INFLUENZA VIRUS

Article 3.6.5.1.

Eggs and egg products

The following times for industry standard temperatures are suitable for the inactivation of highly pathogenic notifiable avian influenza (HPNAI) virus present in eggs and egg products:

	Temperature (°C)	**Time**
Whole egg	60	188 seconds
Whole egg blends	60	188 seconds
Whole egg blends	61.1	94 seconds
Liquid egg white	55.6	~~256~~ 870 seconds
Liquid egg white	56.7	~~228~~ 232 seconds
10% salted yolk	62.2	138 seconds
Dried egg white	67	0.83 days
Dried egg white	54.4	21.38 days

Article 3.6.5.2.

Meat

A procedure which produces a core temperature of 70°C for ~~one~~ 3.5 seconds is suitable for the inactivation of HPNAI virus present in meat.

	Temperature (°C)	**Time**
Poultry meat	60.0	507 seconds
	65.0	42 seconds
	70.0	3.5 seconds
	73.9	0.51 seconds

Appendix XX

APPENDIX 3.5.1.

GENERAL PRINCIPLES

Community comments:

The Community supports these proposals.

Article 3.5.1.1.

1. There is a strong ~~critical~~ relationship between *animal identification* and the traceability of animals and products of animal origin.

2. *Animal traceability* and traceability of products of animal origin should have the capability to be linked to achieve traceability throughout the food chain taking into account relevant OIE and Codex Alimentarius standards.

3. *Animal identification* and *animal traceability* are tools for addressing animal health (including zoonoses) and food safety issues. These tools may significantly improve the effectiveness of activities such as: the management of disease outbreaks and food safety incidents, vaccination programmes, herd/flock husbandry, zoning/compartmentalisation, surveillance, early response and notification systems, animal movement controls, inspection, certification, fair practices in trade and the utilisation of veterinary drugs, feed and pesticides at farm level.

4. The objective(s) ~~and outcomes~~ of *animal identification* and *animal traceability* for a particular country, *zone* or *compartment* and the approach used should be clearly defined following an assessment of the risks to be addressed and a consideration of the factors listed below. They should be defined through consultation between the *Veterinary Administration* and relevant sectors/stakeholders prior to implementation, and periodically reviewed.

5. There are various factors which may determine the system chosen ~~system~~ for *animal identification* and *animal traceability*. Factors such as the outcomes of the risk assessment, the animal and public health situation (including zoonoses) and related programmes, animal population parameters (such as species and breeds, numbers and distribution), types of production, animal movement patterns, available technologies, trade in animals and animal products, cost/benefit analysis and other economic, geographical and environmental considerations, and cultural aspects, should be taken into account when designing the system. Whatever system is used, it should comply with relevant OIE standards to ensure that the defined objectives are able to be achieved.

6. *Animal identification* and *animal traceability* should be under the responsibility of the *Veterinary Administration*, notwithstanding the responsibilities of other Competent Authorities having jurisdiction throughout the food chain.

7. The *Veterinary Administration*, with relevant governmental agencies and in consultation with the private sector, should establish a legal framework for the implementation and enforcement of *animal identification* and *animal traceability* in the country. In order to facilitate compatibility and consistency, relevant international standards and obligations should be taken into account. This legal framework should include elements such as the objectives, scope, organisational arrangements including the choice of technologies used for identification and *registration*, obligations of all the parties involved including third parties implementing traceability systems, confidentiality, accessibility issues and the efficient exchange of information.

8. Whatever the specific objectives of the chosen *animal identification system* and *animal traceability*, there is a series of common basic factors, and these must be considered before implementation, such as the legal framework, procedures, the *Competent Authority*, identification of *establishments*/owners, *animal identification* and animal movements.

9. The equivalent outcomes (performance criteria) rather than identical systems (design criteria) should be the basis for comparison of *animal identification systems* and *animal traceability*.

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— text deleted

APPENDIX 3.6.6.

GENERAL GUIDELINES FOR THE DISPOSAL OF DEAD ANIMALS

Community comments:

The Community supports these proposals and welcomes especially the clarification of the powers of the Veterinary Services and the addition of certain financial issues to be taken into consideration when disposing of dead animals. The present text has improved and became more complete in the aspects to be considered.

However, it believes that the wording of the text can still be improved in some areas.

Furthermore, in Article 3.6.6.6. it should be highlighted that not all recommended methods are equally suitable to efficiently destroy the causative pathogen of a certain disease (e. g. the composting process, which not always achieves a temperature of even 70 °C). Therefore, it should be inserted in the first sentence that not only local conditions, required capacity and speed of outcome should be taken into account when choosing the method for disposal but also the required conditions of treatment for the inactivation of the causative agent.

Article 3.6.6.1.

Introduction

The mass disposal of dead animals associated with an animal *disease outbreak* is often subject to intense public and media scrutiny thereby obligating the *Veterinary Administration* of a Member Country to not only conduct disposal operations within acceptable scientific principles to destroy the causative pathogen but also to address public and environmental concerns.

The guidelines in this Appendix are general in nature. The choice of one or more of the recommended methods should be in compliance with relevant local and national legislation and be attainable with the resources available. The guidelines should also be applied in conjunction with the procedures described for the killing of animals in Appendix 3.7.6.

Strategies for the disposal of dead animals (entire animals or parts thereof) should be prepared well in advance of any emergency. Major issues related to the disposal of dead animals include the number of animals involved, biosecurity concerns over the movement of infected or exposed animals, people and equipment, environmental concerns, and the psychological distress experienced by farmers and animal handlers.

Article 3.6.6.2.

Regulations and jurisdiction

The legislation regulating animal health and the organisation of the *Veterinary Administration* should give the *Veterinary Services* the authority and the legal powers to carry out the activities necessary for the efficient and effective disposal of dead animals. Cooperation between the *Veterinary Service* and other relevant government bodies is necessary to developing a coherent set of legal measures for the disposal of dead animals in advance of any emergency. In this context the following aspects should be regulated:

1. Powers of *Veterinary Services* (inspectors, veterinary officers, etc.) to effect controls and direct persons as well as the right of entry to an *establishment* for the *Veterinary Services* and associated personnel;

2. movement controls and the authority to make exemptions under certain biosecurity conditions, for example for transport of dead animals to another location for disposal;

3. the obligation on the involved farmer and *animal handlers* to cooperate with the *Veterinary Services*;

4. any need to transfer the ownership of animals to the competent authority;

5. the determining of the method and location of disposal, and the necessary equipment and facilities, by the *Veterinary Services,* in consultation with other involved authorities including national and local governmental organisations competent for the protection of human health and of the environment.

Should the chosen option for the disposal of dead animals be applied near the border of a neighbouring country, the competent authorities of that country should be consulted.

Article 3.6.6.3.

Preparedness

The mass killing and disposal of animals in the event of a *disease outbreak* or disposal of animals in the event of natural disasters such as floods, usually must proceed with the minimum delay. The success is determined by the structures, policies and infrastructure established in advance:

1. Technical preparedness

   Standard operating procedures (including documented decision-making processes, training of staff). A relationship with industry is essential to obtain compliance with animal health policies - farmer associations, commodity representatives, animal welfare organisations, support structures such as security services, relevant government agencies, the media and consumer representatives.

2. Financial preparedness

   Financial preparedness means a compensation or insurance mechanism, an access to emergency funding and an access to personnel through agreements with private veterinarians

3. Communication plan

Information sharing with officials involved in the *outbreak,* affected farmers, professional organizations, politicians and the media is essential. A well informed spokesperson should be available at all times to answer enquiries.

4. Resources

The management of resources should address such items as personnel, transport, storage facilities, equipment (such as mobile handling facilities for animals, disinfection equipment), fuel, protective and disposable material and logistical support.

5. ~~Heavy~~ Special equipment

~~Heavy~~ Availability of special equipment including trucks, tractors, bulldozers, and front-end loaders.

Community comment:

The Community acknowledges that point 5 has become clearer in addressing special equipment. However, it is believed that the text would be more readable by using the following wording: "Special equipment, such as trucks, tractors, bulldozers, and front-end loaders should be available."

Article 3.6.6.4.

Critical elements

Critical elements which need to be taken into account in planning and implementation include: ~~The list of critical elements, which has not the pretension to be complete, needs to be taken into account in planning and implementation.~~

1. Timeliness

Early detection of new infections, immediate killing of infected animals and rapid removal of the dead animals with inactivation of the pathogen are important. Spread of the pathogen from the dead animals and their surroundings should be blocked as soon and as effectively as possible.

2. Occupational health and safety

Disposal should be organised in such a way that the workers are safeguarded against the risks of handling decomposing dead animals. Special attention should be given to zoonotic aspects. Workers should receive appropriate training and be sufficiently protected against infection with protective clothing, gloves, face masks, respirators, spectacles, vaccination, anti viral medicines and regular health checks.

3. Pathogen inactivation

The disposal procedure should be selected to result in inactivation of the pathogen.

4. Environmental concerns

Different methods of the disposal of dead animals have different effects on the environment. For instance, pyre burning will produce smoke and smells; burial might lead to gas and leachate production resulting in potential ~~and also a risk of~~ contamination of air, soil, surface and sub surface water.

5. Availability of capacity

An assessment of capacities of different methods of disposal should be made prior to any emergency. Temporary storage of dead animals in cold stores may relieve a lack of processing capacity.

6. ~~Ina~~Adequate funding

Adequacy of funding for the options chosen must be ascertained and committed at the earliest possible stage.

7. Staff resources

For extended and /or large operations. Particularly important for technical and inspectorial personnel who are usually in short supply

Community comment:

The Community acknowledges that the question of staff resources should be addressed. However, it is believed that the text would be more readable by using the following wording: "Availability of sufficient and well trained staff resources in particular for extended and /or large operations should be ensured. This is particularly important for technical and inspection personnel who are usually in short supply."

~~7.~~8. ~~Public reaction~~ Societal acceptance

Societal acceptance is an important point in choosing the method to use.

~~8.~~9. Acceptance by farmers

Farmers will be sensitive to the safety measures taken to prevent spread of the disease by disposal method selected and the transport of the dead animals to the disposal site. Adequate compensation of owners for the loss of animals or for burial or burning sites will improve acceptability.

~~9.~~10. Equipment

Equipment used in the disposal of dead animals can transfer infection to other premises. The cleaning and disinfection of the outside surfaces of equipment such as cranes, containers and trucks, and

the departure of vehicles from the farm should receive special attention. Trucks transporting dead animals should be leak proof.

~~10~~11. ~~Wildlife~~ Scavengers and vectors

When disposing of dead animals, full attention should be given to preventing scavengers and vectors gaining access to dead animals, which might cause spread of disease.

12. Economic impact (short and long term including recovery)

The method of disposal has the potential to influence significantly many aspects economically. This excludes operational costs, subsequent monitoring and re establishment.

Community comment:

The Community acknowledges that the economic impact is a critical element when disposing of dead animals. Reference to this impact clarifies and improves the text further. However, the wording of the proposed text should be clarified in some aspects. Therefore, it is suggested to clarify in the heading to point 12 that "included recovery" refers to "including recovery of losses". In the main text, it is suggested to give examples to "many aspects", explaining, what is included. This seems particularly important given that the following sentence lists what is excluded. Furthermore, it should be explained, what means "excludes operational costs", etc., e. g. to what does "this" refer, does it to (the method of disposal, the potential influence and/or the economic impact, etc.?).

Article 3.6.6.5.

Practical considerations

1. Selection of disposal site

Sufficient top soil to cover the site; water drainage; prevailing wind conditions; easy access to transport; availability of meteorological data; separation from sensitive public sites, and the effect on future use.

2. ~~Selection of c~~ Contractors ~~for transport~~

~~Selection of c~~ Contractors ~~for transport~~ — availability; can they supply in all the needs; exclusive use of vehicles or would they also be used for other purposes (risk of disease transmission); access to available roads; suitable for the purpose to be used.

Community comment:

The Community acknowledges that selection of contractors should not only refer to those for transport and this point should be seen in a more general way. However, deleting the reference to transport in the headline and in the text should be compensated for by clarifying this context subsequently. It might also clarify the text if examples for other contractors than those for transport were given.

The Community proposes the following wording:

"Contractors — availability of manpower, materials and equipment including transport vehicles ; can they supply in all the needs; exclusive use of vehicles or would they also be used for other purposes (risk of disease transmission); access to available roads; suitable for the purpose to be used."

3. Logistical preparedness for the appropriate technology

Availability of fuel ~~(wood, old tyres)~~; sufficient manual labour available; sites and availability of disinfection tents for personnel; storage and disposal of protective clothing; housing for personnel to minimise the spread of infection; facilities for entry and exit control; availability of electricity for night operations; personal facilities for personnel such as toilets, drinking water; availability of communication — mobile phone reception; protection (e.g. vaccination) of personnel; rendering capacity at rendering plants; ~~arms and ammunition,~~ additional cold storage and holding facilities at rendering plants and abattoirs.

4. Procedures and policies for disposal of other possibly contaminated products Animal products such as litter, ~~M~~manure, wool, eggs and milk; ~~non-animal products;~~ animal feed; non-animal products such as protective clothing.

5. Wildlife

Need to address risk posed; expertise availability for capture/culling of wildlife.

Article 3.6.6.6.

Recommended methods for the disposal of dead animals

The method(s) chosen should be based on local conditions and ~~circumstances~~ the required capacity and speed of outcome.

Some of the methods below may require on-farm pre-processing prior to transportation of dead animals to central facilities for rendering or incineration. Preprocessing could include the grinding of dead animals which can then be transported in sealed containers, or be subjected to fermentation, composting or freezing.

Community comment:

In Article 3.6.6.6. it should be highlighted that not all recommended methods are equally suitable to efficiently destroy the causative pathogen of a certain disease (e. g. the

composting process, which not always achieves a temperature of even 70 °C). Therefore, the first sentence should read as follows:

"The method(s) chosen should be based on local conditions, the required capacity, speed of outcome and on the conditions required for the inactivation of the causative agent."

1. Rendering

This is a closed system for mechanical and thermal treatment of animal tissues leading to stable, sterilized products, e.g. animal fat and dried animal protein. The technology exists in dedicated facilities. It produces an effective inactivation of all pathogens with the exception of prions where infectivity is reduced. The availability of the capacity should be determined in advance.

2. Incineration in a dedicated facility

In such a facility, whole dead animals or parts of animals can be completely burned and reduced to ash, often in conjunction with other substances (such as municipal waste, hazardous waste or hospital waste). Effective inactivation of pathogens, including spores, occurs. Fixed facility incineration is wholly contained and has some advantages from the environmental viewpoint as the exhausts may be fitted with afterburner chambers to completely burn hydrocarbon gases and particulate matter from the main combustion chamber.

Community comment:

Plants normally used for municipality waste may not be closed enough to receive contagious material. Birds may have access through gateways, and cleaning and disinfection of the plant after the reception may be impossible. Some plants may also be constructed in a way that it is possible for material to pass through without having been properly incinerated.

3. Rendering and incineration

These may be combined for improved security and to provide additional fuel for furnaces in facilities used for other purposes such as in cement kilns and electricity generation plants.

4. Air curtain incineration

This process fan-forces a mass of air through a manifold, thereby creating a turbulent environment in which incineration is accelerated up to six times for example in a burn-pit. The equipment can be mobile and, because it can be used on site, there is no requirement for transportation of the animal material. It also produces effective inactivation of pathogens.

