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Subject : **General session of the OIE May 2008**

Dear Director General,

Please find attached, for your informal information, two annexes indicating the intended positions of the Community on the reports of the Terrestrial and Aquatic Animal Health Standards Commissions to be raised and drafts proposed for adoption at the General Session in May 2008 in Paris.

Further comments on those draft chapters to be discussed during the September meetings will be sent later following the Annual General Session and before the requested dates for comment.

It is to be noted that for various chapters, the versions proposed show too important changes to be adopted without possible further discussions. This can seriously impede the consensus process that has always been the aim of the OIE and its Members. It should be taken into account for a revision of the procedures.

I trust you will find this useful. Thank you for your continued cooperation.

Yours sincerely,

Paola Testori Coggi
Deputy Director General

Dr. Vida Čadonič Špelič,
CVO of Slovenia
Annex: 1

Copy: All Directors/Chief Veterinary Officers of the Community and Croatia, Iceland, Liechtenstein, Norway, Switzerland and Turkey.

Dr. B. Vallat
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ANNEX

76th General Session International Committee
World organisation for animal health Paris, 25-30 May 2008

76 SG/12/CS1 B

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March 2008

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

Paris, 10-14 March 2008

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The OIE Terrestrial Animal Health Standards Commission (the Code Commission) met at the OIE Headquarters in Paris from 10 to 14 March 2008.

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

The OIE Director General, Dr Vallat was unable to meet with the Code Commission due to duty travel. Dr Thiermann therefore welcomed members of the Code Commission to OIE Headquarters on behalf of Dr Vallat. Dr Thiermann noted the heavy workload for this meeting, in part due to the fact that Members had provided extensive comments on several Chapters. Dr Thiermann was pleased to note that several Members had provided comments for the first time and welcomed Members' increased participation in the standard-setting work of the OIE. However, the Code Commission again registered its concern at the lack of participation by developing countries, particularly in issues of interest to them, such as the control of stray dog populations, animal identification, compartmentalisation and BSE.

Dr Thiermann reminded the Code Commission that they should focus on the texts to be proposed for adoption at the General Session in May 2008 in the event that they were unable to deal with all agenda items in the time available for the meeting.

The Code Commission thanked the following Members for providing written comments: Argentina, Australia, Canada, Chinese Taipei, the European Union (EU), Guatemala, Japan, Kuwait, Malaysia, New Zealand, the People's Republic of China, Philippines, Serbia, South Africa, Sudan, Switzerland, Thailand, and the United States of America (USA). Comments were also received from the International Embryo Transfer Society (IETS), industry organisations and a non-governmental organisation (NGO).

The Code Commission strongly encourages Members to participate in the development of the OIE's international standards by sending comments on this report. The Code Commission reiterates that it would be very helpful if comments were submitted as specific proposed text changes, supported by a scientific rationale. Members are requested **not to use the automatic 'track-change' function** provided by word processing software in preparation of their comments. The Commission also reminded Members that they should follow the established convention in recommending modification of text in the Terrestrial Animal Health Code, i.e. propose new text (shown as double underline) and propose text deletions (shown as ~~strike-through~~) and provide a scientific justification for all changes proposed.

The Code Commission was informed that Dr Thiermann had met with Dr Bernoth, President of the Aquatic Animal Health Standards Commission, and the two presidents had noted that some Members providing comments on proposed changes to horizontal Chapters of the respective Codes (i.e., the Terrestrial Animal Health Code and the Aquatic Animal Health Code) did not seem to be aware that the two Commissions had proposed equivalent changes to matching Chapters (e.g., the Chapter on General obligations). Members are encouraged, therefore, to bear in mind equivalent Chapters in the two Codes when commenting on horizontal Chapters.

The Code Commission examined various draft texts of the Terrestrial Animal Health Code (the Code) in the light of comments received from Members, as well as comments outstanding from the previous Code Commission meeting. It also reviewed advice received from the Scientific Commission for Animal Diseases (the Scientific Commission), the reports of several *ad hoc* Groups and of the Animal Production Food Safety Working Group (APFSWG) and the Animal Welfare Working Group (AWWG).

The outcome of the Code Commission's work is presented as Annexes to this report. Amendments made to the Code Chapters before the September 2007 meeting which had been previously circulated are shown as double underlined text, with deleted text in ~~strikeout~~. Amendments made at this meeting (March 2008) are shown in a similar fashion, with a coloured background to distinguish the two groups of amendments.

All Member comments were considered by the Code Commission. However, because of the very large volume of work, certain agenda items were deferred to the next meeting. In the time available, the Code Commission was not able to prepare a detailed explanation of the reasons for accepting or not accepting each proposal received.

Members are reminded that if comments are resubmitted without modification or new justification the Code Commission will not, as a rule, repeat previous advice, and encourages Members to refer to previous reports.

The texts presented in Part A of this report are proposed for adoption at the 76th OIE General Session. The texts presented in Part B are provided to Members for comment. Several reports of meetings (working groups and *ad hoc* Groups) are presented in Part C for Members' information.

Comments on this report must reach OIE Headquarters by **15 August 2008** in order to be considered at the next meeting of the Code Commission in September 2008. Comments should be sent to the International Trade Department at: trade.dept@oie.int.

A. TEXTS SUBMITTED FOR ADOPTION

1. General definitions (Chapter 1.1.1.)

The Code Commission received comments from Argentina, Australia, Canada, the EU, Japan, Kuwait, New Zealand, the People's Republic of China, Serbia, South Africa, Sudan, Switzerland and the USA.

The Code Commission reviewed Member comments and modified the text as appropriate.

The revised texts are presented at Annex III of this report for adoption.

Community position:

The Community acknowledges and in many cases welcomes the new proposals, but wishes that some of them are amended, to be clearer or more useable. In the case of the definition of *buffer zone*, if an appropriate change is not made to the FMD chapter, the Community cannot support the new definition proposal. There are problems with interpretation which may lead to major trade problems and the EU asks that in the various disease Chapters OIE looks at these definitions of zones and the possible effect or differ the change of definition of buffer zone. A buffer zone should have more flexibility e.g. in Europe in the case of an outbreak of FMD we don't have a buffer area between Member States.

Comments for next Code Commission meeting:

The comments are inserted after each commented definition below. In addition some definitions such as "*Target population*", "*Targeted surveillance*" and "*Epidemiological unit*" are different to the correspondent definitions in the Aquatic code. The EU asks the OIE to look at these differences and try to harmonise the two whenever possible and relevant.

2. Model veterinary certificates

a) Model international veterinary certificates (Section 4)

b) Notes for guidance on veterinary certificates for international trade in live animals, hatching eggs and products of animal origin (Appendix X.X.X.)

c) General obligations (Chapter 1.2.1.)

d) Certification procedures (Chapter 1.2.2.)

The Code Commission noted the report of the *ad hoc* Group, which had reviewed the comments provided by Members at the time of its meeting, and examined comments of Argentina, the EU, New Zealand, South Africa, Sudan, Switzerland, the USA, after the meeting of the *ad hoc* Group. The Code Commission made some further modifications to the text as appropriate.

The revised texts are presented at Annex IV of this report for adoption.

Community position:

The Community can support the proposed changes. However it would like the OIE to take into consideration its comments, in order to avoid unnecessary administrative work for the Veterinary Authorities, and to ensure better traceability of the certificate.

3. Guidelines on import risk analysis (Chapter 1.3.2.)

The Code Commission received comments from the EU, New Zealand and the USA.

Due to inadequate time at this meeting, the Code Commission deferred this item to its September 2008 meeting.

The revised text is presented at Annex V of this report for adoption.

Community position:

The Community can support the proposed changes.

4. Animal health measures applicable before and at departure (Chapter 1.4.1.) and Border posts and quarantine stations in the importing country (Chapter 1.4.3.)

The Code Commission received comments from Argentina, Canada, the EU, South Africa, Sudan, Switzerland and the USA.

During the previous meeting the Code Commission added a definition for "collection centre" and "area of direct transit" to Article 1.4.1.3. and 1.4.3.4., noting that these definitions had been removed from Chapter 1.1.1. as each of them is used only once in the Code.

Due to inadequate time at this meeting, the Code Commission deferred further work on this item to its September 2008 meeting.

The revised texts are presented at Annex VI of this report for adoption.

Community position:

The Community can support the proposed changes.

5. Evaluation of Veterinary Services

The Code Commission received comments from the EU.

a) Evaluation of Veterinary Services (Chapter 1.3.3. and 1.3.4.)

The Code Commission modified Articles 1.3.3.5. and 1.3.4.1. to reflect the changed title of the OIE PVS Tool.

The revised texts are presented at Annex VII of this report for adoption.

Community position:

The Community can support the proposed changes.

b) Update on OIE PVS Tool and programme for evaluating Members

Dr Kahn advised that the OIE has completed evaluations of 50 Members. To date, 15 evaluated countries have released their PVS reports on a conditional basis (ie to OIE partners and/or donor organizations).

6. Zoning and Compartmentalisation

a) Zoning and Compartmentalisation (Chapter 1.3.5)

The Code Commission received comments from Argentina, Australia, Canada, the EU, Japan, New Zealand, the People's Republic of China, South Africa, Sudan, Switzerland and the USA.

The Code Commission discussed comments of several Members on Article 3, regarding the establishment of a containment zone. The Code Commission agreed with the views of Members who recommended that 'a stamping out policy or another effective control strategy could be applied…'. However, this general consideration should be subject to the implementation of measures consistent with disease Chapters (where these mention containment zones) to support the establishment of a containment zone. The Code Commission undertook to modify the text on a containment zone in Chapter 2.2.10. (see item 8. Foot and mouth disease).

Community position:

The Community can support the proposed changes, but reiterates one of its former comments.

Furthermore, the chapter should reflect the work of the ad hoc groups on wildlife disease surveillance and epidemiology to indicate whenever the domestic and wild population can be considered separately or not, and more work still need to be done in this respect.

b) General guidelines on the application of compartmentalisation (Appendix X.X.X.)

The Code Commission received comments from Australia, Canada, the EU, Japan, New Zealand, Serbia, Sudan and the USA.

Texts were amended in response to several comments of Members. One recommendation for much more prescriptive provisions in regard to the role of Veterinary Authorities in approving compartments was not supported as the Code Commission noted that relevant provisions may be found elsewhere in the Code, including in Chapters 1.3.3. and 1.3.4.

Community position:

The Community could support the proposed Appendix, but a reference to HACCP should be made in article 3 and two other very important comments on article 3.x.x.7 should be taken into account:

- firstly it should be made clearer that what is suspended in case of breach in the biosecurity system is the status of the compartment and the certification as a free compartment; the present wording can imply that a suspended compartment cannot trade at all, which is not the case;

- secondly, it is important to consider the case of an outbreak in the close vicinity of the compartment: then an evaluation should be made by the competent autority in order to verify that the biosecurity measures are sufficient and in place; only after a favourable evaluation can the certification take place.

The Community wishes the OIE to continue its work on the guidelines in order to have them in line with the upcoming field experience of compartmentalisation. The Community is ready to participate in this work.

c) Compartmentalisation for vector borne diseases

The Code Commission awaits advice from the Scientific Commission regarding a draft text to propose for inclusion in the Code.

The revised texts are presented at Annex VIII of this report for adoption.

7. Rabies (Chapter 2.2.5.)

The Code Commission received comments from Argentina, Canada, the EU, South Africa and Switzerland.

The Code Commission decided to request advice from the Scientific and Technical Department (the Scientific Department) regarding the scientific rationale for the exclusion of all bat lyssaviruses other than rabies when determining the rabies status of a country. Advice was also sought on the safety of dog semen with regard to rabies.

The revised text is presented at Annex IX of this report for adoption.

Community position:

The Community can support the proposed changes.

8. Foot and mouth disease

a) Foot and mouth disease (Chapter 2.2.10.)

The Code Commission received comments from Argentina, Australia, Canada, Chinese Taipei, the EU, Japan, New Zealand, Switzerland, the USA and the OIE *ad hoc* Group on Epidemiology (EPI-AHG).

The Code Commission proposed a minor amendment to the definition of buffer zone to clarify that a buffer zone is part of, and lies within, a free country/zone (see Annex III).

In response to Member comments, the Code Commission deleted the reference in Article 2 to the conduct of surveillance in accordance with Appendix 3.8.7. to justify retention on the list of free countries/zones.

Based on recommendations from EPI-AHG, the Code Commission amended the final paragraph of Articles 3 and 5 to clarify the provisions for countries/zones making the transition from 'free with vaccination' to 'free without vaccination'.

A Member requested the scientific justification for the Code provision for a waiting period of a minimum of two incubation periods after the last case. The Code Commission clarified that this was based on a recommendation from the Scientific Commission in relation to requirements for a *containment zone.*

One Member had pointed out that the introduction of the concept of a containment zone represents a compromise to minimize the trade impact of an FMD outbreak in a previously free country/zone. Some Members considered the proposed addition of 'another effective control strategy' to be an unacceptable weakening of the safeguards provided against FMD in the Code. While alternative strategies to stamping out were considered acceptable in the General Guidelines (and this text was therefore maintained in Article 1.3.5.3.), the Code Commission agreed that for FMD the requirements to be applied in a containment zone should be no less stringent than those applied to the recovery of free status in the country or zone.

In response to Member comments, the Code Commission deleted "or another effective control strategy" as an alternative to stamping out and made related changes to point 2 of Article 7.

Community position:

Considering the new definition for buffer zone, the Community cannot support the proposed changes, unless the proposal of the ad hoc group for epidemiology is taken into account and the definitions for FMD free country and zones are modified in accordance.

b) Guidelines on surveillance for FMD (Appendix 3.8.7.)

The Code Commission received comments from Canada, the EU and Switzerland.

A member of the Code Commission identified a difference between English and Spanish version and the Code Commission modified the final sentence of Article 5. It was agreed that Members should be required to provide evidence of the effectiveness of a vaccination programme. The Spanish translation was accordingly corrected to read "Se aportaran pruebas de la eficiencia del programa de vacunación"

Community position:

The Community can support the proposed changes.

c) FMD virus inactivation procedures (Appendix 3.6.2.)

The Code Commission received comments from Canada, the EU, New Zealand, Switzerland and Thailand.

A Member of the Code Commission and the President of the Regional Commission for Africa requested clarification as to the need for the requirement for deboning and maturation of beef originating from an FMD free zone without vaccination. The Code Commission reiterated that deboning and maturation are not required for trading meat from an FMD free country or zone without vaccination. The only requirements for such trade are identified in Article 2.2.10.20.

The Code Commission modified Article 8 to better align it with the conclusions of Wijnker *et al.*, (2007) Int. J. Food Microbiol., 115(2), 214-9.

Community position:

The Community can support the proposed changes.

The revised texts are presented at Annex X of this report for adoption.

9. Rinderpest

a) Rinderpest (Chapter 2.2.12.)

The Code Commission received comments from Chinese Taipei, the EU and the USA.

In response to Member comments questioning the need for the annual provision of information, based on Appendix 3.8.2., supporting the continued status of country freedom, the Code Commission clarified that the Code does not impose a requirement for an annual questionnaire but that the surveillance requirements specified in relevant Chapters of the Code should be complied with in order to remain on the list of free

countries. The Code Commission deleted the reference in Article 2 to the conduct of surveillance in accordance with Appendix 3.8.2.

The revised text is presented at Annex XI of this report for adoption.

Community position:

The Community can support the proposed changes.

b) Guidelines on surveillance for rinderpest (Appendix 3.8.2.)

The Code Commission received comments from the EU.

The Code Commission commended the work of the *ad hoc* Group on Rinderpest, which had followed the recommendations arising from the Code Commission's previous meeting. Appendix 3.8.2. has been reformatted for congruency with other Appendices in the Code and some new information has been added (i.e. Article 8 on the use and interpretation of serological tests for serosurveillance of rinderpest).

The revised text, which is presented at Annex XXXI in Part B of this report, is provided for Member comments.

Community position:

The Community will provide the OIE with comments before the 15th of August 2008.

10. Contagious caprine pleuropneumonia (Chapter 2.4.6)

The Code Commission received comments from the IETS.

The Code Commission accepted the recommendations of the IETS and accordingly added two new Articles in Chapter 2.4.6.

The revised text is presented at Annex XII of this report for adoption.

Community position:

The Community can support the proposed changes.

11. Guidelines on Surveillance for bluetongue (Appendix 3.8.10)

The Code Commission received comments from Canada, the EU, New Zealand and Switzerland.

The Code Commission referred three requests from Members to the Scientific Department for advice: i.e., on the use of bulk milk sampling; the use of an ELISA and recommendations on the use of inactivated vaccines.

The revised text is presented at Annex XIII of this report for adoption.

Community position:

The Community can support the proposed changes and is waiting for the Scientific Commission advice on the use of inactivated vaccines.

12. Bovine tuberculosis (Chapter 2.3.3.)

The Code Commission received comments from Argentina, the EU, New Zealand, South Africa, Thailand and the USA.

The Code Commission discussed the comments of several Members on the proposed inclusion of farmed deer in the Chapter and decided to delete the proposed new text on farmed deer. The Code Commission decided to refer all the issues raised by Members on the inclusion of text on farmed deer and goats to the Scientific Commission for further advice. Text in Article 1 (from 'when authorizing' up to and including point 5) was deleted in response to Member comments.

Article 2 was modified by removing 'compartment' from the title and a new Article was drafted with provisions for a compartment for bovine tuberculosis. The proposed amendment of point 3 of Article 2 was also modified, in response to Member comments and advice of the Scientific Commission.

Following the advice of the Biological Standards Commission, the gamma interferon test was introduced into Appendix 3.1.1. Prescribed and Alternative Tests for OIE Listed Diseases. The Code Commission referred Members' questions about diagnostic tests and vaccines to the Biological Standards Commission for consideration and advice.

The revised text is presented at Annex XIV of this report for adoption.

Community position:

The Community can support the proposed changes, though it has two comments on the proposed point 3 of article 2.3.3.2 and would point out the lack of clarity in point 5 of article 2.3.3.4., and wishes these comments to be taken into account.

It is willing to participate in further work by the OIE on this disease in bovines or other species.

13. Bovine spongiform encephalopathy (BSE)

a) BSE (Chapter 2.3.13.)

The Code Commission received comments from Argentina, Australia, Canada, the EU, Japan, New Zealand, the People's Republic of China and the USA, and industry organisations.

The Code Commission again expressed its concern that Members continued to resubmit comments on texts already discussed and adopted in previous meetings without providing any new justification.

With regard to the request of Members to modify the text currently found in Article 1, the Code Commission noted that the European Food Safety Authority (EFSA) has conducted a study on the production of protein free tallow. The results of this study have already been considered by the Code Commission and found not to provide justification for modifying the current text. Some Members raised questions about the safety of deboned muscle meat and proposed that this be removed from Article 1, while other Members are questioning the limitation to 30 months of age. The Code Commission reminded Members that the measures relating to the safety of deboned muscle meat were formulated several years ago, when the magnitude of risk to human health was unknown. These precautionary measures were appropriate at that time. Since that time, scientific understanding regarding the BSE risk classification of countries and the risk to human health associated with BSE in bovine products has progressed. The Code Commission considered that it is timely to reconsider whether there is any need to maintain the current requirement in Chapter 2.3.13. for cattle to be 30 months of age or less for deboned muscle meat to be considered a safe commodity.

The Code Commission agreed with Member comments regarding the need to provide annual updates to support the retention of countries/zones on the list of negligible or controlled risk countries and zones and modified Articles 3 and 4 accordingly.

Members again raised comments on Article 7, proposing to modify this Article by adding the following text: 'or after the date of birth of the last indigenous case if that indigenous case was born after the date of the feed ban'. The Code Commission disagreed with this proposed modification as this principle is already covered in Article 7, i.e. the birth of an indigenous case is an indication that the feed ban has not been effective and the relevant date would be adjusted accordingly.

On the safety of gelatine, the Code Commission reiterated its position that the safety of the gelatine manufacturing process has been well established by peer-reviewed scientific studies and risk assessments on the production of gelatine from bones, regardless of their origin. Recognizing the fact that skulls are not used in the commercial manufacture of gelatine, the Code Commission proposed the exclusion of skulls, thus removing the point of contention raised by Members. Relevant references include the following:

Grobben AH, Steele PJ, Somerville RA, Taylor DM (2004). Inactivation of the bovine spongiform encephalopathy (BSE) agent by the acid and alkaline processes used in the manufacture of bone gelatin. Biotechnology and Applied Biochemistry, 39; 329-338.

Grobben AH, Steel PJ, Taylor DM, Somerville RA, Schreuder BEC (2005). Inactivation of the BSE agent by heat and pressure process for manufacturing gelatin. Veterinary Record, 157; 277-289.

Grobben AH, Steele PH, Somerville RA, Taylor DM (2006). Inactivation of transmissible spongiform encephalopathy agents during the manufacture of dicalcium phosphate from bone. Veterinary Record, 158; 361- 366.

NZFSA (2005). Officials' Review of New Zealand's BSE Country-Categorisation Measure. New Zealand Food Safety Authority, Wellington and published in "Prions in Humans and Animals". Ed. Hornlimann, B., Riesner, D. Kretzschmar, H. De Gruyter Verlag, Berlin (ISBN 978-3-11-018275-0)

The Code Commission noted that the approach taken to gelatine in Chapter 2.3.13. is fully consistent with approaches elsewhere in the Code whereby commodities originating from countries/zones that are not free of specified diseases are identified as safe for trade, based on the processing of the commodity as evaluated by scientific studies and risk assessment.

b) Guidelines on surveillance for BSE (Appendix 3.8.4.)

The Code Commission received comments from Argentina, Canada, the EU, New Zealand and the People's Republic of China.

The Code Commission accepted a comment on Article 4, a modification to correct a typographical error in Table 2 (Surveillance Point Values for Samples Collected from Animals in the Given Subpopulation and Age Category).

c) Factors to consider in conducting the BSE risk analysis in Chapter 2.3.13. (Appendix 3.8.5.)

The Code Commission received comments from Argentina.

The Code Commission also considered recommendations of the *ad hoc* Group on Atypical Scrapie and Atypical Bovine Spongiform Encephalopathy, as endorsed by the Scientific Commission, and modified texts accordingly.

The revised texts are presented at Annex XV of this report for adoption.

Community position:

The Community would like to stress in particular the comments related to the ruminant to ruminant feed ban provisions (Article 2.3.13.3, 4, 7, 8, 9 and 10), SRM definition (Article 2.3.13.14, 15, 16, 16bis), tallow (Article 2.3.13.1.e), the annual update (Article 2.3.13.3.), gelatine (Article 2.3.13.15) and the use of the risk assessment guidelines (Article 3.8.5.1. of Appendix 3.8.5.).

Thus the Community cannot support the proposed chapter, and wishes its comments to be taken into account.

14. Equine influenza (Chapter 2.5.5.)

The Code Commission received comments from Argentina, Australia, the EU, New Zealand, South Africa and Switzerland.

The Code Commission reviewed Member comments and modified the text in two places.

The revised text is presented at Annex XVI of this report for adoption.

Community position:

The Community can support the proposed changes, but reiterates its request for a scientific justification to the minimum of 21 days delay between vaccination and export (formerly 14), and has one comment on article 2.5.5.3.

15. Equine diseases (other than African horse sickness and equine influenza)

a) Equine rhinopneumonitis (Chapter 2.5.7.)

Community position:

The Community can support the proposed changes

b) Equine viral arteritis (Chapter 2.5.10.)

The Code Commission received comments from Argentina, the EU, New Zealand, South Africa, Switzerland and the USA.

The Code Commission reviewed Member comments and modified the text accordingly. The proposed deletion of text in Articles 2.5.10.2. and 2.5.10.3. were referred to the Scientific Department for further advice.

The revised texts are presented at Annex XVII of this report for adoption.

Community position:

The Community thanks the OIE for their proposed changes that it supports. It goes in the right direction, but EU still has important comments and is ready to participate in further discussions with the OIE Scientific Department, especially regarding the proposed deletions of article 2 point 2b) and article 3 points 2 and 3 that it supports.

16. African horse sickness

a) African horse sickness (Chapter 2.5.14.)

The Code Commission received comments from Argentina, the EU, South Africa and the USA.

The Code Commission reviewed comments and made two relevant modifications to the text.

Community position:

The Community can support the proposed changes, but has a comment on articles 8 and 9 in order to take into account the use of inactivated vaccines.

b) Guidelines on surveillance for African horse sickness (Appendix 3.8.X.)

The Code Commission received comments from Argentina and the EU.

The Code Commission reviewed comments and made a relevant modification to the text.

The revised texts are presented at Annex XVIII of this report for adoption.

Community position:

The Community can support the proposed changes, but would like its two comments for clarification to be taken into account.

17. African swine fever (Chapter 2.6.6.)

The Code Commission received comments from Canada, the EU, the People's Republic of China, South Africa and the USA.

Members commented on the absence of conditions for the importation of fresh meat (from domestic or wild pigs) for human consumption from African swine fever infected countries or zones. The Code Commission considered that Article 12 does in fact provide for the importation of fresh meat of domestic pigs from such countries or zones, on the basis that the meat comes from a free compartment within an infected country or zone.

The revised text is presented at Annex XIX of this report for adoption.

Community position:

The Community can support the proposed changes, reiterates the need for Guidelines on the surveillance of ASF, and is ready to assist the OIE in this task.

18. Classical swine fever

a) Classical swine fever (Chapter 2.6.7.)

The Code Commission received comments from Argentina, Canada, the EU, Japan, New Zealand, South Africa, Switzerland and the USA.

The Code Commission reviewed Member comments and made relevant modifications to the text. In response to a Member's request to maintain the reference to conducting a risk assessment in Article 2, Dr Thiermann advised that it is always open to Members to conduct a risk assessment as a basis for decisions on disease risks and management, including international trade measures. It is not necessary to include a specific reference to conducting a risk assessment in each disease Chapter. However, specific references will be maintained where the Code contains provisions relevant to the conduct of the risk assessment e.g. in Chapter 2.3.13. (BSE).

Members commented on the absence of conditions for the importation of fresh meat (from domestic or wild pigs) for human consumption from classical swine fever infected countries or zones. The Code Commission considered that Article 12 does in fact provide for the importation of fresh meat of domestic pigs from such countries or zones, on the basis that the meat comes from a free compartment within an infected country or zone.

The Code Commission compared the text of Chapter 2.6.7. on classical swine fever with that of Chapter 2.6.6. on African swine fever to ensure that the two were consistent and any differences in approach clearly justified.

Community position:

The Community cannot support the proposed changes. CSF cannot be simply compared to ASF as risk management is concerned because of significant differences in the epidemiology of diseases. The possibility given by the Code Commission of exporting fresh meat from free compartments does not provide any useful answer to the Members either, since such compartments do not exist in practice, and the Guidelines to implement them are not even established yet. This will only lead to more unjustified barriers to trade.

Moreover, in this case a disease against which the OIE Members have fought for a long time, sometimes with good results, field experience is to be considered as well: these OIE Member countries have proven through decades that trade of fresh meat of domestic animals from zones infected only in the wild population did not appear to spread the infection as long as relevant preventive and mitigating measures have been in place. The EU is ready to share this data with the ad hoc group that should be convened again, in order to better assess the situation at the light of other ad hoc groups conclusions, especially that on wildlife diseases surveillance.

Thus, the Community is strongly opposed to the proposed chapter.

In addition postponing the adoption of this new version will not affect trade as the current chapter has never created any difficulties among the OIE Members. This would give time to look at the whole question of diseases in wildlife, their affect on other diseases as well as CSF, and the way they should be treated as regards notification, management and trade conditions. This is a general problem, which has been unequally treated among the chapters of the Code, including the general chapters.

The Community proposes that the ad hoc group on epidemiology be asked to address this issue in its next meeting and the following if necessary, as well as the Working Group on wildlife and the ad hoc group on wildlife diseases surveillance in order to find solid and acceptable solutions.

b) Guidelines on surveillance for classical swine fever (Appendix 3.8.8.)

The Code Commission received comments from the EU, New Zealand and the USA.

The Code Commission reviewed comments and made relevant modifications to the text.

Community position:

The Community can support the proposed changes; however it reiterates its former comment concerning compartments, whose conditions should be updated in relevance with the general guidelines on compartmentalisation.

The revised texts are presented at Annex XX of this report for adoption.

19. Avian influenza

a) Avian influenza (Chapter 2.7.12.)

The Code Commission received comments from Argentina, Australia, the EU, Guatemala, Japan, Kuwait, New Zealand, South Africa and the USA.

The Code Commission noted that two Members again raised concerns about the definition of poultry in Chapter 2.7.12. The Code Commission confirmed that the rationale for the current definition is to encourage reporting of HPAI in all species and, at the same time, to discourage Members from introducing trade measures in response to findings in wild birds and other birds that are not considered to be part of the commercial sector. The Code Commission agrees with the comments of Members that noted the potential importance of avian species kept in backyard flocks and for hobby purposes in the epidemiology of avian influenza. This is the reason for requiring reporting of HPAI in such species. However, findings in pet birds (which are not defined as poultry according to the current definition) should not be the rationale for introducing trade bans on the commercial sector. If Members responded to such findings by imposing trade bans, the OIE considers that this would be a serious disincentive to transparency in reporting. It is important to encourage reporting of infection in all avian species and the Code Commission considers that the best way to do this is to maintain the current definition of poultry.

A Member's recommendation that the detection of antibodies to avian influenza should be regarded as an outbreak was not accepted. The Code Commission noted that isolated seropositive findings must be investigated and that, in the absence of confirmatory findings (e.g. virus isolation), isolated cases of seroconversion should not be considered as evidence of infection. The Code Commission confirmed that this approach is consistent with that taken to other diseases in the Code.

A Member's comment about the inactivation of avian influenza in poultry products was referred to the Scientific Department with a request for advice and the development of an appropriate text and/or tables for inclusion in the Code. The Code Commission specifically requested a review of the scientific literature with the aim of improving the current provisions for the inactivation of avian influenza virus in poultry meat and eggs (Appendix 3.6.5) and in poultry products intended for use in animal feeding or for agricultural or industrial use (Articles 21 and 22).

Article 23 was deleted because the fact of trading meat of birds 'other than poultry' effectively means that these birds are being treated as poultry and these products are therefore covered under preceding Articles.

The Code Commission made several amendments to the text in response to Member comments.

Community position:

The Community can support the proposed changes, but wishes the OIE to take into account its comments, especially on compartments from which trade should only be possible if they are free from NAI.

b) Guidelines on the inactivation of the avian influenza virus (Appendix 3.6.5.)

The Code Commission received comments from Australia, the EU and Guatemala.

The Code Commission did not propose any substantial changes to Appendix 3.6.5.

Community position:

The Community can support the proposed changes.

c) Guidelines on surveillance for avian influenza (Appendix 3.8.9.)

The Code Commission received comments from Argentina, the EU, Guatemala and New Zealand.

The Code Commission made some amendments to the text in response to Member comments.

The revised texts are presented at Annex XXI of this report for adoption.

Community position:

The Community can support the proposed changes, but reiterates one comment regarding Guidelines on surveillance for avian influenza, article 3.8.9.3 point 1.

20. Newcastle disease

a) Newcastle disease (Chapter 2.7.13.)

The Code Commission received comments from Argentina, Australia, Canada, the EU, Guatemala, Kuwait, New Zealand, South Africa and the USA.

Dr Karim Ben Jebara, Head of the Animal Health Information Department, joined the Code Commission for this part of the meeting. Several Members commented that there is confusion and/or ambiguity in the definition of Newcastle disease (ND). Specifically, the reporting obligations and the trade implications associated with the detection of ND needed to be clarified. Dr Ben Jebara noted that the definition of ND found in the OIE Manual for Notification of Diseases applies to all avian species. Dr Thiermann clarified that the OIE expects ND, as defined, to be notified, regardless of the species in which it is found. While findings of ND in all birds are notifiable to the OIE, trade measures should only be implemented in response to findings of ND in poultry.

Taking into account the comments of Members, the Code Commission modified Article 1 to clarify the definition of Newcastle disease and of Newcastle disease virus (NDV) and to bring the definition of 'poultry' into alignment with that found in Chapter 2.7.12 (Avian influenza).

Scientific publications provided by a Member and its request that the OIE provide recommendations on the inactivation of NDV in poultry meat and egg products were referred to the Scientific Department with a request for advice and the development of an appropriate text and/or tables for inclusion in the Code. At the suggestion of a Member, Article 19 was deleted, because the fact of trading meat or other products from birds 'other than poultry' effectively means that these birds are being treated as poultry and these products are therefore covered under preceding Articles.

The Code Commission made several modifications to the text.

Community position:

The Community has serious concerns on the proposed changes. On the one hand, it approves and supports the simplification of the definition; but on the other hand it cannot accept that the word "poultry" is again replaced by "birds". Discussions around the adoption of the chapter on AI proved at length the unnecessary trade difficulties that this definition could provoke, especially when it is well known that ND is endemic in the wild birds population throughout the world, and its surveillance as required in Appendix 3.8.X for ND would be impossible.

Thus the words "For the purpose of international trade" should remain, the word "poultry" should replace again the word "birds", and the added sentence at the end of point 1 should be deleted as unnecessary.

In case the OIE cannot accept what is a simple return to a commonly accepted and coherent version, the Community cannot support the changes.

b) Guidelines on surveillance for Newcastle disease (Appendix 3.8.X.)

The Code Commission received comments from Argentina, Australia, the EU, New Zealand and the USA.

The Code Commission made several modifications to the text based on Member comments.

The revised texts are presented at Annex XXII of this report for adoption.

Community position:

The Community can support the proposed changes.

21. Animal identification and traceability

a) Guidelines on the design and implementation of identification systems to achieve animal traceability

The Code Commission received comments from Canada, the EU, Japan, New Zealand, the People's Republic of China and the USA.

The Code Commission commended the work of the *ad hoc* Group on Identification and Traceability, which met in January 2008 and modified the draft text in response to the comments of Members on the text attached to the report of the Code Commission's September 2007 meeting. The Code Commission reviewed the text provided by the *ad hoc* Group in the light of Member comments received after the January meeting and made some further modifications to the draft text.

The revised text is presented at Annex XXIII of this report for adoption.

Community position:

The Community can support the proposed Guidelines, but reiterates some of its previous comments that should to be taken into account in the next Code Commission meeting, as well as by the ad hoc group on identification.

b) Update on the OIE International Conference on Animal Identification and Traceability

Dr Kahn provided an update on progress in organizing the OIE International Conference on Animal Identification and Traceability, which will take place on 17-19 March 2009 in Buenos Aires, Argentina.

Community position:

The Community strongly supports this initiative and will be happy to participate.

22. Animal Welfare

Community position:

The Community thanks the OIE Code Commission for its work that improves the applicability of the Guidelines on the transport, slaughter and humane killing of animals and appreciates that many of the previous Community comments have been taken into account in the revised Annex.

Furthermore, the Community supports the work being carried out on laboratory animals as well as on livestock production systems.

Nevertheless, the Community would appreciate if the scientific background leading to dismiss proposed community comments is provided by the OIE.

a) Definition of animal welfare

The Code Commission received comments from Australia, the EU, Japan, Serbia, South Africa and the USA.

In response to these comments, AWWG modified the proposed definition and provided additional, explanatory text. The Code Commission reviewed Member comments and a modified definition for "animal welfare" received from AWWG. The Code Commission proposed to include this new definition in Chapter 1.1.1.as well as an introductory paragraph to Appendix 3.7.1.

The revised text is presented at Annex III of this report for adoption.

b) Guidelines for the transport of animals by sea (Appendix 3.7.2.) and Guidelines for the transport of animals by land (Appendix 3.7.3.)

The Code Commission received comments from Canada, the EU, Serbia, Japan and the USA, and from an expert. The Code Commission reviewed these comments and modified the two texts accordingly.

The revised texts are presented at Annex XXIV of this report for adoption.

c) Guidelines for the transport of animals by air (Appendix 3.7.4.)

The Code Commission received comments from the EU.

The OIE prepared an update to Appendix 3.7.4 based on the updated IATA Live Animals Regulations, which came into effect on 1 October 2007. Members should note that the original text of this Appendix was based on the previous IATA Live Animals Regulations.

The revised text is presented at Annex XXIV of this report for adoption.

d) Guidelines for the slaughter of animals (Appendix 3.7.5.)

Community position:

The Community welcomes the work carried out by the OIE Code Commission and supports the amendments of the text.

However, as regards the analysis of handling and restraining methods and the associated animal welfare issues as referred to in Article 3.7.5.6, the Community asks that the OIE Code Commission again looks at the need to retain the rotary stunning pen.

The Code Commission received comments from Canada, the EU and the USA. The Code Commission noted that some comments had been submitted previously and dismissed by AWWG and these were not reconsidered. The Code Commission modified the text in response to some Member comments.

The revised text is presented at Annex XXIV of this report for adoption.

e) Guidelines for the killing of animals for disease control purposes (Appendix 3.7.6.)

Community position:

The Community welcomes the work carried out by the OIE Code Commission and supports the amendments of the text.

The Community reiterates its wishes to have included a third method for controlled atmosphere killing (Containerised Gassing Units) which has been tested in the UK, as referred to in the detailed written comments to Article 3.7.6.12. The Community is available for further exchange of scientific background to the abovementioned third method.

The Code Commission received comments from Canada, the EU and the USA. The EU comment regarding the use of 50Hz frequency current for electrical stunning was referred to an expert, who confirmed the acceptability of this text. The EU comments on the use of the controlled atmosphere method for killing poultry were referred to AWWG for detailed consideration and advice. The Code Commission modified the text in response to some Member comments.

The revised text is presented at Annex XXIV of this report for adoption.

f) Guidelines on dog population control

The Code Commission received comments from Australia, Canada, the EU, Japan, New Zealand, Malaysia, the People's Republic of China, Serbia and the USA and from the World Society for the Protection of Animals (WSPA).

The Code Commission noted the extensive comments and varying positions raised by Members. The small number of comments from developing countries was regrettable because this issue is of particular importance to those countries and the Code Commission encouraged developing country National Delegates to identify the relevant Competent Authority in their respective countries and draw this draft text to their attention. The Code Commission considered that it was important to finalise the guidelines in a timely way. However, it was not possible to address all the comments received and the Code Commission referred the text and the comments of Members to AWWG, with a request that the Group prepare advice in time for the September 2008 meeting of the Code Commission.

The Code Commission considers that views and experiences of developing countries on this subject are critical in order to develop recommendations that are truly applicable to those countries where dog borne rabies is a serious concern.

g) Update on the work of the *ad hoc* Group on laboratory animal welfare

Dr Stuardo provided an update on the work of the *ad hoc* Group on Laboratory Animal Welfare. The report of the first meeting, which took place in December 2007, is attached at Annex XL for information of Members. The *ad hoc* Group will hold its next meeting in December 2008. Dr Thiermann drew Delegates' attention to this important new area of OIE work. Given that the competent authority responsible for laboratory animal welfare is not always the Veterinary Authority, the Code Commission encouraged OIE National Delegates to draw this report to the attention of relevant national authorities and collaborate with them in future when a draft Code text is formally circulated for consideration and eventual adoption.

h) Update on the 2nd OIE Global Conference on Animal Welfare

Dr Stuardo provided an update on progress in the organization of this conference.

i) Update on the work of the *ad hoc* Group on livestock production systems

Dr Stuardo provided a brief update on the work of the *ad hoc* Group, which will hold its first meeting in April 2008.

23. Aethina tumida (Chapter 2.9.X.)

The Code Commission received comments from Argentina, Australia, Canada, the EU and New Zealand.

The Code Commission reviewed the comments of Members and made several modifications to the draft text in accordance with these comments. The reference to conducting a risk assessment was removed from Article 3. Dr Thiermann advised that it is always open to Members to conduct a risk assessment as a basis for decisions on disease risks and management, including international trade measures. It is not necessary to include a specific reference to conducting a risk assessment in each disease Chapter.

However, specific references will be maintained where the Code contains specific provisions relevant to the conduct of the risk assessment e.g. in Chapter 2.3.13. (BSE).

The revised text is presented at Annex XXV of this report for adoption.

Community position:

The Community reiterates its previous comment: if *Bombus* spp must be considered to be susceptible of infestation and a possible way of transmission to *Apis mellifera*, since it is the object of a growing trade, notably for the greenhouses, it should be included. Thus the title should only be *AETHINA TUMIDA* (SMALL HIVE BEETLE), and the risk mitigation articles 5, 6 and 7 should include the bumble bees.