5. Pyre burning

This open system of burning dead animals is a well established procedure that can be conducted on site with no requirement for transportation of animal material. However, it takes an extended period of time and has no way of verifying pathogen inactivation, and there may be particulate dissemination from incomplete combustion. Further, because the process is open to view, there may be a lack of acceptance by the public.

6. Composting

Composting is a natural biological decomposition process that takes place in the presence of oxygen. In the first phase, the temperature of the compost pile increases, organic materials break down into relatively small compounds, soft tissue decomposes, and bones soften partially. In the second phase, the remaining materials, mainly bones, break down fully to a dark brown or black humus containing primarily non-pathogenic bacteria and plant nutrients. However, some viruses and spore forming bacteria, such as *Bacillus anthracis,* and other pathogens such as *Mycobacterium tuberculosis* may survive.

Community comment:

The Community believes this should not be recommended as a general method as the efficiency of the decontamination is very uncertain as it is dependent on the temperature reached in the entire material. Temperature can for example depend on outdoor temperature and on the type and particle size of the material to be composted. There is also always a risk that the outlines of the material to be composted have not reached high temperature and can therefore re-contaminate the entire material. The compost can attract wild animals through which disease can be spread.

7. ~~Trench b~~ Burial

In this method, whole dead animals are buried and covered by soil. Burial is an established procedure which may be conducted on site. It may not inactivate all pathogens. In some circumstances, dead animals may be disposed of by mounding whereby they are covered by a layer of soil above ground.

8. Biogas production

This is a closed system of anaerobic fermentation which would require for the disposal of dead animals or their parts prior mechanical and thermal treatment of the input material (such as the liquid product of rendering plants). This process may not inactivate all pathogens.

9. Alkaline hydrolysis

This method uses sodium hydroxide or potassium hydroxide to catalyse the hydrolysis of biological material into a sterile aqueous solution consisting of small peptides, amino acids, sugars, and soaps. Heat is applied (150°C) to accelerate the process. The only solid byproducts are the mineral constituents of bones and teeth. This residue (2% of the original weight of the animal) is sterile and easily crushed into a powder. The temperature and alkali conditions of the process destroy the protein coats of viruses and the peptide bonds of prions. Both lipids and nucleic acids are degraded. The process is carried out in an insulated steam-jacketed, stainless steel pressure vessel.

10. Bio-refining

This is a high pressure, high temperature hydrolytic process, conducted in a sealed pressurised vessel. The waste material is treated at 180°C at 12 bar pressure for 40 minutes, heated by the indirect application of steam kj, other compostable material, paper and comparable materials, and cereal straws either alone or in combination. The process inactivates all microbiological agents.

11. Dead animal disposal at sea

International Conventions define the conditions to be met for the disposal of dead animals at sea.

Community comment:

The Community would like this possibility deleted.

Article 3.6.6.7.

Guidelines for decision-making for the disposal of dead animals

Community comment:

The text in this Article needs to be further clarified as it not very clear.

~~Strategies for dead animal disposal require preparation well in advance of an emergency in order to maximize the efficiency of the response. Major issues related to dead animal disposal can include the number of animals involved, bio security concerns over movement of infected and exposed animals, people and equipment, environmental concerns, and the extreme psychological distress and anxiety experienced by producers and emergency workers.~~

The disposal of large numbers of dead animals will be expensive. As well, fixed and variable costs will vary with the choice of the disposal method. Each method used will result in indirect costs on the environment, local economies, producers, and the livestock industry. Decision makers, in addition to biosecurity considerations, need to understand the economic, social and aesthetic impact of various disposal technologies.

A disposal option hierarchy may be incapable of fully capturing and systematizing the relevant dimensions at stake, and decision makers may be forced to consider the least preferred means. It therefore requires a comprehensive understanding of any array of dead animal disposal technologies and must reflect a balance between the scientific, economic, and social issues at stake. Timely slaughter, maintenance of security and prevention of further spread of disease, are the essential considerations in terms of disease control.

The following is an example of a possible process for aiding decision-making by comparing the suitability of various disposal options against factors that are considered important for the specific disposal event in question:

1. Step 1 - Define the factors to be considered. Include all relevant factors and allow enough flexibility to permit modifications for different situations and locations. Examples of possible factors include operator safety, community concerns, international acceptance, transport availability, industry standards, cost effectiveness and speed of resolution. These factors can be modified or changed, as is shown in the following example, to best fit the situation of event involved.

2. Step 2 - Assess the relative importance of the factors by weighting each on their considered importance to addressing the event in question. The sum of all the weightings, regardless of the number of factors, must total 100.

3. Step 3 - Identify and list all disposal options under consideration. Rate each disposal option against each

factor and assign a Utility Rating of between 1 to 10 to each comparison. The Utility Rating (U) is a number between 1 and 10 which is allocated according to how well the option achieves the ideal with respect to each factor (eg 1 = the worst possible fit, and 10 = the best fit).

4. Step 4 - For each factor and each disposal option, multiply the Factor Weight (F) x Utility Rating (U) to yield a numeric Balanced Value (V), (eg V = F x U).

5. Step 5 - By adding the Balanced Values to a sum for each disposal option, it is possible to compare the suitability of disposal options by numerically ranking the sums of the Balanced Values for each disposal option. The largest sum would suggest that disposal option is the best balanced choice.

An example of the use of this process follows in Table 1. In this example, rendering achieved the highest sum and would be considered as the best balanced choice and the most suitable disposal option for the factors considered.

Table 1: **Decision Making Process**

Method		Rendering		Fixed Incineration		Pyre Burning		Composting		Mass Burial		On-Farm Burial		Commercial Landfill	
	Weight	Utility	Value	Utility	Value	Utility	Value	Utility	Value	Utility	Value	Utility	Value	Utility	Value
Factors															
Operator Safety	20	7	140	4	80	8	160	3	60	7	140	8			
Speed of Resolution	20	8	160	8	160	2	40	5	100	5	100	6			
Pathogen Inactivation	15	10	150	10	150	8	120	5	75	4	60	4			
Impact on Environment	10	10	100	8	80	3	30	10	100	3	30	3			
Reaction of the Public	10	10	100	7	70	1	10	9	90	3	30	4			
Transport Availability	5	1	5	1	5	8	40	5	25	3	15	8			
Acceptable to Industry	5	7	35	7	35	7	35	7	35	6	30	7			
Cost	5	4	20	1	5	6	30	9	45	8	40	9			
Risk to Wildlife	5	10	50	10	50	5	25	4	20	5	25	5			
Capacity to Meet Requirements	5	5	25	3	15	9	45	9	45	9	45	9			
Total Weight to Equal 100 Units	100	sum	785	sum	650	sum	535	sum	595	sum	515	sum		sum	

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— text deleted

Appendix XXII

APPENDIX 3.7.2.

GUIDELINES FOR THE TRANSPORT OF ANIMALS BY SEA

Preamble: These guidelines apply to the following live domesticated animals: cattle, buffalo, deer, camelids, sheep, goats, pigs and equines. They may also be applicable to other domesticated animals.

Article 3.7.2.1.

The amount of time animals spend on a *journey* should be kept to the minimum.

Article 3.7.2.1. bis

1. Animal behaviour

Animal handlers should be experienced and competent in handling and moving farm livestock and understand the behaviour patterns of animals and the underlying principles necessary to carry out their tasks.

The behaviour of individual animals or groups of animals will vary, depending on their breed, sex, temperament and age and the way in which they have been reared and handled. Despite these differences, the following behaviour patterns which are always present to some degree in domestic animals, should be taken into consideration in handling and moving the animals.

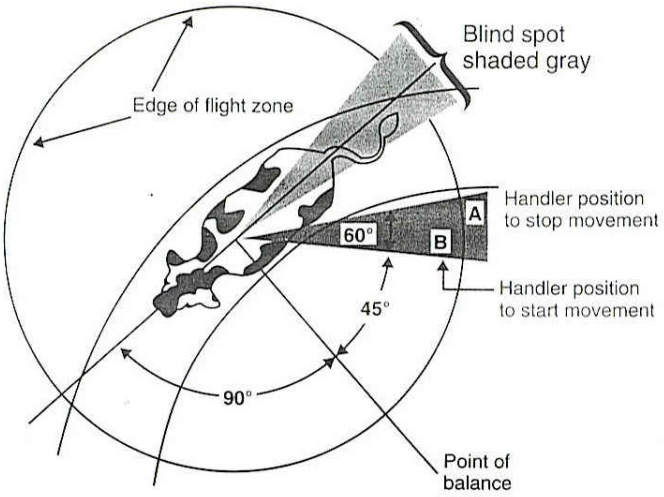
Most domestic livestock are kept in herds and follow a leader by instinct.

Animals which are likely to be hostile to each other in a group situation should not be mixed.

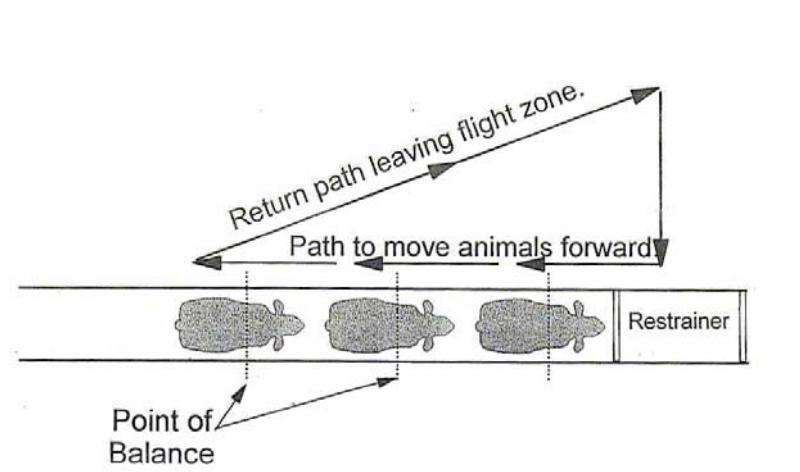
The desire of some animals to control their personal space should be taken into account in designing *loading* and *unloading* facilities, transport *vessels* and *containers.*

Domestic animals will try to escape if any person approaches closer than a certain distance. This critical distance, which defines the flight zone, varies among species and individuals of the same species, and depends upon previous contact with humans. Animals reared in close proximity to humans (i.e. tame) have a smaller flight zone, whereas those kept in free range or extensive systems may have flight zones which may vary from one metre to many metres. A*nimal handlers* should avoid sudden penetration of the flight zone which may cause a panic reaction which could lead to aggression or attempted escape.

An example of a flight zone (cattle)



Animal handler **movement pattern to move cattle forward**



Animal handlers should use the point of balance at the animal's shoulder to move animals, adopting a position behind the point of balance to move an animal forward and in front of the point of balance to move it backward.

Domestic animals have wide-angle vision but only have limited forward binocular vision and poor perception of depth. This means that they can detect objects and movements beside and behind them, but can only judge distances directly ahead.

Although all domestic animals have a highly sensitive sense of smell, they may react differently to the smells encountered during travel. Smells which cause fear or other negative responses should be taken into consideration when managing animals.

Domestic animals can hear over a greater range of frequencies than humans and are more sensitive to higher frequencies. They tend to be alarmed by constant loud noise and by sudden noises, which may cause them to panic. Sensitivity to such noises should also be taken into account when handling animals.

2. Distractions and their removal

Distractions that may cause approaching animals to stop, baulk or turn back should be designed out from new *loading* and *unloading* facilities or removed from existing ones. Below are examples of common distractions and methods for eliminating them:

a) reflections on shiny metal or wet floors - move a lamp or change lighting;

b) dark entrances - illuminate with indirect lighting which does not shine directly into the eyes of approaching animals;

Written community comments:

The following additional point should be added:

c) "dead ends - avoid if possible by curving the passage, or make an illusory passage".

Justification

As dark entrances are mentioned, it could be wise to mention also the phenomenon of "dead ends", i. e. the very end of a passage, with no escape route. Some animals, especially cattle, tend to avoid dead ends (see for example the work of the American scientist Temple Grandin). This could lead to unwanted stops and stressful attempts to move the animal forward.

c) animals seeing moving people or equipment up ahead - install solid sides on chutes and races or install shields;

d) chains or other loose objects hanging in chutes or on fences - remove them;

e) uneven floors or a sudden drop in floor levels – avoid uneven floor surfaces or install a solid false floor to provide an illusion of a solid and continuous walking surface;

f) sounds of air hissing from pneumatic equipment - install silencers or use hydraulic equipment or vent high pressure to the external environment using flexible hosing;

g) clanging and banging of metal objects - install rubber stops on gates and other devices to reduce metal to metal contact;

h) air currents from fans or air curtains blowing into the face of animals - redirect or reposition equipment.

Article 3.7.2.2.

Responsibilities

Once the decision to transport the animals by sea has been made, the welfare of the animals during their *journey* is the paramount consideration and is the joint responsibility of all people involved. ~~with~~ The individual responsibilities of ~~those~~ persons involved ~~being~~ will be described in more detail in this Article. These guidelines may also be applied to the transport of animals by water within a country.

The management of animals at post-discharge facilities is outside the scope of this Appendix.

~~The roles of each of those responsible are defined below:~~

Written community comments:

In this paragraph the word "importers" and the related text should be deleted.

Justification

For the moment it is not clear what the definition and the responsibilities for importers are.

1. General considerations

~~1.~~a) Exporters, importers, owners of animals, business or buying/selling agents, shipping companies, masters of *vessels* and managers of facilities are jointly responsible for the general health of the animals and their fitness for the *journey*, and for their overall welfare during the *journey*, regardless of whether duties are subcontracted to other parties during transport.

~~5.~~b) ~~The~~ Exporters, ~~the~~ shipping companies, business or buying/selling agents, and ~~the~~ masters of ~~the~~ *vessels* are jointly responsible for planning the *journey* to ensure the care of the animals, including:

i)~~a)~~ choosing appropriate *vessels* and ensuring that *animal handlers* are available to care for the animals;

ii)~~b)~~ developing and keeping up to date contingency plans to address emergencies (including adverse weather conditions) and minimise stress during transport;

Written community comments:

Point 1 b) iii) should be changed as follows:

"correct loading of the ship, regular inspections, watering and feeding during the journey and for ……..".

Justification

In the General considerations, point 1.a), it is stated that all persons involved have a joint responsibility of the overall welfare of the animals during the journey. In point 1.b) it is more specifically pointed out whose responsibility it is to plan the journey to ensure the care of the animals; ensuring animal handlers to care for the animals (b i)) and those

regular inspections take place (b iii)). However, it is not explicitly stated who is responsible for providing the animals with water and feed. E. g. in point 2 i), it should state that animal handlers shall provide the animals with water and feed. Furthermore it is not uncommon that masters of vessels do not allow handlers/drivers on the car deck on ferries to check on the animals. It is therefore important to make it clear that handlers are responsible for ensuring that the animals are provided with water and feed.

iii)~~c)~~ correct *loading* of the ship, regular inspections during the *journey* and for appropriate responses to problems arising;

iv)~~d)~~ disposal of carcasses according to international law.

6.c) To carry out ~~these~~ the above mentioned responsibilities, the ~~people~~ parties involved should be competent regarding transport regulations, equipment usage, and the humane handling and care of animals.

~~2. The exporter has overall responsibility for the organisation, carrying out and completion of the journey, regardless of whether duties are subcontracted to other parties during transport. The exporter is also responsible for ensuring that equipment and medication are provided as appropriate for the species and journey, and for the presence during the journey of at least one *animal handler* competent for the species being transported. The exporter is also responsible for ensuring compliance of the animals with any required veterinary certification and, in the case of animals for export, any other requirements of the *importing* and *exporting countries*.~~

2. Specific considerations

a) The responsibilities of the exporters include:

i) the organisation, carrying out and completion of the *journey*, regardless of whether duties are subcontracted to other parties during transport;

ii) ensuring that equipment and medication are provided as appropriate for the species and the *journey*;

iii) securing the presence of the appropriate number of *animal handlers* competent for the species being transported;

iv) ensuring compliance of the animals with any required veterinary certification, and their fitness to travel;

v) in case of animals for export, ensuring compliance with any requirements of the *importing* and *exporting countries*.

b) The responsibilities of the importers include:

(under study)

Written community comments:

In point 2 c) the sentence should be completed with the following text "…..veterinary recommendations, and to check that the exporters have the certificates required."

Additionally a reference to Art. 3.7.2.6 .3 "Fitness to travel" should be made.

Justification

The responsibilities of the owners are stated. However the owners of the animals, when not organising the transport themselves, also are responsible for making sure that the exporters have the necessary skills and certificates.

c) The responsibilities of the owners of the animals include the selection of animals that are fit to travel based on veterinary recommendations.

~~3. Business or buying/selling agents have a joint responsibility with owners for the selection of animals that are fit to travel. They have a joint responsibility with masters of vessels and managers of facilities at the start and at the end of the journey for the availability of suitable facilities for the assembly, *loading*, transport, *unloading* and holding of animals, and for emergencies.~~

d) The responsibilities of the business or buying/selling agent include:

Written community comments:

Under point 2 d i) a reference to the art. 3.7.2.6. 3 should be added.

i) selection of animals that are fit to travel based on veterinary recommendations;

ii) availability of suitable facilities for the assembly, *loading*, transport, *unloading* and holding of animals at the start and at the end of the *journey*, and for emergencies.

e) The responsibilities of shipping companies include:

(under study)

f) The responsibilities of masters of *vessels* include the provision of suitable premises for animals on the *vessel.*

g) The responsibilities of managers of facilities during *loading* include:

~~7. Managers of facilities during *loading* of the animals are responsible for:~~

i)~~a)~~ providing suitable premises for *loading* the animals;

ii)~~b)~~ providing an appropriate number of *animal handlers* to load the animals with minimum stress and the avoidance of injury;

iii) minimising the opportunities for disease transmission while the animals are in the facilities;

iv)~~c)~~ providing appropriate facilities for emergencies;

v)~~d)~~ providing facilities, *veterinarians* or *animal handlers* capable of *killing* animals humanely when required.

h) The responsibilities of managers of facilities during *unloading* include:

~~8. Managers of facilities at the end of the journey are responsible for:~~

i)~~a)~~ providing suitable facilities for *unloading* the animals onto transport *vehicles* for immediate movement or securely holding the animals in *lairage*, with shelter, water and feed, when required, for transit;

ii)~~b)~~ providing *animal handlers* to unload the animals with minimum stress and injury;

iii)~~c)~~ minimising the opportunities for disease transmission while the animals are in the facilities;

iv)~~d)~~ providing appropriate facilities for emergencies;

v)~~e)~~ providing facilities, and *veterinarians* or *animal handlers* capable of *killing* animals humanely when required.

~~4. *Animal handlers* are responsible for the humane handling and care of animals, especially during *loading* and *unloading*. To carry out these responsibilities, they should have the authority to take prompt action.~~

i) The responsibilities of the *animal handlers* include humane handling and care of the animals, especially during *loading* and *unloading*.

~~9.~~j) The responsibilities of the *Competent Authority* of the *exporting country* include:

i)~~a)~~ establishing minimum standards for animal welfare, including requirements for inspection of animals before and during their travel, and for certification and record keeping;

Written community comments:

Under point 2 j ii) the apparent obligation for a Competent Authority to approve all facilities, containers and vessels and facilities in the importing country should be re-considered.

Justification

This would imply a very high administrative burden and would be very difficult to achieve in the case of all transport of animals by sea.

ii)~~b)~~ approv~~e~~ing facilities, *containers*, *vehicles/vessels* for the holding and transport of animals, including that of the *importing country*;

iii)~~c)~~ setting competence standards for *animal handlers* and managers of facilities;

~~d) ensuring that the vessel transporting animals meets the required standards, including those of the *importing country*;~~

v)~~e)~~ implementation of the standards, including through accreditation of / interaction with other organisations and *Competent Authorities*;

Written community comments:

Under point 2 j vi) the apparent obligation for a Competent Authority of the exporting country to monitor animal health and welfare during the journey should be re-considered.

Justification

It may be impossible under practical conditions for a competent authority of the exporting country to monitor the health and welfare of all animals transported by sea.

vi)~~f)~~ monitor~~ing~~ and evaluat~~e~~~~ing~~ health and welfare performance, including the use of any veterinary medications.

~~10.~~k) The responsibilities of the *Competent Authority* of the *importing country* include:

i)a) establishing minimum standards for animal welfare, including requirements for inspection of animals after their travel, and for certification and record keeping;

Written community comments:

Under point 2 k ii) the apparent obligation for a Competent Authority of the importing country to approve all facilities, containers and vessels should be re-considered.

Justification

This would imply a very high administrative burden and would be very difficult to achieve in the case of all transports of animals by sea. The obligations of the importing country should be limited to the facilities in the importing country.

ii)~~b)~~ approv~~e~~~~ing~~ facilities, *containers*, *vehicles/vessels* for the holding and transport of animals;

iii)~~c)~~ setting competence standards for *animal handlers* and managers of facilities;

iv)~~d)~~ implementation of the standards, including through accreditation of / interaction with other organisations and *Competent Authorities*;

v)~~e)~~ ensuring that the *exporting country* is aware of the required standards for the *vessel* transporting the animals;

Written community comments:

Under point 2 k vi) the apparent obligation for a Competent Authority of the importing country to monitor animal health and welfare during the journey should be re-considered.

Justification

It may be impossible under practical conditions for a competent authority to monitor the health and welfare of all animals transported by sea.

vi)~~f)~~ monitor~~ing~~ and evaluat~~ing~~ health and welfare performance, including the use of any veterinary medications.

~~11. When travelling on vessels with the animals, veterinarians are responsible for the humane handling and treatment of the animals during the journey. To carry out these responsibilities, they should have the authority to act and report independently. The veterinarian should meet with the Master, Chief Officer and the *senior animal handler* on a daily basis.~~

Written community comments:

Under point 2 m) the following words should be completed with the follow "….of *veterinarians* or, in the absence of a veterinarian, the animal handlers……".

Justification

The responsibilities for veterinarians travelling with the animals on the vessel are stated, included killing of the animals. However when no veterinarian is on board, it needs to be clarified who is responsible for killing a severely sick or wounded animal.

m) The responsibilities of *veterinarians* travelling on the *vessel* with the animals include:

Written community comments:

Under point 2 m i) the word "euthanasia" should be replaced by "human killing of the animals".

Justification

The wording "Euthanasia" implies that the killing is performed under the highest standards. However due to the circumstances on a ship this is not always possible. The animals should therefore be killed under the best available conditions.

i) humane handling and treatment of animals during the *journey*, including in emergencies, such as euthanasia;

ii) possess ability to report and act independently;

iii) meet daily with the master of the *vessel* to obtain up-to-date information on animal health and welfare status.

~~12.~~n) The receiving *Competent Authority* should report back to the sending *Competent Authority* on significant animal welfare problems which occurred during the *journey*.

Article 3.7.2.3.

Competence

1. All people responsible for animals during *journeys*, should be competent ~~according to their~~ to carry out the relevant responsibilities listed in Article 3.7.2.2. Competence in areas other than animal welfare would need to be addressed separately. Competence may be gained through formal training and/or practical experience.

~~2. The competence of *animal handlers* should be demonstrated through a current certificate from the *Competent Authority* or from an independent body accredited by the *Competent Authority*. The certificate should be in one of the OIE official languages if the international transport of animals is involved.~~

~~3~~2. The assessment of competence of *animal handlers* should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:

a) planning a *journey*, including appropriate *space allowance*, feed, water and ventilation requirements;

b)~~a)~~ responsibilities for the welfare of animals during the *journey*, including *loading* and *unloading*;

c)~~b)~~ sources of advice and assistance;

d)~~c)~~ animal behaviour, general signs of disease, and indicators of poor animal welfare such as stress, pain and fatigue, and their alleviation;

e)~~d)~~ assessment of fitness to travel; if fitness to travel is in doubt, the animal should be examined by a *veterinarian*;

f)~~e)~~ relevant authorities and applicable transport regulations, and associated documentation requirements;

g)~~f)~~ general disease prevention procedures, including cleaning and *disinfection*;

h)~~g)~~ appropriate methods of animal handling during transport and associated activities such as assembling, *loading*, and *unloading*;

i)~~h)~~ methods of inspecting animals, managing situations frequently encountered during transport such as adverse weather conditions, and dealing with emergencies, including euthanasia;

j)~~i)~~ species-specific aspects and age-specific aspects of animal handling and care, including feeding, watering and inspection; and

k)~~j)~~ maintaining a *journey* log and other records.

~~4.~~5. Assessment of competence for exporters should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:

a) planning a *journey*, including appropriate *space allowances*, and feed, water and ventilation requirements;

b) relevant authorities and applicable transport regulations, and associated documentation requirements;

c) appropriate methods of animal handling during transport and associated activities such as cleaning and *disinfection*, assembling, *loading*, and *unloading*;

d) species-specific aspects of animal handling and care, including appropriate equipment and medication;

e) sources of advice and assistance;

f) appropriate record keeping; and

g) managing situations frequently encountered during transport, such as adverse weather conditions, and dealing with emergencies.

Article 3.7.2.4.

Planning the journey

1. General considerations

a) Adequate planning is a key factor affecting the welfare of animals during a *journey*.

b) Before the *journey* starts, plans should be made in relation to:

i) preparation of animals for the *journey*;

ii) type of transport *vessel* required;

iii) route, taking into account distance, expected weather and sea conditions;

iv) nature and duration of *journey*;

v) daily care and management of the animals, including the appropriate number of *animal handlers*, to help ensure the health and welfare of all the animals;

vi) avoiding the mixing of animals from different sources in a single pen group;

vii) provision of appropriate equipment and medication for the numbers and species carried; and

viii) emergency response procedures.

2. Preparation of animals for the journey

a) When animals are to be provided with a novel diet or unfamiliar methods of supplying of feed or water, they should be preconditioned.

b) There should be planning for water and feed availability during the *journey*. Feed should be of appropriate quality and composition for the species, age, condition of the animals, etc.

c) Extreme weather conditions are hazards for animals undergoing transport and require appropriate *vessel* design to minimise risks. Special precautions should be taken for animals that have not been acclimatised or which are unsuited to either hot or cold conditions. In some extreme conditions of heat or cold, animals should not be transported at all.

d) Animals more accustomed to contact with humans and with being handled are likely to be less fearful of being loaded and transported. Animals should be handled and loaded in a manner that reduces their fearfulness and improves their approachability.

e) Behaviour-modifying (such as tranquillisers) or other medication should not be used routinely during transport. Such medicines should only be administered when a problem exists in an individual animal, and should be administered by a *veterinarian* or other person who has been instructed in their use by a *veterinarian*. Treated animals should be placed in a dedicated area.

3. Control of disease

As animal transport is often a significant factor in the spread of infectious diseases, *journey* planning should take into account the following:

a) When possible and agreed by the *Veterinary Authority* of the *importing country*, animals should be vaccinated against diseases to which they are likely to be exposed at their destination.

b) Medications used prophylactically or therapeutically should only be administered by a *veterinarian* or other person who has been instructed in their use by a *veterinarian*.

c) Mixing of animals from different sources in a single consignment should be minimized.

4. Vessel and container design and maintenance

a) *Vessels* used for the sea transport of animals should be designed, constructed and fitted as appropriate to the species, size and weight of the animals to be transported. Special attention should be paid to the avoidance of injury to animals through the use of secure smooth fittings free from sharp protrusions and the provision of non-slip flooring. The avoidance of injury to *animal handlers* while carrying out their responsibilities should be emphasised.

b) *Vessels* should be properly illuminated to allow animals to be observed and inspected.

~~b)~~c) *Vessels* should be designed to permit thorough cleaning and *disinfection*, and the management of faeces and urine.

~~c)~~d) *Vessels* and their fittings should be maintained in good mechanical and structural condition.

~~d)~~c) *Vessels* should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported. The ventilation system should be effective when the *vessel* is stationary. An emergency power supply should be available to maintain ventilation in the case of primary machinery breakdown.

~~e)~~f) The feeding and watering system should be designed to permit adequate access to feed and water appropriate to the species, size and weight of the animals, and to minimise soiling of pens.

~~f)~~g) *Vessels* should be designed so that the faeces or urine from animals on upper levels do not soil animals on lower levels, or their feed or water.

~~g)~~h) *Loading* and stowage of feed and bedding should be carried out in such a way to ensure protection from fire hazards, the elements and sea water.

~~h)~~i) Where appropriate, suitable bedding, such as straw or sawdust, should be added to *vessel* floors to assist absorption of urine and faeces, provide better footing for animals and protect animals (especially young animals) from hard or rough flooring surfaces and adverse weather conditions.

~~i)~~j) The above principles apply also to *containers* used for the transport of animals.

5. Special provisions for transport in road vehicles on roll-on/roll-off vessels or for containers

a) Road *vehicles* and *containers* should be equipped with a sufficient number of adequately designed, positioned and maintained securing points enabling them to be securely fastened to the *vessel*.

b) Road *vehicles* and *containers* should be secured to the ship before the start of the sea *journey* to prevent them being displaced by the motion of the *vessel*.

c) *Vessels* should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported, especially where the animals are transported in a secondary *vehicle*/*container* on enclosed decks.

d) Due to the risk of limited airflow on certain ~~vessels'~~ decks of a *vessel*, a road *vehicle* or *container* may require a forced ventilation system of greater capacity than that provided by natural ventilation.

Written Community comments:

The list of factors described under point 6 to determine the maximum duration of a journey is incomplete and should be placed "under study" pending further analysis and preparation of a more complete list of determining factors.

An additional point should be added:

i) "vessel type used, method of propulsion and risks associated with particular sea conditions".

Justification

The list of factors proposed is incomplete and further evaluation is necessary to more accurately address this point. The proposed text is scientifically incomplete and should be placed "under study" pending further careful analysis by the OIE's ad hoc expert groups.

6. Nature and duration of the journey

Written community comments:

The change in point 6 "……that determine the overall welfare of animals" should be deleted.

Justification

The introduction of the phrase that "…determine the overall welfare of animals" is unnecessary as the Guidelines are annexes to the Chapter which lays down the welfare principles on which they are based so repetition is not needed. Furthermore the way in which it is drafted changes the meaning being more restrictive than the original text which allowed the consideration of other factors. In practice the duration of the journey depends on many other aspects that are important to consider as well.

The maximum duration of a *journey* should be determined ~~according to~~ taking into account factors that determine the overall welfare of animals, such as:

a) the ability of the animals to cope with the stress of transport (such as very young, old, lactating or pregnant animals);

b) the ~~animals'~~ previous transport experience of the animals;

c) the likely onset of fatigue;

d) the need for special attention;

e) the need for feed and water;

f) the increased susceptibility to injury and disease;

g) *space allowance* and *vessel* design;

h) weather conditions.