The Community is ready to share its experience on inactivation of *A. tumida* and to help the OIE in further elaborating the chapter and annexes related to that pest.

24. Guidelines for somatic cell nuclear transfer in production livestock and horses

The Code Commission received comments from Canada and IETS. The Code Commission reviewed the Member comments and discussed and modified the draft text from Biological Standards Commissions.

The revised text is presented at Annex XXVI of this report for adoption.

Community position:

The Community can support the proposed Appendix, but has one comment. This draft was not presented to the former Code Commission meetings, and it is extremely difficult to have a sound opinion in such a short period of time. This document should have been proposed for comments.

25. Categorisation of diseases and pathogenic agents by the IETS (Appendix 3.3.5.)

The Code Commission examined and endorsed recommendations from IETS on modifications to Appendix 3.3.5.

The revised text is presented at Annex XXVII of this report for adoption.

Community position:

The Community can support the proposed changes, but has one comment on scrapie, that could be moved to category 1.

26. The Role of the Veterinary Services in Food Safety

The Code Commission received comments from the EU.

In light of the proposed restructuring of the Code and the relevance of this text to the functioning of national veterinary services, the Director General of the OIE proposed to include this text in Section 6 "Veterinary Public Health" of the Code.

The revised text is presented at Annex XXVIII of this report for adoption.

Community position:

The Community can support the proposed paper, which should be given a numbering.

27. Notification Criteria for Listing Diseases (Chapter 2.1.1.)

a) Report of the *ad hoc* Group on the notification of terrestrial animal diseases/pathogenic agents

b) Report of the Wildlife Working Group

The Code Commission noted these reports. Following the recommendation of the *ad hoc* Group, the Code Commission modified the OIE list from that provided to Members with its September meeting report.

The revised text is presented at Annex XXIX of this report for adoption.

Community position:

The Community can support the proposed changes, but would like to introduce general comments.

For some diseases there are unclear or different definitions between the Code and the Manual and this is also applicable to the disease cards which need updating. This can lead to difficulties in notification by the OIE Members. As for diseases affecting wildlife it is not clear whether they are included or not and what should be the procedure. The Community suggests the ad hoc group on epidemiology look at this, together with the ad hoc group on wild life disease surveillance and working group on wildlife diseases.

28. International transfer of pathogens (Chapter 1.4.5.)

The Code Commission agreed that some text should be deleted from Chapter 1.4.5. as it would be included in Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2008 (also see the Code Commission report in March and October 2006).

The revised text is presented at Annex XXX of this report for adoption.

Community position:

The Community can support the proposed changes.

B. TEXTS NOT FOR ADOPTION / FOR FURTHER DISCUSSION

29. Contagious bovine pleuropneumonia (CBPP)

a) CBPP (Chapter 2.3.15.)

The Code Commission received comments from Chinese Taipei, the EU and the USA.

The Code Commission received a revised Chapter from the Scientific Commission. For consistency with the Chapters on rinderpest and FMD, the Code Commission deleted the reference in Article 2 to the conduct of surveillance in accordance with the relevant Appendix.

b) Guidelines on surveillance for CBPP (Appendix 3.8.3.)

The Code Commission received comments from the EU and New Zealand.

The Code Commission received a revised Appendix from the Scientific Commission.

To facilitate review, the texts are presented as clean text. The texts are presented at Annex XXXII for Member comments.

Community position:

The Community congratulates the OIE for this important work, and will provide the OIE with comments before the 15th of August 2008.

30. Scrapie (Chapter 2.4.8)

The Code Commission thanked the Scientific Department for convening relevant experts and providing advice on atypical scrapie and atypical bovine spongiform encephalopathy.

The Code Commission noted the statement in the report of the *ad hoc* Group to the effect that there is insufficient information to support the establishment of rules or guidelines specific to atypical scrapie, other than in relation to the choice of diagnostic tests used for surveillance. The *ad hoc* Group also observed that scrapie does not represent a public health risk and should not therefore be treated in the same way as BSE. The Code Commission noted that the revised draft Chapter represents a helpful step towards updating the Code's provisions on scrapie, bringing it into line with the structure of the BSE Chapter. To facilitate review, the texts are presented as clean texts.

The revised text is presented at Annex XXXIII for Member comments.

Community position:

The Community will provide the OIE with comments before the 15th of August 2008.

31. West Nile fever (Chapter 2.2.X.X.)

The Code Commission received comments from Argentina, Australia, Canada, the EU, New Zealand, the People's Republic of China, South Africa, Switzerland and the USA.

The Code Commission noted that Members had provided extensive comments on this text. Unfortunately, there was not sufficient time to review the comments in detail at this meeting. The Code Commission decided to review Member comments and consider amendments to this Chapter at its September 2008 meeting. The Code Commission referred to the Scientific Department a Member's recommendation to include 'day-old poultry' in Article 1 ('safe commodities').

Community position:

The Community is waiting for the revised draft of this Chapter, and is willing to participate in any specific work on this topic.

32. Guidelines for the control of hazards of animal health and public health importance in animal feed.

The Code Commission received comments from Canada, the EU, Japan, New Zealand, Switzerland and the USA.

The Code Commission noted that Members had provided extensive comments on this text. Unfortunately there was not sufficient time to review the comments in detail at this meeting. The Code Commission will examine Member comments at its September 2008 meeting.

Community position:

The Community is waiting for the revised draft of this Chapter, and is willing to participate in any specific work on this topic.

33. Salmonella

a) Salmonella Enteritidis and S. Typhimurium in poultry (Chapter 2.10.2)

b) Hygiene and disease security procedures in poultry breeding flocks and hatcheries (Appendix 3.4.1.)

c) Guidelines on the detection, control and prevention of Salmonella Enteritidis and S. Typhimurium in poultry producing eggs for human consumption (Appendix 3.10.2.).

The Code Commission received comments from Australia, Canada, the EU, Japan, South Africa, and the USA.

The Code Commission commended the work of the *ad hoc* Group on Salmonellosis, which had addressed Member comments on the draft Guidelines "*Salmonella* Enteritidis and *S. Typhimurium* in Poultry Producing Eggs for Human Consumption" at its second meeting. Taking into account these comments and the need to eliminate duplication in the Code, the *ad hoc* Group revised Appendix 3.4.1. and renamed it "Hygiene and Disease Security Procedures in Poultry Production", and developed a new document, entitled: "Guidelines on the Detection, Control and Prevention of *Salmonella* Spp. in Poultry" (Appendix X.X.X.), which also included the control of Salmonellosis in broilers. The Code Commission reviewed these two documents and made some minor modifications to them.

The Code Commission generally supported the *ad hoc* Group's proposals for future work and further proposed that *ad hoc* Group develop recommended Salmonellosis prevention and control measures which could be implemented in markets (for eggs and live birds).

To facilitate review, the texts are presented as clean texts.

The texts are presented at Annex XXXIV for Member comments.

Community position:

The Community will provide the OIE with comments before the 15th of August 2008.

34. OIE/FAO Guidelines on Good Farming Practices

The Code Commission received comments from the EU.

The Code Commission noted that APFSWG discussed this text in detail and produced a revised text. Noting that this document is not intended for inclusion in the Code, the Code Commission decided to refer to the International Trade Department with the request that the OIE finalise the Guidelines in consultation with the APFSWG.

Community position:

The Community is waiting for the revised draft of these Guidelines, and is willing to continue participating to the work on this topic.

C. OTHER ISSUES DISCUSSED AND PRESENTED FOR INFORMATION OF MEMBER COUNTRIES

35. Trade in animal products (commodities)

The Code Commission received comments from the EU, Japan and New Zealand. The Code Commission held a meeting with UK acting CVO, Dr Fred Landeg, and colleagues from DEFRA, to progress the collaboration between DEFRA and the OIE on the need to review and update the commodity based approach in the Code. Dr Gideon Bruckner, head of the Scientific Department, participated in this meeting. Dr Landeg outlined the approach to this project proposed by the UK and Dr Thiermann summarised the current status of the OIE's work. Dr Thiermann noted that the Code definition of 'commodities' is very broad whereas the 'commodity based approach' specifically addresses animal products for human consumption.

Dr Thiermann noted that an OIE *ad hoc* Group will hold a first meeting after the General Session and will review the current provisions in the Code to identify where there is scope to introduce additional provisions for 'safe commodities' and/or sourcing and processing methods that could be used to make animal products safe for international trade. The UK (Department of International Development) has proposed to hold a meeting with veterinary representatives of the Southern African Development Community (SADC) in April to discuss the views of African CVOs on impediments to export of commodities and modifications to the Code that could improve the situation. Dr Bruckner will attend this meeting on behalf of the OIE. Dr Thiermann stated that it would be important to ascertain the views of industry and other stakeholders in prioritising commodities for further consideration as the priorities need to be matched with the commercial realities of international trade as well as the relevant scientific considerations. It was agreed that BSE and FMD related restrictions on the export of beef should be considered as priorities for review, with a view to taking action (if required) in the short term.

Draft TOR for
the *ad hoc* Group on Trade in Animal Products ('commodities')

Taking into account:

- the mandate of the OIE to facilitate safe international trade, including through the provision of standards, recommendations and guidelines on sanitary measures for animals and animal products; and

- considering that the OIE supports strengthening of Veterinary Services to ensure that they meet the OIE quality standards set out in Chapter 1.3.3. and 1.3.4. of the Code, including the importance of maintaining efficient disease surveillance networks; and

- the Recommendation No. 4 of the OIE Seminar 'Implementation of Animal Health Standards: the quest for solutions', which called for the OIE "to investigate and promote opportunities with international and regional organizations in developing new standards for risk reduction to trade in livestock commodities".

The ad hoc Group is required to:

1. Examine the current recommendations in the OIE Terrestrial Animal Health Code (the Code) with the aim at facilitating the trade in commodities related to animal products, with special emphasis on the needs of developing countries;

2. Identify and analyse impediments or difficulties to trade in commodities arising from existing OIE standards;

3. Based on the most recent scientific information available, make recommendations on how the standards could be modified or applied to assist countries that are not able to achieve or maintain country/zonal freedom, with science based recommendations on safe trade of animal products.

4. Consider how facilitating risk mitigation concepts in the Code, including surveillance, zoning and compartmentalization, can be applied to facilitate trade in commodities;

5. If appropriate, identify needs for specific, targeted research needed to support the proposed amendment of the Code and/or to assist in further revising the Code recommendations in future;

6. Identify diseases for which the respective Code chapters could be amended to facilitate trade in animal products irrespective of the disease status of an exporting country.

7. Identify those disease specific requirements that should be forwarded to relevant OIE *ad hoc* Groups for specific consideration and advice.

Community position:

The Community is willing to participate to the work on this topic.

36. Anthrax (Chapter 2.2.1)

Comments were received from New Zealand and from an expert. The Code Commission briefly discussed the advice provided on the inactivation of *Bacillus anthracis*. A revised text will be prepared for consideration by the Code Commission at its September meeting.

Community position:

The Community is waiting for the revised text.

37. Division of the Code into two volumes

Comments were received from the EU. The Code Commission briefly reviewed information provided by the International Trade Department regarding the proposed division of the Code into two volumes. The Code Commission agreed with the proposed restructuring of the Code.

A summary document prepared by the OIE is provided for information of Members in Annex XXXV.

Community position:

The Community congratulates the OIE for this important work.

38. Report of the Working Group and *ad hoc* Groups

The Code Commission endorsed the reports of the APFSWG, the *ad hoc* Group on Animal Identification and Traceability, the *ad hoc* Group on Model Veterinary Certificate, *ad hoc* Group on Salmonellosis, and the *ad hoc* Group on Laboratory Animal Welfare.

These reports are attached in Annexes XXXVI - XL for information of Members.

39. Future work programme

The updated work programme is shown in Annex XLI.

40. Others

The next meeting of the Commission is scheduled for 29 September to 10 October 2008.

.../Annexes

Annex I

MEETING OF THE OIE

TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 10–14 March 2008

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Annex II

MEETING OF THE OIE
TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION
Paris, 10–14 March 2008

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Agenda

1. Welcome-President of the Terrestrial Code Commission
2. Update on reports of other OIE Commissions and other relevant activities of the OIE – President of the Commission
3. *Terrestrial Code* revision - update

   Item 1 General definitions (Chapter 1.1.1.)

   Item 2 Model veterinary certificates

   a) Model international veterinary certificates (Section 4)

   b) Notes for guidance on veterinary certificates for international trade in live animals, hatching eggs and products of animal origin (Appendix X.X.X.)

   c) General obligations (Chapter 1.2.1.)

   d) Certification procedures (Chapter 1.2.2.)

   Item 3 Guidelines on import risk analysis (Chapter 1.3.2.)

   Item 4 Animal health measures applicable before and at departure (Chapter 1.4.1.) and Border posts and quarantine stations in the importing country (Chapter 1.4.3.)

   Item 5. Evaluation of Veterinary Services

   a) Evaluation of Veterinary Services (Chapter 1.3.3. and 1.3.4.)

   b) Update on OIE PVS Tool and programme for evaluating Members

   Item 6 Zoning and compartmentalisation

   a) Zoning and compartmentalisation (Chapter 1.3.5.)

   b) General guidelines on the application of compartmentalisation (Appendix X.X.X.)

   c) Compartmentalisation for vector borne diseases

   Item 7 Rabies (Chapter 2.2.5.)

   Item 8 Foot and mouth disease

   a) Foot and mouth disease (Chapter 2.2.10.)

   b) Guidelines on surveillance for FMD (Appendix 3.8.7.)

   c) FMD virus inactivation procedures (Appendix 3.6.2.)

Annex II (contd)

Item 9 Rinderpest

a) Rinderpest (Chapter 2.2.12.)

b) Guidelines on surveillance for rinderpest (Appendix 3.8.2.)

Item 10 Contagious bovine pleuropneumonia

a) CBPP (Chapter 2.3.15.)

b) Guidelines on surveillance for CBPP (Appendix 3.8.3.)

Item 11 Contagious caprine pleuropneumonia (Chapter 2.4.6.)

Item 12 Guidelines on surveillance for bluetongue (Appendix 3.8.10.)

Item 13 Bovine tuberculosis (Chapter 2.3.3.)

Item 14 Bovine spongiform encephalopathy

a) BSE (Chapter 2.3.13.)

b) Guidelines on surveillance for BSE (Appendix 3.8.4.)

c) Factors to consider in conducting the BSE risk analysis in Chapter 2.3.13. (Appendix 3.8.5.)

Item 15 Scrapie (Chapter 2.4.8.)

Item 16 Equine influenza (Chapter 2.5.5.)

Item 17 Equine diseases (other than African horse sickness and equine influenza)

a) Equine rhinopneumonitis (Chapter 2.5.7.)

b) Equine viral arteritis (Chapter 2.5.10.)

Item 18 African horse sickness

a) African horse sickness (Chapter 2.5.14.)

b) Guidelines on surveillance for African horse sickness (Appendix 3.8.X.)

Item 19 African swine fever (Chapter 2.6.6.)

Item 20 Classical swine fever

a) Classical swine fever (Chapter 2.6.7.)

b) Guidelines on surveillance for classical swine fever (Appendix 3.8.8.)

Item 21 Avian influenza

a) Avian influenza (Chapter 2.7.12.)

b) Guidelines on the inactivation of the avian influenza virus (Appendix 3.6.5.)

c) Guidelines on surveillance for avian influenza (Appendix 3.8.9.)

Item 22 Newcastle disease

a) Newcastle disease (Chapter 2.7.13.)

b) Guidelines on surveillance for Newcastle disease (Appendix 3.8.X.)

c) Guidelines on the inactivation of the Newcastle disease virus

Item 23 West Nile fever (Chapter 2.X.XX.)

Item 24 Animal identification and traceability

a) Guidelines on the design and implementation of identification systems to achieve animal traceability

b) Update on the OIE International Conference on Animal Identification and Traceability

Item 25 Guidelines on the control of hazards of animal health and public health importance in animal feed

Item 26 Salmonella

a) Salmonella Enteritidis and S. Typhimurium in poultry (Chapter 2.10.2)

b) Hygiene and disease security procedures in poultry breeding flocks and hatcheries (Appendix 3.4.1.)

c) Guidelines on the detection, control and prevention of Salmonella Enteritidis and S. Typhimurium in poultry producing eggs for human consumption (Appendix 3.10.2.).

Item 27 Animal welfare

a) Definition of animal welfare

b) Guidelines for the transport of animals by sea (Appendix 3.7.2.) and Guidelines for the transport of animals by land (Appendix 3.7.3.)

c) Guidelines for the transport of animals by air (Appendix 3.7.4.)

d) Guidelines for the slaughter of animals (Appendix 3.7.5.)

e) Guidelines for the killing of animals for disease control purposes (Appendix 3.7.6.)

f) Guidelines on dog population control

g) Update on the work of the *ad hoc* Group on laboratory animal welfare

h) Update on 2nd OIE Global Conference on Animal Welfare 2008

i) Update on the work of the *ad hoc* Group on livestorck production systems

Item 28 *Aethina Tumid*a (Chapter 2.9.X.)

Annex II (contd)

Item 29 Guidelines for somatic cell nuclear transfer in production livestock and horses

Item 30 Categorisation of diseases and pathogenic agents by the IETS (Appendix 3.3.5.)

Item 31 The Role of the Veterinary Services in Food Safety

Item 32 Notification Criteria for Listing Diseases (Chapter 2.1.1.)

a) Report of the *ad hoc* Group on the notification of terrestrial animal diseases/pathogenic agents

b) Report of the Wildlife Working Group

Item 33 International transfer of pathogens (Chapter 1.4.5.)

Item 34 OIE/FAO Guidelines on Good Farming Practices

4. Other items

Item 35 Trade in animal products (commodities)

Item 36 Anthrax (Chapter 2.2.1.)

Item 37 Division of the *Terrrestrial Code* into two volumes

Item 38 Future work programme

Item 39 Others

Annex III

CHAPTER 1.1.1.

GENERAL DEFINITIONS

Article 1.1.1.1.

Community position:

The Community acknowledges and in many cases welcomes the new proposals, but wishes that some of them are amended, to be clearer or more useable. In the case of the definition of *buffer zone*, if an appropriate change is not made to the FMD chapter, the Community cannot support the new definition proposal. There are problems with interpretation which may lead to major trade problems and the EU asks that in the various disease Chapters OIE looks at these definitions of zones and the possible effect or differ the change of definition of buffer zone. A buffer zone should have more flexibility e.g in Europe in the case of an outbreak of FMD we don't have a buffer area between Member States

Comments for next Code Commission meeting

The comments are inserted after each commented definition below. In addition some definitions such as "*Target population*", "*Targeted surveillance*" and "*Epidemiological unit*" are different to the correspondant definitions in the Aquatic code. The EU asks the OIE to look at these differences and try to harmonise the two whenever possible and relevant.

For the purposes of the *Terrestrial Code*:

Animal welfare

~~means the state of animal as regards its attempts to cope with its environment and includes both the extent of failure to cope and the ease or difficulty in coping.~~

means how an animal is coping with the circumstances in which it lives. An animal is in a good state of welfare if (as indicated by scientific evidence) it is healthy, comfortable, well nourished, safe, able to express innate behaviour, able to have normal social contact with others of the same species, and if it is not suffering from unpleasant states such as pain, fear, and distress. Good animal welfare requires disease prevention and veterinary treatment, proper housing, management, nutrition, humane handling and humane slaughter/killing. By scientific convention, "animal welfare" refers to the state of the animal; the treatment that an animal receives is covered by other terms such as animal care, animal husbandry, and humane treatment.

Community comments:

The Community welcomes the work carried out by the OIE Code Commission and the improvement of the definition on animal welfare.

- In the definition the word "innate" should be replaced with the words "species-specific behaviour".

Justification: Animals should have the opportunity for both innate and learnt behaviours which are covered by the expression of species specific behaviours (those behaviours which are common to all members of a species).

- In the definition, the words "humane transport" should be included between the words "humane handling" and "humane slaughter".

Justification: Good animal welfare requires also a humane transport.

~~***Approved abattoir***~~

~~means premises used for the slaughter of *animals* for human consumption or animal feeding and approved by the *Veterinary Authority* for export purposes.~~

~~***Area of direct transit***~~

~~means a special area established in a *transit country*, approved by the relevant *Veterinary Authority* and placed under its immediate control, where *animals* stay for a short time pending further transport to their final destination.~~

~~***Breeding birds***~~

~~means birds kept for the purpose of producing *hatching eggs*.~~

Buffer zone

means a *zone* established within a free country or *free zone* to protect the health status of animals ~~in a free country or *free zone*~~, from those in a country or *zone* of a different *animal health status*, using measures based on the epidemiology of the *disease* under consideration to prevent spread of the causative pathogenic agent into a free country or *free zone*. These measures may include, but are not limited to, vaccination, movement control and an intensified degree of disease surveillance.

Community position:

The Community may approve the fact that as the definition is addressed to a country or zone dealing with its own status, it is preferable that the *buffer zone* is within the free zone. Nevertheless it should no be compulsory: a *buffer zone*, which is basically a zone between two zones of a different health status, can be drawn up in collaboration between two adjacent countries or zones according to their environment and common management procedures.

Moreover, this new definition would pose a big problem for some Chapters of the Code, especially the Chapter on FMD, for which the definition of free countries and zones should be changed as proposed by the ad hoc group on epidemiology. If not, then a lot of countries will not comply, while being free.

Thus whether this change is made in the FMD Chapter, or the EU cannot accept the above change in the definition of a buffer zone.

~~***Collecting centre***~~

~~means a premise or a place where *animals for breeding or rearing* or *animals for slaughter* from different *establishments* or *markets* are collected together.~~

Community comment:

The Community acknowledges the fact that this term is used only once in the Code and its definition is in Chapter 1.4.1.

Commodity

means live *animals*, products of animal origin, animal genetic material, ~~intended for human consumption, for animal feeding, for pharmaceutical or surgical use or for agricultural or industrial use, semen, embryos/ova,~~ biological products and *pathological material.*

Compartment

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

~~***Flock of birds***~~

~~means any group of birds continuously housed in one building or part of a building separated from other parts of that building by a solid partition and having its own ventilation system, or, in the case of free range birds, any group of birds having common access to one or more buildings or More than one flock of birds may exist in one *establishment.*~~

Flock

means a number of animals of one kind kept together under human control or a congregation of gregarious wild animals. For the purposes of the *Terrestrial Code*, a flock is usually regarded as an *epidemiological unit.*

Herd

means a number of animals of one kind kept together under human control or a congregation of gregarious wild animals. For the purposes of the *Terrestrial Code*, a herd is usually regarded as an *epidemiological unit.*

Community comment:

The Community wishes to reiterate its former comment: as the definitions are exactly identical, they should be under the same paragraph:

Flock* or *Herd

means a number of animals of one kind kept together under human control or a congregation of gregarious wild animals. For the purposes of the *Terrestrial Code*, a flock or a herd is usually regarded as an *epidemiological unit.*

~~***Infected country***~~

~~means a country in which the absence of the *disease* under consideration has not been demonstrated by the requirements specified in the *Terrestrial Code* being met.~~

Infection

means the ~~presence of the pathogenic agent in the host~~ entry and development or multiplication of an infectious agent in the body of humans ~~men~~ or *animals*.

Community comment :

The Community wishes to reiterate its former comment: proving the development or multiplication of an agent could be difficult, so the following words should be added at the end of the sentence: ", diagnosed in accordance with the OIE Manual of Standards". The two definitions of *infection* in the Terrestrial and Aquatic codes should also be harmonised if possible.

~~***Laying birds***~~

~~means birds kept for the purpose of producing eggs not intended for hatching.~~

Monitoring

means the ~~continuous investigation of~~ intermittent performance and analysis of routine measurements, aimed at detecting changes in the environment or health status of a ~~given~~ *population* ~~or *subpopulation*, and its environment, to detect changes in the *prevalence* of a *disease* or characteristics of a pathogenic agent~~.

Community comment:

The change can be accepted, but it would be more precise to add the words "and observations" after the word "measurements", af it is not clear if it is included. "Measurements" may be interpreted too restrictively.

~~***Official veterinary control***~~

~~means that the *Veterinary Services* knows the location of the *animals* and the identity of their owner or responsible keeper and is able to apply appropriate animal health measures, as required.~~

Official veterinary control (of live animals)

means that the *Veterinary Services* knows the location of the *animals* and the identity of their owner or responsible keeper and is able to apply appropriate animal health measures, as required.

Community comment:

The Community welcomes the reinstatement of the definition.

Quarantine station

means a ~~facility~~ place premises under the control of the *Veterinary Services* where animals are maintained in isolation with no direct or indirect contact with other animals, to prevent the transmission of specified pathogen(s) while the *animals* are undergoing observation for a specified length of time and, if appropriate, testing and treatment.

Community comment:

The Community welcomes the change of the definition.

Risk

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

Risk assessment

means the evaluation of the likelihood and the biological and economic consequences of entry, establishment, ~~or~~ and spread of ~~a pathogenic agent~~ a *hazard*~~s~~ within the territory of an *importing country*.

Community comment:

The Community wishes to reiterate its former comment: the word "or" should not be replaced by "and", as a risk assessment can for example be focused only on spread. Or if it is a language problem, the French and Spanish version should be "ou" and "o".

Sanitary measure

means ~~any~~ a measure ~~applied~~, such as those described in various chapters of the *Terrestrial Code*, designed to protect animal or human health or life within the territory of the Member ~~Country~~ from *risks* arising from the entry, establishment ~~or~~ and spread of a *hazard*. ~~[Note: A detailed definition of sanitary measure may be found in the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization.~~

Community comment:

The word "or" should not be replaced by "and", as a risk can for example arise only from the spread of a hazard already established. Or if it is a language problem, the French and Spanish version should be "ou" and "o".

Surveillance

means ~~the investigation of a given *population* or *subpopulation* to detect the presence of a pathogenic agent or *disease*; the frequency and type of *surveillance* will be determined by the epidemiology of the pathogenic agent or *disease*, and the desired outputs~~ the systematic ongoing collection, collation, and analysis of data related to animal health and the timely dissemination of information to those who need to know so that action can be taken.

Veterinary Services

means the governmental and non-governmental organisations that implement animal health and welfare measures and other standards and guidelines in the *Terrestrial Code* in the country. The Veterinary Services are under the overall control and direction of the *Veterinary Authority*. Private sector organisations, ~~or~~ *veterinarians* or *veterinary paraprofessionals* are normally accredited or approved to deliver functions by the *Veterinary Authority*.

Annex IV

Model Veterinary Certificate for International Trade in Live Animals and Hatching Eggs

COUNTRY:

Part I: Details of dispatched consignment

I.1. Consignor
Name

Address

I.2. Certificate reference number

~~I.3. Veterinary Administration~~

I.43. Veterinary Authority

I.54. Consignee
Name

Address

I.65.Country of origin ISO code* I.76. Zone or compartment of origin**

I.87. Country of destination ISO code* I.98. Zone or compartment of destination**

I.109. Place of origin

Name

Address

I.1110. Place of shipment
~~Address~~

I.1211. Date of departure

I.1312. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:

I.1413. Expected border post

I.1514. CITES permit No(s).**

I.1615. Description of commodity

I.1716. Commodity code (HS code)

I.1817.Total qQuantity

I.1918.

I.2019. Total nNumber of packages

I.2120. Identification of container/seal number

I.2221.

I.2322. Commodities intended for use as:
Breeding/rearing ☐ Competition ☐ Slaughter ☐ Game restocking ☐
Pets ☐ Circus/exhibition ☐ Other ☐

I.2423. For import or admission
Definitive import ☐ Re-entry ☐ Temporary admission ☐

I.2524. Identification of the commodities

~~Species (Scientific name)~~ ~~Breed / Category~~ ~~Identification system~~ ~~Identification number/details~~

~~Age~~ ~~Sex~~ ~~Quantity~~

Species (Scientific name)	Breed* / Category*	Identification system	Identification number/details	Age*	Sex*	Quantity

*: optional
**: if referenced in Part II

Annex IV (contd)

COUNTRY:

Part II: Zoosanitary information

II.a. Certificate reference number

II. The undersigned Official Veterinarian certifies that the animal(s)/hatching eggs described above satisfy(ies) the following requirements:

Official Veterinarian

Name and address (in capital letters):

~~Qualification and title~~ Official position

Date:

Signature:

Stamp

Annex IV (contd)

Model Veterinary Certificate for International Trade in Embryos, Ova and Semen

COUNTRY:

Part I: Details of dispatched consignment

I.1. Consignor
Name

Address

I.2. Certificate reference number

~~I.3. Veterinary Administration~~

I.43. Veterinary Authority

I.54. Consignee
Name

Address

I.65. Country of origin ISO code* I.76. Zone or compartment of origin**

I.87. Country of destination ISO code* I.98. Zone or compartment of destination**

I.109. Place of origin

Name

Address

I.1110. Place of shipment
~~Address~~

I.1211. Date of departure

I.1312. Means of transport
Aeroplane Ship Railway wagon
Road vehicle Other
Identification:

I.1413. Expected border post

I.1514. CITES permit No(s).**

I.1615. Description of commodity

I.1716. Commodity code (HS code)

I.1817.Total qQuantity

I.1918.

I.2019. Total nNumber of packages

I.2120. Identification of container/seal number

I.2221.

I.2322. Commodities intended for use as:
Artificial reproduction Other

I.2423.

I.2524. Identification of the commodities

~~Species (Scientific name)~~ ~~Breed /Category~~ ~~Donor identity~~ ~~Date of collection~~

~~Approval number of the centre/team~~ ~~Identification mark~~ ~~Quantity~~

Species (Scientific name)	Breed*	Donor identity	Date of collection	Approval number of the centre/team	Identification mark	Quantity

*: optional
**: if referenced in Part II

Annex IV (contd)

COUNTRY:

Part II: Zoosanitary information

II.a. Certificate reference number

II. The undersigned Official Veterinarian certifies that the embryos/ova/semen described above satisfy(ies) the following requirements:

Official Veterinarian

Name and address (in capital letters):

~~Qualification and title~~ Official position

Date:

Signature:

Stamp

Annex IV (contd)

Model Veterinary Certificate for International Trade in Products of Animal Origin

COUNTRY:

Part I: Details of dispatched consignment

I.1. Consignor
Name

Address

I.2. Certificate reference number

~~I.3. Veterinary Administration~~

I.43. Veterinary Authority

I.54. Consignee
Name

Address

I.65. Country of origin ISO code* I.76. Zone or compartment of origin**

I.87. Country of destination ISO code* I.98. Zone or compartment of destination**

I.109. Place of origin

Name

Address

I.1110. Place of shipment
~~Address~~

I.1211. Date of departure

I.1312. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:

I.1413. Expected border post

I.1514. CITES permit No(s).**

I.1615. Description of commodity

I.1716. Commodity code (HS code)

I.1817.Total qQuantity

I.1918. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.2019. Total nNumber of packages

I.2120. Identification of container/seal number

I.2221.Type of packaging

I.2322. Commodities intended for use as:
Human consumption ☐ Animal feed ☐ Further processing ☐ Technical use ☐
Other ☐

I.2423.

I.2524. Identification of the commodities

~~Species (Scientific name)~~ ~~Nature of commodity~~ ~~Treatment type~~

~~Approval number of establishments~~
~~Abattoir~~ ~~Cutting plant/~~ ~~Processing plant~~ ~~Cold store/~~

~~Number of packages~~ ~~Net weight~~ ~~Lot identification/date code~~

Species (Scientific name)	Nature of commodity	Treatment type	Approval number of establishments	Number of packages	Net weight	Lot ID/date code

*: optional
**: if referenced in Part II

Annex IV (contd)

COUNTRY:

Part II: Zoosanitary information

II.a. Certificate reference number

II. The undersigned Official Veterinarian certifies that the product(s) of animal origin described above satisfy(ies) the following requirements:

Official Veterinarian

Name and address (in capital letters):

~~Qualification and title~~ Official position

Date:

Signature:

Stamp

Annex IV (contd)

Model Veterinary Certificate for International Trade in Bees and Brood Combs

COUNTRY:

Part I: Details of dispatched consignment

I.1. Consignor
Name

Address

I.2. Certificate reference number

~~I.3. Veterinary Administration~~

I.43. Veterinary Authority

I.54. Consignee
Name

Address

I.65. Country of origin ISO code* I.76. Zone ~~or compartment~~ of origin**

I.87. Country of destination ISO code* I.98. Zone ~~or compartment~~ of destination**

I.109. Place of origin

Name

Address

I.1110. Place of shipment
~~Address~~

I.1211. Date of departure

I.1312. Means of transport
Aeroplane Ship Railway wagon
Road vehicle Other
Identification:

I.1413. Expected border post

I.1514. CITES permit No(s).**

I.1615. Description of commodity

I.1716. Commodity code (HS code)

I.1817.Total qQuantity

I.1918.

I.2019. Total nNumber of packages

I.2120. Identification of container/seal number

I.2221.

I.2322. Commodities intended for use as:
Breeding/rearing Other

I.2423.

I.2524. Identification of the commodities

Category	Breed* / Variety*	Quantity	Identification details

*: optional
**: if referenced in Part II

Annex IV (contd)

COUNTRY:

Part II: Zoosanitary information

II.a. Certificate reference number

II. The undersigned Official Veterinarian certifies that the bees/brood comb(s) described above satisfy(ies) the following requirements:

Official Veterinarian

Name and address (in capital letters):

~~Qualification and title~~ Official position

Date:

Signature:

Stamp

APPENDIX X.X.X

NOTES FOR GUIDANCE ON THE VETERINARY CERTIFICATES FOR INTERNATIONAL TRADE IN LIVE ANIMALS, HATCHING EGGS AND PRODUCTS OF ANIMAL ORIGIN

Community position:

The Community can support the proposed changes.

General: Please complete the certificate in capitals. To confirm an option, mark the box with a cross (X). Ensure that no portion of certificate is left blank in a manner that would allow it to be amended. Non-applicable fields may be crossed out.

PART I. DETAILS OF DISPATCHED CONSIGNMENT

Country: Name of the country that issues the certificate.

Box I.1. Name and full address of the natural or legal person dispatching the consignment. Information on telephone and fax numbers or e-mail address is recommended.

Box I.2. The certificate reference number is the number used by the Veterinary Authority of the country to identify the certificate.

~~Box I.3.~~ ~~Name of the *Veterinary Administration.*~~

Box I.43. Name of the *Veterinary Authority*.

Box I.54. Name and full address of the natural or legal person to whom the consignment is destined at the time the certificate is issued.

Box I.65. Name of the country from which the *animals*, *hatching eggs*, embryos, semen, ova or brood combs are being exported. For products, name the country(ies) where the finished products were produced, manufactured or packed.

"ISO code" refers to the international standard two-letter code (ISO 3166-1 Alpha-2 Code) for a country produced by the International Organization for Standardization.

Box I.76. Name of the zone or compartment of origin, if relevant, in part II of the certificate.

Box I.87. Name of the country of destination.

"ISO code" refers to the international standard two-letter code (ISO 3166-1 Alpha-2 Code) for a country produced by the International Organization for Standardization.

Box I.~~9~~8. Name of the zone or compartment of destination, if relevant, in part II of the certificate.

Box I.~~10~~9. Name and full address of the place(s) from which the *animals* or products are being exported; and official approval or registration number when required.

For *animals* and *hatching eggs*: the *establishment(s)*, wildlife or hunting reserves.

For semen: the *artificial insemination centre*.

For embryos and ova: the name, address and official approval number of the collection team (not the premises of storage).

For products of animal origin: the premises from which the products are to be dispatched.

Box I.~~11~~10. Name ~~and full address~~ of the place from which the *animals* or products are being shipped (this will be a land, sea or airport).

Box I.~~12~~11. Date of departure. For *animals* include the expected time of departure.

Box I.~~13~~12. Details of the means of transport.

Identification of the means of transport at the time the certificate is issued: for air transport, the flight number; for maritime transport, the name of the vessel; for rail transport, the number of the train and the wagon and for road transport, the registration number of the road vehicle and the number of the trailer where used.

Box I.~~14~~13. Name of expected *border post* and, if available, its UN/LOCODE (refer to the United Nations Code for Trade and Transport Locations).

Box I.~~15~~14. CITES permit number(s) if the *commodity* concerns species listed in the Convention on International Trade in Endangered Species of Wild Fauna and Flora ~~the Washington Convention~~.

Box I.~~16~~15. Describe the *commodity* or use the titles as they appear in the Harmonised System of the World Customs Organization.

Box I.~~17~~16. Heading or HS Code of the Harmonized System set up by the World Customs Organization.

Box I.~~18~~17. Total q~~Q~~uantity of the *commodity*.

For *animals*, *hatching eggs* and animal products (semen, ova, embryos) give the total count of *animals*, eggs or straws.

For products give the gross weight and the net weight in kg of the whole consignment.

Box I.~~19~~18. Temperature of products for transport and storage.

Box I.~~20~~19. Total n~~N~~umber of boxes, cages or stalls in which the *animals* or *hatching eggs* are being transported. Total n~~N~~umber of cryogenic containers for semen, ova, embryos. Total n~~N~~umber of packages for products.

Box I.~~21~~20. Identify the containers/seal numbers where required.

Box I.~~22~~21. Identify the type of packaging of products as defined in Recommendation No. 21 – Code of Passengers, Type of Cargo, Package and Packaging Materials of UN/CEFACT (United Nation Centre for Trade Facilitation and Electronic Business) ~~(e.g. cans, boxes)~~.

Box I.~~23~~22. Intended use of the imported *animals* or products.

Breeding/rearing: applies to *animal for breeding or rearing* and *hatching eggs*.

Slaughter: applies to *animal for slaughter*.

Game restocking: applies to game for the purpose of rebuilding stocks.

Pet: applies to *animals* kept for companionship or enjoyment. This excludes livestock species.

Circus/exhibition: applies to *animals* used in a circus, show or exhibition.

Human consumption: applies to products intended for human consumption.

Animal feed: means any product of animal origin (single or multiple), whether processed, semi-processed or raw, which is intended to be fed to *animals*.

Further processing: applies to products of animal origin which have to be further processed before being suitable for end use.

Technical use: applies to products not intended for human or animal consumption. These include animal products that are intended for use in the pharmaceutical, medical, cosmetic and other industries. Such products may be subjected to extensive further processing.

Other: intended for purposes not listed elsewhere in this classification.

Box I.~~24~~23. Mark, if appropriate.

Box I.~~25~~24. Details on the nature of the *commodity* sufficient to identify it.

For *animals* and *hatching eggs*: Species (scientific name); ~~Breed/Category;~~ Identification system; Identification number or other identification details; ~~Age; Sex;~~ Quantity and if required, Breed / Category (e.g. heifer, steer, layer, broiler); Age; Sex. For animals holding an official passport, the international animal passport number should be provided, and a copy of the details on the passport attached to the certificate.

For embryos, ova and semen: Species (Scientific name); ~~Breed/Category;~~ Identification mark according to the International Embryo Transfer Society (IETS) or the International Committee for Animal Recording (ICAR); Collection date; Approval

number of the centre/team; Identification of the donor animal; Quantity. If required, Breed.

For bees and brood combs: Category means hive with bees, swarm, consignment of bees (worker bees, drones), queen bees, brood-combs, royal cells, etc. Identification details include peculiarities (e.g. Marks or age or weight or surface). Breed / Variety if required.

For products of animal origin: Species (Scientific name); Nature of commodity; Treatment type; approval number of establishment(s) (~~e.g. dairy farm,~~ abattoir; cutting plant; processing plant; cold store); Lot identification/date code; Quantity; Number of packages; Net weight.

PART II. ZOOSANITARY INFORMATION

Box II. Complete this part in accordance with the requirements agreed between the *Veterinary ~~Administrations~~ Authorities* of the importing and exporting countries in accordance with the recommendations in the *Terrestrial Code*.

Box II.a. Reference number: see box I.2.

Official veterinarian: Name, address, ~~qualification and title~~ official position, date of signature and official stamp of the *Veterinary Services*.

— text deleted

CHAPTER 1.2.1.

GENERAL OBLIGATIONS

Community position:

The Community can support the proposed changes. However it would like the OIE to take into consideration its comments on article 1.2.1.2 and 1.2.1.3 regarding the obligations of the importing and exporting countries, in order to avoid unnecessary administrative work for the Veterinary Authorities, and to ensure better traceability of the certificate.

Article 1.2.1.1.