7. Space allowance

a) The number of animals which should be transported on a *vessel* and their allocation to different pens on the *vessel* should be determined before *loading*.

b) The amount of space required, including headroom, depends on the species of animal and should allow the necessary thermoregulation. Each animal should be able to assume its natural position for transport (including during *loading* and *unloading*) without coming into contact with the roof or upper deck of the *vessel*. When animals lie down, there should be enough space for every animal to adopt a normal lying posture.

Written Community comments:

In the first sentence of the next bullet point the words "in Appendix XXX, or, in their absence" should be deleted.

Justification

Appendix XXX does not exist and referring to such non-existent text in international guidelines to be adopted by 167 OIE member countries is inappropriate, unhelpful and confusing to the reader.

c) Calculations for the *space allowance* for each animal should be carried out, using the figures given in Appendix X.X.X. or, in their absence, in a relevant national or international document. The size of pens will affect the number of animals in each.

d) The same principles apply when animals are transported in *containers*.

8. Ability to observe animals during the journey

Animals should be positioned to enable each animal to be observed regularly and clearly by *animal handler* or other responsible person, during the *journey* to ensure their safety and good welfare.

9. Emergency response procedures

There should be an emergency management plan that identifies the important adverse events that may be encountered during the *journey*, the procedures for managing each event and the action to be taken in an emergency. For each important event, the plan should document the actions to be undertaken and the responsibilities of all parties involved, including communications and record keeping.

Article 3.7.2.5.

Documentation

1. Animals should not be loaded until the documentation required to that point is complete.

2. The documentation accompanying the consignment should include:

a) *journey* travel plan ~~(including~~ and an emergency management plan~~)~~;

b) time, date and place of *loading*;

c) the *journey* log – a daily record of inspection and important events which includes records of morbidity and mortality and actions taken, climatic conditions, food and water consumed, medication provided, mechanical defects;

d) expected time, date and place of arrival and *unloading*;

e) veterinary certification, when required;

Written community comment:

Under point 2 f) the word "individual" should be deleted.

Justification

The requirement for individual identification of each animal is not practicable for many species e.g. chickens.

f) *animal identification* to allow ~~traceback~~ *animal traceability* of individual animals to the premises of departure, and, where possible, to the premises of origin;

g) details of any animals considered ~~'at risk'~~ at particular risk of suffering poor welfare during transport (point 3e) of Article 3.7.2.6.);

h) number of *animal handlers* on board, and their competencies; and

i) *stocking density* estimate for each load in the consignment.

3. When veterinary certification is required to accompany consignments of animals, it should address:

a) when required, details of *disinfection* carried out;

b) fitness of the animals to travel;

c) *animal identification* (description, number, etc.); and

d) health status including any tests, treatments and vaccinations carried out.

Article 3.7.2.6.

Pre-journey period

1. General considerations

Written community comments:

In point 1 a) the following should be added "…. minimum stress *and risk* to the animals."

Justification

Cleaning can also be a risk for the animals (e. g. gear and chemicals).

a) Before each *journey*, *vessels* should be thoroughly cleaned and, if necessary, treated for animal and public health purposes, using chemicals approved by the *Competent Authority*. When cleaning is necessary during a *journey*, this should be carried out with the minimum of stress to the animals.

b) In some circumstances, animals may require pre-*journey* assembly. In these circumstances, the following points should be considered:

i) Pre-*journey* rest is necessary if the welfare of animals has become poor during the collection period because of the physical environment or the social behaviour of the animals.

Written community comments:

The point 1 b) ii) should be deleted.

Justification

Since the journey on a ship is very long, feed deprivation is not justifiable.

ii) For animals such as pigs which are susceptible to motion sickness, and in order to reduce urine and faeces production during the *journey*, a species-specific short period of feed deprivation prior to *loading* is desirable.

iii) When animals are to be provided with a novel diet or unfamiliar methods of supplying feed or water, they should be preconditioned.

c) Where an *animal handler* believes that there is a significant risk of disease among the animals to be loaded or significant doubt as to their fitness to travel, the animals should be examined by a *veterinarian*.

d) Pre-*journey* assembly / holding areas should be designed to:

i) securely contain the animals;

ii) maintain an environment safe from hazards, including predators and disease;

iii) protect animals from exposure to adverse weather conditions;

iv) allow for maintenance of social groups; and

v) allow for rest, watering and feeding.

2. Selection of compatible groups

Compatible groups should be selected before transport to avoid adverse animal welfare consequences. The following guidelines should be applied when assembling groups of animals:

a) animals of different species should not be mixed unless they are judged to be compatible;

b) animals of the same species can be mixed unless there is a significant likelihood of aggression; aggressive individuals should be segregated (recommendations for specific species are described

in detail in Article 3.7.2.11.). For some species, animals from different groups should not be mixed because poor welfare occurs unless they have established a social structure;

c) young or small animals may need to be separated from older or larger animals, with the exception of nursing mothers with young at foot;

d) animals with horns or antlers should not be mixed with animals lacking horns or antlers, unless judged to be compatible; and

e) animals reared together should be maintained as a group; animals with a strong social bond, such as a dam and offspring, should be transported together.

3. Fitness to travel

a) Animals should be inspected by a *veterinarian* or an *animal handler* to assess fitness to travel. If its fitness to travel is in doubt, ~~the animal should be examined by a veterinarian~~ it is the responsibility of a *veterinarian* to determine its ability to travel. Animals found unfit to travel should not be loaded onto a *vessel*.

b) Humane and effective arrangements should be made by the owner or agent for the handling and care of any animal rejected as unfit to travel.

c) Animals that are unfit to travel include, but may not be limited to:

Written community comments:

The following point should be added:

"Animals that have recently undergone a surgical procedure, such as dehorning".

Justification

The text is in line with the Guidelines for the Transport of animals by Land.

i) those that are sick, injured, weak, disabled or fatigued;

ii) those that are unable to stand unaided or bear weight on each leg;

iii) those that are blind in both eyes;

iv) those that cannot be moved without causing them additional suffering;

v) newborn with an unhealed navel;

vi) females travelling without young which have given birth within the previous 48 hours;

Written community comments:

The point 3 c) vii) should be changed as follows:

"Pregnant animals for which 90% or more of the expected gestation period has already passed or females who have given birth in the previous week".

Justification

Since the beginning of the pregnancy is known, it is more practically to mention the period already passed.

vii) pregnant animals which would be in the final 10% of their gestation period at the planned time of *unloading*.

d) Risks during transport can be reduced by selecting animals best suited to the conditions of travel and those that are acclimatised to expected weather conditions.

e) Animals at particular risk of suffering poor welfare during transport and which require special conditions (such as in the design of facilities and *vehicles*, and the length of the *journey*) and additional attention during transport, may include: ~~Animals at risk and requiring better conditions and additional attention during transport include~~:

i) very large or obese individuals;

ii) very young or old animals;

iii) excitable or aggressive animals;

iv) animals subject to motion sickness;

v) animals which have had little contact with humans;

vi) females in the last third of pregnancy or in heavy lactation.

f) Hair or wool length should be considered in relation to the weather conditions expected during transport.

Written community comments:

The following point should be added:

4. Specific species requirements

Transport procedures should be able to take account of variations in the behaviour of the species. Flight zones, social interactions and other behaviour vary significantly among species and even within species. Facilities and handling procedures that are successful with one species are often ineffective or dangerous with another.

Recommendations for specific species are described in detail in Article 3.7.2.11.

Justification

The text should be in line with the Guidelines for the Transport of animals by Land.

Article 3.7.2.7.

Loading

1. Competent supervision

a) *Loading* should be carefully planned as it has the potential to be the cause of poor welfare in transported animals.

Written Community comments:

Under point 1 b) the words "loading should be supervised by the competent Authority" need to be carefully considered.

Justification

These guidelines may be applicable not just to the international transport of animals but also within national boundaries and journeys of short duration. It is questionable whether all Competent Authorities have the requisite resources to supervise the commencement of all such journeys.

b) *Loading* should be supervised by the *Competent Authority* and conducted by *animal handler(s). Animal handlers* should ensure that animals are loaded quietly and without unnecessary noise, harassment or force, and that untrained assistants or spectators do not impede the process.

2. Facilities

a) The facilities for *loading*, including the collecting area at the wharf, races and loading ramps should be designed and constructed to take into account ~~of~~ the needs and abilities of the animals with regard to dimensions, slopes, surfaces, absence of sharp projections, flooring, sides, etc.

b) Ventilation during *loading* and the *journey* should provide for fresh air, and the removal of excessive heat, humidity and noxious fumes (such as ammonia and carbon monoxide). Under warm and hot conditions, ventilation should allow for the adequate convective cooling of each animal. In some instances, adequate ventilation can be achieved by increasing the *space allowance* for animals.

c) *Loading* facilities should be properly illuminated to allow the animals to be easily inspected by *animal handlers*, and to allow the ~~animals'~~ ease of movement of animals at all times. Facilities should provide uniform ~~lighting~~ light levels directly over approaches to sorting pens, chutes, loading ramps, with brighter ~~lighting~~ light levels inside *vehicles/containers*, in order to minimise baulking. Dim ~~lighting~~ light levels may be advantageous for the catching of some animals. Artificial lighting may be required.

3. Goads and other aids

Written community comments:

The following text should be added:

"When moving animals, their species specific behaviour should be used (see Article 3.7.2.11). If goads and other aids are necessary, the following principles should…..".

Justification

It is important to use the natural behaviour of the animals to get them to move forward, before the use of goads and other device. This should be stressed.

The following principles should apply:

~~a) Animals that have little or no room to move should not be subjected to physical force or goads and other aids which compel movement.~~

~~b) Useful and permitted goads include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles; they should be used in a manner sufficient to encourage and direct movement of the animals.~~

~~c) Painful procedures (including whipping, tail twisting, use of nose twitches, pressure on eyes, ears or external genitalia), or the use of unsuitable goads or other aids (including sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts), should not be used to move animals.~~

~~d) The use of goads which administer electric shocks should be discouraged, and restricted to that necessary to assist movement of the animal. Such use should be limited to battery powered goads on the hindquarters of pigs and large ruminants, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.~~

~~e) Shouting or yelling at animals or making loud noises (e.g., through the cracking of whips) to encourage them to move should not occur, as such actions may make the animals agitated, leading to crowding or falling.~~

~~f) The use of well trained dogs to help with the *loading* of some species may be acceptable.~~

~~g) Manual lifting is permissible for young animals that may have difficulty negotiating ramps, but the lifting of animals by body parts such as their tail, head, horns, ears, limbs, wool or hair should not be permitted. The throwing or dropping of animals should not be permitted.~~

a) Animals that have little or no room to move should not be subjected to physical force or goads and other aids which compel movement. Electric goads and prods should only be used in extreme cases and not on a routine basis to move animals. The use and the power output should be restricted to that necessary to assist movement of an animal and only when an animal has a clear path ahead to move. Goads and other aids should not be used repeatedly if the animal fails

to respond or move. In such cases it should be investigated whether some physical or other impediment is preventing the animal from moving.

b) The use of such devices should be limited to battery-powered goads on the hindquarters of pigs and large ruminants, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.

c) Useful and permitted goads include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles; they should be used in a manner sufficient to encourage and direct movement of the animals without causing undue stress.

d) Painful procedures (including whipping, tail twisting, use of nose twitches, pressure on eyes, ears or external genitalia), or the use of goads or other aids which cause pain and suffering (including large sticks, sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts), should not be used to move animals.

e) Shouting or yelling at animals or making loud noises (e.g., through the cracking of whips) to encourage them to move should not occur, as such actions may make the animals agitated, leading to crowding or falling.

f) The use of well trained dogs to help with the *loading* of some species may be acceptable.

Written community comments:

Under point 3 g) the word “such” should be deleted.

Justification

As feathers are mentioned, the word “such” in point g) do not refer to quadrupeds.

g) Animals should be grasped or lifted in a manner which avoids pain or suffering and physical damage (e.g. bruising, fractures, dislocations). In the case of quadrupeds, manual lifting by a person should only be used in young animals or small species, and in a manner appropriate to the species; grasping or lifting such animals only by their wool, hair, feathers, feet, neck, ears, tails, head, horns, limbs causing pain or suffering should not be permitted, except in an emergency where animal welfare or human safety may otherwise be compromised.

h) Conscious animals should not be thrown, dragged or dropped.

Written community comments:

Under point 3 i) the word "should" should be replaced by "could".

Justification

It should not be an obligation to use such system.

i) Performance standards should be established in which numerical scoring is used to evaluate the use of such instruments, and to measure the percentage of animals moved with an electric instrument and the percentage of animals slipping or falling as a result of their usage.

Article 3.7.2.8.

Travel

1. General considerations

Written community comments:

Under point 1 a) the following should be added: "……should be checked following any incident or situation likely to affect their welfare and in any case within 12 hours of departure ".

Justification

An interval of 12 hours between checks may be long. Much can happen during this time.

a) *Animal handler(s)* should check the consignment immediately before departure to ensure that the animals have been loaded according to the load plan. Each consignment should be checked again within 12 hours.

Written Community comments:

The words "If necessary and where possible" should be added to the start of the next bullet point.

Justification

In many cases stocking density will not need to be changed during the journey. If it is necessary to make changes to the stocking density during the journey, this implies that additional free space should be held in reserve if the aforementioned stocking density changes are necessary. For these reasons the current wording should be changed.

b) Adjustments should be made to the *stocking density* as appropriate during the *journey*.

c) Each pen of animals should be observed on a daily basis for normal behaviour, health and welfare, and the correct operation of ventilation, watering and feeding systems. There should also be a night patrol. Any necessary corrective action should be undertaken promptly.

Written community comments:

Under point 1 d) the following text should added at the end of the sentence: "Animals shall be accustomed to the feed to be provided and be able to use the delivery systems for water and feed.

Justification

Animals which are not used to such systems will not be able to use them properly.

d) Adequate access to suitable feed and water should be ensured for all animals in each pen.

e) Where cleaning or *disinfestation* is necessary during travel, it should be carried out with the minimum of stress to the animals.

2. Sick ~~and~~ or injured animals

a) Sick ~~and~~ or injured animals should be segregated ~~if possible~~.

b) Sick ~~and~~ or injured animals should be appropriately treated or humanely killed, in accordance with a predetermined emergency response plan (Article 3.7.2.4.). Veterinary advice should be sought if necessary. All drugs and products should be used according to recommendations from a veterinarian and in accordance with the manufacturer's ~~or *veterinarian's* recommendations~~ instructions.

c) A record of treatments carried out and their outcomes should be kept.

Written community comments:

Under point 2 d) the word "euthanasia" should be changed by "human killing" and the following text should de added "…… the veterinarian or other person competent in humane killing procedures".

Justification

Refer her to the previous change.

d) When euthanasia is necessary, ~~the person responsible for the animals~~ the *veterinarian* must ensure that it is carried out humanely. ~~Assistance should be sought from a veterinarian or other person(s) competent in euthanasia procedures~~. Recommendations for specific species are described in Appendix 3.7.6. on killing of animals for disease control purposes.

Article 3.7.2.9.

Unloading and post-journey handling

1. General considerations

a) The required facilities and the principles of animal handling detailed in Article 3.7.2.7. apply equally to *unloading*, but consideration should be given to the likelihood that the animals will be fatigued.

b) *Unloading* should be carefully planned as it has the potential to be the cause of poor welfare in transported animals.

c) A livestock *vessel* should have priority attention when arriving in port and have priority access to a berth with suitable *unloading* facilities. As soon as possible after the ~~ship's~~ *vessel's* arrival at the port and acceptance of the consignment by the *Competent Authority*, animals should be unloaded into appropriate facilities.

d) The accompanying veterinary certificate and other documents should meet the requirements of the *importing country*. Veterinary inspection~~s~~ should be completed as quickly as possible.

e) *Unloading* should be supervised by the *Competent Authority* and conducted by ~~an~~ *animal handler(s)*. The *animal handlers* should ensure that animals are unloaded as soon as possible after arrival but sufficient time should be allowed for *unloading* to proceed quietly and without unnecessary noise, harassment or force, and that untrained assistants or spectators do not impede the process.

2. Facilities

a) The facilities for *unloading* including the collecting area at the wharf, races and unloading ramps should be designed and constructed to take into account of the needs and abilities of the animals with regard to dimensions, slopes, surfaces, absence of sharp projections, flooring, sides, etc.

b) All *unloading* facilities should have sufficient lighting to allow the animals to be easily inspected by the *animal handlers*, and to allow the ~~animals'~~ ease of movement of animals at all times.

c) There should be facilities to provide animals with appropriate care and comfort, adequate space, access to quality feed and clean drinking water, and shelter from extreme weather conditions.

3. Sick ~~and~~ or injured animals

Written community comments:

Under point 3 a) the original wording "humanely killed" should be retained instead of "euthanised".

Justification

Refer to previous comment.

a) An animal that has become sick, injured or disabled during a *journey* should be appropriately treated or ~~humanely killed~~ euthanised (see Appendix 3.7.6.). When necessary, veterinary advice should be sought in the care and treatment of these animals.

Written community comments:

Under point 3 b) the word "euthanised" should be replaced by "humanely killed".

Justification

Refer to previous comment.

b) In some cases, where animals are non-ambulatory due to fatigue, injury or sickness, it may be in the best welfare interests of the animal to be treated or euthanised aboard the *vessel*.

c) If *unloading* is in the best welfare interests of animals that are fatigued, injured or sick, there should be appropriate facilities and equipment for the humane *unloading* of such animals. These animals should be unloaded in a manner that causes the least amount of suffering. After *unloading*, separate pens and other appropriate facilities and treatments should be provided for sick or injured animals.

4. Cleaning and disinfection

a) *Vessels* and *containers* used to carry the animals should be cleaned before re-use through the physical removal of manure and bedding, by scraping, washing and flushing *vessels* and *containers* with water until visibly clean. This should be followed by *disinfection* when there are concerns about disease transmission.

b) Manure, litter and bedding should be disposed of in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.

~~c) Where cleaning or *disinfestation* is necessary during travel, it should be carried out with the minimum of stress to the animals.~~

Article 3.7.2.10.

Actions in the event of a refusal to allow the importation of a shipment

1. The welfare of the animals should be the first consideration in the event of a refusal to import.

2. When animals have been refused import, the *Competent Authority* of ~~that~~ the *importing country* should make available suitable isolation facilities to allow the *unloading* of animals from a *vessel* and their secure holding, without posing a risk to the health of the national herd, pending resolution of the situation. In this situation, the priorities should be:

a) The *Competent Authority* of the *importing country* should provide urgently in writing the reasons for the refusal.

b) In the event of a refusal for animal health reasons, the *Competent Authority* of the *importing country* should provide urgent access to an OIE-appointed *veterinarian(s)* to assess the ~~animals'~~ health status of the animals with regard to the ~~*importing country*'s~~ concerns of the *importing country*, and the necessary facilities and approvals to expedite the required diagnostic testing.

c) The *Competent Authority* of the *importing country* should provide access to allow continued assessment of the ongoing health and welfare situation.

d) If the matter cannot be promptly resolved, the *Competent Authority* of the *exporting* and *importing countries* should call on the OIE to mediate.

3. In the event that the animals are required to remain on the *vessel*, the priorities should be:

a) The *Competent Authority* of the *importing country* should allow ~~reprovision~~ provisioning of the *vessel* with water and feed as necessary.

b) The *Competent Authority* of the *importing country* should provide urgently in writing the reasons for the refusal.

c) In the event of a refusal for animal health reasons, the *Competent Authority* of the *importing country* should provide urgent access to an OIE-appointed *veterinarian(s)* to assess the ~~animals'~~ health status of the animals with regard to the ~~*importing country's*~~ concerns of the *importing country*, and the necessary facilities and approvals to expedite the required diagnostic testing.

d) The *Competent Authority* of the *importing country* should provide access to allow continued assessment of the ongoing health and other aspects of the welfare of the animals, and the necessary actions to deal with any issues which arise.

e) If the matter cannot be urgently resolved, the *Competent Authorities* of the *exporting* and *importing countries* should call on the OIE to mediate.

4. The OIE should utilise its dispute settlement mechanism to identify a mutually agreed solution which will address the animal health and welfare issues in a timely manner.

Article 3.7.2.11.

Species specific issues

Written community comments:

The following text should to be added at the end of the cattle part: "Cattle tend to avoid "dead end" in passages".

Justification

Refer to the previous change.

Cattle are sociable animals and may become agitated if they are singled out. Social order is usually established at about two years of age. When groups are mixed, social order has to be re-established and aggression may occur until a new order is established. Crowding of cattle may also increase aggression as the animals try to maintain personal space. Social behaviour varies with age, breed and sex; *Bos indicus* and *B. indicus*-cross animals are usually more temperamental than European breeds. Young bulls, when moved in groups, show a degree of playfulness (pushing and shoving) but become more aggressive and territorial with age. Adult bulls have a minimum personal space of six square metres. Cows with young calves can be very protective, and handling calves in the presence of their mothers can be dangerous.

Goats should be handled calmly and are more easily led or driven than if they are excited. When goats are moved, their gregarious tendencies should be exploited. Activities which frighten, injure or cause agitation to animals should be avoided. Bullying is particularly serious in goats. Housing strange goats together could result in fatalities, either through physical violence, or subordinate goats being refused access to food and water.

Sheep are sociable animals with good eyesight and tend to "flock together", especially when they are agitated. They should be handled calmly and their tendency to follow each other should be exploited when they are being moved. Sheep may become agitated if they are singled out for attention and will strive to rejoin the group. Activities which frighten, injure or cause agitation to sheep should be avoided. They can negotiate steep ramps.

Pigs have poor eyesight, and may move reluctantly in strange surroundings. They benefit from well lit *loading* bays. Since they negotiate ramps with difficulty, these should be as level as possible and provided with secure footholds. Ideally, a hydraulic lift should be used for greater heights. Pigs also negotiate steps with difficulty. A good 'rule-of-thumb' is that no step should be higher than the pig's front knee. Serious aggression may result if unfamiliar animals are mixed. Pigs are highly susceptible to heat stress.

Horses in this context include all solipeds, donkeys, mules, hinnies and zebra. They have good eyesight and a very wide angle of vision. They may have a history of *loading* resulting in good or bad experiences. Good training should result in easier *loading*, but some horses can prove difficult, especially if they are inexperienced or have associated *loading* with poor transport conditions. In these circumstances, two experienced *animal handlers* can load an animal by linking arms or using a strop below its rump. Blindfolding may even be considered. Ramps should be as shallow as possible. Steps are not usually a problem when horses mount a ramp, but they tend to jump a step when descending, so steps should be as low as possible. Horses benefit from being individually stalled, but may be transported in compatible groups. When horses are to travel in groups, their shoes should be removed.

Camelids in this context comprise llamas, alpacas, guanaco and vicuna. They have good eyesight and, like sheep, can negotiate steep slopes, though ramps should be as shallow as possible. They load most easily in a bunch as a single animal will strive to rejoin the others. Whilst they are usually docile, they have an unnerving habit of spitting in self-defence. During transport, they usually lie down. They frequently extend their front legs forward when lying, so gaps below partitions should be high enough so that their legs are not trapped when the animals rise.

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— text deleted

APPENDIX 3.7.3.

GUIDELINES FOR THE TRANSPORT OF ANIMALS BY LAND

Preamble: These guidelines apply to the following live domesticated animals: cattle, buffalo, camels, sheep, goats, pigs, poultry and equines. They will also be largely applicable to some other animals (e.g., deer, other camelids and ratites). Wild, feral and partly domesticated animals may need different conditions.

Article 3.7.3.1.

The amount of time animals spend on a *journey* should be kept to the minimum.

Article 3.7.3.1. bis

1. Animal behaviour

Animal handlers should be experienced and competent in handling and moving farm livestock and understand the behaviour patterns of animals and the underlying principles necessary to carry out their tasks.

The behaviour of individual animals or groups of animals will vary, depending on their breed, sex, temperament and age and the way in which they have been reared and handled. Despite these differences, the following behaviour patterns which are always present to some degree in domestic animals, should be taken into consideration in handling and moving the animals.

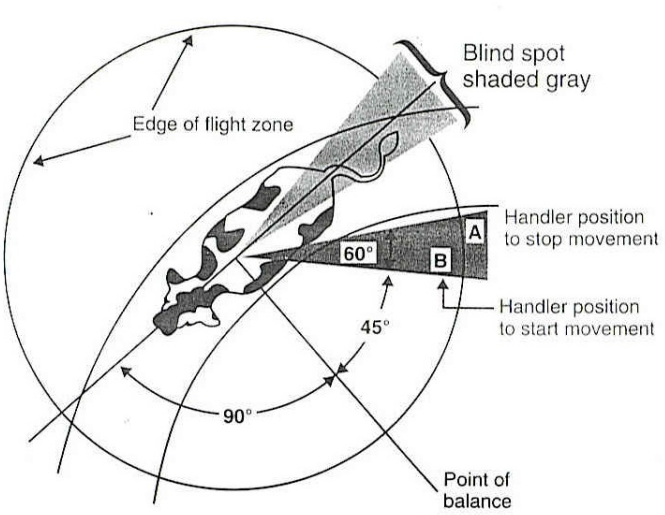
Most domestic livestock are kept in herds and follow a leader by instinct.

Animals which are likely to be hostile to each other in a group situation should not be mixed.

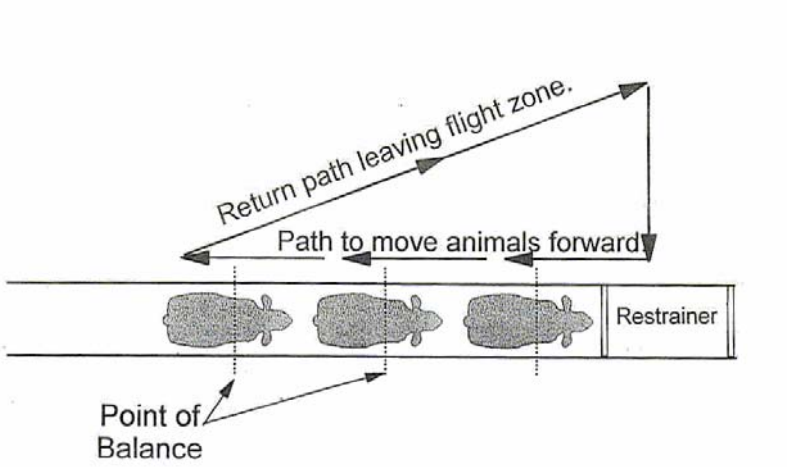
The desire of some animals to control their personal space should be taken into account in designing *loading* and *unloading* facilities, transport *vehicles* and *containers*.

Domestic animals will try to escape if any person approaches closer than a certain distance. This critical distance, which defines the flight zone, varies among species and individuals of the same species, and depends upon previous contact with humans. Animals reared in close proximity to humans (i.e. tame) have a smaller flight zone, whereas those kept in free range or extensive systems may have flight zones which may vary from one metre to many metres. *Animal handlers* should avoid sudden penetration of the flight zone which may cause a panic reaction which could lead to aggression or attempted escape.

An example of a flight zone (cattle)



Animal handler movement pattern to move cattle forward



Animal handlers should use the point of balance at ~~an~~ the animal's shoulder to move animals, adopting a position behind the point of balance to move an animal forward and in front of the point of balance to move it backward.

Domestic animals have wide-angle vision but only have limited forward binocular vision and poor perception of depth. This means that they can detect objects and movements beside and behind them, but can only judge distances directly ahead.

Although all domestic animals have a highly sensitive sense of smell, they may react differently to the smells encountered during travel. Smells which cause fear or other negative responses should be taken into consideration when managing animals.

Domestic animals can hear over a greater range of frequencies than humans and are more sensitive to higher frequencies. They tend to be alarmed by constant loud noise and by sudden noises, which may cause them to panic. Sensitivity to such noises should also be taken into account when handling

animals.

2. Distractions and their removal

Distractions that may cause approaching animals to stop, baulk or turn back should be designed out from new *loading* and *unloading* facilities or removed from existing ones. Below are examples of common distractions and methods for eliminating them:

a) reflections on shiny metal or wet floors - move a lamp or change lighting;

Written community comments:

The following additional point should be added:

c) "dead ends-avoid if possible by curving the passage, or make an illusory passage ".

Justification

Refer to previous change.

b) dark entrances - illuminate with indirect lighting which does not shine directly into the eyes of approaching animals;

c) animals seeing moving people or equipment up ahead - install solid sides on chutes and races or install shields;

d) chains or other loose objects hanging in chutes or on fences - remove them;

e) uneven floors or a sudden drop in floor levels – avoid uneven floor surfaces or install a solid false floor to provide an illusion of a solid and continuous walking surface;

f) sounds of air hissing from pneumatic equipment - install silencers or use hydraulic equipment or vent high pressure to the external environment using flexible hosing;

g) clanging and banging of metal objects - install rubber stops on gates and other devices to reduce metal to metal contact;

h) air currents from fans or air curtains blowing into the face of animals - redirect or reposition equipment.

Article 3.7.3.2.

Responsibilities

Once the decision to transport the animals has been made, the welfare of the animals during their *journey* is the paramount consideration and is the joint responsibility of all people involved. ~~with~~ The individual responsibilities of ~~those~~ persons involved ~~being~~ will be described in more detail in this Article.

The roles of each of those responsible are defined below:

~~1. The owners and managers of the animals are responsible for the general health of the animals and their fitness for the journey, and for their overall welfare during the journey. They are also responsible for ensuring compliance with any required veterinary or other certification, and for the presence during the journey of at least one *animal handler* competent for the species being transported, with the authority to take prompt action. They are also responsible for ensuring that equipment and veterinary assistance are provided as appropriate for the species and journey. These responsibilities should apply regardless of whether duties are subcontracted to other parties during transport.~~

Written community comments:

Under point 1 a reference to Art. 3.7.3.6. 3 "Fitness to travel" should be made.

1. The owners and managers of the animals are responsible for:

   a) the general health, overall welfare and fitness of the animals for the *journey*;

   b) ensuring compliance with any required veterinary or other certification;

   c) the presence of an *animal handler* competent for the species being transported during the *journey* with the authority to take prompt action; in case of transport by individual trucks, the truck driver may be the sole *animal handler* during the *journey*;

   d) the presence of an adequate number of *animal handlers* during *loading* and *unloading*;

   e) ensuring that equipment and veterinary assistance are provided as appropriate for the species and the *journey*.

~~2. Business agents or buying/selling agents have a joint responsibility with owners for the selection of animals that are fit to travel. They have a joint responsibility with market owners and managers of facilities at the start and at the end of the journey for the availability of suitable facilities for the assembly, *loading*, transport, *unloading* and holding of animals, including for any stops at resting points during the journey and for emergencies.~~

2. Business agents or buying/selling agents are responsible for:

Written community comments:

Under point 2 a) a reference to Art. 3.7.3.6 .3 "Fitness to travel" should be made.

   a) selection of animals that are fit to travel;

   b) availability of suitable facilities at the start and at the end of the *journey* for the assembly; *loading*, transport, *unloading* and holding of animals, including for any stops at *resting points* during the *journey* and for emergencies.