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

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

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

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

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

Article 1.2.1.2.

Responsibilities of the importing country

1. The import requirements included in the *international veterinary certificate* should assure that *commodities* introduced into the *importing country* comply with the OIE standards ~~the national level of protection that it has chosen for animal and human health~~. *Importing countries* should restrict their requirements to those ~~justified for such~~ necessary to achieve the national appropriate level of protection. If these are stricter than the OIE standards, they should be based on an import *risk analysis*.

Community comment:

The Community would like the OIE to include the following : "Any request for information should take into account an obligation to use previously available information where this still valid."

2. The *international veterinary certificate* should not include requirements for the exclusion of pathogens or animal *diseases* which are present ~~within the territory of~~ in the *importing country* and are not subject to any *official control programme*. ~~The requirements applying to pathogens or *diseases* subject to *official control programmes* in a country or *zone* should not provide a higher level of protection on imports than that provided for the same pathogens or *diseases* by the measures applied within that country or *zone*.~~ The measures imposed on imports to manage the *risks* posed by a specific pathogen or *disease* should not require a higher level of protection than that provided by measures applied as part of the *official control programme* operating within the *importing country*.

3. The *international veterinary certificate* should not include ~~requirements for disease agents~~ measures against pathogens or *diseases* which are not OIE listed, unless the *importing country* has ~~identified the disease agent as presenting a significant risk for that country, after conducting a scientifically based import risk analysis according o the guidelines in Section 1.3~~ demonstrated through import *risk analysis*, carried out in accordance with Section 1.3., that the pathogen or *disease* poses a significant *risk* to the *importing country*.

4. The transmission by the *Veterinary Authority* of certificates or the communication of import requirements to persons other than the *Veterinary Authority* of another country, necessitates that copies of these documents are also sent to the *Veterinary Authority*. This important procedure avoids delays and difficulties which may arise between traders and *Veterinary Authorities* when the authenticity of the certificates or permits is not established.

   This information is ~~usually~~ the responsibility of *Veterinary Authorities*. However, it can be issued by private sector *veterinarians* at the place of origin of the ~~*animals*~~ *commodities* when this practice is the subject of appropriate approval and authentication by the *Veterinary Authority*.

5. Situations may arise which result in changes to the consignee, identification of the means of transportation, or *border post* after a certificate is issued. Because these do not change the animal or public health status of the consignment, they should not prevent the acceptance of the certificate.

Community comment:

The Community would like the OIE to add the following sentence: "The certificate amended in such a way must be copied to the Competent Authority issuing the certification to ensure traceability."

Article 1.2.1.3.

Responsibilities of the exporting country

1. An *exporting country* should, on request, ~~be prepared to~~ supply the following ~~information~~ to *importing countries* ~~on request~~:

   a) information on the animal health situation and national animal health information systems to determine whether that country is free or has *free zones* of *listed diseases*, including the regulations and procedures in force to maintain its free status;

Community comment:

To be coherent with the chapter on zoning and compartmentalisation, the wording above should include the word "or *compartments*" after the words "*free zones*".

The Community reiterate previous comments that the submissions sent to OIE concerning status recognition should be enough documentation for the exporting country and that these submissions should be made available to all members via the internet i.e. linked to the OIE status list.

b) regular and prompt information on the occurrence of ~~transmissible~~ notifiable *diseases*;

c) details of the country's ability to apply measures to control and prevent the relevant *listed diseases*;

d) information on the structure of the *Veterinary Services* and the authority which they exercise according to Chapters 1.3.3. and 1.3.4.;

~~e) technical information, particularly on biological tests and vaccines applied in all or part of the national territory.~~

e) technical information, particularly on biological tests and vaccines applied in all or part of the national territory.

2. *Veterinary Authorities* of *exporting countries* should:

a) have official procedures for authorisation of certifying *veterinarians*, defining their functions and duties as well as conditions covering possible suspension and termination of the appointment;

b) ensure that the relevant instructions and training are provided to certifying *veterinarians*;

c) monitor the activities of the certifying *veterinarians* to verify their integrity and impartiality.

3. The Head of the *Veterinary Service* of the *exporting country* is ultimately accountable for veterinary certification used in *international trade*.

Article 1.2.1.4.

Responsibilities in case of an incident ~~occurring after~~ related to importation

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

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

3. In case of suspicion, on reasonable grounds, that an official certificate may be fraudulent, the *Veterinary Authority* of the *importing country* and *exporting country* should conduct an investigation.

Consideration should also be given to notifying any third country(ies) that may have been implicated. All associated consignments should be kept under official control, pending the outcome of the investigation. The *Veterinary Authorities* of all countries involved should fully cooperate with the investigation. If the certificate is found to be fraudulent, every effort should be made to identify those responsible so that appropriate action can be taken according to the relevant legislation.

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CHAPTER 1.2.2.

CERTIFICATION PROCEDURE

Community position:

The Community can support the proposed changes, but would like that the OIE takes into consideration its comment in article 1.2.2.3 point 8, regarding the traceability of the certificate, and in coherence with its comment on the previous chapter.

Article 1.2.2.1.

Protection of the professional integrity of the certifying veterinarian

Certification should be based on the highest possible ethical standards, the most important of which is that the professional integrity of the certifying veterinarian must be respected and safeguarded according to Chapters 1.3.3. and 1.3.4.

It is essential not to include in the requirements additional specific matters which cannot be accurately and honestly signed by a veterinarian. For example, these requirements should not include certification of an area as being free from non-notifiable diseases the occurrence of which the signing veterinarian is not necessarily informed about. Equally, to ask certification for events which will take place after the document is signed is unacceptable when these events are not under the direct control and supervision of the signing veterinarian.

Certification of freedom from diseases based on purely clinical freedom and herd history is of limited value. This is also true of diseases for which there is no specific diagnostic test, or the value of the test as a diagnostic aid is limited.

The note of guidance referred to in Article 1.2.1.1. is not only to inform the signing veterinarian but also to safeguard professional integrity.

Article 1.2.2.2.

Certifying veterinarians

Certifying veterinarians should:

1. be authorised by the *Veterinary Authority* of the *exporting country* to sign *international veterinary certificates*;

2. only certify matters that are within their own knowledge at the time of signing the certificate, or that have been separately attested by another competent party authorized by the *Veterinary Authority*;

3. sign only at the appropriate time certificates that have been completed fully and correctly; where a certificate is signed on the basis of supporting documentation, the certifying veterinarian should be in possession of that documentation before signing;

4. have no conflict of interest in the commercial aspects of the *animals* or animal products being certified and be independent from the commercial parties.

Article 1.2.2.3.

Preparation of international veterinary certificates

Certificates should be drawn up in accordance with the following principles:

1. Certificates should be designed so as to minimize the potential for fraud including use of a unique identification number, or other appropriate means to ensure security.Paper certificates should ~~be pre-printed, if possible on one sheet of paper, serially numbered, and issued by the Veterinary Authority on officially headed notepaper and, if possible, printed using techniques which prevent forgery.~~ bear the official identifier of the issuing *Veterinary Authority*. Each page of a multiple page certificate should bear the unique certificate number and a number indicating the number of the page out of the total number of pages. Electronic certification procedures should include equivalent safeguards.

2. They should be written in terms that are as simple, unambiguous and easy to understand as possible, without losing their legal meaning.

3. If so required, they should be written in the language of the *importing country*. In such circumstances, they should also be written in a language understood by the certifying veterinarian.

4. They should require appropriate identification of *animals* and animal products except where this is impractical (e.g. *day-old birds*).

5. They should not require a veterinarian to certify matters that are outside his/her knowledge or which he/she cannot ascertain and verify.

6. Where appropriate, they should be accompanied, when presented to the certifying veterinarian, by notes of guidance indicating the extent of enquiries, tests or examinations expected to be carried out before the certificate is signed.

7. Their text should not be amended except by deletions which must be signed and stamped by the certifying veterinarian. The signature and stamp must be in a colour different to that of the printing of the certificate.

8. Replacement certificates may be issued by a *Veterinary Authority* to replace certificates that have been, for example, lost, damaged, contain errors, or where the original information is no longer correct. These must be clearly marked to indicate that they are replacing the original certificate. A replacement certificate should reference the number and the issue date of the certificate that it supersedes. The superseded certificate should be cancelled and where possible, returned to the issuing authority.

Community comment:

It should be the same authority which issued the original that issues the duplicate one. Therefore the EU proposes the following wording for the beginning of the second sentence of point 8 above: "These duplicates must be provided by the issuing authority and be clearly marked etc"

~~8~~9. Only original certificates are acceptable.

~~Article 1.2.2.3.~~

~~**Certifying veterinarians**~~

~~Certifying veterinarians should:~~

~~1.~~ ~~be authorised by the *Veterinary Authority* of the *exporting country* to sign *international veterinary certificates*;~~

2. only certify matters that are within their own knowledge at the time of signing the certificate, or that have been separately attested by another competent party;

3. sign only at the appropriate time certificates that have been completed fully and correctly; where a certificate is signed on the basis of supporting documentation, the certifying veterinarian should be in possession of that documentation before signing;

4. have no conflict of interest in the commercial aspects of the *animals* or animal products being certified and be independent from the commercial parties.

Article 1.2.2.4.

Electronic certification

1. Certification may be provided by electronic documentation sent directly from the *Veterinary Authority* of the *exporting country* to the *Veterinary Authority* of the *importing country*. Such systems also normally provide an interface with the commercial organisation marketing the *commodity* for provision of information to the certifying authority. The certifying veterinarian must have access to all information such as laboratory results and animal identification data.

2. Electronic certificates should carry the same information as conventional certificates.

3. The *Veterinary Authority* must have in place systems for the security of electronic certificates against access by unauthorised persons or organisations.

4. The certifying veterinarian must be officially responsible for the secure use of his/her electronic signature.

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Annex V

CHAPTER 1.3.2.

GUIDELINES FOR IMPORT RISK ANALYSIS

Community position:

The Community can support the proposed changes.

Article 1.3.2.1.

Introduction

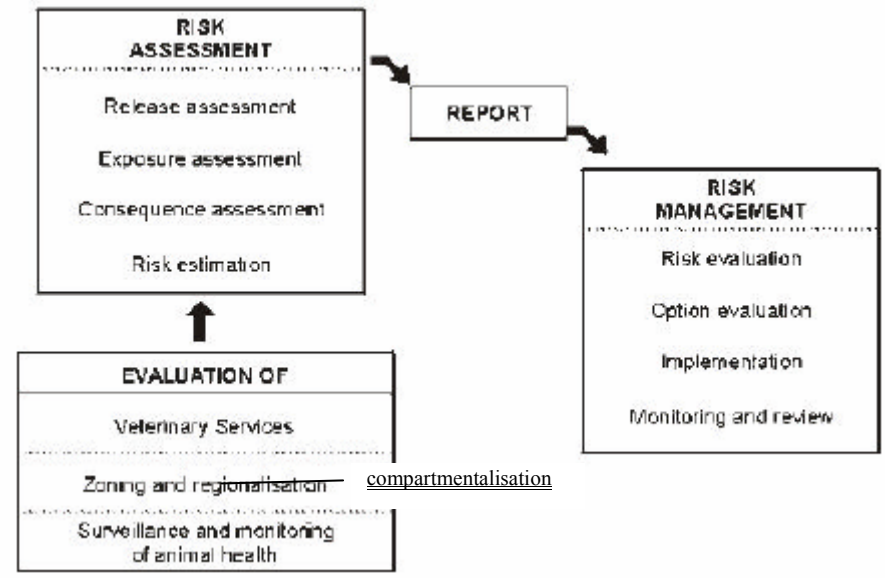
An import risk analysis begins with a description of the *commodity* proposed for import and the likely annual quantity of trade. It must be recognised that whilst an accurate estimate of the anticipated quantity of trade is desirable to incorporate into the risk estimate, it may not be readily available, particularly where such trade is new.

Hazard identification is an essential step which must be conducted before the *risk assessment*.

The *risk assessment* process consists of four interrelated steps. These steps clarify the stages of the *risk assessment*, describing them in terms of the events necessary for the identified potential *risk(s)* to occur, and facilitate understanding and evaluation of the outputs. The product is the *risk assessment* report which is used in *risk communication* and *risk management*.

The relationships between *risk assessment* and *risk management* processes are outlined in Figure 1.

Fig. 1. ***The relationship between risk assessment and risk management processes***



Article 1.3.2.2.

Hazard identification

The *hazard identification* involves identifying the pathogenic agents which could potentially produce adverse consequences associated with the importation of a *commodity*.

The potential *hazards* identified would be those appropriate to the species being imported, or from which the *commodity* is derived, and which may be present in the *exporting country*. It is then necessary to identify

whether each potential *hazard* is already present in the *importing country*, and whether it is a *notifiable disease* or is subject to control or eradication in that country and to ensure that import measures are not more trade restrictive than those applied within the country.

Hazard identification is a categorisation step, identifying biological agents dichotomously as potential *hazards* or not. The *risk assessment* may be concluded if *hazard identification* fails to identify potential *hazards* associated with the importation.

The evaluation of the *Veterinary Services*, surveillance and control programmes and zoning and compartmentalisation systems are important inputs for assessing the likelihood of *hazards* being present in the animal population of the *exporting country*.

An *importing country* may decide to permit the importation using the appropriate sanitary standards recommended in the *Terrestrial Code*, thus eliminating the need for a *risk assessment*.

Article 1.3.2.3.

Principles of risk assessment

1. *Risk assessment* should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. *Risk assessment* must be able to accommodate the variety of animal *commodities*, the multiple *hazards* that may be identified with an importation and the specificity of each *disease*, detection and surveillance systems, exposure scenarios and types and amounts of data and information.

2. Both *qualitative risk assessment* and *quantitative risk assessment* methods are valid.

3. The *risk assessment* should be based on the best available information that is in accord with current scientific thinking. The assessment should be well-documented and supported with references to the scientific literature and other sources, including expert opinion.

4. Consistency in *risk assessment* methods should be encouraged and *transparency* is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding by all the interested parties.

5. *Risk assessments* should document the *uncertainties*, the assumptions made, and the effect of these on the final risk estimate.

6. *Risk* increases with increasing volume of *commodity* imported.

7. The *risk assessment* should be amenable to updating when additional information becomes available.

Article 1.3.2.4.

Risk assessment steps

1. Release assessment

   Release assessment consists of describing the biological pathway(s) necessary for an importation activity to 'release' (that is, introduce) pathogenic agents into a particular environment, and estimating the probability of that complete process occurring, either qualitatively (in words) or quantitatively (as a numerical estimate). The release assessment describes the probability of the 'release' of each of the potential *hazards* (the pathogenic agents) under each specified set of conditions with respect to amounts and timing, and how these might change as a result of various actions, events or measures. Examples of the kind of inputs that may be required in the release assessment are:

a) Biological factors

- species, age and breed of animals
- agent predilection sites
- vaccination, testing, treatment and quarantine.

b) Country factors

- incidence/prevalence
- evaluation of *Veterinary Services*, surveillance and control programmes and zoning systems of the *exporting country*.

c) Commodity factors

- quantity of *commodity* to be imported
- ease of contamination
- effect of processing
- effect of storage and transport.

If the release assessment demonstrates no significant *risk*, the *risk assessment* ~~conclude~~ does not need to continue.

2. Exposure assessment

Exposure assessment consists of describing the biological pathway(s) necessary for exposure of animals and humans in the *importing country* to the *hazards* (in this case the pathogenic agents) released from a given *risk* source, and estimating the probability of the exposure(s) occurring, either qualitatively (in words) or quantitatively (as a numerical estimate).

The probability of exposure to the identified *hazards* is estimated for specified exposure conditions with respect to amounts, timing, frequency, duration of exposure, routes of exposure (e.g. ingestion, inhalation, or insect bite), and the number, species and other characteristics of the animal and human populations exposed. Examples of the kind of inputs that may be required in the exposure assessment are:

a) Biological factors

- properties of the agent.

b) Country factors

- presence of potential vectors
- human and animal demographics
- customs and cultural practices
- geographical and environmental characteristics.

c) Commodity factors

- quantity of *commodity* to be imported

- intended use of the imported animals or products
- disposal practices.

If the exposure assessment demonstrates no significant *risk*, the *risk assessment* may conclude at this step.

3. Consequence assessment

Consequence assessment consists of describing the relationship between specified exposures to a biological agent and the consequences of those exposures. A causal process must exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences. The consequence assessment describes the potential consequences of a given exposure and estimates the probability of them occurring. This estimate may be either qualitative (in words) or quantitative (a numerical estimate).

Examples of consequences include:

a) Direct consequences

- animal *infection*, *disease*, and production losses
- public health consequences.

b) Indirect consequences

- surveillance and control costs
- compensation costs
- potential trade losses
- adverse consequences to the environment.

4. Risk estimation

Risk estimation consists of integrating the results from the release assessment, exposure assessment, and consequence assessment to produce overall measures of *risks* associated with the *hazards* identified at the outset. Thus risk estimation takes into account the whole of the risk pathway from *hazard* identified to unwanted outcome.

For a quantitative assessment, the final outputs may include:

- estimated numbers of herds, flocks, animals or people likely to experience health impacts of various degrees of severity over time;
- probability distributions, confidence intervals, and other means for expressing the *uncertainties* in these estimates;
- portrayal of the variance of all model inputs;
- a sensitivity analysis to rank the inputs as to their contribution to the variance of the risk estimation output;
- analysis of the dependence and correlation between model inputs.

Article 1.3.2.5.

Principles of risk management

1. *Risk assessment* is the process of deciding upon and implementing measures to achieve the Member ~~Country~~'s appropriate level of protection, whilst at the same time ensuring that negative effects on trade are minimised. The objective is to manage *risk* appropriately to ensure that a balance is achieved between a country's desire to minimise the likelihood or frequency of *disease* incursions and their consequences and its desire to import *commodities* and fulfil its obligations under *international trade* agreements.

2. The international standards of the OIE are the preferred choice of *sanitary measures* for *risk management*. The application of these *sanitary measures* should be in accordance with the intentions in the standards.

Article 1.3.2.6.

Risk management components

1. Risk evaluation - the process of comparing the *risk* estimated in the *risk assessment* with the Member ~~Country~~'s appropriate level of protection.

2. Option evaluation - the process of identifying, evaluating the efficacy and feasibility of, and selecting measures in order to reduce the *risk* associated with an importation in line with the Member ~~Country~~'s appropriate level of protection. The efficacy is the degree to which an option reduces the likelihood and/or magnitude of adverse health and economic consequences. Evaluating the efficacy of the options selected is an iterative process that involves their incorporation into the *risk assessment* and then comparing the resulting level of *risk* with that considered acceptable. The evaluation for feasibility normally focuses on technical, operational and economic factors affecting the implementation of the *risk management* options.

3. Implementation - the process of following through with the *risk management* decision and ensuring that the *risk management* measures are in place.

4. Monitoring and review - the ongoing process by which the *risk management* measures are continuously audited to ensure that they are achieving the results intended.

Article 1.3.2.7.

Principles of risk communication

1. *Risk communication* is the process by which information and opinions regarding *hazards* and *risks* are gathered from potentially affected and interested parties during a *risk analysis*, and by which the results of the *risk assessment* and proposed *risk management* measures are communicated to the decision-makers and interested parties in the *importing* and *exporting countries*. It is a multidimensional and iterative process and should ideally begin at the start of the *risk analysis* process and continue throughout.

2. A *risk communication* strategy should be put in place at the start of each *risk analysis*.

3. The *communication of the risk* should be an open, interactive, iterative and transparent exchange of information that may continue after the decision on importation.

4. The principal participants in *risk communication* include the authorities in the *exporting country* and other stakeholders such as domestic and foreign industry groups, domestic livestock producers and consumer groups.

5. The assumptions and *uncertainty* in the model, model inputs and the risk estimates of the *risk assessment* should be communicated.

6. Peer review is a component of *risk communication* in order to obtain scientific critique and to ensure that the data, information, methods and assumptions are the best available.

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Annex VI

CHAPTER 1.4.1.

ANIMAL HEALTH MEASURES APPLICABLE BEFORE AND AT DEPARTURE

Community position:

The Community can support the proposed changes.

Article 1.4.1.1.

1. Countries should only authorise the exportation from their territory of *animals for breeding*, *rearing* or *slaughter* which are correctly identified and which meet the requirements of the *importing country*.

2. Biological tests and/or vaccinations required by the *importing country* should be carried out in accordance with the recommendations in the *Terrestrial Code* and *Terrestrial Manual*, as well as *disinfection* and *disinfestation* procedures.

3. Observation of the *animals* before leaving the country may be carried out either in the *establishment* where they were reared, or in a *quarantine station*. When they have been found to be clinically healthy and free from *diseases listed by the OIE* by an *Official Veterinarian* during the period of observation, the *animals* should be transported to the *place of shipment* in specially constructed *vehicles*, previously cleansed and disinfected. This must be done without delay and without the *animals* coming into contact with other susceptible animals, unless these animals have animal health guarantees similar to those of the transported *animals*.

4. The transportation of the *animals for breeding or rearing* or *animals for slaughter* from the *establishment* of origin to the point of departure from the *exporting country* shall be carried out in conformity with the conditions agreed between the *importing country* and *exporting country*.

Article 1.4.1.2.

Countries should only undertake the export from its territory of:

a) semen,

b) embryos/ova,

c) *hatching eggs*,

from *artificial insemination centres*, *collection centres* or farms which meet the requirements of the *importing country*.

Article 1.4.1.3.

Countries exporting *animals*, semen, embryos/ova or *hatching eggs* should inform the country of destination and where necessary the *transit countries* if, after exportation, a *disease listed by the OIE* occurs within the *incubation period* of that particular *disease*, in the *establishment* of origin, or in an animal which was in a collecting centre where *animals* for breeding or rearing or *animals* for *slaughter* from different *establishments* or *markets* are collected together, or in a *market*, at the same time as the exported *animals*.

Article 1.4.1.4.

Before the departure of *animals*, semen, embryos/ova, *hatching eggs* and brood-combs of bees, an *Official Veterinarian* should, within the 24 hours prior to shipment, provide an *international veterinary certificate* conforming with the models approved by the OIE (as shown in Part 4 of the *Terrestrial Code*) and worded in the languages agreed upon between the *exporting country* and the *importing country*, and, where necessary, with the *transit countries*.

Article 1.4.1.5.

1. Before the departure of an *animal* or a consignment of *animals* on an international journey, the *Veterinary Authority* of the port, airport or district in which the *border post* is situated may, if it is considered necessary, carry out a clinical examination of the *animal* or consignment. The time and place of the examination shall be arranged taking into account customs and other formalities and in such a way as not to impede or delay departure.

2. The *Veterinary Authority* referred to in point 1 above shall take necessary measures to:

   a) prevent the shipment of *animals* affected or suspected of being affected with any *disease listed by the OIE* or with any other infectious *disease*;

   b) avoid entry into the *vehicle* of possible vectors or causal agents of *infection*.

Article 1.4.1.6.

1. Countries should only authorise the export from their territory of *meat* and products of animal origin intended for human consumption, which are fit for human consumption. They must be accompanied by an *international veterinary certificate* conforming with the models approved by the OIE (as shown in Part 4. of the *Terrestrial Code*). These must be worded in the languages agreed upon between the *exporting country* and the *importing country*, and, where necessary, with the *transit countries*.

2. Products of animal origin intended for use in animal feeding, or for pharmaceutical or surgical or agricultural or industrial use, should be accompanied by an *international veterinary certificate* conforming with the models approved by the OIE (as shown in Part 4. of the *Terrestrial Code*).

CHAPTER 1.4.3.

BORDER POSTS AND QUARANTINE STATIONS IN THE IMPORTING COUNTRY

Community position:

The Community can support the proposed changes.

Article 1.4.3.1.

1. Countries and their *Veterinary Authorities* shall, wherever possible, take the necessary action to ensure that the *border posts* and *quarantine stations* in their territory shall be provided with an adequate organisation and sufficient equipment for the application of the measures recommended in the *Terrestrial Code*.

2. Each *border post* and *quarantine station* shall be provided with facilities for the feeding and watering of animals.

Article 1.4.3.2.

When justified by the amount of *international trade* and by the epidemiological situation, *border posts* and *quarantine stations* shall be provided with a *Veterinary Service* comprising personnel, equipment and premises as the case may be and, in particular, means for:

a) making clinical examinations and obtaining specimens of material for diagnostic purposes from live animals or carcasses of animals affected or suspected of being affected by an epizootic *disease*, and obtaining specimens of animal products suspected of contamination;

b) detecting and isolating animals affected by or suspected of being affected by an epizootic *disease*;

c) carrying out *disinfection* and possibly *disinfestation* of *vehicles* used to transport animals and animal products.

In addition to this, each port and international airport should ideally be provided with equipment for the sterilisation or incineration of swill or any other material dangerous to animal health.

Article 1.4.3.3.

When required for the transit of *commodities* in *international trade*, airports shall be provided, as soon as possible, with *areas of direct transit*. These must, however, comply with the conditions required by *Veterinary Authorities*, especially to prevent the risk of introducing *diseases* transmitted by insects.

Article 1.4.3.4.

Each *Veterinary Authority*, when requested, shall make available for the *Central Bureau* and any interested country on request:

a) a list of *border posts*, *quarantine stations*, *approved abattoirs* and storage depots in its territory which are approved for *international trade*;

b) the period of time required for notice to be given for the application of the arrangements contained in point 2 of Articles 1.4.4.1. to 1.4.4.4.;

c) a list of airports in its territory which are provided with an area of direct transit, approved by the relevant *Veterinary Authority* and placed under its immediate control, where *animals* stay for a short time pending further transport to their final destination.

Annex VII

CHAPTER 1.3.3.

EVALUATION OF VETERINARY SERVICES

Community position:

The Community can support the proposed changes.

Article 1.3.3.1.

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

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

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

These fundamental principles are presented in Article 1.3.3.2. Other factors affecting quality are described in Part 1.(notification, principles of certification, etc.).

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

Guidelines for the evaluation of *Veterinary Services* are described in Chapter 1.3.4.

A procedure for evaluating *Veterinary Services* by OIE experts, on a voluntary basis, is described in Article 1.3.3.5.

Article 1.3.3.2.

Fundamental principles of quality

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

1. Professional judgement

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

2. Independence

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

3. Impartiality

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

4. Integrity

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

5. Objectivity

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

6. General organisation

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

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

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

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

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

7. Quality policy

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

8. Procedures and standards

The *Veterinary Services* should develop and document appropriate procedures and standards for all providers of relevant activities and associated facilities. These procedures and standards may for example relate to:

a) programming and management of activities, including international veterinary certification activities;

b) prevention, control and notification of disease *outbreaks*;

c) risk analysis, epidemiological surveillance and zoning;

d) inspection and sampling techniques;

e) diagnostic tests for animal *diseases*;

f) preparation, production, registration and control of biological products for use in the diagnosis or prevention of *diseases*;

g) border controls and import regulations;

h) *disinfection* and *disinfestation*;

i) treatments intended to destroy, if appropriate, pathogens in animal products.

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

9. Information, complaints and appeals

The *Veterinary Authority* should undertake to reply to legitimate requests from *Veterinary Authorities* of other Members ~~Countrie~~s or any other authority, in particular ensuring that any requests for information, complaints or appeals that they may present are dealt with in a timely manner.

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

10. Documentation

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

11. Self-evaluation

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

A procedure for evaluating *Veterinary Services* by OIE experts, on a voluntary basis, is described in Article 1.3.3.5.

12. Communication

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

13. Human and financial resources

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

Article 1.3.3.3.

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

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

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

Article 1.3.3.4.

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

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

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

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

In the event of a dispute between two Member~~ Countrie~~s over the conduct or the conclusions of the evaluation of the *Veterinary Services*, the matter should be dealt with having regard to the procedures set out in Article 1.3.1.3.

Article 1.3.3.5.

Evaluation facilitated by OIE experts under the auspices of the OIE

The OIE has established procedures for the evaluation of the *Veterinary Services* of a Member ~~Country~~, upon request by the Member ~~Country~~.

The OIE International Committee endorses a list of approved experts to facilitate the evaluation process.

Under these procedures, the Director General of the OIE recommends an expert(s) from that list.

The expert(s) facilitate(s) the evaluation of the *Veterinary Services* of the Member ~~Country~~ based on the provisions in Chapter 1.3.4., using the ~~Performance, Vision and Strategy~~ OIE *Tool for the Evaluation of Performance of Veterinary Services* (OIE *PVS Tool*)~~Instrument~~.

The expert(s) produce(s) a report in consultation with the *Veterinary Services* of the Member ~~Country~~.

The report is submitted to the Director General of the OIE and, with the consent of the Member ~~Country~~, published by the OIE.

Annex VII (contd)

CHAPTER 1.3.4.

GUIDELINES FOR THE EVALUATION OF VETERINARY SERVICES

Community position:

The Community can support the proposed changes.

Article 1.3.4.1.

General considerations

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

   Any evaluation should be carried out with due regard for Chapter 1.3.3.

2. In order to ensure that objectivity is maximised in the evaluation process, it is essential for some standards of discipline to be applied. The OIE has developed these guidelines which can be practically applied to the evaluation of *Veterinary Services*. These are relevant for evaluation of the *Veterinary Services* of one country by those of another country for the purposes of *risk analysis* in *international trade*. The guidelines are also applicable for evaluation by a country of its own *Veterinary Services* – the process known as self-evaluation – and for periodic re-evaluation. These guidelines should be used by OIE experts when facilitating an evaluation under the auspices of the OIE, following a request of a Member ~~Country~~. In applying these guidelines for the evaluation, the ~~Performance, Vision and Strategy~~ OIE *Tool for the Evaluation of Performance of Veterinary Services* (OIE *PVS Tool*) ~~Instrument~~ should be used.

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

3. The purpose of evaluation may be either to assist a national authority in the decision-making process regarding priorities to be given to its own *Veterinary Services* (self-evaluation) or to assist the process of *risk analysis* in *international trade* in *animals* and animal-derived products to which official sanitary and/or zoosanitary controls apply.

4. In both situations, the evaluation should demonstrate that the *Veterinary Services* have the capability for effective control of the sanitary and zoosanitary status of *animals* and animal products. Key elements to be covered in this process include resource adequacy, management capability, legislative and administrative infrastructures, independence in the exercise of official functions and performance history, including disease reporting.

5. Competence and integrity are qualities on which others base their confidence in individuals or organisations. Mutual confidence between relevant official *Veterinary Services* of trading partner countries contributes fundamentally to stability in *international trade* in *animals* and animal-related products. In this situation, scrutiny is directed more at the *exporting country* than at the *importing country*.

6. Although quantitative data can be provided on *Veterinary Services*, the ultimate evaluation will be essentially qualitative. While it is appropriate to evaluate resources and infrastructure (organisational, administrative and legislative), it is also appropriate to place emphasis on the evaluation of the quality of outputs and performance of *Veterinary Services*. Evaluation should take into consideration any quality systems used by *Veterinary Services*.

7. An *importing country* has a right of assurance that information on sanitary/zoosanitary situations provided by the *Veterinary Services* of an *exporting country* is objective, meaningful and correct. Furthermore, the *Veterinary Services* of the *importing country* are entitled to expect validity in the veterinary certification of export.

8. An *exporting country* is entitled to expect that its *animals* and animal products will receive reasonable and valid treatment when they are subjected to import inspection in the country of destination. The country should also be able to expect that any evaluation of its standards and performance will be conducted on a non-discriminatory basis. The *importing country* should be prepared and able to defend any position which it takes as a consequence of the evaluation.

9. As the *veterinary statutory body* is not a part of the *Veterinary Services*, an evaluation of that body should be carried out to ensure that the registration/licensing of *veterinarians* and authorisation of *veterinary para-professionals* is included.

Article 1.3.4.2.

Scope

1. In the evaluation of *Veterinary Services*, the following items may be considered, depending on the purpose of the evaluation:

   - organisation, structure and authority of the *Veterinary Services*;
   - human resources;
   - material (including financial) resources;
   - functional capabilities and legislative support;
   - animal health and veterinary public health controls;
   - formal quality systems including quality policy;
   - performance assessment and audit programmes;
   - participation in OIE activities and compliance with OIE Member~~ Countrie~~s' obligations.

2. To complement the evaluation of *Veterinary Services*, the organisational structure and functioning of the *veterinary statutory body* should also be considered.

3. Article 1.3.4.14. outlines appropriate information requirements for:

   - self-evaluation by the *Veterinary Authority* which perceives a need to prepare information for national or international purposes;
   - evaluation by a prospective or actual *importing country* of the *Veterinary Services* of a prospective or actual *exporting country*;
   - verification or re-verification of an evaluation in the course of a visit to the *exporting country* by the *importing country*;

- evaluation by third parties such as OIE experts or regional organisations.

Article 1.3.4.3.

Evaluation criteria for the organisational structure of the Veterinary Services

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

2. The organisational structure should also clearly set out the interface relationships of government Ministers and departmental Authorities with the Chief Veterinary Officer/Veterinary Director and the *Veterinary Services*. Formal relationships with statutory authorities and with industry organisations and associations should also be described. It is recognised that Services may be subject to changes in structure from time to time. Major changes should be notified to trading partners so that the effects of re-structuring may be assessed.

3. Organisational components of *Veterinary Services* which have responsibility for key functional capabilities should be identified. These capabilities include epidemiological surveillance, disease control, import controls, animal disease reporting systems, animal identification systems, traceability systems, animal movement control systems, communication of epidemiological information, training, inspection and certification. Laboratory and field systems and their organisational relationships should be described.

4. To reinforce the reliability and credibility of their services, the *Veterinary Services* may have set up quality systems that correspond with their fields of activity and to the nature and scale of activities that they carry out. Evaluation of such systems should be as objective as possible.

5. The *Veterinary Authority* alone speaks for the country as far as official international dialogue is concerned. This is also particularly important to cases where zoning and compartmentalisation are being applied. The responsibilities of the *Veterinary Authority* should be made clear in the process of evaluation of *Veterinary Services*.

6. The *Veterinary Authority* is defined in Chapter 1.1.1. of the *Terrestrial Code*. As some countries have some relevant roles of the *Veterinary Authority* vested in autonomous sub-national (state/provincial, municipal) government bodies, there is an important need to assess the role and function of these Services. Details of their roles, relationship (legal and administrative) to each other and to the *Veterinary Authority* should be available for evaluation. Annual reports, review findings and access to other information pertinent to the animal health activities of such bodies should also be available.

7. Similarly, where the *Veterinary Authority* has arrangements with other providers of relevant services such as universities, laboratories, information services, etc., these arrangements should also be described. For the purposes of evaluation, it is appropriate to expect that the organisational and functional standards that apply to the *Veterinary Authority* should also apply to the service providers.

Article 1.3.4.4.

Evaluation criteria for quality systems

1. The *Veterinary Services* should demonstrate a commitment to the quality of the processes and outputs of their services. Where services or components of services are delivered under a formal quality systems programme which is based on OIE recommended standards or, especially in the case of laboratory components of *Veterinary Services* other internationally recognised quality standards, the

Veterinary Services undergoing evaluation should make available evidence of accreditation, details of the documented quality processes and documented outcomes of all relevant audits undertaken.

2. Where the *Veterinary Services* undergoing evaluation make large use of formal quality systems in the delivery of their services, it is appropriate that greater emphasis be placed on the outcomes of evaluation of these quality systems than on the resource and infrastructural components of the services.

Article 1.3.4.5.

Evaluation criteria for human resources

1. The *Veterinary Services* should demonstrate that their human resource component includes an integral core of full-time civil service employees. This core must include *veterinarians*. It should also include administrative officials and *veterinary para-professionals*. The human resources may also include part-time and private sector *veterinarians* and *veterinary para-professionals*. It is essential that all the above categories of personnel be subject to legal disciplinary provisions. Data relating to the resource base of the *Veterinary Services* undergoing evaluation should be available.

2. In addition to raw quantitative data on this resource base, the functions of the various categories of personnel in the *Veterinary Services* should be described in detail. This is necessary for analysis and estimation of the appropriateness of the application of qualified skills to the tasks undertaken by the *Veterinary Services* and may be relevant, for example, to the roles of *veterinarians* and *veterinary para-professionals* in field services. In this case, the evaluation should provide assurances that disease monitoring is being conducted by a sufficient number of qualified, experienced field veterinarians who are directly involved in farm visits; there should not be an over-reliance on *veterinary para-professionals* for this task.

3. Analysis of these data can be used to estimate the potential of the *Veterinary Services* to have reliable knowledge of the state of animal health in the country and to support an optimal level of animal disease control programmes. A large population of private veterinarians would not provide the *Veterinary Services* with an effective epizootiological information base without legislative (e.g. compulsory reporting of notifiable diseases) and administrative (e.g. official animal health surveillance and reporting systems) mechanisms in place.

4. These data should be assessed in close conjunction with the other information described in this Chapter. For example, a large field staff (*veterinarians* and *veterinary para-professionals*) need fixed, mobile and budgetary resources for animal health activities in the livestock farming territory of the country. If deficiencies are evident, there would be reason to challenge the validity of epizootiological information.

Article 1.3.4.6.

Evaluation criteria for material resources

1. Financial

   Actual yearly budgetary information regarding the *Veterinary Services* should be available and should include the details set out in the model questionnaire outlined in Article 1.3.4.14. Information is required on conditions of service for veterinary staff (including salaries and incentives) and should provide a comparison with the private sector and perhaps with other professionals. Information should also be available on non-government sources of revenue available to *veterinarians* in their official responsibilities.

2. Administrative

   a) Accommodation

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

b) Communications

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

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

c) Transport systems

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

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

3. Technical

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

a) Cold chain for laboratory samples and veterinary medicines

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

b) Diagnostic laboratories

Analysis of the laboratory service component of *Veterinary Services*, which would include official governmental laboratories and other laboratories accredited by the *Veterinary Services* for specified purposes, is an essential element of the evaluation process. The quality of the veterinary

diagnostic laboratories of a country underpins the whole control and certification processes of the zoosanitary/sanitary status of exported *animals* and animal products, and therefore these laboratories should be subject to rigid quality assurance procedures and should use international quality assurance programmes (wherever available) for standardising test methodologies and testing proficiency. An example is the use of International Standard Sera for standardising reagents.

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

c) Research

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

Article 1.3.4.7.

Functional capabilities and legislative support

1. Animal health and veterinary public health

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

2. Export/import inspection

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

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

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

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

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

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

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

Article 1.3.4.8.

Animal health controls

1. Animal health status

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

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

2. Animal health control

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

3. National animal disease reporting systems

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

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

Article 1.3.4.9.

Veterinary public health controls

1. Food hygiene

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

2. Zoonoses

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

3. Chemical residue testing programmes

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

4. Veterinary medicines

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

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

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

5. Integration between animal health controls and veterinary public health

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

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

Article 1.3.4.10.

Performance assessment and audit programmes

1. Strategic plans

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

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

2. Performance assessment

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

3. Compliance

Matters which can compromise compliance and adversely affect a favourable evaluation include instances of inaccurate or misleading official certification, evidence of fraud, corruption, or

interference by higher political levels in international veterinary certification, and lack of resources and poor infrastructure.

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

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

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

4. Veterinary Services administration

a) Annual reports

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

b) Reports of government review bodies

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

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

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

d) In-service training and development programme for staff

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

e) Publications

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

f) Formal linkages with sources of independent scientific expertise

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

g) Trade performance history

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

Article 1.3.4.11.

Participation in OIE activities

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

Article 1.3.4.12.

Evaluation of veterinary statutory body

1. Scope

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

a) objectives and functions;

b) legislative basis, autonomy and functional capacity;

c) the composition and representation of the body's membership;

d) accountability and transparency of decision-making;

e) sources and management of funding;

f) administration of training programmes and continuing professional development for *veterinarians* and *veterinary para-professionals*.

2. Evaluation of objectives and functions

The *veterinary statutory body* should define its policy and objectives, including detailed descriptions of its powers and functions such as:

a) to regulate *veterinarians* and *veterinary para-professionals* through licensing and/or registration of such persons;

b) to determine the minimum standards of education (initial and continuing) required for degrees, diplomas and certificates entitling the holders thereof to be registered as *veterinarians* and *veterinary para-professionals*;

c) to determine the standards of professional conduct of *veterinarians* and *veterinary para-professionals* and to ensure these standards are met.