3. Animal handlers are responsible for the humane handling and care of the animals, especially during *loading* and *unloading*, and for maintaining a journey log. To carry out their responsibilities, they should have the authority to take prompt action. In the absence of a separate *animal handler*, the driver is the *animal handler*.

4. Transport companies, *vehicle* owners and drivers are responsible for planning the *journey* to ensure the care of the animals, in particular they are responsible for:

a) ~~transport companies and vehicle owners are responsible for~~ choosing appropriate *vehicles* for the species transported and the *journey*;

b) ~~and~~ ensuring that properly trained staff are available for *loading* ~~and caring for~~/*unloading* of animals;

c) ensuring adequate competency of the driver in matters of animal welfare for the species being transported in case a separate *animal handler* is not assigned to the truck;

~~b~~d) ~~transport companies and vehicle owners are responsible for~~ developing and keeping up-to-date contingency plans to address emergencies (including adverse weather conditions) and minimise stress during transport;

~~c~~e) ~~transport companies and vehicle owners are responsible for~~ producing a *journey* plan which includes a *loading* plan, *journey* duration, itinerary and location of resting places;

~~d~~f) ~~drivers are responsible for~~ *loading* only those animals which are fit to travel, for their correct *loading* into the *vehicle* and their inspection during the *journey*, and for appropriate responses to problems arising. If its fitness to travel is in doubt, the animal should be examined by a *veterinarian* in accordance with point 5 a) of Article 3.7.3.6;

g) welfare of the animals during the actual transport.

Written Community comments:

Under point 5 "Managers of facilities" should be defined.

Justification

In order to ensure that these guidelines can be applied it is important that they are drafted in as clear and precise a manner as possible, especially with regard to the responsibilities of those involved in the animal transport chain.

5. Managers of facilities at the start and at the end of the *journey* and at *resting points* are responsible for:

a) providing suitable premises for *loading*, *unloading* and securely holding the animals, with water and feed when required, until further transport, sale or other use (including rearing or slaughter);

Written Community comments:

Point 5 b) should be replaced with the following text:

"-providing appropriate personnel to hold and care for the animal in a manner that causes minimum stress and injury

-providing appropriate personnel including animal handlers to load, unload, hold and care for animals in the facility in a manner that causes minimum stress and injury".

Justification

The responsibility of managers of facilities should be changed because loading, unloading and driving are the responsibility of animal handlers and/or drivers rather than the manager of the facilities. Also cooperation between the animal handler (driver) and personnel of the facility during loading and unloading should take place.

b) providing an adequate number of *animal handlers* to load, unload, drive and hold animals in a manner that causes minimum stress and injury. In the absence of a separate *animal handler*, the driver is the *animal handler.*

c) minimising the opportunities for disease transmission;

d) providing appropriate facilities, with water and feed when required;

e) providing appropriate facilities for emergencies;

f) providing facilities for washing and disinfecting *vehicles* after *unloading*;

g) providing facilities and competent staff to allow the humane killing of animals when required

h) ensuring proper rest times and minimal delay during stops.

6. The responsibilities of *Competent Authorities* include:

a) establishing minimum standards for animal welfare, including requirements for inspection of animals before, during and after their travel, defining 'fitness to travel' and appropriate certification and record keeping;

b) setting standards for facilities, *containers* and *vehicles* for the transport of animals;

c) setting standards for the competence of *animal handlers*, drivers and managers of facilities in relevant issues in animal welfare;

d) ensuring appropriate awareness and training of *animal handlers*, drivers and managers of facilities in relevant issues in animal welfare;

e) implementation of the standards, including through accreditation of / interaction with other organisations;

f) monitoring and evaluating the effectiveness of standards of health and other aspects of welfare;

g) monitoring and evaluating the use of veterinary medications;

h) ~~expediting the passage of animal consignments at frontiers~~ give animal consignments priority at frontiers in order to allow them to pass without unnecessary delay.

7. All individuals, including *veterinarians*, involved in transporting animals and the associated handling procedures should receive appropriate training and be competent to meet their responsibilities.

8. The receiving *Competent Authority* should report back to the sending *Competent Authority* on significant animal welfare problems which occurred during the *journey*.

Article 3.7.3.3.

Competence

1. All people responsible for animals during *journeys*, should be competent according to their responsibilities listed in Article 3.7.3.2. Competence may be gained through formal training and/or practical experience. Competence in areas other than animal welfare would need to be addressed separately.

~~2~~. ~~The competence of *animal handlers* should be demonstrated through a current certificate from the *Competent Authority* or an independent body, accredited by the *Competent Authority*. The certificate should be in one of the OIE official languages if the international transport of animals is involved.~~

~~3~~2. The assessment of the competence of *animal handlers* should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:

Written community comments:

Under point 2a) the wording "planning the journey" should be replaced by "maintaining a journey log".

Justification

The planning of the journey is responsibility of transport companies, vehicle owners and drivers (Art 3.7.3.2. 4). The responsibility of the animal handler is to maintaining a journey log (Art 3.7.3.2. 3).

a) planning a *journey*, including appropriate *space allowance*, and feed, water and ventilation requirements;

b) responsibilities for animals during the *journey*, including *loading* and *unloading*;

c) sources of advice and assistance;

d) animal behaviour, general signs of disease, and indicators of poor animal welfare such as stress, pain and fatigue, and their alleviation;

e) assessment of fitness to travel. If fitness to travel is in doubt, the animal should be examined by a *veterinarian*;

f) relevant authorities and applicable transport regulations, and associated documentation requirements;

g) general disease prevention procedures, including cleaning and *disinfection*;

h) appropriate methods of animal handling during transport and associated activities such as assembling, *loading*, and *unloading*;

Written community comments:

Under point 2 i) the word "euthanasia" should be changed by "human killing".

Justification

Refer to previous comment.

i) methods of inspecting animals, managing situations frequently encountered during transport such as adverse weather conditions, and dealing with emergencies, including euthanasia;

j) species-specific aspects and age-specific aspects of animal handling and care, including feeding, watering and inspection; and

k) maintaining a *journey* log and other records.

Article 3.7.3.4.

Planning the journey

1. General considerations

a) Adequate planning is a key factor affecting the welfare of animals during a *journey*.

b) Before the *journey* starts, plans should be made in relation to:

i) preparation of animals for the *journey*;

ii) choice of road, ~~or~~ rail~~;~~ roll-on roll-off *vessels* or *containers*;

iii) nature and duration of the *journey*;

iv) *vehicle/container* design and maintenance, including roll-on roll-off *vessels*;

v) required documentation;

vi) *space allowance*;

vii) rest, water and feed;

viii) observation of animals en route;

ix) control of disease; ~~and~~

x) emergency response procedures;

xi) forecast weather conditions (e.g. conditions being too hot or too cold to travel during certain periods of the day);

xii) transfer time when changing mode of transport, and

xiii) waiting time at frontiers and inspection points.

c) Regulations concerning drivers (for example, maximum driving periods) should be harmonised with maximum transport *journey* intervals appropriate for the species based on sound science.

Written community comments:

The point 1 c) should be deleted.

Justification

Legislation on drivers can not be based only on welfare considerations for the animals. Drivers' legislation applies to all road transport and animal transport usually does not represent the majority of the road transport. In particular considerations related to road safety are also important aspects to be kept in mind.

c) Regulations concerning drivers (for example, maximum driving periods) should be harmonised with maximum transport *journey* intervals appropriate for the species.

2. Preparation of animals for the journey

Written Community comments:

Under point 2 a) the last part of the sentence can be changed as follow:".....of feed deprivation, for example 10-12 hours for pigs prior to loading may be desirable. There should be no period of water deprivation before transport".

Justification

To avoid different interpretations of the last sentence "a short period" should be more clearly defined or otherwise the whole sentence should be deleted. According to the Report of the Scientific Committee on Animal Health and Animal welfare adopted on 11 March 2002, 10 to 12 hours fasting is recommended. It should also be clarified that it is not justified to deprive animals of water prior to transport.

Written community comments:

Under point 2 a) the following text should be deleted: "and in order to reduce urine and faeces production during the journey".

The following text should be added: "For all animals it is extra important that the rest stops during long journeys are long enough to fulfil their needs of feed and water".

Justification

Food deprivation should never be used to reduce urine and faeces during journey. There should be enough equipment and bedding to keep the animal compartments clean. It is important that the resting periods during the journey are long enough for them to drink and eat and start digestion. On the whole it is important to pay attention to the needs of different species (see further the EFSA- reports on transports).

a) When animals are to be provided with a novel diet or method of water provision during transport, an adequate period of adaptation should be planned. For animals such as pigs which are susceptible to motion sickness, and in order to reduce urine and faeces production during the *journey*, a species-specific short period of feed deprivation prior to *loading* may be desirable.

b) Animals more accustomed to contact with humans and with being handled are likely to be less fearful of being loaded and transported. ~~People handling animals~~ *Animal handlers* should handle and load animals in a manner that reduces their fearfulness and improves their approachability.

Written community comments:

Under point 2 c) the text should be modified as follows: " …(such as tranquillisers or other medication)…".

Justification

Other medication may be required by health conditions e.g. treatment for external parasites which would be required either for the welfare of the transported stock or those of the place of destination.

c) Behaviour-modifying compounds (such as tranquillisers) or other medication should not be used routinely during transport. Such compounds should only be administered when a problem exists in an individual animal, and should be administered by a *veterinarian* or other person who has been instructed in their use by a *veterinarian*.

Written Community comments:

The list of factors described under point 3 to determine the maximum duration of a journey is incomplete and should be placed "under study" pending further analysis and preparation of a more complete list of determining factors.

Justification

When determining the duration of a journey a risk-based approach should be taken which balances the risks of welfare costs to the benefit of each risk factor. The list of factors proposed is incomplete and further evaluation is necessary to more accurately address this point. The proposed text is scientifically incomplete and should be placed "under study" pending further analysis by the OIE's ad hoc expert groups.

3. Nature and duration of the journey

Written community comments:

The change in point 3 "……that determine the overall welfare of animals" should be deleted.

Justification

Refer to previous change in Guidelines for the Transport of Animals by Sea.

The maximum duration of a *journey* should be determined ~~according to~~ taking into account factors that determine the overall welfare of animals, such as:

a) the ability of the animals to cope with the stress of transport (such as very young, old, lactating or pregnant animals);

b) the ~~animals'~~ previous transport experience of the animals;

c) the likely onset of fatigue;

d) the need for special attention;

e) the need for feed and water;

f) the increased susceptibility to injury and disease;

g) *space allowance*, *vehicle* design, road conditions and driving quality;

h) weather conditions;

i) *vehicle* type used, terrain to be traversed, road surfaces and quality, skill and experience of the driver.

4. Vehicle and container design and maintenance

a) *Vehicles* and *containers* used for the transport of animals should be designed, constructed and fitted as appropriate ~~to~~ for the species, size and weight of the animals to be transported. Special attention should be paid to ~~the avoidance~~ avoid ~~of~~ the injury to animals through the use of secure smooth fittings free from sharp protrusions. The avoidance of injury to drivers, and *animal handlers* while carrying out their responsibilities should be emphasised.

b) *Vehicles* and *containers* should be designed with the structures necessary to provide protection from adverse weather conditions and to minimise the opportunity for animals to escape.

c) In order to minimise the likelihood of the spread of infectious disease during transport, *vehicles* and *containers* should be designed to permit thorough cleaning and *disinfection*, and the containment of faeces and urine during a *journey*.

d) *Vehicles* and *containers* should be maintained in good mechanical and structural condition.

Written Community comments:

Under point 4 e) the following should be added again: "and the airflow should be adjustable".

Justification

The temperature can change during the journey. Therefore the airflow should be adjustable.

e) *Vehicles* and *containers* should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported; the ventilation system (natural or mechanical) should be effective when the *vehicle* is stationary.

f) *Vehicles* should be designed so that the faeces or urine from animals on upper levels do not soil animals on lower levels, nor their feed and water.

g) When *vehicles* are carried on board ferries, facilities for adequately securing them should be available.

h) If feeding or watering while the *vehicle* is moving is required, adequate facilities on the *vehicle* should be available.

i) When appropriate, suitable bedding should be added to *vehicle* floors to assist absorption of urine and faeces, to minimise slipping by animals, and protect animals (especially young animals) from hard flooring surfaces and adverse weather conditions.

5. Special provisions for transport in vehicles (road and rail) on roll-on/roll-off vessels or for containers

a) *Vehicles* and *containers* should be equipped with a sufficient number of adequately designed, positioned and maintained securing points enabling them to be securely fastened to the *vessel*.

b) *Vehicles* and *containers* should be secured to the ~~ship~~ *vessel* before the start of the sea *journey* to prevent them being displaced by the motion of the *vessel*.

c) Roll-on/roll-off *vessels* should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported, especially where the animals are transported in a secondary *vehicle/container* on enclosed decks.

6. Space allowance

a) The number of animals which should be transported on a *vehicle* or in a *container* and their allocation to compartments should be determined before *loading*.

b) The space required on a *vehicle* or in a *container* depends upon whether or not the animals need to lie down (for example, pigs, camels and poultry), or to stand (horses). Animals which will need to lie down often stand when first loaded or when the *vehicle* is driven with too much lateral movement or sudden braking.

c) When animals lie down, they should all be able to adopt a normal lying posture which allows necessary thermoregulation.

Written Community comments:

Under point 6 d) the words "in Appendix XXX, or, in their absence" should be deleted.

Justification

Appendix XXX does not exist and referring to such non-existent text in international guidelines to be adopted by 167 OIE member countries is inappropriate, unhelpful and confusing to the reader.

d) When animals are standing, they should have sufficient space to adopt a balanced position as appropriate to the climate and species transported (~~Article~~ Appendix X.X.X.).

Written Community comments:

Under point 6 e) the words "…and there should be sufficient headroom to allow adequate airflow over the animals" should be added to the end of the sentence.

Justification

If the space is not sufficient this can limit the airflow, with potentially serious welfare consequences.

e) The amount of headroom necessary depends on the species of animal. Each animal should be able to assume its natural position for transport (including during *loading* and *unloading*) without coming into contact with the roof or upper deck of the *vehicle*.

Written Community comments:

Under point 6 f) the words "in Appendix XXX, or, in their absence" should be deleted.

Justification

Appendix XXX does not exist and referring to such non-existent text in international guidelines to be adopted by 167 OIE member countries is inappropriate, unhelpful and confusing to the reader.

f) Calculations for the *space allowance* for each animal should be carried out using the figures given in Appendix X.X.X. or, in their absence, in a relevant national or international document. The number and size of pens on the *vehicle* should be varied to where possible accommodate already established groups of animals while avoiding group sizes which are too large.

g) Other factors which may influence *space allowance* include:

i) *vehicle/container* design;

ii) length of *journey*;

iii) need to provide feed and water on the *vehicle*;

iv) quality of roads;

v) expected weather conditions;

vi) category and sex of the animals.

7. Rest, water and feed

a) ~~There should be planning for the availability of~~ Suitable water and feed should be available as appropriate and needed for the species, age, and condition of the animals, as well as the duration of the *journey*, climatic conditions, etc.

b) ~~There should be planning for the resting of animals at~~ Animals should be allowed to rest at *resting points* at appropriate intervals during the *journey*. The type of transport, the age and species of the animals being transported, and climatic conditions should determine the frequency of rest stops and whether the animals should be unloaded. ~~There should be planning for~~ Water and feed should be available ~~availability~~ during rest stops.