3. Evaluation of legislative basis, autonomy and functional capacity

The *veterinary statutory body* should be able to demonstrate that it has the capacity, supported by appropriate legislation, to exercise and enforce control over all *veterinarians* and *veterinary para-professionals*. These controls should include, where appropriate, compulsory licensing and registration, minimum standards of education (initial and continuing) for the recognition of degrees, diplomas and certificates, setting standards of professional conduct and exercising control and the application of disciplinary procedures.

The *veterinary statutory body* should be able to demonstrate autonomy from undue political and commercial interests.

Where applicable, regional agreements for the recognition of degrees, diplomas and certificates for *veterinarians* and *veterinary para-professionals* should be demonstrated.

4. Evaluation of membership representation

Detailed descriptions should be available in respect of the membership of the *veterinary statutory body* and the method and duration of appointment of members. Such information includes:

a) veterinarians designated by the *Veterinary Authority*, such as the Chief Veterinary Officer;

b) veterinarians elected by members registered by the *veterinary statutory body*;

c) veterinarians designated or nominated by the veterinary association(s);

d) representative(s) of veterinary para-professions;

e) representative(s) of veterinary academia;

f) representative(s) of other stakeholders from the private sector;

g) election procedures and duration of appointment;

h) qualification requirements for members.

5. Evaluation of accountability and transparency of decision-making

Detailed information should be available on disciplinary procedures regarding the conducting of enquiries into professional misconduct, transparency of decision-making, publication of findings, sentences and mechanisms for appeal.

Additional information regarding the publication at regular intervals of activity reports, lists of registered or licensed persons including deletions and additions should also be taken into consideration.

6. Evaluation of financial sources and financial management

Information regarding income and expenditure, including fee structure(s) for the licensing/registration of persons should be available.

7. Evaluation of training programmes and programmes for continuing professional development, for veterinarians and veterinary para-professionals

Descriptive summary of continuing professional development, training and education programmes should be provided, including descriptions of content, duration and participants; documented details of quality manuals and standards relating to Good Veterinary Practice should be provided.

Article 1.3.4.13.

1. The *Veterinary Services* of a country may undertake self-evaluation against the above criteria for such purposes as national interest, improvement of internal efficiency or export trade facilitation. The way in which the results of self-evaluation are used or distributed is a matter for the country concerned.

2. A prospective *importing country* may undertake an evaluation of the *Veterinary Services* of an *exporting country* as part of a *risk analysis* process, which is necessary to determine the sanitary or zoosanitary measures which the country will use to protect human or animal life or health from *disease* or pest threats posed by imports. Periodic evaluation reviews are also valid following the commencement of trade.

3. In the case of evaluation for the purposes of *international trade*, the authorities of an *importing country* should use the principles elaborated above as the basis for the evaluation and should attempt to acquire information according to the model questionnaire outlined in Article 1.3.4.14. The *Veterinary Services* of the *importing country* are responsible for the analysis of details and for determining the outcome of the evaluation after taking into account all the relevant information. The relative ranking of importance ascribed, in the evaluation, to the criteria described in this Chapter will necessarily vary according to case-by-case circumstances. This ranking should be established in an objective and justifiable way. Analysis of the information obtained in the course of an evaluation study must be performed in as objective a manner as possible. The validity of the information should be established and reasonableness should be employed in its application. The assessing country must be willing to defend any position taken on the basis of this type of information, if challenged by the other party.

Article 1.3.4.14.

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

1. Organisation and structure of Veterinary Services

   a) National Veterinary Authority

      Organisational chart including numbers, positions and numbers of vacancies.

   b) Sub-national components of the Veterinary Authority

      Organisational charts including numbers, positions and number of vacancies.

   c) Other providers of veterinary services

      Description of any linkage with other providers of veterinary services.

2. National information on human resources

   a) Veterinarians

      i) Total numbers of *veterinarians* registered/licensed by the *Veterinary statutory body* of the country

      ii) Numbers of:

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

iii) Animal health:

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

- full time government *veterinarians*: national and sub-national;
- part time government *veterinarians*: national and sub-national;
- other *veterinarians*.

iv) Veterinary public health:

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

- full time government *veterinarians*: national and sub-national;
- part time government *veterinarians*: national and sub-national;
- other *veterinarians*.

v) Numbers of *veterinarians* relative to certain national indices:

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

vi) Veterinary education:

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

vii) Veterinary professional associations.

b) Graduate personnel (non-veterinary)

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

c) Veterinary para-professionals employed by the Veterinary Services

i) Animal health:

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

ii) Veterinary public health:

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

d) Support personnel

Numbers directly available to *Veterinary Services* per sector (administration, communication, transport).

e) Descriptive summary of the functions of the various categories of staff mentioned above

f) Veterinary, *veterinary para-professionals*, livestock owner, farmer and other relevant associations

g) Additional information and/or comments.

3. Financial management information

a) Total budgetary allocations to the *Veterinary Authority* for the current and past two fiscal years:

i) for the national *Veterinary Authority*;

ii) for each of any sub-national components of the *Veterinary Authority*;

iii) for other relevant government-funded institutions.

b) Sources of the budgetary allocations and amount:

i) government budget;

ii) sub-national authorities;

iii) taxes and fines;

iv) grants;

v) private services.

c) Proportional allocations of the amounts in a) above for operational activities and for the programme components of *Veterinary Services*.

d) Total allocation proportionate of national public sector budget. *[This data may be necessary for comparative assessment with other countries which should take into account the contexts of the importance of the livestock sector to the national economy and of the animal health status of the country.]*

e) Actual and proportional contribution of animal production to gross domestic product.

4. Administration details

a) Accommodation

Summary of the numbers and distribution of official administrative centres of the *Veterinary Services* (national and sub-national) in the country.

b) Communications

Summary of the forms of communication systems available to the *Veterinary Services* on a nation-wide and local area bases.

c) Transport

i) Itemised numbers of types of functional transport available on a full-time basis for the *Veterinary Services*. In addition provide details of transport means available part-time.

ii) Details of annual funds available for maintenance and replacement of motor vehicles.

5. Laboratory services

a) Diagnostic laboratories (laboratories engaged primarily in diagnosis)

i) Descriptive summary of the organisational structure and role of the government veterinary laboratory service in particular its relevance to the field *Veterinary Services*.

ii) Numbers of veterinary diagnostic laboratories operating in the country:

- government operated laboratories;

- private laboratories accredited by government for the purposes of supporting official or officially-endorsed animal health control or public health testing and monitoring programmes and import/export testing.

iii) Descriptive summary of accreditation procedures and standards for private laboratories.

iv) Human and financial resources allocated to the government veterinary laboratories, including staff numbers, graduate and post-graduate qualifications and opportunities for further training.

v) List of diagnostic methodologies available against major diseases of farm livestock (including poultry).

vi) Details of collaboration with external laboratories including international reference laboratories and details on numbers of samples submitted.

vii) Details of quality control and assessment (or validation) programmes operating within the veterinary laboratory service.

viii) Recent published reports of the official veterinary laboratory service which should include details of specimens received and foreign animal disease investigations made.

ix) Details of procedures for storage and retrieval of information on specimen submission and results.

x) Reports of independent reviews of the laboratory service conducted by government or private organisations (if available).

xi) Strategic and operational plans for the official veterinary laboratory service (if available).

b) Research laboratories (laboratories engaged primarily in research)

i) Numbers of veterinary research laboratories operating in the country:

- government operated laboratories;

- private laboratories involved in full time research directly related to animal health and veterinary public health matters involving production animal species.

ii) Summary of human and financial resources allocated by government to veterinary research.

iii) Published programmes of future government sponsored veterinary research.

iv) Annual reports of the government research laboratories.

6. Functional capabilities and legislative support

a) Animal health and veterinary public health

i) Assessment of the adequacy and implementation of relevant legislation (national or sub-national) concerning the following:

- animal and veterinary public health controls at national frontiers;

- control of endemic animal diseases, including zoonoses;

- emergency powers for control of exotic disease outbreaks, including zoonoses;

- inspection and registration of facilities;

- veterinary public health controls of the production, processing, storage and marketing of meat for domestic consumption;

- veterinary public health controls of the production, processing, storage and marketing of fish, dairy products and other foods of animal origin for domestic consumption;

- registration and use of veterinary pharmaceutical products including vaccines.

ii) Assessment of ability of *Veterinary Services* to enforce legislation.

b) Export/import inspection

i) Assessment of the adequacy and implementation of relevant national legislation concerning:

- veterinary public health controls of the production, processing, storage and transportation of meat for export;

- veterinary public health controls of production, processing, storage and marketing of fish, dairy products and other foods of animal origin for export;

- animal health and veterinary public health controls of the export and import of *animals*, animal genetic material, animal products, animal feedstuffs and other products subject to veterinary inspection;

- animal health controls of the importation, use and bio-containment of organisms which are aetiological agents of animal diseases, and of pathological material;

- animal health controls of importation of veterinary biological products including vaccines;

- administrative powers available to *Veterinary Services* for inspection and registration of facilities for veterinary control purposes (if not included under other legislation mentioned above);

- documentation and compliance.

ii) Assessment of ability of *Veterinary Services* to enforce legislation.

7. Animal health and veterinary public health controls

a) Animal health

i) Description of and sample reference data from any national animal disease reporting system controlled and operated or coordinated by the *Veterinary Services*.

ii) Description of and sample reference data from other national animal disease reporting systems controlled and operated by other organisations which make data and results available to *Veterinary Services*.

iii) Description and relevant data of current official control programmes including:

- epidemiological surveillance or monitoring programmes;

- officially approved industry administered control or eradication programmes for specific diseases.

iv) Description and relevant details of animal disease emergency preparedness and response plans.

v) Recent history of animal disease status:

- animal diseases eradicated nationally or from defined sub-national zones in the last ten years;

- animal diseases of which the prevalence has been controlled to a low level in the last ten years;

- animal diseases introduced to the country or to previously free sub national regions in the last ten years;

- emerging diseases in the last ten years;

- animal diseases of which the prevalence has increased in the last ten years.

b) Veterinary public health

i) Food hygiene

- Annual national slaughter statistics for the past three years according to official data by species of animals (bovine, ovine, porcine, caprine, poultry, farmed game, wild game, equine, other).

- Estimate of total annual slaughterings which occur but are not recorded under official statistics.

- Proportion of total national slaughter which occurs in registered export establishments, by category of animal.

- Proportion of total national slaughter which occurs under veterinary control, by category of animal.

- Numbers of commercial fresh meat establishments in the country which are registered for export by the *Veterinary Authority*:

  - slaughterhouses (indicate species of *animals*);

  - cutting/packing plants (indicate meat type);

  - meat processing establishments (indicate meat type);

  - cold stores.

- Numbers of commercial fresh meat establishments in the country approved by other *importing countries* which operate international assessment inspection programmes associated with approval procedures.

- Numbers of commercial fresh meat establishments under direct public health control of the *Veterinary Services* (including details of category and numbers of inspection staff associated with these premises).

- Description of the veterinary public health programme related to production and processing of animal products for human consumption (including fresh meat, poultry meat, meat products, game meat, dairy products, fish, fishery products, molluscs and crustaceans and other foods of animal origin) especially including details applying to exports of these *commodities*.

- Descriptive summary of the roles and relationships of other official organisations in public health programmes for the products listed above if the *Veterinary Authority* does not have responsibility for those programmes which apply to national production destined to domestic consumption and/or exports of the *commodities* concerned.

ii) Zoonoses

- Descriptive summary of the numbers and functions of staff of the *Veterinary Authority* involved primarily with monitoring and control of zoonotic diseases.

- Descriptive summary of the role and relationships of other official organisations involved in monitoring and control of zoonoses to be provided if the *Veterinary Authority* does not have these responsibilities.

iii) Chemical residue testing programmes

- Descriptive summary of national surveillance and monitoring programmes for environmental and chemical residues and contaminants applied to animal-derived foodstuffs, *animals* and animal feedstuffs.

- Role and function in these programmes of the *Veterinary Authority* and other *Veterinary Services* to be described in summary form.

- Descriptive summary of the analytical methodologies used and their consistency with internationally recognised standards.

iv) Veterinary medicines

- Descriptive summary of the administrative and technical controls involving registration, supply and use of veterinary pharmaceutical products especially including biological products. This summary should include a focus on veterinary public health considerations relating to the use of these products in food-producing *animals*.

- Role and function in these programmes of the *Veterinary Authority* and other *Veterinary Services* to be described in summary form.

8. Quality systems

a) Accreditation

Details and evidence of any current, formal accreditation by external agencies of the *Veterinary Services* of any components thereof.

b) Quality manuals

Documented details of the quality manuals and standards which describe the accredited quality systems of the *Veterinary Services*.

c) Audit

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

9. Performance assessment and audit programmes

a) Strategic plans and review

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

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

b) Compliance

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

c) Annual reports of the Veterinary Authority

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

d) Other reports

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

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

e) Training

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

ii) Summary descriptions of training courses and duration.

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

f) Publications

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

g) Sources of independent scientific expertise

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

10. Membership of the OIE

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

11. Other assessment criteria

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— text deleted

Annex VIII

CHAPTER 1.3.5.

ZONING AND COMPARTMENTALISATION

Community position:

The Community can support the proposed changes, but reiterates one of its former comments.

Furthermore, the chapter should reflect the work of the ad hoc groups on wildlife disease surveillance and epidemiology to indicate whenever the domestic and wild population can be considered separately or not, and more work still need to be done in this respect.

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 in establishing and maintaining a *subpopulation* with a distinct health status within its territory. *Subpopulations* may be separated by natural or artificial geographical barriers or, in certain situations, by the application of appropriate management practices.

Zoning and compartmentalisation are procedures implemented by a country under the provisions of this chapter with a view to defining *subpopulations* of distinct health status within its territory for the purpose of *disease* control and/or *international trade*. While zoning applies to an animal *subpopulation* defined primarily on a geographical basis (using natural, artificial or legal boundaries), compartmentalisation applies to an animal *subpopulation* defined primarily by management and husbandry practices related to biosecurity. In practice, spatial considerations and good management including *biosecurity plans* play important roles in the application of both concepts.

A particular application of the concept of zoning is the establishment of a *containment zone*. In the event of a limited *outbreak* of a specified *disease* within an otherwise free country or *zone*, a single *containment zone*, which includes all *cases*, can be established for the purpose of minimizing the impact on the entire country or *zone*.

This chapter is to assist OIE Members wishing to establish and maintain different *subpopulations* within their territory using the principles of compartmentalisation and zoning. These principles should be applied in accordance with the measures recommended in the relevant *disease* chapter(s). This chapter also outlines a process through which trading partners may recognise such *subpopulations*. 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.

As well as contributing to the safety of *international trade*, zoning and compartmentalisation may assist *disease* control or eradication within a Member's territory ~~Countries~~. Zoning may encourage the more

efficient use of resources within certain parts of a country and compartmentalisation may allow 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*, the use of compartmentalization may allow a Member 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 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*, Members 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 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* should be able to explain to the *Veterinary Services* of an *importing country* the basis for claiming ~~its claim of~~ a distinct *animal health status* for the given *zone* or *compartment* ~~in such terms~~ under consideration.

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.

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 with the *Veterinary Authority*.

In the context of maintaining the animal health status of a population, references to 'import', 'importation' and 'imported animals/products' found in the *Terrestrial Code* apply both to importation into a country and to the movement of animals and their products into *zones* and *compartments*. Such movements should be the subject of appropriate measures to preserve the health status of the *zone/compartment*.

The *exporting country* should be able to demonstrate, through detailed documentation provided to the *importing country*, that it has implemented the 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 Authority* 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 compartmentalisation, and the arrangements should be developed through cooperation of industry and *Veterinary Services*.

Industry's responsibilities 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 provide movement certification, and carry out documented periodic inspections of facilities, biosecurity measures, records and surveillance procedures. *Veterinary Services* should conduct or audit surveillance, reporting and laboratory diagnostic examinations.

Article 1.3.5.3.

Principles for defining a zone or compartment, including containment zone

In conjunction with the above considerations, the following principles should apply when Members define a *zone* or a *compartment*.

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

2. Establishment of a *containment zone* should be based on a rapid response including appropriate standstill of movement of animals and *commodities* upon notification of suspicion of the specified *disease* and the demonstration that the *outbreak*~~s~~ ~~is~~ are contained within this *zone* through epidemiological investigation (trace-back, trace-forward) after confirmation of *infection*. The primary *outbreak* and likely source of the *outbreak* should be identified and all *cases* shown to be epidemiologically linked. For the effective establishment of a *containment zone*, it is necessary to demonstrate that there have been no new *cases* in the *containment zone* within a minimum of two *incubation periods* from the last detected *case*.

   A *stamping-out policy* or another effective control strategy aimed at eradicating the *disease* should be applied and the susceptible animal population within the *containment zones* should be clearly identifiable as belonging to the *containment zone*. Increased passive and targeted surveillance in accordance with Appendix 3.8.7. in the rest of the country or *zone* should be carried out and has not detected any evidence of *infection*. Measures consistent with the *disease* specific chapter should be in place 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*~~, should be 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, once the *containment zone* is clearly established, irrespective of the provisions of the *disease* specific chapter.

   The recovery of the free status of the *containment zone* should follow the provisions of the *disease* specific chapter.

~~2~~3. The factors defining a *compartment* should be established by the *Veterinary Authority* on the basis of relevant criteria such as management and husbandry practices related to biosecurity, and made public through official channels.

~~3~~4. Animals and herds belonging to such *subpopulations* need to be 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 Authority* should document in detail the measures taken to ensure the identification of the *subpopulation* and the establishment and maintenance of its *animal health status* through a *biosecurity plan*. The 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 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~~5. Relevant 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. Relevant animal movements into and out of the *zone* or *compartment* should be well documented, controlled and supervised. The existence of a valid animal identification system is a prerequisite to assess the integrity of the *zone* or *compartment*.

Community comment :

The Community reiterates its former comment: in order to better stress the importance of documentation in the traceability the above paragraph should be amended as follows:

45. Relevant 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. Relevant animal movements into and out of the *zone* or *compartment* should be well documented, controlled and supervised. The existence of a valid animal identification system is a prerequisite to assess the integrity of the *zone* or *compartment*.

56. For a *compartment*, the *biosecurity plan* should describe the partnership between the relevant industry and the *Veterinary Authority*, 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 of relevant personnel 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.

Article 1.3.5.4.

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

There is no single sequence of steps which should be followed in 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 the countries and at 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.

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

   c) The *exporting country* provides:

      i) the above information to the *importing country*, with an explanation of why the area can be treated as an epidemiologically separate *zone* for *international trade* purposes;

      ii) access to enable the procedures or systems that establish the *zone* to be examined and

evaluated upon request by the *importing country*.

d) The *importing country* determines whether it 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 its determination and the underlying reasons, within a reasonable period of time, being:

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 recognition 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.)

g) The *Veterinary Authorities* of the *importing* and *exporting countries* should enter into a formal agreement recognizing the *zone*.

2. For compartmentalisation

a) Based on discussions with the relevant industry, the *exporting country* identifies within its territory a *compartment* ~~of~~ comprising an *animal subpopulation* contained in one or more *establishments* or other premises ~~which operates~~ operating under common management practices related to biosecurity. The *compartment* ~~and which~~ contains an identifiable animal *subpopulation* with a distinct health status with respect to ~~a~~ specific *disease(s)/ specific diseases,* ~~t~~The *exporting country* describes how this status is maintained through a partnership between the relevant industry and the *Veterinary Authority* of the *exporting country*.

b) The *exporting country* examines the *compartment*'s *biosecurity plan* and confirms through an audit that:

i) the *compartment* is epidemiologically closed throughout its routine operating procedures as a result of effective implementation of its *biosecurity plan*; and

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

c) The *exporting country* describes the *compartment*, in accordance with the recommendations in the *Terrestrial Code*.

d) The *exporting country* provides:

i) the above information to the *importing country*, with an explanation of why such ~~an~~ a ~~*establishment(s)*~~ *subpopulation* can be treated as an epidemiologically separate *compartment* for *international trade* purposes; and

ii) access to enable the procedures or systems that establish the *compartment* to be examined and evaluated upon request by the *importing country*.

e) The *importing country* determines whether it accepts such ~~establishment(s)~~ a ***subpopulation*** 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 its determination and the underlying reasons, within a reasonable period of time, being:

i) recognition of the *compartment*; or

ii) request for further information; or

iii) rejection of such a ~~*establishment(s)*~~ ***subpopulation*** as a *compartment* for international trade purposes.

g) An attempt should be made to resolve any differences over recognition 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.).

h) The *Veterinary Authorities* of the *importing* and *exporting countries* should enter into a formal agreement recognizing the *compartment*.

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Annex VIII (contd)

APPENDIX 3.x.x.

GENERAL GUIDELINES ~~FOR~~ ON THE APPLICATION OF COMPARTMENTALISATION

Community position:

The Community could support the proposed Appendix, but a reference to HACCP should be made in article 3 and two other very important comments on article 3.x.x.7 should be taken into account:

- firstly it should be made clearer that what is suspended in case of breach in the biosecurity system is the status of the compartment and the certification as a free compartment; the present wording can imply that a suspended compartment cannot trade at all, which is not the case;

- secondly, it is important to consider the case of an outbreak in the close vicinity of the compartment: then an evaluation should be made by the competent autority in order to verify that the biosecurity measures are sufficient and in place; only after a favourable evaluation can the certification take place.

The Community wishes the OIE to continue its work on the guidelines in order to have them in line with the upcoming field experience of compartmentalisation. The Community is ready to participate in this work.

Article 3.x.x.1.

Introduction and objectives

The guidelines in this ~~appendix~~ Appendix provide a structured framework for the application and recognition of *compartments* within countries or *zones*, based on the provisions of Chapter 1.3.5. with the objective to facilitate trade in *animals* and products of animal origin and as a tool for *disease* management.

Establishing and maintaining a disease-free status for an entire country may be difficult, especially in the case of *diseases* that can easily cross international boundaries. For many *diseases*, OIE Members ~~Countries~~ have traditionally applied the concept of zoning to establish and maintain an animal *subpopulation* with a different animal health status within national boundaries.

Chapter 1.1.1. defines a *compartment* as "~~one~~ an *animal subpopulation* contained in one or more *establishments* under a common biosecurity management system ~~containing an animal *subpopulation*~~ with a distinct health status with respect to a specific *disease* or specific *diseases* for which required surveillance, control and biosecurity measures have been applied for the purpose of *international trade*."

The essential difference between zoning and compartmentalisation is that the recognition of *zones* is based on geographical boundaries whereas the recognition of *compartments* is based of management practices and biosecurity. However, spatial considerations and good management practices play a role in the application of both concepts.

Compartmentalisation is not a new concept for *Veterinary Services*; in fact, it has been applied for a long time in many *disease* control programmes that are based on the concept of *disease*-free herds/flocks.

The fundamental requirement for compartmentalisation is the implementation and documentation of management and biosecurity measures to create a functional separation of ~~*establishments*~~ *subpopulations* ~~and allows the *Veterinary Services* to make a clear epidemiological differentiation to be made between *subpopulations* of differing health status~~.

For example, a ~~confinement operation for a poultry or swine~~ an animal production operation in an infected country or *zone* might have biosecurity measures and management practices that result in negligible risk from *diseases* or agents. The concept of a *compartment* extends the application of a 'risk boundary' beyond that of a geographical interface and considers all epidemiological factors that can help to create an effective *disease*-specific separation between *subpopulations*.

In *disease*-free countries or *zones*, *compartments* preferably should be defined prior to the occurrence of a *disease outbreak*. In the event of an *outbreak* or in ~~endemic~~ infected countries or *zones*, compartmentalisation may be used to facilitate trade.

For the purpose of *international trade*, *compartments* must be under the ~~direct control and~~ responsibility of the *Veterinary ~~Administration~~ Authority* in the country. For the purposes of this ~~appendix~~ Appendix, compliance by the Members with Chapters 1.1.2. and 1.3.3. ~~are~~ is an essential prerequisite.

Article 3.x.x.2.

Principles for defining a compartment

A *compartment* may be established with respect of a specific *disease* or *diseases*. A *compartment* must be clearly defined, indicating the location of all its components including *establishments*, as well as related functional units (such as feed mills, *slaughterhouses*, rendering plants, etc.), their interrelationships and their contribution to an epidemiological separation between the animals in a *compartment* and *subpopulations* with a different health status. The definition of *compartment* may revolve around *disease* specific epidemiological factors, animal production systems, biosecurity practices infrastructural factors and surveillance. ~~and similar functional demarcations~~.

Article 3.x.x.3.

Separation of a compartment from potential sources of infection

The management of a *compartment* must provide to the *Veterinary ~~Administration~~ Authority* documented evidence on the following:

a) Physical or spatial factors that affect the status of biosecurity in a compartment

While a *compartment* is primarily based on management and biosecurity measures, a review of geographical factors is needed to ensure that the functional boundary provides adequate separation of a *compartment* from adjacent animal populations with a different health status. The following factors should be taken into consideration in conjunction with biosecurity measures and, in some instances, may alter the degree of confidence achieved by general biosecurity and surveillance measures:

i) *disease* status in adjacent areas and in areas epidemiologically linked to the *compartment*;

ii) location, *disease* status and biosecurity of the nearest *epidemiological units* or other epidemiologically relevant premises. Consideration should be given to the distance and physical separation from:

- flocks or herds with a different health status in close proximity to the *compartment*, including wildlife and their migratory routes;

- *slaughterhouses*, rendering plants or feed mills;

- markets, fairs, agricultural shows, sporting events, zoos, circuses and other points of animal concentration.

b) Infrastructural factors

Structural aspects of the *establishments* within a *compartment* contribute to the effectiveness of its biosecurity. Consideration should be given to:

i) fencing or other effective means of physical separation;

ii) facilities for people entry including access control, changing area and showers;

iii) *vehicle* access including washing and *disinfection* procedures;

iv) *unloading* and *loading* facilities;

v) isolation facilities for introduced animals;

vi) facilities for the introduction of material and equipment;

vii) infrastructure to store feed and veterinary products;

viii) disposal of carcasses, manure and waste;

~~vii~~ix)water supply;

ix) ~~physical~~ measures to prevent exposure to living mechanical or biological vectors such as insects, rodents and wild birds;

x) air supply;

xi) feed supply/source.

More detailed recommendations for certain *establishments* can be found in Sections 3.2., 3.3. and 3.4. of the *Terrestrial Code*.

c) Biosecurity plan

The integrity of the *compartment* relies on effective biosecurity. The management of the *compartment* should develop, implement and monitor a comprehensive *biosecurity plan*.

The *biosecurity plan* should describe in detail:

i) potential pathways for introduction and spread into the *compartment* of the agents for which the *compartment* was defined, including animal movements, rodents, fauna, aerosols, arthropods, *vehicles*, people, biological products, equipment, fomites, feed, waterways, drainage or other means. Consideration should also be given to the survivability of the agent in the environment;

ii) the critical control points for each pathway;

iii) measures to mitigate exposure for each critical control point;

iv) standard operating procedures including:

- implementation, maintenance, monitoring of the measures;

- application of corrective actions;

- verification of the process;
- record keeping;

v) contingency plan in the event of a change in the level of exposure;

vi) reporting procedures to the *Veterinary ~~Administration~~ Authority*;

vii) the programme for educating and training workers to ensure that all persons involved are knowledgeable and informed on biosecurity principles and practices;

viii) the surveillance programme in place.

In any case, sufficient evidence should be submitted to assess the efficacy of the biosecurity plan in accordance with the level of *risk* for each identified pathway. The biosecurity risk of all operations of the *compartment* should be regularly re-assessed and documented at least on a yearly basis. Based on the outcome of the assessment, concrete and documented mitigation steps should be taken to reduce the likelihood of introduction of the *disease* agent into the *compartment*.

Community comment:

The Community reiterates its former comment: a reference to HACCP should be included in the above paragraph, which should read:

In any case, sufficient evidence should be submitted to assess the efficacy of the biosecurity plan in accordance with the level of *risk* for each identified pathway. This evidence shall be structured in line with the international recognised guidance provided for the application of the Hazard Analysis and Critical Control Point (HACCP) system. The biosecurity risk of all operations of the *compartment* should be regularly re-assessed and documented at least on a yearly basis. Based on the outcome of the assessment, concrete and documented mitigation steps should be taken to reduce the likelihood of introduction of the *disease* agent into the *compartment*.

NB : HACCP is mentioned in the Code once, under appendix 3.9.1.3 (antimicrobian resistance).

d) Traceability system

A prerequisite for assessing the integrity of a *compartment* is the existence of a valid traceability system. All animals within a *compartment* should be individually identified and registered in such a way that their history and movements can be documented and audited. In cases where individual identification may not be feasible, such as broilers and day-old chicks, the *Veterinary ~~Administration~~ Authority* should provide sufficient assurance of traceability.

All animal movements into ~~and out of~~ and out of the *compartment* should be ~~certified by the *Veterinary Administration Authority* and~~ recorded at the *compartment* level, and when needed, based on a *risk assessment*, certified by the *Veterinary Authority*. Movements within the *compartment* need not be certified but should be recorded at the *compartment* level.

Article 3.x.x.4.

Documentation ~~of factors critical to the definition of a compartment~~

Documentation must provide clear evidence that the biosecurity, surveillance, traceability and management practices defined for a *compartment* are effectively and consistently applied. In addition to animal movement information, the necessary documentation should include herd or flock production records, feed sources, laboratory tests, birth and death records, the visitor logbook, morbidity history,

medication and vaccination records, *biosecurity plans*, training documentation and any other criteria necessary for the evaluation of *disease* exclusion.

The historical status of a *compartment* for the *disease(s)* for which it was defined should be documented and demonstrate compliance with the requirements for freedom in the relevant *Terrestrial Code* chapter.

In addition, a *compartment* seeking recognition should submit to the *Veterinary ~~Administration~~ Authority* a baseline animal health report indicating the presence or absence of OIE *listed diseases*. This report should be regularly updated to reflect the current animal health situation of the *compartment*.

Vaccination records including the type of vaccine and frequency of administration must be available to enable interpretation of surveillance data.

The time period for which all records should be kept may vary according to the species and *disease(s)* for which the *compartment* was defined.

All relevant information must be recorded in a transparent manner and be easily accessible so as to be auditable by the *Veterinary ~~Administration~~ Authority*.

Article 3.x.x.5.

Surveillance for the agent or disease

The surveillance system should comply with Appendix 3.8.1. on General Guidelines for Surveillance and the specific guidelines for surveillance for the *disease(s)* for which the *compartment* was defined, if available.

If there is an increased risk of exposure to the agent for which the *compartment* has been defined, the detection level of the internal and external surveillance should be reviewed and where necessary raised. ~~and the level of biosecurity should be raised.~~ At the same time, biosecurity measures in place should be reassessed and increased if necessary.

a) Internal surveillance

Surveillance should involve the collection and analysis of *disease/infection* data ~~such~~ so that the *Veterinary ~~Administration~~ Authority* can certify that the animal~~s~~ *subpopulation* contained in all the *establishments* comply with the defined status of that *compartment*. A surveillance system that is able to ensure early detection in the event that the agent enters a~~n~~ *~~establishment~~ subpopulation* is essential. Depending on the *disease(s)* for which the *compartment* was defined, different surveillance strategies may be applied to achieve the desired confidence in *disease* freedom.

b) External surveillance

The biosecurity measures applied in a *compartment* must be appropriate to the level of exposure of the *compartment*. External surveillance will help identify a significant change in the level of exposure for the identified pathways for *disease* introduction into the *compartment*.

An appropriate combination of active and passive surveillance is necessary to achieve the goals described above. Based on the recommendations of ~~appendix~~ Appendix 3.8.1., targeted surveillance based on an assessment of risk factors may be the most efficient surveillance approach. Targeted surveillance should in particular include *epidemiological units* in close proximity to the *compartment* or those that have a potential epidemiological link with it.

Article 3.x.x.6.

Diagnostic capabilities and procedures

Officially-designated laboratory facilities complying with the OIE standards for quality assurance, as defined in Chapter I.1.2. of the *Terrestrial Manual*, should be available for sample testing. All laboratory

tests and procedures should comply with the recommendations of the *Terrestrial Manual* for the specific *disease*. Each laboratory that conducts testing should have systematic procedures in place for rapid reporting of *disease* results to the *Veterinary ~~Administration~~ Authority*. Where appropriate, results should be confirmed by an OIE Reference Laboratory.

Article 3.x.x.7.

Emergency response and notification

Early detection, diagnosis and notification of *disease* are critical to minimi~~s~~ze the consequences of *outbreaks*.

In the event of suspicion of occurrence of the *disease* for which the *compartment* was defined, export certification should be immediately suspended. If confirmed, the status of the *compartment* should be immediately revoked and *importing countries* should be notified following the provisions of Chapter 1.1.2.

In case of ~~a suspicion or~~ an occurrence of any ~~OIE *listed disease*~~ infectious *disease* not present according to the baseline animal health report of the *compartment* referred to in ~~article~~ Article 3.x.x.4., the management of the *compartment* should notify the *Veterinary ~~Administration~~ Authority*, and initiate a review ~~as this may~~ to determine whether there has been ~~indicate~~ a breach in the biosecurity measures. ~~The *Veterinary Administration Authority* should immediately suspend export certification and should notify the importing countries re-assess the biosecurity of the *compartment* and I~~if a significant breach is detected, export certification should be suspended. Trade may only be resumed after the *compartment* has adopted the necessary measures to re-establish the biosecurity level and the *Veterinary ~~Administration~~ Authority* re-approves the *compartment* for trade.

~~In the event of suspicion of occurrence of the *disease* for which the *compartment* was defined, export certification should be immediately suspended. If confirmed, the status of the *compartment* should be immediately revoked and *importing countries* should be notified following the provisions of Chapter 1.1.2.~~

~~Positive findings of the disease(s) for which the compartment has been defined, should be immediately notified following the provisions of Chapter 1.1.2.~~

Community comments:

1. The last two sentences should read:

If a significant breach is detected (even if no infectious disease has occurred but the audit has detected the breach), export certification as "approved *compartment*" should be suspended and the general conditions, especially concerning the regionalisation and/or other relevant risk mitigation measures, should apply to trade from the compartment. ~~Trade~~ Certification as "approved free *compartment*" may only be resumed after the *compartment* has adopted the necessary measures to re-establish the biosecurity level and the *Veterinary Authority* re-approves the *compartment* ~~for trade~~.

Rationale: The above paragraph should be amended so as not to impose more stringent trade conditions to a compartment than to a normal population. With the present wording, even if there is no contagious disease declared or even suspected, but if the compartment is only not certifiable as "free" because of a major breach in the biosecurity measures, it cannot trade. This is absurd, as it should still be able to trade according to the normal general animal health conditions rather than certify as an approved compartment. We should continuously bear in mind that compartmentalisation is simply a way of having a status of a certain subpopulation higher than the rest of the population, but the fact that the compartment does not function properly does not make that subpopulation's status lower than the rest's… A compartment is not approved "for trade", but is approved "free from a specified disease". If not, there is very little interest in compartmentalisation.

2. Furthermore, in order to deal with all possible situations, of which an outbreak in the close vicinity of the compartment is one, the Community proposes the following paragraph is added:

"In the event of a compartment or one of the establishments of a compartment, coming within an infected zone established as a result of an outbreak of the disease for which the compartment was defined, the Veterinary Authority should reevaluate without delay the biosecurity status of the compartment to ensure that its integrity has been maintained. During this period export certification should be temporarily suspended".

Article 3.x.x.8.

Supervision and control of a compartment

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 OIE *Terrestrial Code*, to provide confidence in the integrity of the *compartment*.

The *Veterinary ~~Administration~~ Authority* has the final authority in granting, suspending and revoking the status of a *compartment*. The *Veterinary ~~Administration~~ Authority* should continuously supervise compliance with all the requirements critical to the maintenance of the *compartment* status described in this ~~appendix~~ Appendix and ensure that all the information is readily accessible to the *importing countries*. Any significant change should be notified to the *importing country.*

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Annex IX

CHAPTER 2.2.5.

RABIES

Community position:

The Community can support the proposed changes.

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 an Australian or 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 Authorities* 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 Authorities* 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 Authorities* 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 identified by a permanent mark (such as a microchip) and their identification number shall be stated in the certificate; and

23. 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 glycoprotein; and ~~were identified by a permanent mark (including a microchip) before the vaccination (their identification number shall be stated in the certificate);~~

34. 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

45. have not been vaccinated against rabies or do not meet all the conditions set out in points 1, 2, 3 and 34 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 Authorities* 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. 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 Authorities* 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 Authorities* 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 Authorities* 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.

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Annex X

CHAPTER 2.2.10.

FOOT AND MOUTH DISEASE

Community position:

Considering the new definition for buffer zone, the Community cannot support the proposed changes, unless the proposal of the ad hoc group for epidemiology is taken into account and the definitions for FMD free country and zones are modified in accordance.

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 ribonucleic acid (RNA) specific to one or more of the serotypes of FMDV has been identified in samples from one or more animals, whether showing clinical signs consistent with FMD or not, or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV; or

3. antibodies to structural or nonstructural proteins of FMDV that are not a consequence of vaccination, have been identified in one or more animals 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 with a different health status by a *buffer zone*, or physical or geographical barriers, and animal health measures that effectively prevent the entry of the virus should be implemented.

Community position:

The measures are the most important, and a buffer zone may be one of these measures, which can vary according to the geography. Thus the above paragraph should be modified as follows:

Susceptible animals in the FMD free country should be separated from neighbouring countries with a different health status by animal health measures that effectively prevent the entry of the virus, which may include a *buffer zone*, ~~or~~ taking into consideration 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;

3. supply documented evidence that:

   a) surveillance for both FMD and FMDV *infection* in accordance with Appendix 3.8.7. is in operation;

   b) regulatory measures for the early detection, prevention and control of FMD have been implemented.

The country will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information in points 2 and 3~~a~~b) above be re-submitted annually and changes in the epidemiological situation or other significant events should be reported ~~promptly~~ to the OIE according to the requirements in Chapter 1.1.2.

Article 2.2.10.3.

FMD free country where vaccination is practised

Susceptible animals in the FMD free country where vaccination is practised should be separated from neighbouring ~~infected~~ countries with a different health status by a *buffer zone* or by physical/geographical barriers, and animal health measures that effectively prevent the entry of the virus should be implemented.

Community position:

The measures are the most important, and a buffer zone may be one of these measures, which can vary according to the geography. The above paragraph should be modified as follows:

Susceptible animals in the FMD free country where vaccination is practised should be separated from neighbouring countries with a different health status by animal health measures that effectively prevent the entry of the virus, which may include a *buffer zone*, ~~or~~ taking into consideration 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. Retention on the list requires that the information in point 2 above be re-submitted annually and changes in the epidemiological situation or other significant events should be reported ~~promptly~~ to the OIE according to the requirements in Chapter 1.1.2.

If a country that meets the requirements of a ~~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~~ the status of this country remains unchanged for a period of at least 12 months after vaccination has ceased, ~~then notify the OIE and provide~~ Eevidence should also be provided showing that FMDV ~~circulation~~ infection 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 by a *buffer zone* or by physical/geographical barriers from the rest of the country and from neighbouring countries if they are of a different health status, and animal health measures that effectively prevent the entry of the virus should be implemented.

Community position:

The measures are the most important, and a buffer zone may be one of these measures, which can vary according to the geography. The second sentence of the above paragraph should be modified as follows:

Susceptible animals in the FMD free *zone* should be separated from the rest of the country and from neighbouring countries if they are of a different health status by animal health measures that effectively prevent the entry of the virus, which may include a *buffer zone*, ~~or by~~ taking into consideration physical or geographical barriers~~, and 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 since the cessation of vaccination, except in accordance with Article 2.2.10.9.;

e) documented evidence shows that surveillance in accordance with Appendix 3.8.7. is in operation for both FMD and FMDV *infection*;

3. 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 2.2.10.9. 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 and 3c) above should be re-submitted annually ~~as well as~~ and ~~any relevant~~ changes in the epidemiological situation or other significant events including those relevant to ~~under~~ points 3a) and 3b) should be reported ~~promptly~~ to the OIE according to the requirements in Chapter 1.1.2.

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 practised should be separated by a *buffer zone* or by physical/geographical barriers from the rest of the country and from neighbouring countries if they are of a different health status, and animal health measures that effectively prevent the entry of the virus should be implemented.

Community position:

The measures are the most important, and a buffer zone may be one of these measures, which can vary according to the geography. The second sentence of the above paragraph should be modified as follows:

Susceptible animals in the FMD free *zone* where vaccination is practised should be separated from the rest of the country and from neighbouring countries if they are of a different health status by animal health measures that effectively prevent the entry of the virus, which may include a *buffer zone*, ~~or by~~ taking into consideration physical or geographical barriers~~, and 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 and that within the proposed FMD free *zone*:

   a) there has been no *outbreak* of FMD for the past 2 years;

   b) no evidence of FMDV circulation for the past 12 months;

   c) documented evidence shows that surveillance in accordance with Appendix 3.8.7. is in operation for FMD and FMDV circulation;

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 2.2.10.9. is implemented),

   and supply 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 practised only after the submitted evidence has been accepted by the OIE. The information required in points 2, 3 and 4c) above should be re-submitted annually ~~as well as~~ and ~~any relevant~~ changes in the epidemiological situation or other significant events including those relevant to ~~under~~ points 4a) and 4b) should be reported ~~promptly~~ to the OIE according to the requirements in Chapter 1.1.2.

If a country that has a zone which meets the requirements of a ~~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, the status of this zone remains unchanged for a ~~waiting~~ period of at least 12 months after vaccination has ceased, ~~is required and~~ Eevidence ~~must~~ should also 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 2.2.10.7.

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 single *containment zone*, which includes all *cases*, can be established for the purpose of minimizing the impact on the entire country or *zone*. For this to be achieved, the *Veterinary Authority* should provide documented evidence that:

Community position:

The Commission reiterates its comment to amend this article in coherence with the chapter on Zoning and Compartmentalisation and to correct the contradiction within the Article (if there is a primary outbreak it's because there may be more than one). Moreover, it should be stated that the containment zone is large enough to be effective.

Thus the first sentence above should read: "In the event of a limited number of *outbreaks* within an FMD free country or *zone* with or without vaccination, a single *containment zone*, which should be large enough to includes all *cases* and possibly contaminated herds or animals, can be established for the purpose of minimizing the impact on the entire country or *zone*."

And in point 1 below the words "*outbreak* is" should be replaced by "*outbreaks* are" and in 1.e) the second word "*outbreak*" should be replaced by "*outbreaks*".

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, and effective controls on the movement of other *commodities* mentioned in this chapter are in place;

   c) epidemiological investigation (trace-back, trace-forward) has been completed;

   d) the *infection* has been confirmed;

   e) the primary *outbreak* and likely source of the *outbreak* has been identified;

   f) all *cases* have been shown to be epidemiologically linked;

   g) no new *cases* have been found in the *containment zone* within a minimum of two *incubation periods* as defined in Article 2.2.10.1. after the stamping-out of ~~from~~ the last detected *case* is completed.

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

~~3~~2. a *stamping-out policy* ~~or another effective control strategy~~ has been applied;

3. the susceptible animal population within the *containment zones* should be clearly identifiable as belonging to the *containment zone*;

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 2.2.10.8., 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 2.2.10.8.

Article 2.2.10.8.

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 but either Article 2.2.10.2. or Article 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 nonstructural 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 nonstructural proteins of FMDV demonstrates the absence of virus circulation.

Article 2.2.10.9.

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 2.2.10.12.

Article 2.2.10.10.

When importing from FMD free countries where vaccination is not practised or FMD free *zones* where vaccination is not practised, *Veterinary Authorities* 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 2.2.10.11.

When importing from FMD free countries where vaccination is practised or from FMD free zones where vaccination is practised, *Veterinary Authorities* 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 2.2.10.12.

When importing from FMD infected countries or *zones*, *Veterinary Authorities* 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, that 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, that 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 2.2.10.13.

When importing from FMD free countries where vaccination is not practised or FMD free *zones* where vaccination is not practised, *Veterinary Authorities* 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 2.2.10.14.

When importing from FMD free countries where vaccination is not practised or FMD free *zones* where vaccination is not practised, *Veterinary Authorities* 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 2.2.10.15.

When importing from FMD free countries where vaccination is practised or from FMD free *zones* where vaccination is practised, *Veterinary Authorities* 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 2.2.10.16.

When importing from FMD infected countries or *zones*, *Veterinary Authorities* 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 2.2.10.17.

Irrespective of the FMD status of the *exporting country* or *zone*, *Veterinary Authorities* 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 2.2.10.18.

When importing from FMD free countries where vaccination is not practised or FMD free *zones* where vaccination is not practised, *Veterinary Authorities* 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 2.2.10.13., 2.2.10.14., 2.2.10.15. or 2.2.10.16., 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 2.2.10.19.

When importing from FMD free countries where vaccination is practised or from FMD free *zones* where vaccination is practised, *Veterinary Authorities* 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 2.2.10.13., 2.2.10.14., 2.2.10.15. or 2.2.10.16., 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 2.2.10.20.

When importing from FMD free countries where vaccination is not practised or FMD free *zones* where vaccination is not practised, *Veterinary Authorities* 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 2.2.10.10., Article 2.2.10.11. or Article 2.2.10.12.;

2. have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections to rule out the presence of FMD with favourable results.

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 Authorities* 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 2.2.10.10., Article 2.2.10.11. or Article 2.2.10.12.;

2. have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections to rule out the presence of FMD with favourable results.

Community position:

The Community wishes to reiterate its former comment regarding the importance of implementing complementary risk mitigation measures in case of a free country or zone with vaccination in which a outbreak occurred and a containment zone is applied.

Thus a point 3 should be added: "3. if the principle of containment zone has been used, comply with article 2.2.10.23, point 2. a) and b)."

Article 2.2.10.22.

When importing from FMD free countries where vaccination is practised or from FMD free *zones* where vaccination is practised, *Veterinary Authorities* 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 2.2.10.10., Article 2.2.10.11. or Article 2.2.10.12.;

2. have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections to rule out the presence of FMD with favourable results.

Article 2.2.10.23.

When importing from FMD infected countries or *zones*, where an official control programme exists, involving compulsory systematic vaccination of cattle, *Veterinary Authorities* 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 to rule out the presence of 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 2.2.10.24.

When importing from FMD infected countries or *zones*, *Veterinary Authorities* 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 to rule out the presence of 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 2.2.10.25.

When importing from FMD free countries or *zones* (where vaccination either is or is not practised), *Veterinary Authorities* 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 2.2.10.10., Article 2.2.10.11. or Article 2.2.10.12.

Article 2.2.10.26.

When importing from FMD infected countries or *zones* where an official control programme exists, *Veterinary Authorities* 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 2.2.10.27.

When importing from FMD infected countries, *Veterinary Authorities* 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 2.2.10.28.

When importing from FMD infected countries, *Veterinary Authorities* 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 Authorities 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 2.2.10.29.

When importing from FMD infected countries or *zones*, *Veterinary Authorities* 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 2.2.10.30.

When importing from FMD free countries or *zones* (where vaccination either is or is not practised),*Veterinary Authorities* 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 in such a country or *zone*, or which have been imported from a country or *zone* free of FMD (where vaccination either is or is not practised).

Article 2.2.10.31.

When importing from FMD infected countries or *zones*, *Veterinary Authorities* 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.

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Annex X (contd)

APPENDIX 3.8.7.

GUIDELINES ~~FOR~~ ON ~~THE~~ SURVEILLANCE ~~OF~~ FOR FOOT AND MOUTH DISEASE

Community position:

The Community can support the proposed changes.

Article 3.8.7.1.

Introduction

This Appendix defines the principles and provides a guide for the surveillance of foot and mouth disease (FMD) in accordance with Appendix 3.8.1. applicable to countries seeking recognition from the OIE for freedom from FMD, either with or without the use of vaccination. This may be for the entire country or a *zone* within the country. Guidance for countries seeking reestablishment of freedom from FMD for the whole country or a *zone* within the country, either with or without vaccination, following an *outbreak*, as well as guidelines for the maintenance of FMD status are provided. These guidelines are intended to expand on and explain the requirements of Chapter 2.2.10. Applications to the OIE for recognition of freedom should follow the format and answer all the questions posed by the "Questionnaire on FMD" available from the OIE *Central Bureau*.

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

Surveillance for FMD should be in the form of a continuing programme designed to establish that the whole territory or part of it is free from FMDV *infection*/circulation.

For the purposes of this Appendix, virus circulation means transmission of FMDV as demonstrated by clinical signs, serological evidence or virus isolation.

Article 3.8.7.2.

General conditions and methods

1. A surveillance system in accordance with Appendix 3.8.1. should be under the responsibility of the *Veterinary Authority*. A procedure should be in place for the rapid collection and transport of samples

from suspect cases of FMD to a laboratory for FMD diagnoses as described in the *Terrestrial Manual*.

2. The FMD 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 livestock, as well as diagnosticians, should report promptly any suspicion of FMD. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspect cases of FMD should be investigated immediately. Where suspicion cannot be resolved by epidemiological and clinical investigation, samples should be taken and submitted to an ~~*approved*~~ *laboratory*. This requires that sampling kits and other equipment are available for those responsible for surveillance. Personnel responsible for surveillance should be able to call for assistance from a team with expertise in FMD diagnosis and control;

   b) implement, when relevant, regular and frequent clinical inspection and serological testing of high-risk groups of animals, such as those adjacent to an FMD infected country or *zone* (for example, bordering a game park in which infected wildlife are present).

An effective surveillance system will periodically identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is FMDV. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from FMDV *infection*/circulation 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 3.8.7.3.

Surveillance strategies

1. Introduction

The target population for surveillance aimed at identifying *disease* and *infection* should cover all the susceptible species within the country or *zone* to be recognised as free from FMDV *infection*/circulation.

The strategy employed may be based on randomised sampling requiring surveillance consistent with demonstrating the absence of FMDV *infection*/circulation at an acceptable level of statistical confidence. The frequency of sampling should be dependent on the epidemiological situation. Targeted surveillance (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. The applicant country should justify the surveillance strategy chosen as adequate to detect the presence of FMDV *infection*/circulation in accordance with Appendix 3.8.1. and the epidemiological situation. It may, for example, be appropriate to target clinical surveillance at particular species likely to exhibit clear clinical signs (e.g. cattle and pigs). If a Member wishes to apply for recognition of a specific *zone* within the country as being free from FMDV *infection*/circulation, the design of the survey and the basis for the sampling process would need to be aimed at the population within the *zone*.

For random surveys, the design of the sampling strategy will need to incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect *infection*/circulation 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 design 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 production class of animals in the target population.

Irrespective of the testing system employed, surveillance 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*/circulation or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as herds 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 FMDV *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.

2. Clinical surveillance

Clinical surveillance aims at detecting clinical signs of FMD by close physical examination of susceptible animals. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, surveillance based on clinical inspection should not be underrated. It may be able to provide a high level of confidence of detection of *disease* if a sufficiently large number of clinically susceptible animals is examined.

Clinical surveillance and laboratory testing should always be applied in series to clarify the status of FMD 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 contrary evidence is produced.

A number of issues must be considered in clinical surveillance for FMD. The often underestimated labour intensity and the logistical difficulties involved in conducting clinical examinations should not be underestimated and should be taken into account.

Identification of clinical cases is fundamental to FMD surveillance. Establishment of the molecular, antigenic and other biological characteristics of the causative virus, as well as its source, is dependent upon disclosure of such animals. It is essential that FMDV 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 detecting antibodies against FMDV. Positive FMDV antibody test results can have four possible causes:

a) natural *infection* with FMDV;

b) vaccination against FMD;

c) maternal antibodies derived from an immune dam (maternal antibodies in cattle are usually found only up to 6 months of age but in some individuals and in some species, maternal antibodies can be detected for considerably longer periods);

d) heterophile (cross) reactions.

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

It may be possible to use serum collected for other survey purposes for FMD surveillance. However, the principles of survey design described in this Appendix and the requirement for a statistically valid survey for the presence of FMDV should not be compromised.

The discovery of clustering of seropositive reactions should be foreseen. It may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of field strain *infection*. As clustering may signal field strain *infection*, the investigation of all instances must be incorporated in the survey design. If vaccination cannot be excluded as the cause of positive serological reactions, diagnostic methods should be employed that detect the presence of antibodies to nonstructural proteins (NSPs) of FMDVs as described in the *Terrestrial Manual*.

The results of random or targeted serological surveys are important in providing reliable evidence that FMDV *infection* is not present in a country or *zone*. It is therefore essential that the survey be thoroughly documented.

Article 3.8.7.4.

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

In addition to the general conditions described in Chapter 2.2.10., a Member applying for recognition of FMD freedom for the country or a *zone* where vaccination is not practised should provide evidence for the existence of an effective surveillance programme. The strategy and design of the surveillance programme will depend on the prevailing epidemiological circumstances and will be planned and implemented according to general conditions and methods in this Appendix, to demonstrate absence of FMDV *infection*, during the preceding 12 months in susceptible populations. This requires the support of a national or other laboratory able to undertake identification of FMDV *infection* through virus/antigen/genome detection and antibody tests described in the *Terrestrial Manual*.

Article 3.8.7.5.

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

In addition to the general conditions described in Chapter 2.2.10., a Member applying for recognition of country or *zone* freedom from FMD with vaccination should show evidence of an effective surveillance programme planned and implemented according to general conditions and methods in this Appendix. Absence of clinical *disease* in the country or *zone* for the past 2 years should be demonstrated. Furthermore, surveillance should demonstrate that FMDV has not been circulating in any susceptible population during the past 12 months. This will require serological surveillance incorporating tests able to detect antibodies to NSPs as described in the *Terrestrial Manual*. Vaccination to prevent the transmission of FMDV may be part of a *disease* control programme. The level of herd immunity required to prevent transmission will depend on the size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive. However, the aim should, in general, be to vaccinate at least 80% of the susceptible population. The vaccine must comply with the *Terrestrial Manual*. Based on the epidemiology of FMD in the country or *zone*, it may be that a decision is reached to vaccinate only certain species or other subsets of the total susceptible population. In that case, the rationale should be contained within the dossier accompanying the application to the OIE for recognition of status.

Evidence to show the effectiveness of the vaccination programme should be provided.

Article 3.8.7.6.

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

In addition to the general conditions described in Chapter 2.2.10., a country re-applying for country or *zone* freedom from FMD where vaccination is practised or not practised should show evidence of an active surveillance programme for FMD as well as absence of FMDV *infection*/circulation. This will require serological surveillance incorporating, in the case of a country or a *zone* practising vaccination, tests able to detect antibodies to NSPs as described in the *Terrestrial Manual*.

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

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

The time periods before which an application can be made for re-instatement of freedom from FMD depends on which of these alternatives is followed. The time periods are prescribed in Article 2.2.10.8.

In all circumstances, a Member re-applying for country or *zone* freedom from FMD with vaccination or without vaccination should report the results of an active surveillance programme implemented according to general conditions and methods in this Appendix.

Article 3.8.7.7.

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

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

Animals infected with FMDV produce antibodies to both the structural proteins (SP) and the nonstructural proteins (NSP) of the virus. Tests for SP antibodies to include SP-ELISAs and the virus neutralisation test (VNT). The SP tests are serotype specific and for optimal sensitivity should utilise an antigen or virus closely related to the field strain against which antibodies are being sought. Tests for NSP

antibodies include NSP I-ELISA 3ABC and the electro-immunotransfer blotting technique (EITB) as recommended in the *Terrestrial Manual* or equivalent validated tests. In contrast to SP tests, NSP tests can detect antibodies to all serotypes of FMD virus. Animals vaccinated and subsequently infected with FMD virus develop antibodies to NSPs, but in some, the titre may be lower than that found in infected animals that have not been vaccinated. Both the NSP I-ELISA 3ABC and EITB tests have been extensively used in cattle. Validation in other species is ongoing. Vaccines used should comply with the standards of the *Terrestrial Manual* insofar as purity is concerned to avoid interference with NSP antibody testing.

Serological testing is a suitable tool for FMD surveillance. The choice of a serosurveillance system will depend on, amongst other things, the vaccination status of the country. A country, which is free from FMD without vaccination, may choose serosurveillance of high-risk *subpopulations* (e.g. based on geographical risk for exposure to FMDV). SP tests may be used in such situations for screening sera for evidence of FMDV *infection*/circulation if a particular virus of serious threat has been identified and is well characterised. In other cases, NSP testing is recommended in order to cover a broader range of strains and even serotypes. In both cases, serological testing can provide additional support to clinical surveillance. Regardless of whether SP or NSP tests are used in countries that do not vaccinate, a diagnostic follow-up protocol should be in place to resolve any presumptive positive serological test results.

In areas where animals have been vaccinated, SP antibody tests may be used to monitor the serological response to the vaccination. However, NSP antibody tests should be used to monitor for FMDV *infection*/circulation. NSP-ELISAs may be used for screening sera for evidence of *infection*/circulation irrespective of the vaccination status of the animal. All herds with seropositive reactors should be investigated. Epidemiological and supplementary laboratory investigation results should document the status of FMDV *infection*/circulation for each positive herd. Tests used for confirmation should be of high diagnostic specificity to eliminate as many false positive screening test reactors as possible. The diagnostic sensitivity of the confirmatory test should approach that of the screening test. The EITB or another OIE-accepted test should be used for confirmation.

Information should be provided on the protocols, reagents, performance characteristics and validation of all tests used.

1. <u>The follow-up procedure in case of positive test results if no vaccination is used in order to establish or re-establish FMD free status without vaccination</u>

   Any positive test result (regardless of whether SP or NSP tests were used) should be followed up immediately using appropriate clinical, epidemiological, serological and, where possible, virological investigations of the reactor animal at hand, of susceptible animals of the same epidemiological unit and of susceptible animals that have been in contact or otherwise epidemiologically associated with the reactor animal. If the follow-up investigations provide no evidence for FMDV *infection*, the reactor animal shall be classified as FMD negative. In all other cases, including the absence of such follow-up investigations, the reactor animal should be classified as FMD positive.

2. <u>The follow-up procedure in case of positive test results if vaccination is used in order to establish or re-establish FMD free status with vaccination</u>

   In case of vaccinated populations, one has to exclude 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 FMD vaccinated populations.

   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.

   It is suggested that in the primary sampling units where at least one animal reacts positive to the NSP test, the following strategy(ies) should be applied:

   a) Following clinical examination, a second serum sample should be taken from the animals tested

in the initial survey after an adequate interval of time has lapsed, on the condition that they are individually identified, accessible and have not been vaccinated during this period. Antibody titres against NSP at the time of retest should be statistically either equal to or lower than those observed in the initial test if virus is not circulating.

The animals sampled should remain in the holding pending test results and should be clearly identifiable. If the three conditions for retesting mentioned above cannot be met, a new serological survey should be carried out in the holding after an adequate period of time, repeating the application of the primary survey design and ensuring that all animals tested are individually identified. These animals should remain in the holding and should not be vaccinated, so that they can be retested after an adequate period of time.

b) Following clinical examination, serum samples should be collected from representative numbers of cattle that were in physical contact with the primary sampling unit. The magnitude and prevalence of antibody reactivity observed should not differ in a statistically significant manner from that of the primary sample if virus is not circulating.

c) Following clinical examination, epidemiologically linked herds should be serologically tested and satisfactory results should be achieved if virus is not circulating.

d) Sentinel animals can also be used. These can be young, unvaccinated animals or animals in which maternally conferred immunity has lapsed and belonging to the same species resident within the positive initial sampling units. They should be serologically negative if virus is not circulating. If other susceptible, unvaccinated ruminants (sheep, goats) are present, they could act as sentinels to provide additional serological evidence.

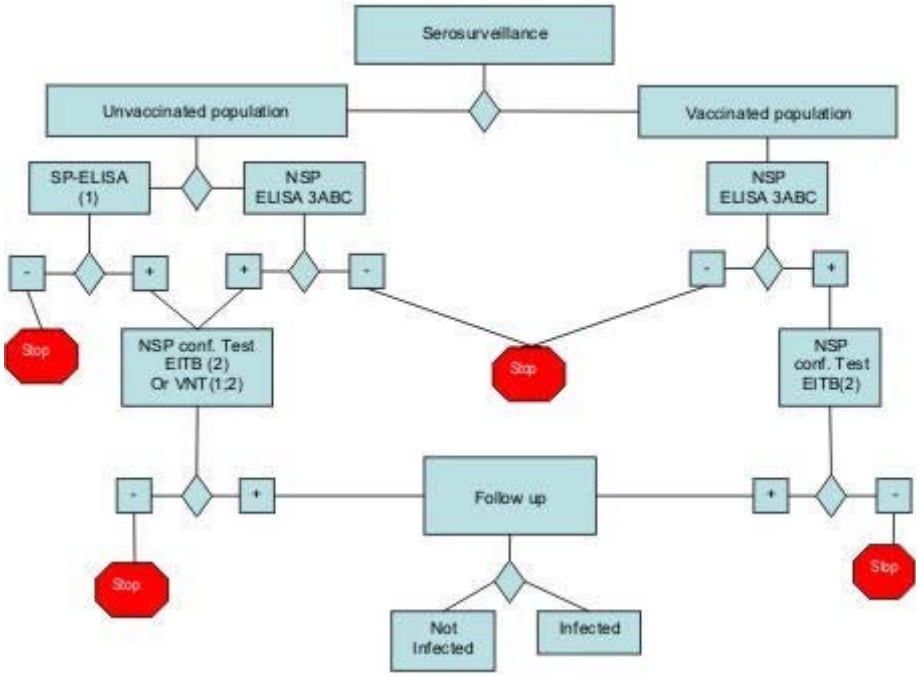
Laboratory results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:

- characterization of the existing production systems;
- results of clinical surveillance of the suspects and their cohorts;
- quantification of vaccinations performed on the affected sites;
- sanitary protocol and history of the *establishments* with positive reactors;
- control of animal identification and movements;
- other parameters of regional significance in historic FMDV transmission.

The entire investigative process should be documented as standard operating procedure within the surveillance programme.

Annex X (contd)

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



Key:	
ELISA	Enzyme-linked immunosorbent assay
VNT	Virus neutralisation test
NSP	Nonstructural protein(s) of foot and mouth disease virus (FMDV)
3ABC	NSP antibody test
EITB	Electro-immuno transfer blotting technique (Western blot for NSP antibodies of FMDV)
SP	Structural protein test
S	No evidence of FMDV

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Annex X (contd)

APPENDIX 3.6.2.

FOOT AND MOUTH DISEASE VIRUS INACTIVATION PROCEDURES

Community position:

The Community can support the proposed changes.

Article 3.6.2.1.

Meat

For the inactivation of viruses present in meat, one of the following procedures should be used:

1. Canning

   Meat is subjected to heat treatment in a hermetically sealed container to reach an internal core temperature of at least 70°C for a minimum of 30 minutes or to any equivalent treatment which has been demonstrated to inactivate the FMD virus.

2. Thorough cooking

   Meat, previously deboned and defatted, shall be subjected to heating so that an internal temperature of 70°C or greater is maintained for a minimum of 30 minutes.

   After cooking, it shall be packed and handled in such a way that it cannot be exposed to a source of virus.

3. Drying after salting

   When *rigor mortis* is complete, the meat must be deboned, salted with cooking salt (NaCl) and completely dried. It must not deteriorate at ambient temperature.

   'Drying' is defined in terms of the ratio between water and protein which must not be greater than 2.25:1.

Article 3.6.2.2.

Wool and hair

For the inactivation of viruses present in wool and hair for industrial use, one of the following procedures should be used:

1. industrial washing, which consists of the immersion of the wool in a series of baths of water, soap and sodium ~~hydroxyde~~ hydroxide (soda) or potassium ~~hydroxyde~~ hydroxide (potash);

2. chemical depilation by means of slaked lime or sodium sulphide;

3. fumigation in formaldehyde in a hermetically sealed chamber for at least 24 hours. The most practical method is to place potassium permanganate in containers (which must NOT be made of plastic or polyethylene) and add commercial formalin; the amounts of formalin and potassium permanganate are respectively 53 ml and 35 g per cubic metre of the chamber;

4. industrial scouring which consists of the immersion of wool in a water-soluble detergent held at 60-70°C;

5. storage of wool at 18°C for 4 weeks, or 4°C for 4 months, or 37°C for 8 days.

Article 3.6.2.3.

Bristles

For the inactivation of viruses present in bristles for industrial use, one of the following procedures should be used:

1. boiling for at least one hour;

2. immersion for at least 24 hours in a 1% solution of formaldehyde prepared from 30 ml commercial formalin per litre of water.

Article 3.6.2.4.

Raw hides and skins

For the inactivation of viruses present in raw hides and skins for industrial use, the following procedure should be used: salting for at least 28 days in sea salt containing 2% sodium carbonate.

Article 3.6.2.5.

Milk and cream for human consumption

For the inactivation of viruses present in *milk* and cream for human consumption, one of the following procedures should be used:

1. a sterilisation process applying a minimum temperature of 132°C for at least one second (ultra-high temperature [UHT]), or

2. if the milk has a pH less than 7.0, a sterilisation process applying a minimum temperature of 72°C for at least 15 seconds (high temperature - short time pasteurisation [HTST]), or

3. if the milk has a pH of 7.0 or over, the HTST process applied twice.

Article 3.6.2.6.

Milk for animal consumption

For the inactivation of viruses present in *milk* for animal consumption, one of the following procedures should be used:

1. the HTST process applied twice;

2. HTST combined with another physical treatment, e.g. maintaining a pH 6 for at least one hour or additional heating to at least 72°C combined with dessication;

3. UHT combined with another physical treatment referred to in point 2 above.

Article 3.6.2.7.

Skins and trophies from wild animals susceptible to foot and mouth disease

For the inactivation of viruses present in skins and trophies from wild animals susceptible to FMD, one of the following procedures should be used prior to complete taxidermal treatment:

1. boiling in water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed;

2. gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher);

3. soaking, with agitation, in a 4% (w/v) solution of washing soda (sodium carbonate - Na_2CO_3) maintained at pH 11.5 or above for at least 48 hours;

4. soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at below pH 3.0 for at least 48 hours; wetting and dressing agents may be added;

5. in the case of raw hides, salting for at least 28 days with sea salt containing 2% washing soda (sodium carbonate - Na_2CO_3).

Article 3.6.2.8.

Casings of small ruminants and pigs

For the inactivation of viruses present in casings of small ruminants and pigs, the following procedures should be used:

salting for at least 30 days either with dry salt (NaCl) or with saturated brine (Aw < 0.80), or with phosphate salts/sodium chloride mixture,and kept at room temperature at about 20°C during this entire period.

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Annex XI

CHAPTER 2.2.12.

RINDERPEST

Community position:

The Community can support the proposed changes.

Article 2.2.12.1.

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

For the purpose of this chapter, a *case* includes an animal infected with rinderpest virus (RPV).

For the purpose of this chapter, susceptible animals apply to both domestic and wild artiodactyls.

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

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

1. Animal not vaccinated against RP means:

    a) for large ruminants and pigs: an animal that has received neither a RP vaccine nor a heterologous vaccine against RP;

    b) for small ruminants: an animal that has not received a RP vaccine.

2. The following defines the occurrence of RPV *infection*:

    a) RPV has been isolated and identified as such from an animal or a product derived from that animal; or

    b) viral antigen or viral ribonucleic acid (RNA) specific to RP has been identified in samples from one or more animals showing one or more clinical signs consistent with RP, or epidemiologically linked to an *outbreak* of RP, or giving cause for suspicion of association or contact with RP; or

    c) antibodies to RPV antigens which are not the consequence of vaccination, have been identified in one or more animals with either epidemiological links to a confirmed or suspected *outbreak* of RP in susceptible animals, or showing clinical signs consistent with recent *infection* with RP.

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

Article 2.2.12.2.

RP free country

To qualify for inclusion in the existing list of RP free countries, 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 RP during the past 24 months,

   b) no evidence of RPV *infection* has been found during the past 24 months,

   c) no vaccination against RP has been carried out during the past 24 months,

   and supply documented evidence that surveillance for both RP and RPV *infection* in accordance with Appendix 3.8.2. is in operation and that regulatory measures for the prevention and control of RP have been implemented;

3. not have imported since the cessation of vaccination any animals vaccinated against RP.

The country will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information in points 2a), 2b), 2c), and 3 above be re-submitted annually and changes in the epidemiological situation or other significant events should be reported ~~promptly~~ to the OIE according to the requirements in Chapter 1.1.2.

Article 2.2.12.3.

Recovery of free status

When a RP *outbreak* or RPV *infection* occurs in a RP free country, one of the following waiting periods is required to regain the status of RP free country:

1. 3 months after the last *case* where a *stamping-out policy* and serological surveillance are applied in accordance with Appendix 3.8.2.; or

2. 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 3.8.2.; or

3. 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 *slaughter* of all vaccinated animals, and serological surveillance are applied in accordance with Appendix 3.8.2.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply but Article 2.2.12.2. applies.

Article 2.2.12.4.

Infected country

When the requirements for acceptance as a RP free country are not fulfilled, a country shall be considered as RP infected.

Article 2.2.12.5.

When importing from RP free countries, *Veterinary Authorities* should require:

for RP susceptible animals

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

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

2. remained in a RP free country since birth or for at least 30 days prior to shipment.

Article 2.2.12.6.

When importing from RP infected countries, *Veterinary Authorities* should require:

for RP susceptible animals

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

1. RP is the subject of a national surveillance programme according to Appendix 3.8.2.;

2. RP has not occurred within a 10-kilometre radius of the *establishment* of origin of the animals destined for export for at least 21 days prior to their shipment to the *quarantine station* referred to in point 3b) below;

3. the animals:

   a) showed no clinical sign of RP on the day of shipment;

   b) were kept in the *establishment* of origin since birth or for at least 21 days before introduction into the *quarantine station* referred to in point c) below;

   c) have not been vaccinated against RP, were isolated in a *quarantine station* for the 30 days prior to shipment, and were subjected to a diagnostic test for RP on two occasions with negative results, at an interval of not less than 21 days;

   d) were not exposed to any source of *infection* during their transportation from the *quarantine station* to the place of shipment;

4. RP has not occurred within a ten-kilometre radius of the *quarantine station* for 30 days prior to shipment.

Article 2.2.12.7.

When importing from RP free countries, *Veterinary Authorities* should require:

for semen of RP susceptible animals

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

1. the donor animals:

   a) showed no clinical sign of RP on the day of collection of the semen;

   b) were kept in a RP free country for at least 3 months prior to collection;

2. the semen was collected, processed and stored in conformity with the provisions of either Appendix 3.2.1. or Appendix 3.2.2., as relevant.

Article 2.2.12.8.

When importing from RP infected countries, *Veterinary Authorities* should require:

for semen of RP susceptible animals

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

1. RP is the subject of a national surveillance programme according to Appendix 3.8.2.;

2. the donor animals:

    a) showed no clinical sign of RP on the day of collection of the semen;

    b) were kept in an *establishment* where no RP susceptible animals had been added in the 21 days before collection, and that RP has not occurred within 10 kilometres of the *establishment* for the 21 days before and after collection;

    c) were vaccinated against RP at least 3 months prior to collection; or

    d) have not been vaccinated against RP, and were subjected to a diagnostic test on two occasions with negative results, at an interval of not less than 21 days within the 30 days prior to collection;

3. the semen was collected, processed and stored in conformity with the provisions of either Appendix 3.2.1. or Appendix 3.2.2., as relevant.

Article 2.2.12.9.

When importing from RP free countries, *Veterinary Authorities* should require:

for *in vivo* derived embryos of RP susceptible animals

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

1. the donor females were kept in an *establishment* located in a RP free country at the time of collection;

2. the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1. or Appendix 3.3.3., as relevant.

Article 2.2.12.10.

When importing from RP infected countries, *Veterinary Authorities* should require:

for *in vivo* derived embryos of RP susceptible animals

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

1. RP is the subject of a national surveillance programme according to Appendix 3.8.2.;

2. the donor females:

    a) and all other animals in the *establishment* showed no clinical sign of RP at the time of collection and for the following 21 days;

    b) were kept in an *establishment* where no RP susceptible animals had been added in the 21 days before collection of the embryos;

    c) were vaccinated against RP at least 3 months prior to collection; or

    d) have not been vaccinated against RP, and were subjected to a diagnostic test for RP on two occasions with negative results, at an interval of not less than 21 days within the 30 days prior to collection;

3. the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1. or Appendix 3.3.3., as relevant.

Article 2.2.12.11.

When importing from RP free countries, *Veterinary Authorities* should require:

for *fresh meat* or *meat products* of susceptible animals

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

Article 2.2.12.12.

When importing from RP infected countries, *Veterinary Authorities* should require:

for *fresh meat* (excluding offal) of susceptible animals

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

1. comes from a country where RP is the subject of a national surveillance programme according to Appendix 3.8.2.;

2. comes from animals which:

   a) showed no clinical sign of RP within 24 hours before *slaughter*;

   b) have remained in the country for at least 3 months prior to *slaughter*;

   c) were kept in the *establishment* of origin since birth or for at least 30 days prior to shipment to the approved *abattoir*, and that RP has not occurred within a ten-kilometre radius of the *establishment* during that period;

   d) were vaccinated against RP at least 3 months prior to shipment to the approved *abattoir*;

   e) had been transported, in a *vehicle* which was cleansed and disinfected before the animals were loaded, directly from the *establishment* of origin to the approved *abattoir* without coming into contact with other animals which do not fulfil the required conditions for export;

   f) were slaughtered in an approved *abattoir* in which no RP has been detected during the period between the last *disinfection* carried out before *slaughter* and the date on which the shipment has been dispatched.

Article 2.2.12.13.

When importing from RP infected countries, *Veterinary Authorities* should require:

for *meat products* of susceptible animals

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

1. only *fresh meat* complying with the provisions of Article 2.2.12.12. has been used in the preparation of the *meat products*; or

2. the *meat products* have been processed to ensure the destruction of the RPV in conformity with one of the procedures referred to in Article 3.6.2.1.;

3. the necessary precautions were taken after processing to avoid contact of the *meat products* with any possible source of RPV.

Article 2.2.12.14.

When importing from RP free countries, *Veterinary Authorities* should require:

for *milk* and *milk products* intended for human consumption and for products of animal origin (from RP 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 since birth or for at least 3 months.

Article 2.2.12.15.

When importing from RP infected countries, *Veterinary Authorities* should require:

for *milk* and cream

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

1. these products:

    a) originate from herds or flocks which were not subjected to any restrictions due to RP at the time of *milk* collection;

    b) have been processed to ensure the destruction of the RPV 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 RPV.

Article 2.2.12.16.

When importing from RP infected countries, *Veterinary Authorities* should require:

for *milk products*

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

1. these products are derived from *milk* complying with the above requirements;

2. the necessary precautions were taken after processing to avoid contact of the *milk products* with a potential source of RPV.

Article 2.2.12.17.

When importing from RP infected countries, *Veterinary Authorities* should require:

for blood and meat-meals (from susceptible animals)

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 2.2.12.18.

When importing from RP infected countries, *Veterinary Authorities* should require:

for wool, hair, bristles, raw hides and skins (from susceptible animals)

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

1. these products have been processed to ensure the destruction of the RPV 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 processing to avoid contact of the products with any potential source of RPV.

Veterinary Authorities 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 2.2.12.19.

When importing from RP infected countries, *Veterinary Authorities* should require:

for hooves, claws, bones and horns, hunting trophies and preparations destined for museums (from susceptible animals)

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

1. were completely dried and had no trace on them of skin, flesh or tendon; and/or

2. have been adequately disinfected.

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1 *[Note:* International veterinary certificates *for animal products coming from RP infected countries, may not be required if the products are transported in an approved manner to premises controlled and approved by the Veterinary Authority of the importing country for processing to ensure the destruction of the RPV as described in Article 3.6.2.2., Article 3.6.2.3. and Article 3.6.2.4.]*

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Annex XII

CHAPTER 2.4.6.

CONTAGIOUS CAPRINE PLEUROPNEUMONIA

Community position:

The Community can support the proposed changes.

Article 2.4.6.1.

For the purposes of the *Terrestrial Code*, contagious caprine pleuropneumonia (CCPP) is defined as a disease of goats caused by *Mycoplasma capricolum* subsp. *capripneumoniae*. The *incubation period* for the disease shall be 45 days (chronic carriers occur).

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

Article 2.4.6.2.

Country free from contagious caprine pleuropneumonia

A country may be considered free from CCPP when it has been shown that CCPP is not present and that one year has elapsed after the slaughter of the last affected animal for countries in which a *stamping-out policy* is practised.

Article 2.4.6.3.

Zone infected with contagious caprine pleuropneumonia

A zone shall be considered as infected with CCPP until at least 45 days have elapsed after the confirmation of the last *case* and the completion of a *stamping-out policy* and *disinfection* procedures.

Article 2.4.6.4.

Veterinary Authorities of CCPP free countries may prohibit importation or transit through their territory, from countries considered infected with CCPP, of domestic and wild goats, and may prohibit importation into their territory, from countries considered infected with CCPP, of semen of domestic and wild goats and of embryos/ova of domestic goats.

Article 2.4.6.5.

When importing from CCPP free countries, *Veterinary Authorities* should require:

for domestic goats

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

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

2. were kept in a CCPP free country since birth or for at least 3 months.

Article 2.4.6.6.

When importing from CCPP free countries, *Veterinary Authorities* should require:

for wild goats

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

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

2. were kept in a CCPP free country;

if the animals originated from an area adjacent to a country considered infected with CCPP:

3. were kept in a *quarantine station* for at least the 45 days prior to shipment.

Article 2.4.6.7.

When importing from countries considered infected with CCPP, *Veterinary Authorities* should require:

for domestic goats

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

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

2. were subjected to a complement fixation test for CCPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between each test, the second test being performed within 14 days prior to shipment (under study);

3. were isolated from other domestic goats from the day of the first complement fixation test until shipment;

4. were kept since birth, or for at least the past 45 days, in an *establishment* where no *case* of CCPP was officially reported during that period, and that the *establishment* of origin was not situated in a CCPP infected zone;

5. have not been vaccinated against CCPP; or

6. were vaccinated not more than 4 months prior to shipment. In this case, point 2 above is not required (under study).

Article 2.4.6.8.

When importing from countries considered infected with CCPP, *Veterinary Authorities* should require:

for goats for immediate slaughter

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

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

2. were kept since birth, or for at least the past 45 days, in an *establishment* where no *case* of CCPP was officially reported during that period, and that the *establishment* of origin was not situated in a CCPP infected zone.

Article 2.4.6.9.

When importing from countries considered infected with CCPP, *Veterinary Authorities* should require:

for wild goats

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

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

2. were kept, for at least the past 45 days prior to shipment, in a *quarantine station* where no *case* of CCPP was officially reported during that period, and that the *quarantine station* was not situated in a CCPP infected zone;

3. have not been vaccinated against CCPP; or

4. were vaccinated not more than 4 months prior to shipment (under study).

Article 2.4.6.10

When importing from CCPP free countries, *Veterinary Authorities* should require:

for embryos/oocytes of goats

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

1. the donor animals:

   a) showed no clinical sign of CCPP on the day of collection;

   b) were kept in a CCPP free country;

2. the embryos/oocytes were collected in conformity with the conditions laid down in Appendix 3.3.1.

Article 2.4.6.11

When importing from countries considered infected with CCPP, *Veterinary Authorities* should require:

for embryos/oocytes of goats

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

1. the donor animals:

   a) showed no clinical sign of CCPP on the day of collection; and

   b) were isolated from other domestic goats from the day of the test until collection;

   c) were kept since birth, or for at least the 45 days prior to collection, in an *establishment* where no *case* of CCPP was officially reported during that period and that the *establishment* of origin was not situated in a CCPP infected zone;

2. the collection fluids and/or degenerated and unfertilized ova were subjected to a validated culture or PRC test for CCPP with negative results;

3. the embryos/oocytes were collected in conformity with the conditions laid down in Appendix 3.3.1.

Article 2.4.6.1~~0~~2.

When importing from countries considered infected with CCPP, *Veterinary Authorities* should require:

for *fresh meat* of goats

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

1. which originate from *establishments* free of CCPP;

2. which have been slaughtered in an *approved abattoir* and have been subjected to an ante-mortem inspection for CCPP with favourable results; and

3. which showed no lesion of CCPP at the post-mortem inspection.

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Annex XIII

APPENDIX 3.8.10.

GUIDELINES ~~FOR~~ ON ~~THE~~ SURVEILLANCE ~~OF~~ FOR BLUETONGUE

Community position:

The Community can support the proposed changes and is waiting for the Scientific Commission advice on the use of inactivated vaccines.

Article 3.8.10.1.