8. Ability to observe animals during the *journey*

a) Animals should be positioned to enable each animal to be observed regularly during the *journey* to ensure their safety and good welfare.

Written Community comments:

Under point 8 b) "If" should be changed to "However" and this point b) combined with bullet point a).

Justification

This change is necessary for linguistic reasons and to improve readability and clarity, which are very important if guidelines are to be correctly interpreted, understood and ultimately applied by the OIE's member countries.

b) If the animals are in crates or on multi-tiered *vehicles* which do not allow free access for observation, for example where the roof of the tier is too low ~~(i.e. less than 1.3 m),~~ animals cannot be inspected adequately, and serious injury or disease could go undetected. In these circumstances, a shorter *journey* duration should be allowed, and the maximum duration will vary according to the rate at which problems arise in the species and under the conditions of transport.

9. Control of disease

As animal transport is often a significant factor in the spread of infectious diseases, *journey* planning should take the following into account:

a) mixing of animals from different sources in a single consignment should be minimised;

b) contact at *resting points* between animals from different sources should be avoided;

c) when possible, animals should be vaccinated against diseases to which they are likely to be exposed at their destination;

Written Community comments:

Under point 9 d) the original wording should be retained: "….medications used prophylactically or therapeutically should only be administered by a veterinarian or other person who has been instructed in their use by a veterinarian and agreed by the Veterinary Authority of the importing country".

Justification

The original text should be retained due to the varying procedures for medicine registration and licensing in countries around the world and the legal implications of such obligations.

d) medications used prophylactically or therapeutically should be approved by the *Veterinary Authority* of the *importing country* and should only be administered by a *veterinarian* or other person who has been instructed in their use by a *veterinarian*.

10. Emergency response procedures

There should be an emergency management plan that identifies the important adverse events that may be encountered during the *journey*, the procedures for managing each event and the action to be taken in an emergency. For each important event, the plan should document the actions to be undertaken and the responsibilities of all parties involved, including communications and record keeping.

11. Other considerations

a) Extreme weather conditions are hazardous for animals undergoing transport and require appropriate *vehicle* design to minimise risks. Special precautions should be taken for animals that have not been acclimatised or which are unsuited to either hot or cold conditions. In some extreme conditions of heat or cold, animals should not be transported at all.

b) In some circumstances, transportation during the night may reduce thermal stress or the adverse effects of other external stimuli.

Article 3.7.3.5.

Documentation

1. Animals should not be loaded until the documentation required to that point is complete.

2. The documentation accompanying the consignment should include:

a) *journey* travel plan ~~(including~~ and an emergency management plan~~)~~;

b) date, time, and place of *loading* and *unloading*;

c) veterinary certification, when required;

d) ~~driver's~~ animal welfare competencies of the driver;

Written community comment:

Under point 2 e) the word "individual" should be deleted.

Justification

The requirement for individual identification of each animal is not practicable for many species e.g. chickens.

e) ~~identities of the~~ *animal identification* ~~transported~~ to allow ~~traceback~~ *animal traceability* of individual animals to the premises of departure and, where possible, to the premises of origin;

f) details of any animals considered ~~'at risk'~~ at particular risk of suffering poor welfare during transport (point 3e) of Article 3.7.3.6.);

g) documentation of the period of rest, and access to feed and water, prior to the *journey*;

h) *stocking density* estimate for each load in the consignment;

i) the *journey* log - daily record of inspection and important events, including records of morbidity and mortality and actions taken, climatic conditions, rest stops, travel time and distance, feed and water offered and estimates of consumption, medication provided, and mechanical defects.

3. When veterinary certification is required to accompany consignments of animals, it should address:

a) fitness of animals to travel;

b) *animal identification* (description, number, etc.);

c) health status including any tests, treatments and vaccinations carried out;

d) when required, details of *disinfection* carried out.

At the time of certification, the *veterinarian* should notify a*nimal handler* or the driver of any factors affecting the ~~animals'~~ fitness of animals to travel for a particular *journey*.

Article 3.7.3.6.

Pre-journey period

1. General considerations

a) Pre-*journey* rest is necessary if the welfare of animals has become poor during the collection period because of the physical environment or the social behaviour of the animals. The need for rest should be judged by a veterinarian or other competent person.

b) Pre-*journey* assembly/holding areas should be designed to:

i) securely hold the animals;

ii) maintain a safe environment from hazards, including predators and disease;

iii) protect animals from exposure to severe weather conditions;

iv) allow for maintenance of social groups; ~~and~~

v) allow for rest, and appropriate water and feed;

c) Consideration should be given to ~~an animal's~~ the previous transport experience, training and conditioning of the animals, if known, as these may reduce fear and stress in animals.

d) Feed and water should be provided pre-*journey* if the *journey* duration is greater than the normal inter-feeding and drinking interval for the animal. Recommendations for specific species are described in detail in Article 3.7.3.11.

e) When animals are to be provided with a novel diet or method of feed or water provision during the *journey*, an adequate period of adaptation should be ~~planned~~ allowed.

Written community comments:

In point 1 f) the following should be added "….minimum stress *and risk* to the animals".

Justification

Cleaning can also be a risk for the animals (e. g. gear and chemicals).

f) Before each *journey*, *vehicles* and *containers* should be thoroughly cleaned and, if necessary, treated for animal health and public health purposes, using methods approved by the *Competent Authority*. When cleaning is necessary during a *journey*, this should be carried out with the minimum of stress to the animals.

g) Where an *animal handler* believes that there is a significant risk of disease among the animals to be loaded or significant doubt as to their fitness to travel, the animals should be examined by a *veterinarian*.

2. Selection of compatible groups

Compatible groups should be selected before transport to avoid adverse animal welfare consequences. The following guidelines should be applied when assembling groups of animals:

a) Animals reared together should be maintained as a group; animals with a strong social bond, such as a dam and offspring, should be transported together.

b) Animals of the same species can be mixed unless there is a significant likelihood of aggression; aggressive individuals should be segregated (recommendations for specific species are described in detail in Article 3.7.3.11.). For some species, animals from different groups should not be mixed because poor welfare occurs unless they have established a social structure.

c) Young or small animals should be separated from older or larger animals, with the exception of nursing mothers with young at foot.

d) Animals with horns or antlers should not be mixed with animals lacking horns or antlers unless judged to be compatible.

e) Animals of different species should not be mixed unless they are judged to be compatible.

3. Fitness to travel

a) Each animal should be inspected by a *veterinarian* or an *animal handler* to assess fitness to travel. If its fitness to travel is in doubt, the animal should be examined by a *veterinarian*. Animals found unfit to travel should not be loaded onto a *vehicle*, except for transport to receive veterinary treatment.

Written Community comments:

The point 3 b) should be clarified.

Justification

Sharing the responsibilities between different agents "e.g. the owner or agent" is likely to give rise to confusion and ineffective handling of animal welfare problems when they arise.

b) Humane and effective arrangements should be made by the owner or agent for the handling and care of any animal rejected as unfit to travel.

c) Animals that are unfit to travel include, but may not be limited to:

i) those that are sick, injured, weak, disabled or fatigued;

ii) those that are unable to stand unaided and bear weight on each leg;

iii) those that are blind in both eyes;

iv) those that cannot be moved without causing them additional suffering;

v) newborn with an unhealed navel;

Written community comments:

The point 3 c) vi) should be changed as follows:

"Pregnant animals for which 90% or more of the expected gestation period has already passed or females who have given birth in the previous week".

Justification

Since the beginning of the pregnancy is known, it is more practically to mention the period already passed.

vi) pregnant animals which would be in the final 10% of their gestation period at the planned time of *unloading*;

vii) females travelling without young which have given birth within the previous 48 hours;

viii) those whose body condition would result in poor welfare because of the expected climatic conditions.

d) Risks during transport can be reduced by selecting animals best suited to the conditions of travel and those that are acclimatised to expected weather conditions.

e) Animals ~~'at risk'~~ at particular risk of suffering poor welfare during transport and which require special conditions (such as in the design of facilities and *vehicles*, and the length of the *journey*) and additional attention during transport, may include:

i) large or obese individuals;

ii) very young or old animals;

iii) excitable or aggressive animals;

iv) animals which have had little contact with humans;

v) animal subject to motion sickness;

vi) females in late pregnancy or heavy lactation, dam and offspring;

vii) animals with a history of exposure to stressors or pathogenic agents prior to transport;

viii) animals that have recently undergone a surgical procedure, such as dehorning.

4. Specific species requirements

Transport procedures should be able to take account of variations in the behaviour of the species. Flight zones, social interactions and other behaviour vary significantly among species and even within species. Facilities and handling procedures that are successful with one species are often ineffective or dangerous with another.

Recommendations for specific species are described in detail in Article 3.7.3.11.

Article 3.7.3.7.

Loading

1. Competent supervision

a) *Loading* should be carefully planned as it has the potential to be the cause of poor welfare in transported animals.

Written Community comments:

The point 1 b) should be returned to its original text.

Justification

Stating that "loading should be supervised and/or conducted by animal handlers" is confusing and gives rise to the question of who will actually conduct and supervise the loading. To ensure proper application of the guidelines such responsibilities need to be clearly and carefully described.

b) *Loading* should be supervised and/or conducted by *animal handlers*. ~~These *animal handlers* should ensure that~~ The animals are to be loaded quietly and without unnecessary noise, harassment or force~~, . and that u~~Untrained assistants or spectators ~~do~~ should not impede the process.

c) When *containers* are loaded onto a *vehicle*, this should be carried out in such a way to avoid poor animal welfare.

2. Facilities

a) The facilities for *loading* including the collecting area, races and loading ramps should be designed and constructed to take into account the needs and abilities of the animals with regard to dimensions, slopes, surfaces, absence of sharp projections, flooring, etc.

b) *Loading* facilities should be properly illuminated to allow the animals to be observed by *animal handler(s)*, and to allow the ~~animals'~~ ease of movement of the animals at all times. Facilities should provide uniform light levels directly over approaches to sorting pens, chutes, loading ramps, with brighter light levels inside *vehicles/containers*, in order to minimise baulking. Dim light levels may be advantageous for the catching of poultry and some other animals. Artificial lighting may be required.

c) Ventilation during *loading* and the *journey* should provide for fresh air, the removal of excessive heat, humidity and noxious fumes (such as ammonia and carbon monoxide), and the prevention of accumulations of ammonia and carbon dioxide. Under warm and hot conditions, ventilation should allow for the adequate convective cooling of each animal. In some instances, adequate ventilation can be achieved by increasing the *space allowance* for animals.

3. Goads and other aids

Written community comments:

The following text should be added:

"When moving animals, their species specific behaviour should be used (see Article 3.7.3.11). If goads and other aids are necessary, the following principles…".

Justification

It is important to use the natural behaviour of the animals to get them to move forward, before the use of goads and other device. This should be stressed.

The following principles should apply:

~~a) Animals which have little or no room to move should not be subjected to physical force or goads and other aids which compel movement.~~

~~b) Useful and permitted aids include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles; they should be used in a manner sufficient to encourage and direct movement of the animals.~~

~~c) Painful procedures (including whipping, tail twisting, use of nose twitches, pressure on eyes, ears or external genitalia), or the use of unsuitable goads or other aids (including sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts), should not be used to move animals.~~

~~d) The use of goads which administer electric shocks should be discouraged, and restricted to that necessary to assist movement of the animal. Such use should be limited to battery-powered goads on the hindquarters of adult pigs and cattle, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on other animals.~~

~~e) The use of well trained dogs to help with the *loading* of some species may be acceptable.~~

~~f) The throwing or dropping of animals, or their lifting or dragging by body parts such as their tail, head, horns, ears, limbs, wool, hair or feathers, should not be permitted. The manual lifting of small animals is permissible.~~

~~g) Shouting or yelling at animals or making loud noises e.g. through the cracking of whips to encourage them to move should not occur, as such actions may make the animals agitated, leading to crowding or falling.~~

a) Animals that have little or no room to move should not be subjected to physical force or goads and other aids which compel movement. Electric goads and prods should only be used in extreme cases and not on a routine basis to move animals. The use and the power output should be restricted to that necessary to assist movement of an animal and only when an animal has a clear path ahead to move. Goads and other aids should not be used repeatedly if the animal fails to respond or move. In such cases it should be investigated whether some physical or other impediment is preventing the animal from moving.

b) The use of such devices should be limited to battery-powered goads on the hindquarters of pigs and large ruminants, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.

c) Useful and permitted goads include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles; they should be used

in a manner sufficient to encourage and direct movement of the animals without causing undue stress.

d) Painful procedures (including whipping, tail twisting, use of nose twitches, pressure on eyes, ears or external genitalia), or the use of goads or other aids which cause pain and suffering (including large sticks, sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts), should not be used to move animals.

e) Shouting or yelling at animals or making loud noises (e.g., through the cracking of whips) to encourage them to move should not occur, as such actions may make the animals agitated, leading to crowding or falling.

f) The use of well trained dogs to help with the *loading* of some species may be acceptable.

Written community comments:

Under point 3 g) the word “such” should be deleted.

Justification

As feathers are mentioned, the word “such” in point g) do not refer to quadrupeds.

g) Animals should be grasped or lifted in a manner which avoids pain or suffering and physical damage (e.g. bruising, fractures, dislocations). In the case of quadrupeds, manual lifting by a person should only be used in young animals or small species, and in a manner appropriate to the species; grasping or lifting such animals only by their wool, hair, feathers, feet, neck, ears, tails, head, horns, limbs causing pain or suffering should not be permitted, except in an emergency where animal welfare or human safety may otherwise be compromised.

h) Conscious animals should not be thrown, dragged or dropped.

Written community comments:

Under point 3 i) the word "should" should be replaced by "could".

Justification

It should not be an obligation to use such system.

i) Performance standards should be established in which numerical scoring is used to evaluate the use of such instruments, and to measure the percentage of animals moved with an electric instrument and the percentage of animals slipping or falling as a result of their usage.

Article 3.7.3.8.

Travel

1. General considerations

Written Community comments:

Under point 1 a), the words "especially at rest or re-fuelling stops or during meal breaks when the vehicle is stationary" should be added to the end of the sentence.

Justification

Drivers or conveyors of animals should be encouraged to take any available opportunity when the vehicle is stationary for a period of time in order to examine the animals.

a) *D*rivers and *animal handlers* should check the load immediately before departure to ensure that the animals have been properly loaded. Each load should be checked again early in the trip and adjustments made as appropriate. Periodic checks should be made throughout the trip.

b) Drivers should utilise smooth, defensive driving techniques, without sudden turns or stops, to minimise uncontrolled movements of the animals.

2. Methods of restraining or containing animals

a) Methods of restraining animals should be appropriate to the species and age of animals involved and the training of the individual animal.

b) Recommendations for specific species are described in detail in Article 3.7.3.11.

3. Regulating the environment within vehicles or containers

Written Community comments:

Under point 3 a) the words "in Appendix XXX," should be deleted.

Justification

Appendix XXX does not exist and referring to such non-existent text in international guidelines to be adopted by 167 OIE member countries is inappropriate, unhelpful and confusing to the reader.

a) Animals should be protected against harm from hot or cold conditions during travel. Effective ventilation procedures for maintaining the ~~animals'~~ environment within *vehicles* or *containers* will vary according to whether conditions are cold, hot and dry or hot and humid, but in all conditions a build-up of noxious gases should be prevented. Specific temperature and humidity parameters are described in detail in Appendix X.X.X.

b) The ~~animals'~~ environment within *vehicles* or *containers* in hot and warm weather can be regulated by the flow of air produced by the movement of the *vehicle*. In warm and hot weather, the duration of *journey* stops should be minimised and *vehicles* should be parked under shade, with adequate and appropriate ventilation.

c) To minimise slipping and soiling, and maintain a healthy environment, urine and faeces should be removed from floors when necessary and disposed of in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.