Introduction

This Appendix defines the principles and provides a guide on the surveillance for bluetongue (BT) ~~in accordance with~~ complementary to Appendix 3.8.1., applicable to countries seeking to demonstrate ~~recognition for a declared~~ BT status~~, with or without the use of vaccination~~. This may be for the entire country or *zone*. 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 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 Members ~~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, seasonally free or infected country or *zone*) to the local conditions. There is considerable latitude available to Members ~~Countries~~ to justify their *infection* status at an acceptable level of confidence.

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

Article 3.8.10.2.

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 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 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 ribonucleic acid (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 clinical signs consistent with BT, or epidemiologically linked to a confirmed or suspected *case*, or give cause for suspicion of previous association or contact with BTV

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

Article 3.8.10.3.

General conditions and methods

1. A surveillance system in accordance with Appendix 3.8.1. should be under the responsibility of the *Veterinary Authority*. 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 Authority*. 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*.

Generally, the conditions to prevent exposure of susceptible animals to BTV infected vectors will be difficult to apply. However, under specific situations, in *establishments* such as ~~like~~ *artificial insemination centres*

or *quarantine stations* exposure to vectors may be preventable. The testing requirements for animals kept in these facilities are described in Articles 2.2.13.11. and 2.2.13.15.

Article 3.8.10.4.

Surveillance strategies

The target population for surveillance aimed at identification of *disease* and/or *infection* should cover susceptible domestic ruminants within the country or *zone*. 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 surveillance using randomised sampling that would demonstrate 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 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 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 or *zone*. 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 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 animals

Sentinel 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 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 animal programmes allow the timing and dynamics of *infections* to be observed.

A sentinel 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~~ bias, 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 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.

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 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 occurrence, and abundance. Vector surveillance has particular relevance to potential areas of spread. Long term surveillance can also be used to assess vector suppression 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 the number and type of traps to be used in vector surveillance and the frequency of their use should take into account the size and ecological characteristics of the area to be surveyed.

The operation of vector surveillance sites at the same locations as sentinel 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 animals of domestic ruminants) are preferred to detect virus circulation.

Article 3.8.10.5.

Documentation of BTV infection free status

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

In addition to the general conditions described in Chapter 2.2.13. of the *Terrestrial Code*, a Member declaring freedom from BTV *infection* for the entire country or a *zone* 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 or zones 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 or *zone*, it may be that a decision is reached to vaccinate only certain species or other subpopulations.

In countries or *zones* 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 3.8.10.6.

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.

Annex XIII (contd)

Fig. 1. Application of laboratory tests in serological surveillance

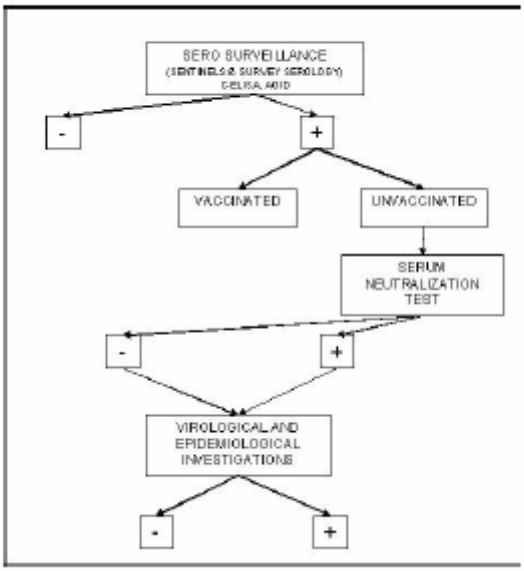
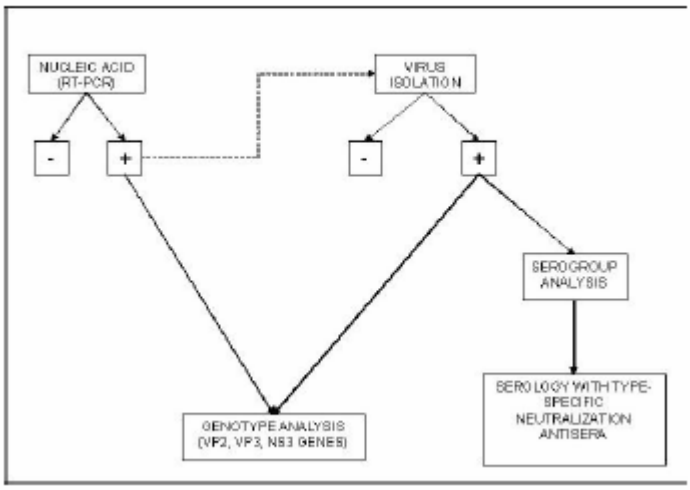


Fig. 2. Application of laboratory tests in virological surveillance



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Annex XIV

CHAPTER 2.3.3.

BOVINE TUBERCULOSIS

Community position:

The Community can support the proposed changes, though it has two comments on the proposed point 3 of article 2.3.3.2 and would point out the lack of clarity in point 4 of article 2.3.3.4.

It is willing to participate in further work by the OIE on this disease in bovines or other species.

Article 2.3.3.1.

The recommendations in this Chapter are intended to manage the human and animal health risks associated with *Mycobacterium bovis* (*M. bovis*) *infection* in domestic (permanently captive and owned free-range) bovines including cattle (*Bos taurus*, *B. indicus* and *B. grunniens*), water buffaloes (*Bubalus bubalis*) and wood bisons (*Bison bison* and *B. bonasus*) ~~and in farmed deer (red, wapiti, sika, samba, rusa, fallow, white-tailed, black-tailed and mule deer (*Cervus elaphus*, *C. canadensis*, *C. nippon*, *C. unicolor unicolor*, *C. timorensis*, *Dama dama dama*, *Odocoileus virginianus borealis*, *Odocoileus hemionus columbianus* and *Odocoileus hemionus hemionus*)~~.

~~When authorising import or transit of the following *commodities*, *Veterinary Authorities* should comply with the requirements prescribed in this Chapter relevant to the status of bovine tuberculosis in the *exporting country*, *zone* or *compartment*:~~

~~1. live animals;~~

~~2. semen, ova and *in vivo* derived embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;~~

~~3. *meat* and *meat products*;~~

~~4. *milk* and *milk products*;~~

~~5. antler velvet.~~

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

Article 2.3.3.2.

Country~~,~~ or zone ~~or compartment~~ free from bovine tuberculosis

To qualify as free from bovine tuberculosis, a country~~,~~ or *zone* ~~or *compartment*~~ should satisfy the following requirements:

1. *M. bovis infection* in domestic (permanently captive and owned free-range) bovines including cattle ~~(*Bos taurus*, *B. indicus* and *B. grunniens*)~~, water buffalo ~~(*Bubalus bubalis*)~~ and wood bison ~~(*Bison bison* and *B. bonasus*)~~ ~~and in farmed deer as specified in Article 2.3.3.1~~ is a *notifiable disease* in the country;

2. an on-going awareness programme should be in place to encourage reporting of all cases suggestive of ~~clinical~~ bovine tuberculosis;

3. ~~surveillance programme, involving regular and periodic testing of all cattle, water buffalo, and , and wood bison and farmed deer herds and capable of detecting *infection* at an annual period prevalence of 0.2% of herds and 0.1% of animals with 95% confidence has failed to detect *infection* shown that at least 99.8% of the herds and 99.9% of the animals in the country, *zone* or *compartment* have been found free from bovine tuberculosis and the percentage of herds confirmed infected with *M. bovis* has not exceeded 0.1% per year for 3 consecutive years.~~ regular and periodic testing of all cattle, water buffalo, and wood bison herds did not detect *M. bovis* infection in at least 99.8% of the herds and 99.9% of the animals in the country or zone for 3 consecutive years;

Community comment:

The Community considers that the guarantees on absence of disease should be given by the combination of a very high percentage of free herds at the end of the year for several consecutive years (noting that a herd can be infected and re-qualified as free in six months) and a very low percentage of herd confirmed infected during the year for several consecutive years. The OIE ad hoc group on tuberculosis accepted that position and the Community wishes that the above point be modified in order to reflect this.

Thus the Community proposes the following wording:

"**3. regular and periodic testing of all cattle, water buffalo, and bison herds has shown that at least 99.8% of the herds and 99.9% of the animals in the country or zone have been found free from bovine tuberculosis and the percentage of herds confirmed infected with tuberculosis has not exceeded 0.1% per year for 3 consecutive years."**

4. a surveillance programme should be in place to detect bovine tuberculosis in the country~~,~~ or *zone* ~~or *compartment*~~, through ~~monitoring at slaughter~~ ante-mortem and post-mortem inspection ~~based on the inspection~~ as described in ~~Article~~ Appendix ~~2.3.3.8.~~ 3.10.1.;

5. if the surveillance programme described in points 3 and 4 above has not detected *infection* with ~~failed to detect~~ *M. bovis* for ~~3~~ 5 consecutive years, surveillance may be maintained through ~~monitoring at *slaughter* alone~~ ante-mortem and post-mortem inspection as described in Appendix 3.10.1.;

Comunity comment:

The surveillance programme described in points 3 and 4 provide possibility of finding infection, but if the results are in line with the requirements the free status is obtained after 3 years. Then after two more years of the same status, the testing regime can be changed for a slaughterhouse surveillance. But the wording of point 5 above implies that if any infection is found then the whole testing regime has to be re-introduced, which is not what the point is here for. So it should read: "if the surveillance programme decribed in points 3 and 4 above has shown favourable outcome for at least five consecutive years, surveillance may be maintained through ante-mortem and post-mortem inspection as described in Appendix 3.10.1."

~~5~~6. cattle, water buffalo ~~and~~, wood bison ~~and farmed deer~~ introduced into a country~~,~~ or *zone* ~~or *compartment*~~ free from bovine tuberculosis should be accompanied by a certificate from an *official Veterinarian* attesting that they come from a country~~,~~ or *zone* ~~or *compartment*~~ or herd free from bovine tuberculosis or comply with the relevant provisions in Article 2.3.3.4. or in Article 2.3.3.5.

Article 2.3.3.2bis.

Compartment free from bovine tuberculosis

To qualify as a *compartment* free from bovine tuberculosis, a herd or herds of cattle, water buffalo or wood bison should be certified by the *Veterinary Authority* as satisfying the following requirements:

1. cattle, water buffalo and wood bison in the herd or herds:

   a) showed no sign of bovine tuberculosis or lesions at ante-mortem or post-mortem inspection for at least 3 consecutive years;

   b) over 6 weeks of age, have shown a negative result to at least two tuberculin tests carried out at an interval of a minimum of 6 months, the first test being performed at least 6 months following the *slaughter* of the last affected animal;

   c) showed a negative result to an annual tuberculin test to ensure the continuing absence of bovine tuberculosis; or

      i) showed a negative result to a tuberculin test every 2 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of herds confirmed as infected with tuberculosis is not more than 1% of all herds in the country or *zone* during the last 2 years; or

      ii) showed a negative result to a tuberculin test every 3 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of herds confirmed as infected with tuberculosis is not more than 0.2% of all herds in the country or *zone* during the last 4 years; or

      iii) showed a negative result to a tuberculin test every 4 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of herds confirmed as infected with tuberculosis is not more than 0.1% of all herds in the country or *zone* during the last 6 years;

2. cattle, water buffalo and wood bison introduced into the *compartment* come from a herd free from bovine tuberculosis. This condition may be waived for animals which have been isolated for at least 90 days and which, prior to entry into the *compartment*, were subjected to at least two tuberculin tests carried out at a 6-month interval with negative results.

Article 2.3.3.3.

Herd free from bovine tuberculosis

To qualify as free from bovine tuberculosis, a herd of cattle, water buffalo~~,~~ or wood bison~~s~~ ~~or farmed deer~~ should satisfy the following requirements:

1. the herd is in a country, or *zone* ~~or *compartment*~~ free from bovine tuberculosis and is certified free by the *Veterinary Authority*; or

2. cattle, water buffalo ~~and,~~ and wood bison ~~and farmed deer~~ in the herd:

   a) showed no ~~clinical~~ sign~~s~~ of bovine tuberculosis or lesions at ante-mortem or post-mortem inspection for at least 3 consecutive years;

   b) over 6 weeks of age, have shown a negative result to at least two tuberculin tests carried out at an interval of a minimum of 6 months, the first test being performed at least 6 months following the *slaughter* of the last affected animal;

c) showed a negative result to an annual tuberculin test to ensure the continuing absence of bovine tuberculosis; or

i) showed a negative result to a tuberculin test every 2 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of herds confirmed as infected with tuberculosis is not more than 1% of all herds in the country or zone during the last 2 years; or

ii) showed a negative result to a tuberculin test every 3 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of herds confirmed as infected with tuberculosis is not more than 0.2% of all herds in the country or zone during the last 4 years; or

iii) showed a negative result to a tuberculin test every 4 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of herds confirmed as infected with tuberculosis is not more than 0.1% of all herds in the country or zone during the last 6 years;

3. cattle, water buffalo, ~~and~~ and wood bison ~~and farmed deer~~ introduced into the herd come from a herd free from bovine tuberculosis. This condition may be waived for animals which have been isolated for at least 90 days and which, prior to entry into the herd, were subjected to at least two tuberculin tests carried out at a 6-month interval with negative results.

Article 2.3.3.4.

Veterinary Authorities of *importing countries* should require:

for cattle, water buffalo ~~and~~, and wood bison ~~and farmed deer~~ for breeding or rearing

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

1. showed no ~~clinical~~ signs of bovine tuberculosis on the day of shipment;

2. originate from a herd free from bovine tuberculosis that is in a country, *zone* or *compartment* free from bovine tuberculosis; or

3. were subjected to the tuberculin test for bovine tuberculosis with negative results during the 30 days prior to shipment and come from a herd free from bovine tuberculosis; or

4. have been isolated for at least 90 days and prior to entry into the herd were subjected to at least two tuberculin tests carried out at a six-month interval with negative results.

Community comments:

The Community suggests the following wording for point 4 above:

4. were subjected to at least two tuberculin tests carried out at a six-month interval with negative results, the second being performed at the earliest after 6 weeks of an isolation period of 90 days prior to shipment.

Rationale: the proposed wording is not clear; this article deals with imports of bovine from a country, zone or herd not free from TB, whatever its final destination; imports cannot be less strict when introducing animals than the qualification period for a free herd.

Article 2.3.3.5.

Veterinary Authorities of *importing countries* should require:

for cattle, water buffalo ~~and~~, ~~and~~ wood bison ~~and farmed deer~~ for slaughter

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

1. showed no ~~clinical~~ signs of bovine tuberculosis on the day of shipment;

~~1~~2. originated from a herd free from bovine tuberculosis or were subjected to a tuberculin test for bovine tuberculosis with negative results during the 30 days prior to shipment;

~~2~~3. were not being eliminated as part of an eradication programme against bovine tuberculosis.

Article 2.3.3.6.

Veterinary Authorities of *importing countries* should require:

for semen of cattle, water buffalo ~~and~~, and wood bison ~~and farmed deer~~

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

1. the donor animals:

   a) showed no ~~clinical~~ signs of bovine tuberculosis on the day of collection of the semen;

   b) were kept in an *artificial insemination centre* free from bovine tuberculosis in a country, *zone* or *compartment* free from bovine tuberculosis and which only accepts animals from free herds in a free country, *zone* or *compartment*; or

   c) showed negative results to tuberculin tests carried out annually and were kept in a herd free from bovine tuberculosis;

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

Article 2.3.3.7.

Veterinary Authorities of *importing countries* should require:

for embryos/ova of cattle, water buffalo ~~and~~, and wood bison ~~and farmed deer~~

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

1. the donor females:

   a) and all other susceptible animals in the herd of origin showed no ~~clinical~~ signs of bovine tuberculosis during the 24 hours prior to embryo collection;

   b) originated from a herd free from bovine tuberculosis in a country, *zone* or *compartment* free from bovine tuberculosis; or

   c) were kept in a herd free from bovine tuberculosis, and were subjected to a tuberculin test for bovine tuberculosis with negative results during an isolation period of 30 days in the *establishment* of origin prior to ~~departure to the~~ collection ~~centre~~;

2. the embryos/ova were collected, processed and stored in conformity with the provisions of Appendix 3.3.1., Appendix 3.3.2. or Appendix 3.3.3., as relevant.

Article 2.3.3.8.

Veterinary Authorities of *importing countries* should require:

for *fresh meat* and *meat products* of cattle, water buffalo ~~and~~, and wood bison ~~and farmed deer~~

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from animals which have been subjected to *ante-mortem* and *post-mortem* inspections as described in Appendix 3.10.1.

Article 2.3.3.9.

Veterinary Authorities of *importing countries* should require:

for *milk* and *milk products* of cattle, water buffalo and wood bison

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

1. has been derived from animals in a herd free from bovine tuberculosis; or
2. was subjected to pasteurization; or
3. was subjected to a combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

~~Article 2.3.3.10.~~

~~*Veterinary Authorities* of *importing countries* should require:~~

~~for antler velvet of farmed deer~~

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

~~1. has been derived from animals in a herd free from bovine tuberculosis; or~~

~~2. has been cooked at 60º C for 3 hours, or an equivalent temperature/time treatment.~~

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APPENDIX 3.1.1.

PRESCRIBED AND ALTERNATIVE DIAGNOSTIC TESTS FOR OIE LISTED DISEASES

Community position:

The Community can support the proposed changes

NOTE

In many of the *Terrestrial Code* chapters relating to specific diseases, the reader is referred to the *Terrestrial Manual* for information on OIE standards for the relevant diagnostic tests and vaccines.

However, some readers of the *Terrestrial Code* may need to know which diagnostic tests are recommended by the OIE for use in the *international trade* of *animals* or animal products, without requiring the details of how these tests should be performed.

The tables in this Appendix have been included to meet this need. These tables show, for each OIE *listed diseases*, the diagnostic tests which can be used when the *Terrestrial Code* recommends a testing procedure.

These tests should be performed according to the specifications in the *Terrestrial Manual*, in order to avoid any differences between the *exporting* and *importing countries* in the interpretation of results.

In the tables, the diagnostic tests have been divided into two categories - 'prescribed tests' and 'alternative tests' (a similar categorisation is made in the *Terrestrial Manual*). The 'prescribed tests' are those that are considered optimal for determining the health status of animals before shipment. 'Alternative tests' do not demonstrate the absence of infection in the tested animals with the same level of confidence as the prescribed tests do. However, the OIE Terrestrial Animal Health Standards Commission considers that an 'alternative test', chosen by mutual agreement between the *importing* and *exporting countries*, can provide valuable information for evaluating the risks of any proposed trade in *animals* or animal products. The diseases for which the *Terrestrial Code* does not require any test are not included in the tables.

ABBREVIATIONS

Agent id.	Agent identification
Agg.	Agglutination test
AGID	Agar gel immunodiffusion
BBAT	Buffered *Brucella* antigen test
CF	Complement fixation (test)
DTH	Delayed-type hypersensitivity
ELISA	Enzyme-linked immunosorbent assay
FAVN	Fluorescent antibody virus neutralisation
FPA	Fluorescence polarisation assay
HI	Haemagglutination inhibition
IFA	Indirect fluorescent antibody (test)
MAT	Microscopic agglutination test
NPLA	Neutralising peroxidase-linked assay
PCR	Polymerase chain reaction
PRN	Plaque reduction neutralisation
VN	Virus neutralisation
_	No test designated yet

Annex XIV (contd)

Terrestrial Code chapter No.	Terrestrial Manual chapter No.	Disease name	Prescribed tests	Alternative tests
OIE listed diseases				
Multiple species				
2.2.2.	2.~~2~~1.2.	Aujeszky's disease	ELISA, VN	_
2.2.4.	2.~~2~~1.~~4~~9.	Leptospirosis	_	MAT
2.2.5.	2.~~2~~1.~~5~~13.	Rabies	VN, ELISA	_
2.2.6.	2.~~2~~1.~~6~~11.	Paratuberculosis	_	DTH, ELISA
2.2.7.	2.~~2~~1.~~7~~6.	Heartwater	_	ELISA, IFA
2.2.8.	2.~~2~~1.~~8~~10.	New world screwworm (*Cochliomyia hominivorax*) and old world screwworm (*Chrysomya bezz iana*)	_	Agent id.
2.2.9.	2.~~2~~1.~~9~~16.	Trichinellosis	Agent id.	ELISA
2.2.10.	2.1.~~1~~5.	Foot and mouth disease	ELISA[1], VN	CF
2.2.11.	2.1.~~2~~19.	Vesicular stomatitis	CF, ELISA, VN	_
2.2.12.	2.1.~~4~~15.	Rinderpest	ELISA	VN
2.2.13.	2.1.~~9~~3.	Bluetongue	Agent id., AGID, ELISA, PCR	VN
2.2.14.	2.1.~~8~~14.	Rift Valley fever	VN	HI, ELISA
2.2.16.	2.~~8~~1.~~2~~18	Tularemia	_	Agent id.
Cattle				
2.3.1.	2.~~3~~4.~~1~~3	Bovine brucellosis	BBAT, CF, ELISA, FPA	_
2.3.2.	2.~~3~~4.~~2~~5.	Bovine genital campylobacteriosis	Agent id.	_
2.3.3.	2.~~3~~4.~~3~~7.	Bovine tuberculosis	Tuberculin test	Gamma interferon test
2.3.4.	2.~~3~~4.~~4~~11	Enzootic bovine leukosis	AGID, ELISA	PCR
2.3.5.	2.~~3~~4.~~5~~13.	Infectious bovine rhinotracheitis/ infectious pustular vulvovaginitis	VN, ELISA, Agent id. (semen only), PCR	_
2.3.6.	2.~~3~~4.~~6~~17.	Trichomonosis	Agent id.	Mucus agg.
2.3.7.	2.~~3~~4.~~7~~1.	Bovine anaplasmosis	_	CF, Agg. card
2.3.8.	2.~~3~~4.~~8~~2.	Bovine babesiosis	_	ELISA, IFA, CF
~~2.3.9.~~	~~2.3.9.~~	~~Bovine cysticercosis~~	~~_~~	~~Agent id.~~
2.3.11.	2.~~3~~4.1~~4~~6.	Theileriosis	Agent id., IFA	_
2.3.12.	2.~~3~~4.12.	Haemorrhagic septicaemia	_	Agent id.
2.3.14.	2.~~1~~4.~~7~~14	Lumpy skin disease	_	VN
2.3.15.	2.~~1~~4.~~6~~2.	Contagious bovine pleuropneumonia	CF, ELISA	_
Sheep and goats				
2.4.1.	2.~~4~~7.~~1~~8.	Ovine epididymitis (*Brucella ovis*)	CF	ELISA
2.4.2.	2.~~4~~7.~~2~~1.	Caprine and ovine brucellosis (excluding *Brucella ovis*)	BBAT, CF	Brucellin test, FPA
2.4.4.	2.~~4~~7.~~4~~2.	Caprine arthritis/encephalitis	AGID, ELISA	_
2.4.5.	2.~~4~~7.~~5~~3.	Maedi-visna	AGID, ELISA	_
2.4.6.	2.~~4~~7.~~6~~5.	Contagious caprine Pleuropneumonia	CF	_
2.4.7.	2.~~4~~7.~~7~~6.	Enzootic abortion of ewes	_	CF
2.4.9.	2.~~4~~7.1~~5~~0.	Peste des petits ruminants	VN	ELISA
2.4.10.	2.~~4~~7.1~~0~~3.	Sheep pox and goat pox	_	VN

Annex XIV (contd)

Terrestrial Code chapter No.	Terr estr ial Manual chapter No.	Disease name	Prescribed tests	Alternative tests
OIE listed diseases (contd)				
Equines				
2.5.1.	2.5.~~1~~2.	Contagious equine metritis	Agent id.	_
2.5.2.	2.5.~~2~~3.	Dourine	CF	IFA, ELISA
2.5.3.	2.5.~~3~~5.	Equine encephalomyelitis (Eastern and Western)	_	HI, CF, PRN
2.5.4.	2.5.~~4~~6.	Equine infectious anaemia	AGID	ELISA
2.5.5.	2.5.~~5~~7.	Equine influenza	_	HI
2.5.6.	2.5.~~6~~8.	Equine piroplasmosis	IFA, ELISA	CF
2.5.7.	2.5.~~7~~9.	Equine rhinopneumonitis	_	VN
2.5.8.	2.5.~~8~~11.	Glanders	Mallein test, CF	_
2.5.10.	2.5.10.	Equine viral arteritis	VN, Agent id. (semen only)	_
2.5.12.	2.5.1~~2~~4.	Venezuelan equine encephalomyelitis	_	HI, CF, PRN
2.5.14.	2.~~1~~5.1~~1~~.	African horse sickness	CF, ELISA	VN, Agent id. (real-time PCR)
Swine				
2.6.2.	2.~~6~~8.~~2~~5.	Porcine brucellosis	ELISA	BBAT, FPA
~~2.6.3.~~	~~2.6.3.~~	~~Enterovirus encephalomyelitis~~	~~–~~	~~VN~~
2.6.4.	2.~~6~~8.~~1~~10.	Transmissible gastroenteritis	_	VN, ELISA
2.6.5.	2.~~1~~8.~~3~~8.	Swine vesicular disease	VN	ELISA
2.6.6.	2.~~1~~8.1~~2~~.	African swine fever	ELISA	IFA
2.6.7.	2.~~1~~8.~~1~~3.	Classical swine fever	NPLA, FAVN, ELISA	_
Birds				
2.7.1.	2.~~7~~2.~~1~~12.	Infectious bursal disease	_	AGID, ELISA
2.7.2.	2.~~7~~2.~~2~~13.	Marek's disease	_	AGID
2.7.3.	2.~~7~~2.~~3~~5.	Avian mycoplasmosis (*My coplasma gallisepticum*)	_	Agg., HI
2.7.5.	2.~~7~~2.~~5~~11.	Fowl typhoid and Pullorum disease	_	Agg., Agent id.
2.7.6.	2.~~7~~2.~~6~~2.	Avian infectious bronchitis	_	VN, HI, ELISA
2.7.7.	2.~~7~~2.~~7~~3.	Avian infectious laryngotracheitis	_	AGID, VN, ELISA
~~2.7.8.~~	~~2.2.6.~~	~~Avian tuberculosis~~	~~–~~	~~Tuberculin test, Agent id.~~
2.7.12.	2.~~1~~2.~~1~~4.	Avian influenza	Virus isolation with pathogenicity testing	AGID, HI
2.7.13.	2.~~1~~2.1~~5~~4.	Newcastle disease	_	HI
Lagomorphs				
2.8.1.	2.8.1.	Myxomatosis	_	AGID, CF, IFA
2.8.2.	2.8.3.	Rabbit haemorrhagic disease	_	HI

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Annex XV

CHAPTER 2.3.13.

BOVINE SPONGIFORM ENCEPHALOPATHY

Community position:

The Community would like to stress in particular the comments related to the ruminant to ruminant feed ban provisions (Article 2.3.13.3, 4, 7, 8, 9 and 10), SRM definition (Article 2.3.13.14, 15, 16, 16bis), the annual update (Article 2.3.13.3.), gelatine (Article 2.3.13.15), tallow (2.3.13.1.e) and the use of the risk assessment guidelines (Article 3.8.5.1. of Appendix 3.8.5.). The Community cannot support the amended chapter and wishes its comments to be taken into account.

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 Authorities* 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;

Community comments

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 2.3.13.14.;

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 Authorities* 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.

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;

Community comment

The assessment of the birth cohorts of the positive BSE cases should be taking into account which will allow better assessing the correct implementation of the feed ban provisions.

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 2.3.13.14. 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.

Community comment

The results of the surveillance programmes should also be taken into account in carrying out this assessment.

The Community propose the following wording:

" The results of surveillance and other epidemiological investigation into the disposition of the commodities identified above should be taken into account in carrying out the assessment.

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 subpopulations 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 carried out in accordance with the *Terrestrial Manual* in an ~~*approved*~~ *laboratory* of brain or other tissues collected within the framework of the aforementioned surveillance and monitoring system.

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;

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;

Community comment

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 3a) ii) as follows:

"ii) it has been demonstrated, through an appropriate level of control and audit, that for at least 8 years meat-and-bone meal or greaves derived from mammals has not been fed to ruminants;"

This comment also applies to Article 2.3.13.3.., point 3b) ii), Article 2.3.13.4, point 3a)(ii) and 3b), Article 2.3.13.7,point 2), Article 2.3.13.8, point 3, Article 2.3.13.9, point 1) en 3b) and Article 10, point 3).

   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.

The country or *zone* will be included in the list of negligible risk only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information ~~above~~ for the previous 12 months on surveillance results and feed controls be re-submitted annually and changes in the epidemiological situation or other significant events should be reported ~~promptly~~ to the OIE according to the requirements in Chapter 1.1.2.

Community comment

The Community supports the amendment made and is grateful to the OIE for limiting the annual updates, to data on surveillance and feed controls.

The Community has taken the position that the OIE should take a leading role in the categorisation of countries according its BSE risk. However in order not to jeopardise the process it is of utmost importance that the OIE give the necessary follow up to the OIE recommendations made in the report attributing the BSE risk status to a OIE Member country, including the update of the information related to the feed ban and surveillance. The same comment also applies to the last paragraph in Article 2.3.13.4..

In addition the Community propose editorial change: " … 12 months on surveillance results and feed controls are re-submitted annually …"

Article 2.3.13.4.

Controlled BSE risk

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;~~

Community comment

The Community proposes a slight rewording as follows:

" b) there has been an indigenous case of BSE, the criteria in points 2 to 4 of Article 2.3.13.2. are being 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 is being fed to ruminants."

~~AND~~

~~iii)~~ and 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.

The country or *zone* will be included in the list of controlled risk only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information ~~above~~ for the previous 12 months on surveillance results and feed controls be re-submitted annually and changes in the epidemiological situation or other significant events should be reported ~~promptly~~ to the OIE according to the requirements in Chapter 1.1.2.

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 Authorities* 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 2.3.13.7.

When importing from a country, *zone* or *compartment* posing a negligible BSE risk, but where there has been an indigenous *case*, *Veterinary Authorities* should require:

for cattle selected for export

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

1. are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as described in point 3.b)iii) of Article 2.3.13.3.;

2. 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 want to re-iterate its previous comment. The possibility of cases born 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:

"2. were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from mammals 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 implementation of the feed ban ."

This comment also applies to Article 2.3.13.8, point 3..

In addition the cattle selected for export should be born and continuously reared in the exporting country or a country with at least a corresponding status. Therefore the Community propose to add a point 3:

"3. the animals were born and continuously reared in a country, zone or compartment posing a negligible BSE risk"

Article 2.3.13.8.

When importing from a country, *zone* or *compartment* posing a controlled BSE risk, *Veterinary Authorities* 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 in such a way as to demonstrate that they are not exposed cattle as described in point 3.b)~~iii)~~ of Article 2.3.13.4.;

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 ruminants was effectively enforced.

Article 2.3.13.9.

When importing from a country, *zone* or *compartment* with an undetermined BSE risk, *Veterinary Authorities* 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 in such a way as to demonstrate that they are not exposed cattle as demonstrated in point 2 above;

   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.

Community comment

The possibility of cases born 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:

"2. 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 or after the date of birth of the last indigenous case if that indigenous case was born more than two years after the date of the implementation of the feed ban ."

Article 2.3.13.10.

When importing from a country, *zone* or *compartment* posing a negligible BSE risk, *Veterinary Authorities* 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

The cattle from which the fresh meat and meat products were derived from should be born and continuously reared in the exporting country with the negligible BSE risk. Therefore the Community propose to amend point 2:

"2. the cattle from which the fresh meat and meat products were derived, were born and continuously reared in a country, zone or compartment posing a negligible BSE risk and passed ante-mortem and post-mortem inspections."

3. in countries with negligible BSE risk where there have been indigenous *cases*, the cattle from which the *fresh meat* and *meat products* were derived 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.

Article 2.3.13.11.

When importing from a country, *zone* or *compartment* with a controlled BSE risk, *Veterinary Authorities* 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 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 2.3.13.14.;

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

Community comment

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 4 b) with:

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

This comment also applies to Article 2.3.13.12, point 2c).

Article 2.3.13.12.

When importing from a country, *zone* or *compartment* with an undetermined BSE risk, *Veterinary Authorities* 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 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 2.3.13.14.;

   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.

Article 2.3.13.13.

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., but where there has been an indigenous *case* of BSE, 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 effectively enforced.

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.

Article 2.3.13.14.

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.

Community comment

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.

On 19 April 2007 the EFSA adopted an opinion which took into account the latest results of the pathogenesis studies as well as the epidemiological data available from the monitoring programme in the European Union since 2001. The opinion concluded that the situation has not changed despite some new information with regard to tissues comprised of, or containing, lymphoid tissue designated 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.

Community comment

On 19 April 2007 the EFSA adopted an opinion which took into account the latest results of the pathogenesis studies as well as the epidemiological data available from the monitoring programme in the European Union since 2001.

Based on this opinion, the Community amended the age for the removal of the vertebral column as SRM from 24 to 30 months. No modifications were proposed for the age limit for the removal of brains, eyes, spinal cord and skull as SRM.

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 2.3.13.15.

Veterinary Authorities of *importing countries* should require:

<u>for gelatine and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices</u>

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 <u>or undetermined</u> BSE risk and are derived from cattle which have passed ante-mortem and post-mortem inspections; and that

a) skulls ~~from cattle over 30~~ 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) 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) 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).~~

Community comment

The Community supports the reduction of the age limit for the removal of the skull as SRM from bovine animals originating from controlled BSE risk countries for the production of gelatine from 30 to 12 months.

On the other hand, the use of vertebral column from bovine animals of all ages from a country where the initial risk has not been identified (i.e. undetermined risk country) and therefore cannot be assessed, to be used for the production of gelatine for food, poses a problem of principle for which the Community thinks more discussions should take place. The Community thus proposes that the words "(under study)" be added after the word "undetermined".

Article 2.3.13.16.

Veterinary Authorities 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*~~ tallow came from a country, *zone* or *compartment* posing a negligible BSE risk; or

~~2.~~ ~~they~~ it originated from a country, *zone* or *compartment* posing a controlled BSE risk, ~~are~~ is derived from cattle which ~~have~~ ~~has~~ have passed ante-mortem and post-mortem inspections, and ~~have~~ has not been prepared using the tissues listed in points 1 and 2 of Article 2.3.13.14.

Community comment

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. Tallow can be considered safe if no SRM is used for the production of tallow, the animals of which the raw material has been derived have passed ante- and post mortem inspection.

The Community propose to impose the same rules for tallow coming from undetermined risk countries. The Community proposes to include a new point 3.

"3. it originate from a country, zone or compartment posing an undetermined BSE risk, is derived from cattle which have passed ante-mortem and post-mortem inspections, and has not been prepared using the tissues listed in points 1 and 3 of Article 2.3.13.14."

Article 2.3.13.16. bis

Veterinary Authorities of *importing countries* should require:

for 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 dicalcium phosphate came from a country, *zone* or *compartment* posing a negligible BSE risk; or

2. it originates from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk and is a by-product of bone gelatine produced according to Article 2.3.13.15.

Community comment

On 16 March 2006 the EFSA adopted an opinion on the "Quantitative assessment of the residual BSE risk posed by di-calcium phosphate (DCP) and tri-calcium phosphate (TCP) from bovine bones used as an animal feed additive or as fertiliser".

The opinion defines that when the scenario is considered including the vertebral column from bovine animals originating from countries with a adequate surveillance system, this scenario would result in an adult dairy cow population of 20 million to on average 38 infected cattle per year.

Based on the scientific evidence, the Community oppose to the proposed amendment.

The Community proposes the following amendment replacing point 2:

"2. it originate from a country, zone or compartment posing a controlled BSE risk, is derived from cattle which have passed ante-mortem and post-mortem inspections, and has not been prepared using the tissues listed in points 1 and 2 of Article 2.3.13.14.

3. it originate from a country, zone or compartment posing an undetermined BSE risk, is derived from cattle which have passed ante-mortem and post-mortem inspections, and has not been prepared using the tissues listed in points 1 and 3 of Article 2.3.13.14"

Article 2.3.13.17.

Veterinary Authorities 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. the *commodities* 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 2.3.13.16.; or

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

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APPENDIX 3.8.4.

GUIDELINES ON SURVEILLANCE FOR BOVINE SPONGIFORM ENCEPHALOPATHY

Article 3.8.4.1.

Community position

The Community can support the proposed changes but wishes the OIE to take its comments into account.

Introduction

1. Depending on the risk category of a country, *zone* or *compartment* with regard to bovine spongiform encephalopathy (BSE), surveillance for BSE may have one or more goals:

   a) detecting BSE, to a pre-determined design prevalence, in a country, *zone* or *compartment;*

   b) monitoring the evolution of BSE in a country, *zone* or *compartment;*

   c) monitoring the effectiveness of a feed ban and/or other risk mitigation measures, in conjunction with auditing;

   d) supporting a claimed BSE status;

   e) gaining or regaining a higher BSE status.

2. When the BSE agent is present in a country or *zone,* the cattle population will comprise the following sectors, in order of decreasing size:

   a) cattle not exposed to the infective agent;

   b) cattle exposed but not infected;

   c) infected cattle, which may lie within one of three stages in the progress of BSE:

      i) the majority will die or be killed before reaching a stage at which BSE is detectable by current methods;

      ii) some will progress to a stage at which BSE is detectable by testing before clinical signs appear;

      iii) the smallest number will show clinical signs.

3. The BSE status of a country, *zone* or *compartment* cannot be determined only on the basis of a surveillance programme but should be determined in accordance with all the factors listed in Article 2.3.13.2. The surveillance programme should take into account the diagnostic limitations associated with the above sectors and the relative distributions of infected cattle among them.

4. With respect to the distribution and expression of the BSE agent within the sectors described above, the following four subpopulations of cattle have been identified for surveillance purposes:

   a) cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical

suspects);

b) cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency *slaughter* or condemned at ante-mortem inspection (casualty or emergency *slaughter* or downer cattle);

c) cattle over 30 months of age which are found dead or killed on farm, during transport or at an *abattoir* (fallen stock);

Community comment

The Community would propose the following amendment to point b) and c) which better defines the subpopulations:

"b) cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency slaughter for human consumption or showing abnormal clinical signs at ante-mortem inspection (casualty or emergency slaughter or downer cattle);

c) cattle over 30 months of age which are found dead on farm or during transport , or killed other than for human consumption (fallen stock);"

d) cattle over 36 months of age at routine *slaughter*.

5. A gradient is used to describe the relative value of surveillance applied to each subpopulation. Surveillance should focus on the first subpopulation, but investigation of other subpopulations will help to provide an accurate assessment of the BSE situation in the country, *%me* or *compartment*. This approach is consistent with Appendix 3.8.1. on general guidelines for animal health surveillance.

6. When establishing a surveillance strategy, authorities need to take into account the inherent difficulties of obtaining samples on farm, and overcome them. These difficulties include higher cost, the necessity to educate and motivate owners, and counteracting potentially negative socio-economic implications.

Article 3.8.4.2.

Description of cattle subpopulations

1. Cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects)

Cattle affected by illnesses that are refractory to treatment, and displaying progressive behavioural changes such as excitability, persistent kicking when milked, changes in herd hierarchical status, hesitation at doors, gates and barriers, as well as those displaying progressive neurological signs without signs of infectious illness are candidates for examination. These behavioural changes, being very subtle, are best identified by those who handle animals on a daily basis. Since BSE causes no pathognomonic clinical signs, all countries with cattle populations will observe individual animals displaying clinical signs consistent with BSE. It should be recognised that cases may display only some of these signs, which may also vary in severity, and such animals should still be investigated as potential BSE affected animals. The rate at which such suspicious cases are likely to occur will differ among epidemiological situations and cannot therefore be predicted reliably.

This subpopulation is the one exhibiting the highest prevalence. The accurate recognition, reporting and classification of such animals will depend on the ongoing owner/veterinarian awareness programme. This and the quality of the investigation and laboratory examination systems (Article

2.3.13.2.), implemented by the *Veterinary Services,* are essential for the credibility of the surveillance system.

2. Cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency slaughter or condemned at ante-mortem inspection (casualty or emergency slaughter, or downer cattle)

   These cattle may have exhibited some of the clinical signs listed above which were not recognised as being consistent with BSE. Experience in countries where BSE has been identified indicates that this subpopulation is the one demonstrating the second highest prevalence. For that reason, it is the second most appropriate population to target in order to detect BSE.

3. Cattle over 30 months of age which are found dead or killed on farm, during transport or at an abattoir (fallen stock)

   These cattle may have exhibited some of the clinical signs listed above prior to death, but were not recognised as being consistent with BSE. Experience in countries where BSE has been identified indicates that this subpopulation is the one demonstrating the third highest prevalence.

4. Cattle over 36 months of age at routine slaughter

   Experience in countries where BSE has been identified indicates that this subpopulation is the one demonstrating the lowest prevalence. For that reason, it is the least appropriate population to target in order to detect BSE. However, sampling in this subpopulation may be an aide in monitoring the progress of the epizootic and the efficacy of control measures applied, because it offers continuous access to a cattle population of known class, age structure and geographical origin. Testing of routine *slaughter* cattle 36 months of age or less is of relatively very little value (Table 2).

Article 3.8.4.3.

Implementation of surveillance

In order to implement efficiently a surveillance strategy for BSE, a country must use documented records or reliable estimates of the age distribution of the adult cattle population and the number of cattle tested for BSE stratified by age and by subpopulation within the country, *zone* or *compartment*.

The approach assigns 'point values' to each sample, based on the subpopulation from which it was collected and the likelihood of detecting infected cattle in that subpopulation. The number of points a sample is assigned isdetermined by the subpopulation from which the sample is collected and the age of the animal sampled. The total points accumulation is then periodically compared to the target number of points for a country, *zone* or *compartment*.

A surveillance strategy should be designed to ensure that samples are representative of the herd of the country, *zone* or *compartment,* and include consideration of demographic factors such as production type and geographic location, and the potential influence of culturally unique husbandry practices. The approach used and the assumptions made should be fully documented, and the documentation retained for 7 years.

The points targets and surveillance point values in this Appendix were obtained by applying the following factors to a statistical model:

a) the design prevalence for Type A or Type B surveillance;

b) a confidence level of 95%;

c) the pathogenesis, and pathological and clinical expression of BSE:

i) sensitivity of diagnostic methods used;

ii) relative frequency of expression by age;

iii) relative frequency of expression within each subpopulation;

iv) interval between pathological change and clinical expression;

d) demographics of the cattle population, including age distribution;

e) influence of BSE on culling or attrition of animals from the cattle population via the four subpopulations;

f) percentage of infected animals in the cattle population which are not detected.

Although the procedure accepts very basic information about a cattle population, and can be used with estimates and less precise data, careful collection and documentation of the data significantly enhance their value. Since samples from clinical suspect animals provide many times more information than samples from healthy or dead-of-unknown-cause animals, careful attention to the input data can substantially decrease the procedure's cost and the number of samples needed. The essential input data are:

g) cattle population numbers stratified by age;

h) the number of cattle tested for BSE stratified by age and by subpopulation.

This Appendix utilises Tables 1 and 2 to determine a desired surveillance points target and the point values of surveillance samples collected.

Within each of the subpopulations above in a country, *zone* or *compartment,* a country may wish to target cattle identifiable as imported from countries or *zones* not free from BSE and cattle which have consumed potentially contaminated feedstuffs from countries or *zones* not free from BSE.

All clinical suspects should be investigated, regardless of the number of points accumulated. In addition, animals from the other subpopulations should be tested.

Community comment

For consistency the text should make it clear that overall, animals from at least three out of four of the sub populations should be tested as stipulated in Article 3.8.4.4, point 2, second paragraph. The Community propose to replace the last phrase as follows:

"In addition, countries should sample at least three of the four subpopulations."

1. Type A surveillance

   The application of Type A surveillance will allow the detection of BSE around a design prevalence of at least one case per 100,000 in the adult cattle population in the country, *zone* or *compartment* of concern, at a confidence level of 95%.

2. Type B surveillance

   The application of Type B surveillance will allow the detection of BSE around a design prevalence of at least one case per 50,000 in the adult cattle population in the country, *zone* or *compartment* of concern, at a confidence level of 95%.

Type B surveillance may be carried out by countries, *zones* or *compartments* of negligible BSE risk status (Article 2.3.13.3.) to confirm the conclusions of the risk assessment, for example by demonstrating the effectiveness of the measures mitigating any risk factors identified, through surveillance targeted to maximise the likelihood of identifying failures of such measures.

Type B surveillance may also be carried out by countries, *zones* or *compartments* of controlled BSE risk status (Article 2.3.13.4.), following the achievement of the relevant points target using Type A surveillance, to maintain confidence in the knowledge gained through Type A surveillance.

Article 3.8.4.4.

1. Selecting the points target

The surveillance points target should be selected from Table 1, which shows target points for adult cattle populations of different sizes. The size of the adult cattle population of a country, *zone* or *compartment* may be estimated or may be set at one million because, for statistical reasons, one million is the point beyond which sample size does not further increase with population size.

Table 1. ***Points targets for different adult cattle population sizes in a country, zone or compartment***

Points targets for country, zone or compartment		
Adult cattle population size (24 months and older)	**Type A surveillance**	**Type B surveillance**
>1,000,000	300,000	150,000
800,000-1,000,000	240,000	120,000
600,000-800,000	180,000	90,000
400,000-600,000	120,000	60,000
200,000-400,000	60,000	30,000
100,000-200,000	30,000	15,000
50,000-100,000	15,000	7,500

Community comment

Points targets should also be specified for Member countries with a small adult cattle population.

Where in the framework of the categorisation of countries with a small adult cattle population lower target points already were applied, the Community propose to include, for transparency reasons, an additional line for countries with a adult cattle population between 25,000 -50,000 (Type A: 7,500 points and type B surveillance: 3,750 points).

2. Determining the point values of samples collected

Table 2 can be used to determine the point values of the surveillance samples collected. The approach assigns point values to each sample according to the likelihood of detecting *infection* based on the subpopulation from which the sample was collected and the age of the animal sampled. This approach takes into account the general principles of surveillance described in Appendix 3.8.1. and the epidemiology of BSE.

Because precise aging of the animals that are sampled may not be possible, Table 2 combines point values into five age categories. The point estimates for each category were determined as an average for the age range comprising the group. The age groups were selected on their relative likelihoods of expressing BSE according to scientific knowledge of the incubation of the *disease* and the world BSE experience. Samples may be collected from any combination of subpopulations and ages but should reflect the demographics of the cattle herd of the country, *zone* or *compartment*. In addition, countries should sample at least three of the four subpopulations.

If a country, *zone* or *compartment* determines, based on the demographics and epidemiological characteristics of its cattle population, that precise classification of the subpopulations 'casualty or emergency *slaughter*, or downer cattle' and 'fallen stock' is not possible, these subpopulations may be combined. In such a case, the surveillance point values accorded to the combined subpopulation would be that of 'fallen stock'.

The total points for samples collected may be accumulated over a period of a maximum of 7 consecutive years to achieve the target number of points determined in Table 1.

Table 2. *Surveillance point values for samples collected from animals in the given subpopulation and age category*

Surveillance subpopulation			
Routine slaughter[1]	**Fallen stock[2]**	**Casualty slaughter[3]**	**Clinical suspect[4]**
Age≥1 year and ≤≦2years			
0.01	0.2	0.4	N/A
Age ≥2 years and ≤≦4 years (young adult)			
0.1	0.2	0.4	260
Age ≥4 years and ≤≦7 years (middle adult)			
0.2	0.9	1.6	750
Age ≥7 years and ≤≦9 years (older adult)			
0.1	0.4	0.7	220
Age ≥9 years (aged)			
0.0	0.1	0.2	45

Surveillance points remain valid for 7 years (the 95th percentile of the incubation period).

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1. See point 4) of Article 3.8.4.2.
2. See point 3) of Article 3.8.4.2.
3. See point 2) of Article 3.8.4.2.
4. See point 1) of Article 3.8.4.2

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APPENDIX 3.8.5.

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

Article 3.8.5.1.

Community position

The Community can support the proposed changes but wishes the OIE to take its comments into account.

Introduction

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

1. Release assessment

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

   a) *meat-and-bone meal* or *greaves*;

   b) live animals;

   c) animal feed and feed ingredients;

   d) products of animal origin for human consumption.

2. Exposure assessment

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

   a) epidemiological situation concerning ~~all animal T~~BSE agents in the country or *zone*;

   b) recycling and amplification of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;

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

   d) implementation and enforcement of feed bans, including measures to prevent cross-contamination of animal feed.

The following guidelines are intended to assist *Veterinary Services* in conducting such a *risk assessment*. They provide guidance on the issues that need to be addressed when conducting a country-based assessment of

BSE risk. They apply equally to self-assessment in preparation of dossiers for categorisation of countries, [or to the evaluation of risk arising from trading partners if OIE categorisation of such countries is considered insufficient before trade rules are agreed.] The guidelines are supported by greater detail in the questionnaire used for the submission of data for country assessment.

Community comment

The Community has taken the position that the OIE should take a leading role in the categorisation of countries according its BSE risk. With a Resolution adopted in 2003, the OIE has accepted this role. Furthermore the final agreement on the categorisation of countries according their BSE risk is preceded by a wide 60 days consultation period and final vote at the OIE General Session.

The specific wording between brackets i.e. [or to the evaluation of risk arising from trading partners if OIE categorisation of such countries is considered insufficient before trade rules are agreed]" could be seen as an acceptance by the OIE of a separate system and will without any doubt jeopardise the validity of the current OIE categorisation system.

Article 3.8.5.2.

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

This point is irrelevant if the exposure assessment outlined below in Article 3.8.5.5. indicates that *meat-and-bone meal* or *greaves* has not been fed, either deliberately or accidentally, in the past 8 years. Nevertheless, documentation should be provided on the control systems (including relevant legislation) in place to ensure that *meat-and-bone meal* or *greaves* has not been fed to ruminants.

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

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

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

Evidence required:

- Documentation to support claims that *meat-and-bone meal*, *greaves* or feedstuffs containing either *meat-and-bone meal* or *greaves* have not been imported, OR

- Where *meat-and-bone meal*, *greaves* or feedstuffs containing them have been imported, documentation of country of origin and, if different, the country of export.

- Documentation on annual volume, by country of origin, of *meat*, *greaves* or feedstuffs containing them imported during the past 8 years.

- Documentation describing the composition (on a species and class of stock basis) of the imported *meat-and-bone meal*, *greaves* or feedstuffs containing them.

- Documentation, from the country of production, supporting why the rendering processes used to produce *meat-and-bone meal*, *greaves* or feedstuffs containing them would have inactivated, or significantly reduced the titre of ~~T~~BSE agent, should it be present.

- Documentation describing the fate of imported *meat-and-bone meal* and *greaves*.

Article 3.8.5.3.

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

Assumptions:

- Countries which have imported ruminants from countries infected with ~~animal~~ ~~T~~BSEs are more likely to experience BSE.

- Cattle pose the only known risk although other species are under stud.

- Animals imported for breeding may pose a greater risk than animals imported for slaughter because of the hypothetical risk of maternal transmission and because they are kept to a greater age than animals imported for slaughter.

- Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.

- Risk is proportional to volume of imports (Article 1.3.2.3.).

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

Rationale: The release risks are dependent on:

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

- feeding and management of the animals in the country of origin;

- use to which the commodity has been put as apart from representing risk of developing clinical disease, the slaughter, rendering and recycling in *meat-and-bone meal* of imported animals represents a potential route of exposure of indigenous livestock even if *meat-and-bone meal* and *greaves*, or feedstuffs containing them, have not been imported;

- species;

- dairy versus meat breeds, where there are differences in exposure in the country of origin because feeding practices result in greater exposure of one category;

- age at slaughter.

Evidence required:

- Documentation on the country of origin of imports. This should identify the country of breeding of animals, the length of time they lived in that country and of any other country in which they have resided during their lifetime.

- Documentation describing origins, species and volume of imports.

- Documentation describing the fate of imported animals, including their age at slaughter.

- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article 3.8.5.4.

The potential for the release of the BSE agent through the importation of products of animal origin potentially infected with a ~~T~~BSE

Assumptions:

- Semen, embryos, hides and skins or milk are not considered to play a role in the transmission of BSE.

- Countries which have imported products of animal origin from countries with ~~animal T~~BSEs are more likely to experience BSE.

- Risk is influenced by the date at which imports occurred, relative to the ~~animal T~~BSE status of the country of origin.

- Risk is proportional to volume of imports (Article 1.3.2.3.).

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

Rationale: The release risks are dependent on:

- the species of origin of the animal products and whether these products contain tissues known to contain BSE infectivity (Article 2.3.13.13.);

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

- feeding and management of the animals in the country of origin;

- use to which the commodity has been put as apart from representing risk of developing clinical disease, the slaughter, rendering and recycling in *meat-and-bone meal* of imported animals represents a potential route of exposure of indigenous livestock even if *meat-and-bone meal* and *greaves*, or feedstuffs containing them, have not been imported;

- species;

- dairy versus meat breeds, where there are differences in exposure in the country of origin because feeding practices result in greater exposure of one category;

- age at slaughter.

Evidence required:

- Documentation on the country of origin of imports. This should identify the country of breeding of animals, the length of time they lived in that country and of any other country in which they have resided during their lifetime.

- Documentation describing origins, species and volume of imports.

- Documentation describing the end use of imported animal products, and the disposal of waste.

- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article 3.8.5.5.

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

Assumptions:

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

- That commercially-available products of animal origin used in animal feeds may contain *meat-and-bone meal* or *greaves* of ruminant origin.

- Milk and blood are not considered to play a role in the transmission of BSE.

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

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

~~Article 3.8.5.6.~~

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

~~*Assumptions:*~~

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

- ~~Theoretically, scrapie in small ruminants might mask the presence of BSE and no field methods are available to differentiate between different TSEs.~~

- ~~Available evidence suggests there is no link between chronic wasting disease of cervids and BSE.~~

- ~~It has been suggested that transmissible mink encephalopathy may be an indicator of a hitherto undefined and hypothetical TSE of cattle.~~

- ~~If a hypothetical 'spontaneous' TSE of cattle is assumed to occur, it must also be assumed to occur in all countries at a similar rate.~~

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

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

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

Article 3.8.5.~~7~~6.

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

Assumptions:

- ~~T~~BSE ~~of livestock~~ have long *incubation periods* and insidious onset of signs, so cases may escape detection.

- Pre-clinical ~~T~~BSE cannot be detected by any method and may enter rendering, in particular if specified risk materials are not removed.

Community comment

The statement made is not scientifically correct since certain tests are available to detect BSE infectivity prior to the clinical onset of the disease. Therefore the Community propose the following wording:

"-Pre-clinical BSE infectivity cannot be reliably detected by any method and may enter rendering, in particular if specified risk materials are not removed..

- Tissues most likely to contain high titres of ~~T~~BSE infectivity (brain, spinal cord, eyes) may not be harvested for human consumption and may be rendered.

- ~~T~~BSE ~~of livestock~~ may manifest in sudden death, chronic disease, or recumbency, and may be presented as fallen stock or materials condemned as unfit for human consumption.

- ~~T~~BSE agent survival in rendering is affected by the method of processing. Adequate rendering processes are described in Appendix 3.6.3.

- ~~T~~BSE agent is present at much higher titres in central nervous system and reticulo-endothelial tissues (so-called 'Specified Risk Materials', or SRM).

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

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

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

Evidence required:

- Documentation describing the collection and disposal of fallen stock and materials condemned as unfit for human consumption.

- Documentation describing the definition and disposal of specified risk material, if any.

- Documentation describing the rendering process and parameters used to produce *meat-and-bone meal* and *greaves*.

- Documentation describing methods of animal feed production, including details of ingredients used, the extent of use of *meat-and-bone meal* in any livestock feed, and measures that prevent cross-contamination of cattle feed with ingredients used in monogastric feed.

- Documentation describing monitoring and enforcement of the above.

Article 3.8.5.~~8~~7.

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

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Annex XVI

CHAPTER 2.5.5.

EQUINE INFLUENZA

Community position:

The Community can support the proposed changes, but reiterates its request for a scientific justification to the minimum of 21 days delay between vaccination and export (formerly 14).

It also has a comment on article 2.5.5.3.

Article 2.5.5.1.

For the purposes of the *Terrestrial Code*, equine influenza (EI) is defined as an *infection* of domestic horses, 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*.

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.

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 the *disease* is notifiable in the whole country and 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*.

A country, *zone* or *compartment* seeking freedom from EI, in which vaccination is practised, should also demonstrate that EIV has not been circulating in the domestic horse population during the past 12 months, through surveillance, in accordance with Appendix 3.8.1.~~, 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%~~. In a country in which vaccination is not practised, surveillance could be conducted using serological testing. In countries where vaccination is practised, the surveillance should include methods of virus detection.

Community comment:

Proposed text for the first sentence of the above paragraph:

A country, *zone* or *compartment* seeking freedom from EI, in which vaccination is practised, should also demonstrate that EIV has not been circulating in the population of domestic equidae during the past 12 months, through surveillance, in accordance with Appendix 3.8.1.

Rationale:

It is not justified to assume that equine influenza virus may only circulate in the domestic horse population and not in other equidae.

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~~ in accordance with Appendix 3.8.1. ~~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.
~~(under study)~~

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

1. semen;

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

Article 2.5.5.5

When importing horses for immediate *slaughter*, the *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the horses showed no clinical sign of EI on the day of shipment.

Article 2.5.5.6.

When importing horses for unrestricted movement, *Veterinary Authorities* 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 EI, 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 immunised ~~vaccinated~~ according to the manufacturer's instructions, with a vaccine complying with standards described in the *Terrestrial Manual*, between 21 and 90 days before shipment either with a primary course or a booster.

Article 2.5.5.7.

When importing horses which will be kept in isolation (see Article 2.5.5.1.), *Veterinary Authorities* 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 21 days prior to shipment nor on the day of shipment; and

3. were immunised ~~vaccinated~~ according to the manufacturer's instructions, with a vaccine complying with standards described in the *Terrestrial Manual*.

Article 2.5.5.8.

When importing *fresh meat* of horses, mules or donkeys, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the *fresh meat* came from horses, mules or donkeys which had been subjected to ante-mortem and post-mortem inspections as described in Appendix 3.10.1.

— text deleted

Annex XVII

CHAPTER 2.5.7.

EQUINE RHINOPNEUMONITIS
(Equine herpes virus type 1 infection)

Community position:

The Community can support the proposed changes.

Article 2.5.7.1.

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

Article 2.5.7.2.

Veterinary Authorities 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 herpes virus type 1 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 herpes virus type 1 infection was reported during that period.

- - - - - - - - - - - - - - -
— text deleted

CHAPTER 2.5.10.

EQUINE VIRAL ARTERITIS

Community position:

The Community thanks the OIE for their proposed changes that it supports. It goes in the right direction, but EU still has important comments and is ready to participate in further discussions with the OIE Scientific Department, especially regarding the proposed deletions of article 2 point 2b) and article 3 points 2 and 3 that it supports.

Article 2.5.10.1.

The *infective period* for equine viral arteritis (EVA) shall be 28 days for all categories of equine except sexually mature stallion where the *infective period* may be for the life of the animal. 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 Authorities 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 isolated for the 28 days prior to shipment and subjected, to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out either:

   a) on a single 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

Community comment:

Proposed text:

2. were isolated for the 28 days prior to shipment and subjected, to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out on a single blood sample collected during the 21 days prior to shipment with negative result,

Rationale:

1. The blood samples of a naïve animal should be taken a certain time after entry into isolation to allow antibodies to develop in case of incubation of the disease; thus the test should be made only during the 21 days prior to shipment, i.e. at least one week after entry into isolation.

2. Stable or declining antibodies are, at least where maternal antibodies can be ruled out, indicative for a previous exposure to the EAV and do not guarantee the absence of virus in the semen; thus, only negative testing is acceptable in this case, and point b) should be deleted.

3. were isolated for the 28 days prior to shipment and 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

Community comment:

The Community proposes to delete the words "isolated for the 28 days prior to shipment and".

Rationale:

Because vaccinated, and revaccinated, uncastrated male equidae are considered to be non-receptive to the EAV, there is no need for 28 days isolation for the purpose of preventing the introduction of this disease into the country of destination.

4. were isolated for the 28 days prior to shipment and 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

Community comment:

The Community proposes the following wording:

4. were subjected to a test for EVA, as prescribed in the *Terrestrial Manual*, on a blood sample taken during isolation of at least 28 days 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

Rationale:

Because vaccinated, and revaccinated, uncastrated male equidae are considered to be non-receptive to the EAV, there is no need for 28 days isolation prior to shipment, but on the other hand, the non-immune uncastrated male equine animal should be protected from possible infection with the EAV in order to ensure that the negative result in the serological test is valid and that following vaccination sufficient protection against infection is provided until post-vaccination immunity is ensured; thus the isolation should be performed at the time of testing and vaccination.

5. have been subjected to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out 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* 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 test for equine arteritis virus as prescribed in the *Terrestrial Manual* with negative results, carried out on semen collected during the 28 days prior to shipment.

Community comment:

Proposed text:

5. have been subjected to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out with positive results on a blood sample taken within 12 months prior to shipment and were subsequently within 12 months after the serological result and prior to shipment

a) test mated to two mares which 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 mating; or

b) subjected with negative results to a test for equine arteritis virus as prescribed in the *Terrestrial Manual*, carried out on semen collected prior to shipment.

Rationale:

1. As the nature of immunity is not specified, a positive serological result has only a limited validity, as otherwise revaccination would not make sense. This validity is set at 12 months.

2. Where an uncastrated male equine animals is immune, the non-shedder status, i.e. the absence of virus in the semen, should be reconfirmed every 12 months. In consequence, a positive serology in combination with a negative semen-virology should have a validity of 12 months.

3. There should be no difference between test-mating and laboratory testing, unless it is specified in the Manual of Standards that the sensitivity of the laboratory test is inferior to the test system using test mating. However, in such cases of limited sensitivity it would rather be beneficial to repeat the test, than to shorten the period prior to dispatch.

Article 2.5.10.3.

Veterinary Authorities 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 the 28 days prior to shipment;

2. were isolated for the 28 days prior to shipment and subjected to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out either:

   a) on a single blood sample collected during the 28 days prior to shipment with negative results, 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 isolated for the 28 days prior to shipment and subjected, between 6 and 9 months of age, to a diagnostic test for EVA, as prescribed in the *Terrestrial Manual*, carried out on two blood samples collected at least 14 days apart, with negative results or stable or declining titre, and immediately vaccinated for EVA and regularly revaccinated.

Community comment:

The test requirements in points 2 and 3 of Article 2.5.10.3 should be deleted.

Rationale:

The main risk is the uncastrated male equine animal shedding EAV in its semen. The risk from aerosol transmission is addressed by the requirements for the holding of origin and the pre-export isolation.

Article 2.5.10.4.

Veterinary Authorities of *importing countries* should require:

for semen

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

1. were kept for the 28 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 9 months of age to a test for EVA as prescribed in the *Terrestrial Manual* on a blood sample 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

5. were subjected to a 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 been separated from other equidae for 14 days prior to blood sampling from the time of the taking of the blood sample ~~to the time~~ until the end of semen collection; or

Community comment:

Proposed text:

4. were subjected to a test for EVA, as prescribed in the *Terrestrial Manual*, on a blood sample taken during isolation of at least 28 days 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

5. were subjected to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out with positive results on a blood sample taken within 12 months prior to the collection of the semen to be exported and were after obtaining the serological result and prior to the collection of the semen to be exported

a) either test mated, not later than 30 days prior to the collection of the semen to be exported, to two mares which 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 mating; or

b) subjected with negative results to a test for equine arteritis virus as prescribed in the *Terrestrial Manual*, carried out on semen collected after the serological result was obtained and prior to the collection of the semen to be exported.

Rationale (4)

The non-immune uncastrated male equine animal should be protected from possible infection with the EAV in order to ensure that the negative result in the serological test is valid and that after vaccination protection against infection is provided until post-vaccination immunity is ensured.

Rationale (5)

1. As we do not specify the nature of the immunity a positive serological result has only a limited validity, as otherwise revaccination would not make sense. This validity is set at 12 months.

2. Where an uncastrated male equine animals is immune, the non-shedder status, i.e. the absence of virus in the semen, should be reconfirmed every 12 months. In consequence, a positive serology in combination with a negative semen-virology should have a validity of 12 months.

3. There should be no difference between test-mating and laboratory testing, unless it is specified in the Manual of standards that those tests are not equivalent. However, in such cases of limited sensitivity it would rather be beneficial to repeat the test, than to shorten the period prior to dispatch.

6. have been subjected to a 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 semen collection, which 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 test for equine arteritis virus as prescribed in the *Terrestrial Manual* with negative results, carried out on semen collected within one year prior to collection of the semen to be exported.

Community comment:

It is proposed to add a point 7:

7. were, in the case of frozen semen to be exported, subjected with negative results

a) either to a test for EVA as prescribed in the *Terrestrial Manual* carried out on a blood sample taken not earlier than 14 days and not later than 12 months after the collection of the semen for export, or

b) to a test for equine arteritis virus as prescribed in the *Terrestrial Manual* carried out on an aliquot of the entire semen collected within 30 days after the collection of the semen for export;

Rationale:

Increasingly equine semen is shipped as frozen semen. This way of preserving and storing equine semen allows to resort to post-collection testing, which is the most reliable testing regime.

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— text deleted

Annex XVIII

CHAPTER 2.5.14.

AFRICAN HORSE SICKNESS

Community position:

The Community can support the proposed changes, but has a comment on articles 8 and 9 in order to take into account the use of inactivated vaccines.

Article 2.5.14.1.

For the purposes of the *Terrestrial Code*, the *infective period* for African horse sickness virus (AHSV) shall be 40 days for domestic horses. Although critical information is lacking for some species, this Chapter applies to all equidae.

All countries or *zones* neighbouring, or considered to be at risk from, a country or *zone* not having free status should determine their AHSV status from an ongoing surveillance programme. Throughout the Chapter surveillance is in all cases understood as being conducted as described in Appendix 3.8.X.

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

Article 2.5.14.2.

AHSV free country or zone

1. A country or *zone* may be considered free from AHSV when African horse sickness (AHS) is notifiable in the whole country, systematic vaccination is prohibited, importation of equidae, their semen~~,~~ and oocytes or embryos, ~~and *pathological material* and biological products from these species~~ are carried out in accordance with this chapter, and either:

   a) historical freedom as described in Appendix 3.8.1. has demonstrated no evidence of AHSV in the country or *zone*; or

   b) the country or *zone* has not reported any case of AHS for at least 2 years and is not adjacent to a country or *zone* not having a free status; or

   c) a surveillance programme has demonstrated no evidence of AHSV in the country or *zone* for at least 12 months; or

   d) the country or *zone* has not reported any *case* of AHS for at least 40 days and a surveillance programme has demonstrated no evidence of *Culicoides* likely to be competent AHSV vectors for at least 2 years in the country or *zone*.

2. An AHSV free country or *zone* will not lose its free status through the importation of vaccinated or seropositive equidae, their semen, oocytes or embryos from infected countries or *infected zones*, provided these imports are carried out in accordance with this chapter.

Article 2.5.14.3.

AHSV seasonally free zone

1. An AHSV seasonally free *zone* is a part of an infected country or an *infected zone* for which for part of a

year, ongoing surveillance and monitoring demonstrate no evidence of AHSV transmission and of the presence of adult *Culicoides* likely to be competent AHSV vectors.

2. For the application of Articles 2.5.14.6., 2.5.14.8. and 2.5.14.9., the seasonally free period is:

   a) taken to commence the day following the last evidence of AHSV transmission and of the cessation of activity of adult *Culicoides* likely to be competent AHSV vectors as demonstrated by an ongoing surveillance programme, and

   b) taken to conclude either:

      i) at least ~~28~~ 40 days before the earliest date that historical data show AHSV activity has recommenced; or

      ii) immediately when current climatic data or data from a surveillance and monitoring programme indicate an earlier resurgence of activity of adult *Culicoides* likely to be competent AHSV vectors.

3. An AHSV seasonally free *zone* will not lose its free status through the importation of vaccinated or seropositive equidae, their semen, oocytes or embryos from infected countries or *infected zones*, provided these imports are carried out in accordance with this chapter.

Article 2.5.14.4.

AHSV infected country or zone

An AHSV infected country or *infected zone* is ~~a clearly defined area where~~ one in which the conditions of Article 2.5.14.2. or Article 2.5.14.3. do not apply.

Article 2.5.14.5.

When importing from AHSV free countries that are neither neighbouring nor considered to be at risk from an AHSV infected country or *infected zone*, *Veterinary ~~Administrations~~ Authorities* should require:

for equidae

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

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

2. have not been vaccinated against AHS within the last 40 days;

3. were kept in an AHSV free country since birth or for at least 40 days prior to shipment;

4. either:

   a) did not transit through an infected country or *infected zone*; or

   b) were protected from attack by *Culicoides* ~~likely to be competent AHSV vectors~~ at all times when transiting through an infected country or *infected zone*.

Article 2.5.14.6.

When importing from AHSV free countries or free *zones* or from AHSV seasonally free *zones* (during the seasonally free period) that are neighbouring or are considered to be at risk from an AHSV infected country or *infected zone*, *Veterinary ~~Administrations~~ Authorities* should require:

for equidae

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

1. showed no clinical signs of AHS on the day of shipment;

2. have not been vaccinated against AHS within the last 40 days;

3. were kept in an AHSV free country, free *zone* or seasonally free *zone* during the seasonally free period since birth or for at least 40 days prior to shipment; or

4. in a country or *zone* considered to be at risk, were held in quarantine for at least 40 days prior to shipment and protected at all times from attack by *Culicoides* ~~likely to be competent AHSV vectors~~; and

    a) a serological test according to the *Terrestrial Manual* to detect antibodies to the AHSV group, was carried out with a negative result on a blood sample collected at least 28 days after introduction into the *quarantine station*; or

    b) serological tests according to the *Terrestrial Manual* to detect ~~serotype specific~~ antibodies against ~~to the~~ AHSV ~~serotypes known to occur within the region~~ were carried out with no significant increase in antibody titre on blood samples collected on two occasions, with an interval of not less than 21 days, the first sample being collected at least 7 days after introduction into the *quarantine station*; or

    c) agent identification tests according to the *Terrestrial Manual* were carried out with negative results on blood samples collected on two occasions with an interval of not less than 14 days between collection, the first sample being collected at least 7 days after introduction into the *quarantine station*;

5. were protected from attack by *Culicoides* ~~likely to be competent AHSV vectors~~ at all times during transportation (including to and at the *place of shipment*).

Article 2.5.14.7.

When importing from an AHSV infected country or an AHSV *infected zone*, *Veterinary ~~Administrations~~ Authorities* should require:

for equidae

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

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

2. have not been vaccinated against AHS within the last 40 days;

3. were held continuously during the quarantine period of at least 40 days, in a vector-proof *quarantine station* and protected at all times from attack by *Culicoides* ~~likely to be competent AHSV vectors~~; and

    a) a serological test according to the *Terrestrial Manual* to detect antibodies to the AHSV group, was carried out with a negative result on a blood sample collected at least 28 days after introduction into the *quarantine station*; or

    b) serological tests according to the *Terrestrial Manual* to detect ~~serotype specific~~ antibodies against

~~to the~~ AHSV ~~serotypes known to occur within the region~~ were carried out with no significant increase in antibody titre on blood samples collected on two occasions, with an interval of not less than 21 days, the first sample being collected at least 7 days after introduction into the *quarantine station*; or

c) agent identification tests according to the *Terrestrial Manual* were carried out with negative results on blood samples collected on two occasions with an interval of not less than 14 days between collection, the first sample being collected at least 7 days after introduction into the *quarantine station*;

4. were protected from attack by *Culicoides* ~~likely to be competent AHSV vectors~~ at all times during transportation (including ~~during~~ transportation to and at the *place of shipment*).

Article 2.5.14.8.

Veterinary ~~Administrations~~ Authorities of *importing countries* should require:

for equid semen

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

1. showed no clinical sign of AHS on the day of collection of the semen and for the following 40 days;

2. had not been vaccinated against AHS within 40 days prior to the day of collection;

Community comment:

Proposed text:

2. had not been vaccinated against AHS by use of a live attenuated vaccine within 40 days prior to the day of collection;

Rationale:

As the donor stallion remains in the area potentially at risk and only the semen is collected for export, possibly a certain time after collection, there is no need to prohibit the vaccination by use of a vaccine other than live attenuated vaccines.

3. were either:

a) kept in an AHSV free country or free *zone* or from an AHSV seasonally free *zone* (during the seasonally free period) for at least 40 days before commencement of, and during collection of the semen, or

b) kept in an AHSV free vector-proof *artificial insemination centre* throughout the collection period, and subjected to either:

i) a serological test according to the *Terrestrial Manual* to detect antibody to the AHSV group, carried out with a negative result on a blood sample collected at least 28 days and not more than 90 days after the last collection of semen; or

ii) agent identification tests according to the *Terrestrial Manual* carried out with negative results on blood samples collected at commencement and conclusion of, and at least every 7 days, during semen collection for this consignment.

Article 2.5.14.9.

Veterinary ~~Administrations~~ Authorities of *importing countries* should require:

for *in vivo* derived equid embryos/oocytes

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

1. the donor animals:

   a) showed no clinical sign of AHS on the day of collection of the ~~semen~~ embryos/oocytes and for the following 40 days;

   b) had not been vaccinated against AHS within 40 days prior to the day of collection;

Community comment:

Proposed text:

b. had not been vaccinated against AHS by use of a live attenuated vaccine within 40 days prior to the day of collection;

Rationale:

As the donor remains in the area potentially at risk and only the embryos are collected for export, possibly a certain time after collection, there is no need to prohibit the vaccination by use of a vaccine other than live attenuated vaccines.

   c) were either:

      i) kept in an AHSV free country or free *zone* or from an AHSV seasonally free *zone* (during the seasonally free period) for at least 40 days before commencement of, and during collection of the embryos/oocytes, or

      ii) kept in an AHSV free vector-proof *collection centre* throughout the collection period, and subjected to either:

         – a serological test according to the *Terrestrial Manual* to detect antibody to the AHSV group carried out with a negative result on a blood sample collected at least 28 days and not more than 90 days after the last collection of ~~semen~~ embryos/oocytes; or

         – agent identification tests according to the *Terrestrial Manual* carried out with negative results on blood samples collected at commencement and conclusion of, and at least every 7 days during ~~semen~~ embryos/oocytes collection for this consignment;

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

3. semen used to fertilize the oocytes, complies at least with the requirements in Article 2.5.14.8.

Article 2.5.14.10.

Protecting animals from *Culicoides* attack

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

Potential risk management strategies include a combination of:

1. treating animals with chemical repellents prior to and during transportation, in ~~insecticide treated and~~ sanitized *vehicles* treated with appropriate residual contact insecticide;

2. *loading*, transporting and *unloading* animals at times of low vector activity (i.e. bright sunshine and 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 shade cloth;

5. monitoring for vectors at common stopping and offloading points to gain information on seasonal variations;

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

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APPENDIX 3.8.X.

GUIDELINES ON SURVEILLANCE FOR AFRICAN HORSE SICKNESS

Community position:

The Community can support the proposed changes, but would like its two comments for clarification to be taken into account.

Article 3.8.X.1.

Introduction

This Appendix defines the principles and provides a guide on the surveillance for African horse sickness (AHS), complementary to Appendix 3.8.1., applicable to countries seeking to demonstrate ~~recognition for a declared~~ African horse sickness virus (AHSV) status. This may be for the entire country or *zone*. ~~Guidelines~~ Guidance for countries seeking free status following an *outbreak* and for the maintenance of AHS status is also provided.

AHS is a vector-borne *infection* transmitted by a limited number of species of *Culicoides* insects. Unlike the related bluetongue virus, AHSV is so far geographically restricted to sub Saharan Africa with periodic excursions into North Africa, southwest Europe, the Middle East and adjacent regions of Asia. An important component of AHSV epidemiology is vectorial capacity which provides a measure of *disease risk* that incorporates vector competence, abundance, seasonal incidence, biting rates, survival rates and the extrinsic incubation period. However, methods and tools for measuring some of these vector factors remain to be developed, particularly in a field context.

~~In addition to the general conditions described in~~ According to Chapter 2.5.14. of the *Terrestrial Code*, a Member ~~declaring~~ demonstrating freedom from AHSV *infection* for the entire country, or a *zone* 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. This requires the support of a laboratory able to undertake identification of AHSV *infection* through the virus detection and antibody tests described in the *Terrestrial Manual*.

Susceptible wild equid populations should be included in the surveillance programme ~~when these animals are intended for trade~~.

Case definition

For the purposes of surveillance, a *case* refers to an equid infected with AHSV.

The purpose of surveillance is to determine if a country or *zone* is free from AHSV or if a *zone* is seasonally free from AHSV. Surveillance deals not only with the occurrence of clinical signs caused by AHSV, but also with evidence of *infection* with AHSV in the absence of clinical signs.

The following defines the occurrence of AHSV *infection*:

1. AHSV has been isolated and identified as such from an equid or a product derived from that equid, or

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

3. serological evidence of active *infection* with AHSV by detection of seroconversion with production of antibodies to structural or nonstructural proteins of AHSV that are not a consequence of vaccination have been identified in one or more equids that either show clinical signs consistent with AHS, or epidemiologically linked to a confirmed or suspected *case*, or give cause for suspicion of previous association or contact with AHSV.

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

Article 3.8.X.2.

General conditions and methods

1. A surveillance system should be under the responsibility of the *Veterinary ~~Administration~~ Authority*. In particular the following should be in place:

Community comment:

It is proposed to add a point at the beginning:

a) African horse sickness (AHS) is notifiable in the whole country.

Rationale:

Notifiability of a disease is the first element in a passive surveillance system.

   a) a formal and ongoing system for detecting and investigating *outbreaks of disease*;

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

   c) a system for recording, managing and analysing diagnostic, epidemiologic and surveillance data.

2. The AHS surveillance programme should:

   a) in a country/*zone*, free or seasonally free, include an early warning system for reporting suspicious cases. Persons who have regular contact with equids, as well as diagnosticians, should report promptly any suspicion of AHS to the *Veterinary Authority*. 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 AHS. 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 AHS 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* in accordance with Appendix 3.8.1.

Article 3.8.X.3.

Surveillance strategies

The target population for surveillance aimed at identification of *disease* and/or *infection* should cover susceptible ~~domestic~~ equids within the country or *zone*. Active and passive surveillance for AHSV *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*.

A country should justify the surveillance strategy chosen as appropriate to detect the presence of AHSV *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. horses). Similarly, virological and serological testing may be targeted to species that rarely show clinical signs (e.g. donkeys).

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

If a Member wishes to declare freedom from AHSV *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 *infection* if it were to occur at a predetermined minimum rate. The sample size, expected prevalence and diagnostic sensitivity of the tests 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 for surveillance for *disease*/*infection* are technically well defined. Surveillance programmes to prove the absence of AHSV *infection*/circulation, need to be carefully designed to avoid producing results that are either insufficiently reliable to be accepted by 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 AHS in equids particularly during a newly introduced *infection*. In horses, clinical signs may include pyrexia, oedema, hyperaemia of mucosal membranes and dyspnoea.

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

2. Serological surveillance

Serological surveillance of equid populations is ~~useful~~ an important tool to confirm absence of AHSV transmission in a country or *zone*. The species tested should reflect the local epidemiology of AHSV *infection*, and the equine species available. Management variables that may reduce the likelihood of *infection*, such as the use of insecticides and animal housing, should be taken into account when selecting equids to be included in the surveillance system.

Samples should be examined for antibodies against AHSV using tests prescribed in the *Terrestrial Manual*. Positive AHSV antibody tests results can have four possible causes:

a) natural *infection* with AHSV;

b) vaccination against AHSV;

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 purposes for AHSV surveillance. However, the principles of survey design described in these guidelines and the requirements for a statistically valid survey for the presence of AHSV *infection* should not be compromised.

The results of random or targeted serological surveys are important in providing reliable evidence that no AHSV *infection* is present in a country or *zone*. 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 AHSV 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 AHSV, either random or targeted sampling is suitable to select herds and/or animals for testing.

Serological surveillance in a free country or *zone* should be carried out over an appropriate distance from the border with an infected country or *infected zone*, based upon geography, climate, history of *infection* and other relevant factors. 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 AHSV. An AHSV free country or *zone* may be protected from an adjacent infected country or *infected zone* by a *buffer zone*.