4. Sick, injured or dead animals

a) A driver or *animal handler* finding sick, injured or dead animals should act according to a predetermined emergency response plan.

b) ~~If possible,~~ Sick or injured animals should be segregated.

c) Ferries (roll-on roll-off) should have procedures to treat sick or injured animals during the *journey*.

d) In order to reduce the likelihood that animal transport will increase the spread of infectious disease, contact between transported animals, or the waste products of the transported animals, and other farm animals should be minimised.

e) During the *journey*, when disposal of a dead animal becomes necessary, this should be carried out in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.

Written community comments:

Under point 4 f) the word "euthanasia" should be changed by "killing".

Justification

Refer to previous comment.

f) When euthanasia is necessary, ~~the driver or *animal handler* should ensure that~~ it ~~is~~ should be carried out as quickly as possible and assistance should be sought from a *veterinarian* or other person(s) competent in humane euthanasia procedures. Recommendations for specific species are described in Appendix 3.7.6. on killing of animals for disease control purposes.

5. Water and feed requirements

a) If *journey* duration is such that feeding or watering is required or if the species requires feed or water throughout, access to suitable feed and water for all the animals (appropriate for their species and age) carried in the *vehicle* should be provided. There should be adequate space for all animals to move to the feed and water sources and due account taken of likely competition for feed.

b) Recommendations for specific species are described in detail in Article 3.7.3.11.

6. Rest periods and conditions including hygiene

a) Animals that are being transported should be rested at appropriate intervals during the *journey* and offered feed and water, either on the *vehicle* or, if necessary, unloaded into suitable facilities.

b) Suitable facilities should be used en route, when resting requires the *unloading* of the animals. These facilities should meet the needs of the particular animal species and should allow access of all animals to feed and water.

7. In-transit observations

a) Animals being transported by road should be observed soon after a *journey* is commenced and whenever the driver has a rest stop ~~(with a maximum interval of 5 hours)~~. After meal breaks and refuelling stops, the animals should be observed immediately prior to departure.

b) Animals being transported by rail should be observed at each scheduled stop ~~nearest to 5 hours since the last observation~~. The responsible rail transporter should monitor the progress of trains carrying animals and take all appropriate action to minimise delays.

c) During stops, it should be ensured that the animals continue to be properly confined, have appropriate feed and water, and their physical condition is satisfactory.

Article 3.7.3.9.

Unloading and post-journey handling

1. General considerations

a) The required facilities and the principles of animal handling detailed in Article 3.7.3.7. apply equally to *unloading*, but consideration should be given to the likelihood that the animals will be fatigued.

b) *Unloading* should be supervised and/or conducted by an *animal handler* with knowledge and experience of the behavioural and physical characteristics of the species being unloaded. Animals should be unloaded from the *vehicle* into appropriate facilities as soon as possible after arrival at the destination but sufficient time should be allowed for *unloading* to proceed quietly and without unnecessary noise, harassment or force.

c) Facilities should provide all animals with appropriate care and comfort, adequate space and ventilation, access to feed (if appropriate) and water, and shelter from extreme weather conditions.

d) For details regarding the *unloading* of animals at a *slaughterhouse*, see Appendix 3.7.5. on slaughter of animals for human consumption.

2. Sick ~~and~~ or injured animals

Written community comments:

Under point 2 a) the word "euthanasia" should be replaced by "killing".

Justification

Refer to previous comment.

a) An animal that has become sick, injured or disabled during a *journey* should be appropriately treated or humanely killed (see Appendix 3.7.6. on killing of animals for disease control purposes). ~~When~~ If necessary, veterinary advice should be sought in the care and treatment of these animals. In some cases, where animals are non-ambulatory due to fatigue, injury or sickness, it may be in the best welfare interests of the animal to be treated or euthanized aboard the *vehicle*. Assistance should be sought from a *veterinarian* or other person(s) competent in humane euthanasia procedures

b) At the destination, the *animal handler* or the driver during transit should ensure that responsibility for the welfare of sick, injured or disabled animals is transferred to a veterinarian or other suitable person.

Written community comments:

Under point 3 c) the word "euthanasia" should be replaced by "human killing".

Justification

Refer to previous comment.

c) If treatment or euthanasia is not possible aboard the *vehicle*, there should be appropriate facilities and equipment for the humane *unloading* of animals that are non-ambulatory due to fatigue, injury or sickness. These animals should be unloaded in a manner that causes the least amount of suffering. After *unloading*, separate pens and other appropriate facilities should be available for sick or injured animals.

d) Feed, if appropriate, and water should be available for each sick or injured animal.

3. Addressing disease risks

The following should be taken into account in addressing the greater risk of disease due to animal transport and the possible need for segregation of transported animals at the destination:

a) increased contact among animals, including those from different sources and with different disease histories;

b) increased shedding of pathogens and increased susceptibility to infection related to stress and impaired defences against disease, including immunosuppression;

c) exposure of animals to pathogens which may contaminate *vehicles*, *resting points*, *markets*, etc.

4. Cleaning and disinfection

a) *Vehicles*, crates, *containers*, etc. used to carry the animals should be cleaned before re-use through the physical removal of manure and bedding by scraping, washing and flushing ~~vehicles and containers~~ with water and detergent. This should be followed by *disinfection* when there are concerns about disease transmission.

b) Manure, litter, bedding and the bodies of any animals which die during the *journey* should be disposed of in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.

c) Establishments like livestock *markets*, *slaughterhouses*, *resting sites*, railway stations, etc. where animals are unloaded should be provided with appropriate areas for the cleaning and *disinfection* of *vehicles*.

~~d) Where *disinfestation* is necessary, it should be carried out with the minimum stress to the animals.~~

Article 3.7.3.10.

Actions in the event of a refusal to allow the completion of the journey

1. The welfare of the animals should be the first consideration in the event of a refusal to allow the completion of the *journey*.

2. When the animals have been refused import, the *Competent Authority* of ~~that~~ the *importing country* should make available suitable isolation facilities to allow the *unloading* of animals from a *vehicle* and their secure holding, without posing a risk to the health of national herd or flock, pending resolution of the situation. In this situation, the priorities should be:

   a) The *Competent Authority* of the *importing country* should provide urgently in writing the reasons for the refusal.

   b) In the event of a refusal for animal health reasons, the *Competent Authority* of the *importing country* should provide urgent access to a *veterinarian*, where possible an OIE *veterinarian(s)* appointed by the Director General, to assess the ~~animals'~~ health status of the animals with regard to the concerns of the *importing country*~~'s concerns~~, and the necessary facilities and approvals to expedite the required diagnostic testing.

   c) The *Competent Authority* of the *importing country* should provide access to allow continued assessment of the health and other aspects of the welfare of the animals.

   d) If the matter cannot be promptly resolved, the *Competent Authorities* of the *exporting* and *importing countries* should call on the OIE to mediate.

3. In the event that a *Competent Authority* requires the animals to remain on the *vehicle*, the priorities should be:

   a) ~~The *Competent Authority* should~~ to allow ~~re~~provisioning of the *vehicle* with water and feed as necessary.

   b) ~~The *Competent Authority* should~~ to provide urgently in writing the reasons for the refusal.

   c) ~~In the event of a refusal for animal health reasons, the *Competent Authority* should~~ to provide urgent access to an independent *veterinarian(s)* to assess the ~~animals'~~ health status of the animals, and the necessary facilities and approvals to expedite the required diagnostic testing in the event of a refusal for animal health reasons.

   d) ~~The *Competent Authority* should~~ to provide access to allow continued assessment of the health and other aspects of the welfare of the animals, and the necessary actions to deal with any animal issues which arise.

4. The OIE should utilise its dispute settlement mechanism to identify a mutually agreed solution which will address animal health and any other welfare issues in a timely manner.

Article 3.7.3.11.

Species specific issues

(To be developed)

Written community comments:

The following text should to be added at the end of the cattle part: "Cattle tend to avoid "dead end" in passages".

Justification

Refer to previous comment.

Cattle are sociable animals and may become agitated if they are singled out. Social order is usually established at about two years of age. When groups are mixed, social order has to be re-established and aggression may occur until a new order is established. Crowding of cattle may also increase aggression as the animals try to maintain personal space. Social behaviour varies with age, breed and sex; *Bos indicus* and *B. indicus*-cross animals are usually more temperamental than European breeds. Young bulls, when moved in groups, show a degree of playfulness (pushing and shoving) but become more aggressive and territorial with age. Adult bulls have a minimum personal space of six square metres. Cows with young calves can be very protective, and handling calves in the presence of their mothers can be dangerous.

Goats should be handled calmly and are more easily led or driven than if they are excited. When goats are moved, their gregarious tendencies should be exploited. Activities which frighten, injure or cause agitation to animals should be avoided. Bullying is particularly serious in goats. Housing strange goats together could result in fatalities, either through physical violence, or subordinate goats being refused access to food and water.

Sheep are sociable animals with good eyesight and tend to "flock together", especially when they are agitated. They should be handled calmly and their tendency to follow each other should be exploited when they are being moved. Sheep may become agitated if they are singled out for attention and will strive to rejoin the group. Activities which frighten, injure or cause agitation to sheep should be avoided. They can negotiate steep ramps.

Pigs have poor eyesight, and may move reluctantly in strange surroundings. They benefit from well lit *loading* bays. Since they negotiate ramps with difficulty, these should be as level as possible and provided with secure footholds. Ideally, a hydraulic lift should be used for greater heights. Pigs also negotiate steps with difficulty. A good 'rule-of-thumb' is that no step should be higher than the pig's front knee. Serious aggression may result if unfamiliar animals are mixed. Pigs are highly susceptible to heat stress.

Horses in this context include all solipeds, donkeys, mules, hinnies and zebra. They have good eyesight and a very wide angle of vision. They may have a history of *loading* resulting in good or bad experiences. Good training should result in easier *loading*, but some horses can prove difficult, especially if they are inexperienced or have associated *loading* with poor transport conditions. In these circumstances, two experienced *animal handlers* can load an animal by linking arms or using a strop below its rump. Blindfolding may even be considered. Ramps should be as shallow as possible. Steps are not usually a problem when horses mount a ramp, but they tend to jump a step when descending, so steps should be as low as possible. Horses benefit from being individually stalled, but may be transported in compatible groups. When horses are to travel in groups, their shoes should be removed.

Camelids in this context comprise llamas, alpacas, guanaco and vicuna. They have good eyesight and, like sheep, can negotiate steep slopes, though ramps should be as shallow as possible. They load most easily in a bunch as a single animal will strive to rejoin the others. Whilst they are usually docile, they have an unnerving habit of spitting in self-defence. During transport, they usually lie down. They frequently extend their front legs forward when lying, so gaps below partitions should be high enough so that their legs are not trapped when the animals rise.

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Appendix XXIV

FUTURE WORK PROGRAMME FOR THE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Topic	Action	How to be managed	Status (October 2006)
(New topic) **Rinderpest**	Revise chapter and pathway	SCAD	TCC waiting recommendation to revise chapter in March 2007
Traceability	*Ad hoc* Group to develop specific Chapter on animal identification and traceability	Animal Production Food Safety Working Group (APFS WG).	Appendix 3.5.1. part of 2006 Oct report for 2007 revision. MC comments on guidelines to be considered by APFSWG in Nov 2006
Consolidation of *Terrestrial* and *Aquatic Codes*	To work with the Aquatic Commission to maximise harmonisation of present Codes, with an ultimate goal of a single Code in three parts: horizontal chapters, terrestrial animal disease chapters and aquatic animal disease chapters.	Trade Dep will continue to harmonise horizontal chapters, and work towards their consolidation. Each Commission to invite other Commission President to its meetings.	Ongoing
Good farming practices	To coordinate with the FAO's work to publish a single guideline on good farming practices for the guidance of Member Countries and the public.	APFS WG	Ongoing
Control of hazards of animal health and public health importance through ante- and post-mortem meat inspection	To develop Code guidelines	APFS WG	Appendix 3.10.1. adopted May 2006. New work (NZ proposal) to be addressed by APFSWG in Nov 2006.
Anthrax	To develop an appendix on the inactivation of the bacillary and spore forms of *Bacillus anthracis.*	Secretariat	Pending
BSE – safety of	To update 'safe commodities'	*ad hoc* Group	Modified Chapter 2.3.13.

gelatine and tallow	article		part of 2006 report.
BSE supporting document	To update	expert	Part of Oct 2006 report.
BSE risk assessment	To update	expert	Draft Appendix 3.8.5. with MCs' comments transferred to SCAD for further work based on TOR for BSE categorisation.
Current chapter on Veterinary Services	To revise to better address the role of the Statutory Body, the early detection of disease and greater detail on how the auditing of Veterinary Services could be implemented.	expert	*ad hoc* Group in Nov 2006

Appendix XXIV (contd)

Topic	Action	How to be managed	Status (October 2006)
Other *Terrestrial Code* texts in need of revision	To update chapter on equine influenza	Reference Laboratory	Part of 2006 Oct report for 2007 revision.
	To update chapter on brucellosis	SCAD then APFS WG	With SCAD
	To update chapter on Newcastle disease	SCAD	With SCAD
	To update chapter on African swine fever	SCAD	With SCAD
***Terrestrial Code* texts identified as priorities by APFS WG**	Salmonellosis	SCAD	APFSWG *ad hoc* Group within 2007
	Cysticercosis	SCAD	Monitor progress
Harmonisation of international health certificates	To finalise with view of replacing existing Code certificates	APFS WG	*ad hoc* Group within 3 months
Dead animal disposal	To finalise Code appendix	SCAD	Part of 2006 Oct report for 2007 revision.
Animal welfare – companion animals and laboratory animals	To draft new chapters	AW WG	Work programme of this year to produce a draft for the Commission in March 2007
Alternative approaches to providing OIE advice	To develop alternative mechanism for providing guidance to Member Countries on managing certain animal health and welfare issues outside the Code framework	TCC, AW WG and APFS WG	Ongoing
Surveillance for vectors	To develop guidelines for the surveillance of vectors capable of transmitting animal diseases	SCAD	With SCAD

Community comments:

The Community believes that African horse sickness should be added as it appears to have been missed off as the Chapter has not yet been fully completed and finally approved by the International Committee.

Furthermore, relating to the inactivation of various pathogen agents, there is often a gap in knowledge about the various methods of inactivation of these pathogens. New pathogens emerge about which very little is known. The Commission suggests that the OIE initiates studies in order to continuously update the standards and chapter related.

Planned distribution of chapters and appendices into two volumes

Current structure		Volume 1 (non-disease specific)	Volume 2 (disease specific)
PART 1	GENERAL PROVISIONS		
SECTION 1.1.	GENERAL DEFINITIONS AND NOTIFICATION OF ANIMAL DISEASES	SECTION 1.1.	
SECTION 1.2.	OBLIGATIONS AND ETHICS IN INTERNATIONAL TRADE	SECTION 1.2.	
SECTION 1.3.	RISK ANALYSIS	SECTION 1.3.	
SECTION 1.4.	IMPORT/EXPORT PROCEDURE	SECTION 1.4.	
SECTION 1.5.	RISK ANALYSIS FOR BIOLOGICALS FOR VETERINARY USE	SECTION 1.5.	
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