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

3. Virological surveillance

Isolation and genetic analysis of AHSV 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 animals

Sentinel animals are a form of targeted surveillance with a prospective study design. They comprise groups of unexposed equids managed at fixed locations and sampled regularly to detect new AHSV *infections*.

Community comment:

Proposed text for the above paragraph:

Sentinel animals are a form of targeted surveillance with a prospective study design. They comprise groups of unexposed equids that are not vaccinated by use of an attenuated live vaccine and managed at fixed locations and clinically observed in case of highly receptive horses and/or sampled regularly to detect new AHSV *infections*.

Rationale:

Sentinels should not have been vaccinated with a vaccine that does not allow to discriminate between vaccination and infection, therefore the requirement not having been exposed is in fact insufficient. In addition it should be clarified that the animals were at least not exposed to the prevailing serotypes.

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

A sentinel equid 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 AHSV 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 AHSV 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 AHSV *infection*. The only feature distinguishing groups of sentinels should be their geographical location. Sera from sentinel 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 should reflect the equid species used and the reason for choosing the sampling site. In endemic areas virus isolation will allow monitoring of the serotypes and genotypes of AHSV 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 AHSV *infections* are not occurring unobserved. Here sampling prior to and after the possible period of transmission is sufficient.

Definitive information on AHSV 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 some samples are collected during the period of viraemia.

5. Vector surveillance

AHSV is transmitted between equine hosts by 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 occurrence, and 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 equids.

Vector surveillance should be based on scientific sampling techniques. The choice of the number and types of traps to be used in vector surveillance and the frequency of their use should take into account the size and ecological characteristics of the area to be surveyed.

The operation of vector surveillance sites at the same locations as sentinel 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 are preferred to detect virus circulation.

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Annex XIX

CHAPTER 2.6.6.

AFRICAN SWINE FEVER

Community position:

The Community can support the proposed changes, reiterates the need for Guidelines on the surveillance of ASF, and is ready to assist the OIE in this task.

Article 2.6.6.1.

The pig and its close relatives are ~~is~~ the only natural hosts for African swine fever (ASF) virus. ~~The definition of pig~~ These includes all varieties of *Sus scrofa*, both domestic and wild, warthogs (*Phacochoerus* spp.), bushpigs (*Potamochoerus* spp.) and giant forest hog (*Hylochoerus meinertzhageni*). For the purposes of this chapter, a distinction is made between domestic pigs (permanently captive and farmed free-range pigs) and wild pigs (including feral pigs and wild boar) as well as between *Sus scrofa* and African pig species.

All varieties of *Sus scrofa* are susceptible to the pathogenic effects of ASF virus, while the African wild pigs are not and act as reservoirs of the *infection*. Ticks of the genus *Ornithodoros* are natural hosts of the virus and act as biological vectors of the *infection*.

For the purpose of the *Terrestrial Code*, the *incubation period* in *Sus scrofa* is 15 days.

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

Article 2.6.6.2.

The ASF status of a country, *zone* or *compartment* can only be determined after considering the following criteria in domestic and wild pigs, as applicable:

1. ASF should be notifiable in the whole country, and all clinical signs suggestive of ASF should be subjected to appropriate field and~~/or~~ laboratory investigations;

2. an on-going awareness programme should be in place to encourage reporting of all *cases* suggestive of ASF;

3. the *Veterinary ~~Administration~~ Authority* should have current knowledge of, and authority over, all domestic pigs in the country, *zone* or *compartment*;

4. the *Veterinary ~~Administration~~ Authority* should have current knowledge about the species, population and habitat of wild pigs in the country or *zone*.

Article 2.6.6.3.

ASF free country, zone or compartment

~~1. ASF free status~~

~~a)~~1. Historically free status

A country or *zone* may be considered free from ASF 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 an eradication programme

A country or *zone* which does not meet the conditions of point a) above or a *compartment* may be considered free from ASF when:

~~i~~a) there has been no *outbreak* of ASF during the past 3 years; this period can be reduced to 12 months when there is no evidence of tick involvement in the epidemiology of the *infection*;

~~ii~~b) no evidence of ASFV *infection* has been found during the past 12 months;

~~iiii~~c) surveillance ~~in accordance with appendix 3.8.8.~~ has been in place in domestic pigs for the past 12 months;

~~iii) no evidence of ASFV infection has been found during the past 12 months~~

d) imported domestic pigs comply with the requirements in Article 2.6.6.5. or Article 2.6.6.6.

AND

~~in the case of a country or *zone,*~~ Based on surveillance ~~in accordance with Appendix 3.8.8.~~, ASF infection has been demonstrated not to be present in ~~place to determine the ASF status of the~~ any wild pig population in the country or *zone*, and:

~~iv~~e) there has been no clinical evidence, nor virological evidence of ASF in wild pigs during the past 12 months;

~~v~~f) no seropositive wild pigs have been detected in the age class 6-12 months during the past 12 months;

~~vi~~g) imported wild pigs comply with the ~~relevant~~ requirements in Article 2.6.6.~~9~~7.

Article 2.6.6.4.

Recovery of free status

Should an ASF *outbreak* occur in a free country, *zone* or *compartment*, the free status ~~of the country, *zone* or *compartment*~~ may be restored where surveillance ~~in accordance with Appendix 3.8.8.~~ has been carried out with negative results, either:

1. 3 months after the last *case* where a *stamping-out policy* is practised and ~~there is no evidence of tick involvement in the epidemiology of the *infection*;~~

~~OR~~

2. in the case where ticks are suspected to be involved in the epidemiology of the *infection*, ~~3 months after the last *case* where a *stamping-out policy*,~~ followed by acaricide treatment and the use of sentinel pigs, ~~is practised~~; or

~~OR~~

~~3~~2. where a *stamping-out policy* is not practised, the provisions of point ~~b)~~2. of Article 2.6.6.3. should be followed;

AND

4. ~~in the case of a country or *zone*,~~ Bbased on surveillance ~~in accordance with Appendix 3.8.8.~~, ASF *infection* has been demonstrated not to be present ~~is not known to occur~~ in any wild pig population in the country or *zone*.

Article 2.6.6.5.

When importing from ASF free countries, *zones* or *compartments*, *Veterinary ~~Administrations~~ Authorities* should require:

for domestic pigs

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

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

2. were kept in an ASF free country, *zone* or *compartment* since birth or for at least the past 40 days.

Article 2.6.6.6.

When importing from ASF infected countries or *infected zones* ~~with ASF infection in domestic pigs~~, *Veterinary ~~Administrations~~ Authorities* should require:

for domestic pigs

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

1. ~~were kept since birth or for the past 40 days in a ASF free *compartment*~~ showed no clinical sign of ASF on the day of shipment;

2. ~~showed no clinical sign of ASF on the day of shipment~~ were kept since birth or for the past 40 days in an ASF free *compartment*.

Article 2.6.6.7.

When importing from ASF free countries or *zones*, *Veterinary ~~Administrations~~ Authorities* should require:

for wild pigs

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

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

2. have been captured in an ASF free country or *zone*;

and, if the *zone* where the animal has been captured is adjacent to a *zone* with *infection* in wild pigs:

3. 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 2.6.6.8.

When importing from ASF free countries, *zones* or *compartments*, *Veterinary ~~Administrations~~ Authorities* should require:

for semen of domestic pigs

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

1. the donor animals:

   a) were kept in an ASF free country, *zone* or *compartment* since birth or for at least 40 days prior to collection ~~in accordance with 2.6.6.6.~~;

   b) showed no clinical sign of ASF 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 2.6.6.9.

When importing from ASF infected countries or *infected zones* ~~considered infected with ASF in domestic pigs~~, *Veterinary ~~Administrations~~ Authorities* should require:

for semen of domestic pigs

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

1. the donor animals:

   a) were kept in an ASF free *compartment* ~~and~~ since birth or for at least 40 days prior to collection;

   b) showed no clinical sign of ASF on the day of collection of the semen and for the following 40 days;

2. the semen was collected ~~in accordance with 2.6.6.8.~~, processed and stored in conformity with the provisions of Appendix 3.2.2.

Article 2.6.6.10.

When importing from ASF free countries, *zones* or *compartments*, *Veterinary ~~Administrations~~ Authorities* should require:

for *in vivo* derived embryos of domestic pigs

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

1. the donor females:

   a) were kept in an ASF free country, *zone* or *compartment* ~~in domestic pigs~~ since birth or for at least 40 days ~~in accordance with 2.6.6.6.~~ prior to collection;

   b) showed no clinical sign of ASF 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 2.6.6.11.

When importing from ASF infected countries or *infected zones* ~~considered infected with ASF in domestic pigs~~, *Veterinary ~~Administrations~~ Authorities* should require:

for *in vivo* derived embryos of domestic pigs

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

1. the donor females;

   a) were kept in an ASF free *compartment* ~~and~~ since birth or for at least 40 days prior to collection;

   b) showed no clinical sign of ASF on the day of collection of the embryos and for the following 40 days;

2. the embryos were collected ~~in accordance with 2.6.6.10.~~, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.6.6.12.

When importing from ASF free countries, *zones* or *compartments*, *Veterinary ~~Administrations~~ Authorities* 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 an ASF free country, *zone* or *compartment* since birth or for at least the past 40 days, or which have been imported in accordance with Article 2.6.6.5. or Article 2.6.6.6.;

2. have been slaughtered in an approved *abattoir*, have been subjected to ante-mortem and post-mortem inspections in accordance with Appendix 3.10.1. and have been found free of any sign suggestive of ASF.

Article 2.6.6.13.

When importing from ASF free countries or *zones*, *Veterinary ~~Administrations~~ Authorities* 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:

   ~~1.~~a)have been killed in an ASF free country or *zone*;

   ~~2.~~b)have been subjected to a post-mortem inspection in accordance with Appendix 3.10.1. in an approved examination centre, and have been found free of any sign suggestive of ASF~~.~~;

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 killed and has been subjected to a virological test and a serological test for ASF, with negative results.

Article 2.6.6.14.

Veterinary ~~Administrations~~ Authorities 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 2.6.6.12. or 2.6.6.13., as relevant;

   b) in a processing establishment:

      i) approved by the *Veterinary ~~Administration~~ Authority* for export purposes;

      ii) processing only meat meeting the conditions laid down in Articles 2.6.6.12. or 2.6.6.13., as relevant;

OR

2. have been processed in an establishment approved by the *Veterinary ~~Administration~~ Authority* for export purposes so as to ensure the destruction of the ASF virus and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASF virus.

Article 2.6.6.15.

Veterinary ~~Administrations~~ Authorities 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 2.6.6.12. or 2.6.6.13., as relevant;

   b) in a processing establishment:

      i) approved by the *Veterinary ~~Administration~~ Authority* 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~~ Authority* for export purposes so as to ensure the destruction of the ASF virus and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASF virus.

Article 2.6.6.15.bis

Veterinary Authorities of *importing countries* should require:

for bristles (from pigs)

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

1. come from an ASF free country, *zone* or *compartment*; or

2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the ASF virus and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASF virus.

Article 2.6.6.16.

Veterinary ~~Administrations~~ Authorities 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 an ASF free country, *zone* or *compartment*; or

2. have been processed in an establishment approved by the *Veterinary ~~Administration~~ Authority* for export purposes so as to ensure the destruction of the ASF virus and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASF virus.

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Annex XX

CHAPTER 2.6.7.

CLASSICAL SWINE FEVER

Community position:

The Community cannot support the proposed changes. CSF cannot be simply compared to ASF as risk management is concerned because of significant differences in the epidemiology of diseases. The possibility given by the Code Commission of exporting fresh meat from free compartments does not provide any useful answer to the Members either, since such compartments do not exist in practice, and the Guidelines to implement them are not even established yet. This will only lead to more unjustified barriers to trade.

Moreover, in this case a disease against which the OIE Members have fought for a long time, sometimes with good results, field experience is to be considered as well: these OIE Member countries have proven through decades that trade of fresh meat of domestic animals from zones infected only in the wild population did not appear to spread the infection as long as relevant preventive and mitigating measures have been in place. The EU is ready to share this data with the ad hoc group that should be convened again, in order to better assess the situation at the light of other ad hoc groups conclusions, especially that on wildlife diseases surveillance.

Thus, the Community is strongly opposed to the proposed chapter.

In addition postponing the adoption of this new version will not affect trade as the current chapter has never created any difficulties among the OIE Members. This would give time to look at the whole question of diseases in wildlife, their affect on other diseases as well as CSF, and the way they should be treated as regards notification, management and trade conditions. This is a general problem, which has been unequally treated among the chapters of the Code, including the general chapters.

The Community proposes that the ad hoc group on epidemiology be asked to address this issue in its next meeting and the following if necessary, as well as the Working Group on wildlife and the ad hoc group on wildlife diseases surveillance in order to find solid and acceptable solutions.

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~~ farmed 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*.

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 appropriate 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~~ Authority* should have current knowledge of, and authority over, all domestic pigs in the country, *zone* or *compartment;*

5. the *Veterinary ~~Administration~~ Authority* 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)~~1. Historically free status

A country, or *zone* ~~or *compartment*~~ may be considered free from CSF ~~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) 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.~~

~~2.~~ ~~CSF free status following an outbreak~~ ~~b)~~2. Free status as a result of an eradication programme

A country, or *zone* ~~or *compartment*~~ which does not meet the conditions of point a) ~~or b)~~ above or a *compartment* may be considered free from CSF when: ~~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*.~~

~~i~~a) there has been no *outbreak* of CSF during the past 12 months;

~~ii~~b) no evidence of CSFV *infection* has been found during the past 12 months;

~~iii~~c) no vaccination against CSF has been carried out during the past 12 months;

~~iv~~d) surveillance in accordance with Appendix 3.8.8. has been in place in domestic pigs for the past 12 months;

e) imported domestic pigs comply with the requirements in Articles 2.6.7.5. or Articles 2.6.7.6.

AND

~~in the case of a country or *zone*,~~ Based on surveillance in accordance with Appendix 3.8.8., CSFV infection has been demonstrated not to be present in ~~place to determine the CSF status of the~~ any wild pig population in the country or zone, and:

~~v~~f) there has been no clinical evidence or virological evidence of CSF in wild pigs during the past 12 months;

~~vi~~g) no seropositive wild pigs have been detected in the age class 6–12 months during the past 12 months;

~~vii~~h) there has been no vaccination in wild pigs for the past 12 months;

~~viii~~i) imported wild pigs comply with the ~~relevant~~ requirements in Article 2.6.7.7.

~~Article 2.6.7.4.~~

~~**Country free of CSF in domestic pigs but with a wild pig population**~~

~~Requirements in points 2a to 2c 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~~4.

Recovery of free status

Should a CSF *outbreak* occur in a ~~previously~~ free country, *zone* or *compartment*, the free 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~~.~~, either:

~~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.~~

1. 3 months after the last *case* where a *stamping-out policy* without vaccination is practised;

Community comments:

The Community wishes to know if this new period of 3 months and the 3 months period prescribed in article 12 for import of fresh meat are concurrent or cumulative.

The Community wishes to point out that if the period for the recovery of free status is to be 3 months instead of 30 days, then the article 12 regarding import of fresh meat should also be changed, as the 3 months period there would then be unnecessary.

OR

2. where a *stamping-out policy* with emergency vaccination is practised:

   a) 3 months after the last *case* and the *slaughter* of all vaccinated animals, or

   b) 3 months after the last *case* without the *slaughter* of vaccinated animals where there are ~~validated~~ means, validated to OIE standards (Chapter I.1.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs;

OR

3. where a *stamping-out policy* is not practised, the provisions of point ~~b)~~2. of Article 2.6.7.3 should be followed;

AND

~~in the case of a country or *zones*,~~ B~~b~~ased on surveillance in accordance with Appendix 3.8.8., CSFV *infection* has been demonstrated not to be present ~~is not known to occur~~ in any wild pig population in the country or zone.

~~Article 2.6.7.6.~~

~~**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~~5.

When importing from CSF free countries, *zones* or *compartments*, *Veterinary ~~Administrations~~ Authorities* 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, validated to OIE standards (Chapter I.1.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs.

~~Article 2.6.7.8.~~

~~When importing from countries free of CSF in domestic pigs but 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~~6.

When importing from CSF infected countries or *infected zones* ~~with CSF infection in domestic pigs~~, *Veterinary ~~Administrations~~ Authorities* 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~~ showed no clinical sign of CSF on the day of shipment;

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~~ have not been vaccinated against CSF nor are they the progeny of vaccinated sows, unless there are ~~validated~~ means, validated to OIE standards (Chapter I.1.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs.

Article 2.6.7.~~10~~7.

When importing from CSF free countries or *zones*, *Veterinary ~~Administrations~~ Authorities* 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, validated to OIE standards (Chapter I.1.3. of the *Terrestrial Manual*), 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~~8.

When importing from CSF free countries, *zones* or *compartments*, *Veterinary ~~Administrations~~ Authorities* 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:~~

~~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~~9.

When importing from CSF infected countries or infected *zones* ~~considered infected with CSF in domestic pigs~~, *Veterinary ~~Administrations~~* *Authorities* 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;

   or

   d) have been vaccinated against CSF and were subjected to a serological test performed at least 21 days after collection and it has been conclusively demonstrated by means, validated to OIE standards (Chapter I.1.3. of the *Terrestrial Manual*), that any antibody is due to the vaccine;

2. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.2.

Article 2.6.7.~~14~~10.

When importing from CSF free countries, *zones* or *compartments*, *Veterinary ~~Administrations~~* *Authorities* should require:

for *in vivo* derived embryos of domestic 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:~~

~~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~~11.

When importing from CSF infected countries or *infected zones* ~~considered infected with CSF in domestic pigs~~, *Veterinary ~~Administrations~~ Authorities* should require:

for *in vivo* derived embryos of domestic pigs

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

1. the donor females:

   a) were kept in a CSF free *compartment* ~~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;

   or

   d) have been vaccinated against CSF and were subjected to a serological test performed at least 21 days after collection and it has been conclusively demonstrated by means, validated to OIE standards (Chapter I.1.3. of the *Terrestrial Manual*), that any antibody is due to the vaccine;

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

Article 2.6.7.~~17~~12.

When importing from CSF free countries, *zones* or *compartments*, *Veterinary ~~Administrations~~ Authorities* 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, or which have been imported in accordance with Article 2.6.7.5. or Article 2.6.7.6.;

Community comments:

The Community reiterates its comment that the delay of 3 months is useless if the period is already 3 months for the status recovery. In order to avoid a possible addition of periods (that would then be 6 months), the words "since birth or for at least the past 3 months" should be deleted.

2. have been slaughtered in an approved *abattoir,* have been subjected to ante-mortem and post-mortem inspections in accordance with Appendix 3.10.1. 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 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.~~

Community position:

If the above article is deleted, it should be replaced by the following:

Article 2.6.7.12 bis

When importing from countries or zones not complying with one or more points 2f) to i) of article 2.6.7.3, *Veterinary Administrations* should require:

***for fresh meat* of domestic pigs**

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

1. were kept in a country or zone in which the domestic pig population is separated from the wild pig population through biosecurity measures to prevent transmission of CSF from wild pigs to domestic pigs, and complies with the relevant points of article 2.6.7.3 or 2.6.7.4;

2. have been slaughtered in an *approved abattoir,* have been subjected to ante-mortem and post-mortem inspections as described in Appendix 3.10.1 and have been found free of any sign suggestive of CSF.

3. were not fed with uncooked swill.

Article 2.6.7.~~19~~13.

When importing from CSF free countries or *zones*, *Veterinary ~~Administrations~~ Authorities* 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 CSF free country or *zone*;

   b) have been subjected to a post-mortem inspection ~~as described in the Codex Alimentarius Code of Hygienic Practice for Meat~~ in accordance with Appendix 3.10.1. 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~~ killed, and has been subjected to a virological test and a serological test for CSF, with negative results.

Article 2.6.7.~~20~~14.

Veterinary ~~Administrations~~ Authorities 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~~12.~~, 2.6.7.18~~. or 2.6.7.~~19~~13., as relevant;

   b) in a processing establishment:

      i) approved by the *Veterinary ~~Administration~~ Authority* for export purposes;

      ii) processing only meat meeting the conditions laid down in Articles 2.6.7.~~17~~12.~~, 2.6.7.18.~~ or 2.6.7.~~19~~13., as relevant;

OR

2. have been processed in an establishment approved by the *Veterinary ~~Administration~~ Authority* 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. and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 2.6.7.~~21~~15.

Veterinary ~~Administrations~~ Authorities 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~~12.~~, 2.6.7.18.~~ or 2.6.7.~~19~~13., as relevant;

b) in a processing establishment:

i) approved by the *Veterinary ~~Administration~~ Authority* 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~~ Authority* 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. and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 2.6.7.~~22~~16.

Veterinary ~~Administrations~~ Authorities of *importing countries* should require:

for bristles (from pigs)

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

1. come from a CSF free country, *zone* or *compartment*; or

2. have been processed in an establishment approved by the *Veterinary ~~Administration~~ Authority* for export purposes so as to ensure the destruction of the CSF virus and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 2.6.7.~~23~~17.

Veterinary ~~Administrations~~ Authorities 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~~ Authority* for export purposes so as to ensure the destruction of the CSF virus and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

- - - - - - - - - - - - - -

— text deleted

Annex XX (contd)

APPENDIX 3.8.8.

GUIDELINES ~~FOR THE~~ ON SURVEILLANCE ~~OF~~ FOR CLASSICAL SWINE FEVER

Community position:

The Community can support the proposed changes, however it reiterates its former comment concerning compartments, whose conditions should be updated in relevance with the general guidelines on compartmentalisation.

Article 3.8.8.1.

Introduction

This Appendix defines the principles and provides a guide on the surveillance for classical swine fever (CSF), complementary to ~~in accordance with~~ Appendix 3.8.1., applicable to countries seeking to demonstrate ~~recognition of freedom from~~ CSF status. This may be for the entire country or a *zone* ~~within the country~~. Guidance for countries seeking ~~reestablishment of freedom~~ free status ~~from CSF for the whole country or a *zone,*~~ following an *outbreak,* ~~as well as guidelines~~ and for ~~demonstrating~~ the maintenance of CSF ~~free~~ status ~~are~~ is also provided. ~~This Appendix complements Chapter 2.6.7.~~

The impact and epidemiology of CSF differ widely in different regions of the world, and it is, therefore, impossible to provide specific guidelines for all situations. ~~It is axiomatic that t~~The surveillance strategies employed for demonstrating freedom from CSF at an acceptable level of confidence will need to be adapted to the local situation. For example, the approach must be tailored in order to prove freedom from CSF for a country or *zone* where wild pigs provide a potential reservoir of *infection*, or where CSF is present in adjacent countries. The method must examine the epidemiology of CSF in the region concerned and adapt to the specific risk factors encountered. This should include provision of scientifically based supporting data. There is, therefore, latitude available to Members to provide a well-reasoned argument to prove that absence of classical swine fever virus (CSFV) *infection* is assured at an acceptable level of confidence.

Surveillance for CSF should be in the form of a continuing programme designed to ~~either~~ establish that a population in a country, *zone,* or *compartment* is free from CSFV *infection* ~~(either the whole country, or a *zone* within the country is free from CSFV infection infection or a *compartment*)~~ or to detect the introduction of CSFV into a population already recognized as free. Consideration should be given to the specific characteristics of CSF epidemiology which include: the role of swill feeding and the impact of different production systems on *disease* spread, the role of semen in transmission of the virus, the lack of pathognomonic gross lesions and clinical signs, the frequency of clinically inapparent *infections*, the occurrence of persistent and chronic *infections*, and the genotypic, antigenic, and virulence variability exhibited by different strains of CSFV. Serological cross-reactivity with other pestiviruses has to be taken into consideration when interpreting data from serological surveys. A common route by which ruminant pestiviruses can infect pigs is the use of vaccines contaminated with bovine viral diarrhoea virus (BVDV).

For the purposes of this Appendix, virus *infection* means presence of CSFV as demonstrated directly by virus isolation, the detection of virus antigen or virus nucleic acid, or indirectly by seroconversion which is not the result of vaccination.

Article 3.8.8.2.

General conditions and methods

1. A surveillance system in accordance with Appendix 3.8.1. should be under the responsibility of the *Veterinary ~~Administration~~ Authority*. A procedure should be in place for the rapid collection and transport of samples to an accredited laboratory as described in the *Terrestrial Manual*.

2. The CSF 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 livestock, as well as diagnosticians, should report promptly any suspicion of CSF 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~~ Authority*. Since many strains of CSFV do not induce pathognomonic gross lesions or clinical signs, cases in which CSF cannot be ruled out should be immediately investigated employing clinical, pathological, and laboratory diagnosis. This requires that sampling kits and other equipment are available to those responsible for surveillance. Personnel responsible for surveillance should be able to call for assistance from a team with expertise in CSF diagnosis, epidemiological evaluation, and control;

   b) implement, when relevant, regular and frequent clinical inspections and serological testing of high-risk groups of animals (for example, where swill feeding is practised), or those adjacent to a CSF infected country or *zone* (for example, bordering areas where infected wild pigs are present).

An effective surveillance system will periodically identify suspicious cases that require follow -up and investigation to confirm or exclude that the cause of the condition is CSFV. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot, therefore, be reliably predicted. Recognitions for freedom from CSFV *infection* should, as a 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 standstill orders, etc.).

Article 3.8.8.3.

Surveillance strategies

1. Introduction

   There are two basic strategies that can be employed for CSF surveillance depending on the purpose of the country for seeking recognition of freedom from CSF. In countries historically free of CSF, surveillance programmes should be designed to detect the introduction of CSFV into domestic or wild swine. The optimal strategy to meet this objective is most often targeted surveillance.

   The ~~target~~ population ~~for~~ covered by surveillance aimed at ~~identifying~~ detecting *disease* and *infection* should include domestic and wild pig populations within the country or *zone* to be recognised as free from CSFV *infection*. Such surveillance may involve opportunistic testing of samples submitted for other purposes, but a more efficient and effective strategy is one which includes targeted surveillance.

   ~~Depending on the local epidemiological situation, targeted surveillance could be considered as more effective than a randomized surveillance strategy.~~ Surveillance is targeted to the pig population which

presents the highest risk of *infection* (for example, swill fed farms, pigs reared outdoors or farms in proximity to infected wild pigs). Each country will need to identify its individual risk factors. These may include: temporal and spatial distribution of past *outbreaks,* pig movements and demographics, etc.

For reasons of cost, the longevity of antibody levels, as well as the existence of clinically inapparent *infections* and difficulties associated with differential diagnosis of other *diseases*, serology is often the most effective and efficient surveillance methodology. In some circumstances, which will be discussed later, clinical and virological surveillance may also have value.

The country should justify the surveillance strategy chosen as adequate to detect the presence of CSFV *infection* in accordance with Appendix 3.8.1. and the epidemiological situation. Cumulative survey results in combination with the results of passive surveillance, over time, will increase the level of confidence in the surveillance strategy. If a Member wishes to apply for recognition by other Members of a specific *zone* within the country as being free from CSFV *infection*, the design of the surveillance strategy and the basis for any sampling process 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 *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 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 design 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 production class of animals in the target population.

Irrespective of the testing system employed, the surveillance system design should anticipate the occurrence of false positive reactions. This is especially true of the serological diagnosis of CSF because of the recognized cross-reactivity with ruminant pestiviruses. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether or not they are indicative of CSFV *infection*. This should involve confirmatory and differential tests for pestiviruses, as well as further investigations concerning the original sampling unit as well as animals which may be epidemiologically linked.

2. Clinical and virological surveillance

Beyond their role in targeted surveillance, clinical and virological surveillance for CSF has two aims: a) to shorten the period between introduction of CSF virus into a *disease* free country or *zone* and its detection, and b) to confirm that no unnoticed *outbreaks* have occurred.

In the past, clinical identification of *cases* was the cornerstone of early detection of CSF. However, emergence of low virulence strains of CSF, as well as new *diseases* - ~~in particular~~ such as post-weaning multisystemic wasting syndrome and porcine dermatitis and nephropathy syndrome have made such reliance less effective, and, in countries where such *diseases* are common, can add significant risk of masking the presence of CSF.

~~One element of clinical surveillance involves the detection of clinical signs of CSF by close physical examination of susceptible animals.~~ The spectrum of *disease* signs and gross pathology seen in CSF *infections*, along with the plethora of other agents that can mimic CSF, renders the value of clinical examination alone somewhat inefficient as a surveillance tool. These factors, along with the compounding effects of concurrent *infections* and *disease* caused by ruminant pestiviruses, dictate the need for laboratory testing in order to clarify the status of CSF suspects detected by clinical monitoring.

Nevertheless, clinical presentation should not be ignored as a tool for early detection; in particular, any cases where clinical signs or lesions consistent with CSF are accompanied by high morbidity and/or mortality should be investigated without delay. In CSFV *infections* involving low virulence strains, high mortality may only be seen in young animals. Otherwise close physical examination of susceptible animals is useful as a selection criteria for CSF surveillance, particularly in diagnostic laboratories or *slaughter* establishments or when applied to high risk populations such as swill feeding operations.

~~In the past, clinical identification of cases was the cornerstone of early detection of CSF. However, emergence of low virulence strains of CSF, as well as new diseases – in particular post weaning multisystemic wasting syndrome and porcine dermatitis and nephropathy syndrome have made such reliance less effective, and, in countries where such diseases are common, can add significant risk of masking the presence of CSF. In *zones* or countries where such diseases exist, careful clinical and virological surveillance of such cases should be applied.~~

~~Clinical signs and pathology of CSF infection will also vary considerably, depending on the strain of virus as well as host factors, such as age, nutrition and health status. These factors, along with the compounding effects of concurrent infections and disease caused by ruminant pestiviruses, dictate the need for laboratory testing in order to clarify the status of CSF suspects detected by clinical monitoring.~~ The difficulties in detecting chronic *disease* manifested by non-specific clinical signs and delayed seroconversion and seronegativity, in persistently infected piglets, both of which may be clinically normal, makes virological investigation essential. As part of a herd investigation, such animals are likely to be in a minority and would not confound a diagnosis based on serology. Individually or as part of recently mixed batches, such animals may, however, escape detection by this method. A holistic approach to investigation, taking note of herd history, pig, personnel and vehicle movements and *disease* status in neighbouring *zones* or countries, can also assist in targeting surveillance in order to increase efficiency and enhance the likelihood of early detection.

The labour-intensive nature of clinical, pathological and virological investigations, along with the smaller 'window of opportunity' inherent in virus, rather than antibody detection, has, in the past, resulted in greater emphasis being placed on mass serological screening as the best method for surveillance. However, surveillance based on clinical and pathological inspection and virological testing should not be underrated. If targeted at high risk groups in particular, it provides an opportunity for early detection that can considerably reduce the subsequent spread of *disease*. Herds predominated by adult animals, such as nucleus herds and artificial insemination studs, are particularly useful groups to monitor, since *infection* by low virulence viruses in such groups may be clinically inapparent, yet the degree of spread may be high.

Clinical and virological monitoring may also provide a high level of confidence of rapid detection of *disease* if a sufficiently large number of clinically susceptible animals is examined. In particular, molecular detection methods are increasingly able to offer the possibility of such large-scale screening for the presence of virus, at reasonable cost.

Wild pigs and, in particular, those with a wholly free-living existence, rarely present the opportunity for clinical observation, but should form part of any surveillance scheme and should, ideally, be monitored for virus as well as antibody.

Vaccine design and diagnostic methodologies, and in particular methods of virus detection, are increasingly reliant on up-to-date knowledge of the molecular, antigenic and other biological characteristics of viruses currently circulating and causing *disease*. Furthermore, epidemiological understanding of the pathways of spread of CSFV can be greatly enhanced by molecular analyses of viruses in endemic areas and those involved in *outbreaks* in *disease* free areas. It is therefore essential that CSFV isolates are sent regularly to the regional OIE Reference Laboratory for genetic and antigenic characterisation.

3. Serological surveillance

Serological surveillance aims at detecting antibodies against CSFV. Positive CSFV antibody test results can have five possible causes:

a) natural *infection* with CSFV;

b) legal or illegal vaccination against CSF;

c) maternal antibodies derived from an immune sow (maternal antibodies) are usually found only up to 4.5 months of age, but, in some individuals, maternal antibodies can be detected for considerably longer periods;

d) cross-reactions with other pestiviruses;

e) non-specific reactors.

The *infection* of pigs with other pestiviruses may complicate a surveillance strategy based on serology. Antibodies to bovine viral diarrhoea virus (BVDV) and Border disease virus (BDV) can give positive results in serological tests for CSF, due to common antigens. Such samples will require differential tests to confirm their identity. Although persistently infected immunotolerant pigs are themselves seronegative, they continuously shed virus, so the prevalence of antibodies at the herd level will be high. Chronically infected pigs may have undetectable or fluctuating antibody levels.

It may be possible to use sera collected for other survey purposes for CSF surveillance. However, the principles of survey design described in this Appendix and the requirement for statistical validity should not be compromised.

The discovery of clustering of seropositive reactions should be foreseen. It may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of *infection* by field strains or other pestiviruses. Because clustering may signal field strain *infection*, the investigation of all instances must be incorporated in the survey design. Clustering of positive animals is always epidemiologically significant and therefore should be investigated.

In countries or *zones* that are moving towards freedom, serosurveillance can provide valuable information on the *disease* status and efficacy of any control programme. Targeted serosurveillance of young stock will indicate whether newly circulating virus is present, although the presence of maternal antibody will also need to be considered. If conventional attenuated vaccine is currently being used or has been used in the recent past, serology aimed at detecting the presence of field virus will likewise need to be targeted at unvaccinated animals and after the disappearance of maternal antibody. General usage in such situations may also be used to assess levels of vaccine coverage.

Vaccines also exist which, when used in conjunction with dedicated serological tests, may allow discrimination between vaccinal antibody and that induced by field *infection*. Such tools, described in the *Terrestrial Manual,* will need to be fully validated. They do not confer the same degree of protection as that provided by conventional vaccines, particularly with respect to preventing transplacental *infections*. Furthermore, serosurveillance using such differentiation requires cautious interpretation on a herd basis.

The results of random or targeted serological surveys are important in providing reliable evidence that no CSFV *infection* is present in a country or *zone*. It is therefore essential that the survey be thoroughly documented.

Article 3.8.8.4.

Country or zone historically free of CSF ~~in domestic and wild pigs~~

~~1. Historically free status~~

The free status should be reviewed whenever evidence emerges to indicate that changes which may alter the underlying assumption of continuing historical freedom, has occurred. Such changes include but are not limited to:

a) an emergence or an increase in the prevalence of CSF in countries or *zones* from which live pigs or products are imported;

b) an increase in the volume of imports or a change in their country or *zone* of origin;

c) an increase in the prevalence of CSF in the domestic or wild pigs of adjacent countries or *zones;*

d) an increased entry from, or exposure to, infected wild pig populations of adjacent countries or *zones*.

~~2. Free status as a result of an eradication programme~~

~~In addition to the general conditions described in Chapter 2.6.7., a Member Country seeking recognition of CSF freedom for the country or a *zone,* whether or not vaccination had been practised, should provide evidence for the existence of an effective surveillance programme. The strategy and design of the surveillance programme will depend on the prevailing epidemiological circumstances and will be planned and implemented according to the general conditions and methods described in this Appendix, to demonstrate the absence of CSFV infection in domestic and wild pig populations. This requires the support of a national or other laboratory able to undertake identification of CSFV infection through virus detection and serological tests described in the *Terrestrial Manual*.~~

Article 3.8.8.5

Countries, zones or compartments ~~applying for~~ declaring freedom from CSF ~~where vaccination is practised~~

1. Country or zone free of CSF

In addition to the general conditions described in Chapter 2.6.7., a Member seeking recognition of CSF freedom for the country or a *zone,* whether or not vaccination had been practised, should provide evidence for the existence of an effective surveillance programme. The strategy and design of the surveillance programme will depend on the prevailing epidemiological circumstances in and around the country or *zone* and will be planned and implemented according to the general conditions and methods described in this Appendix, to demonstrate the absence of CSFV *infection* in domestic and wild pig populations. This requires the support of a national or other laboratory able to undertake identification of CSFV *infection* through virus detection and serological tests described in the *Terrestrial Manual*.

2. Compartment free of CSF

The objective of surveillance ~~in this instance is to demonstrate that the two subpopulations are effectively separated by measures that ensure the biosecurity of domestic pigs~~ is to demonstrate the absence of CSFV *infection* in the *compartment*. The provisions of Chapter 1.3.5. should be followed. The effective separation of the two *subpopulations* should be demonstrated. To this end, a *biosecurity* ~~programme which~~ *plan* that includes but is not limited to the following provisions should be implemented:

~~a) a programme for the management of CSF in wild pigs;~~

~~b) delineation of CSF wild pig control areas around every CSF case reported in wild pigs;~~

~~c) assessment of the presence and mitigative role of natural boundaries;~~

~~d) documentation of the ecology of the wild pig population;~~

~~e) proper containment of domestic pigs;~~

a) proper containment of domestic pigs;

~~f~~b) control of movement of *vehicles* with cleaning and *disinfection* as appropriate;

~~g~~c) control of personnel entering into the *establishments* and awareness of risk of fomite spread;

~~h~~d) prohibition of introduction to the *establishments* of ~~hunted~~ wild caught animals and their products;

~~i~~e) ~~registry~~ record of animal movements into and out of *establishments*;

~~j~~f) information and training programmes for farmers, ~~hunters,~~ processors, veterinarians, etc.

~~3.~~ The *biosecurity* ~~programme~~ *plan* implemented ~~would~~ also requires internal and external monitoring by the *Veterinary ~~Authorities~~ Authority*. ~~These elements~~ This monitoring should include ~~but are not limited to~~:

a) periodic clinical and serological monitoring of herds in the country or *zone,* and adjacent wild pig populations following these guidelines;

b) herd registration;

c) official accreditation of *biosecurity* ~~programme~~ *plan*;

d) periodic monitoring and review.

~~4.~~ Monitoring the CSF status of wild and domestic pig populations outside the *compartment* will be of value in assessing the degree of risk they pose to the CSF free ~~domestic population~~ *compartment*. The design of a monitoring system ~~for wild pig~~ is dependent on several factors such as the size and distribution of the population, the organisation of the *Veterinary Services* and resources available. The occurrence of CSF in wild and domestic pigs may vary considerably among countries. Surveillance design should be epidemiologically based, and the Member ~~must~~ should justify its choice of design prevalence and level of confidence based on Appendix 3.8.1.

~~5.~~ The geographic distribution and approximate size of wild pig populations need to be assessed as a prerequisite for designing a monitoring system. Sources of information may include wildlife conservation organisations, hunter associations and other available sources. The objective of a surveillance programme when the *disease* is already known to exist should be to determine the geographic distribution and the extent of the *infection*.

Article 3.8.8.6.

Recovery of free status

1. Countries or zones seeking re-establishment of freedom from CSF following an outbreak

In addition to the general conditions described in Chapter 2.6.7., a country seeking reestablishment of country or *zone* freedom from CSF should show evidence of an active surveillance programme ~~for CSF as well as~~ to demonstrate absence of CSFV *infection*.

Populations under this surveillance programme should include~~, but not be limited to~~:

a) *establishments* in the ~~area~~ proximity of the *outbreak*;

b) *establishments* epidemiologically linked to the *outbreak*;

c) animals used to re-populate affected *establishments* and any *establishments* where contiguous culling is carried out;

d) wild pig populations in the area of the *outbreak*.

In all circumstances, a Member seeking reestablishment of country or *zone* freedom from CSF with vaccination or without vaccination should report the results of an active and a passive surveillance programme in which the pig population undergoes regular clinical, pathological, virological, and/or serological examination, planned and implemented according to the general conditions and methods described in these guidelines. The surveillance should be based on a statistically representative sample of the populations at risk.

2. ~~Country or zone free of~~ Surveillance for CSF in wild pigs

While the same principles apply, surveillance in wild pigs presents challenges beyond those encountered in domestic populations in each of the following areas:

a) determination of the distribution, size and movement patterns associated with the wild pig population;

b) assessment of the possible presence of CSF within the population;

~~c) determination of the practicability of establishing *zone*.~~

c) determination of the practicability of establishing a *zone*.

~~The design of a monitoring system for wild pigs is dependent on several factors such as the organisation of the *Veterinary Services* and resources available. The geographic distribution and approximate size of wild pig populations need to be assessed as a prerequisite for designing a monitoring system. Sources of information may include wildlife conservation organisations, hunter associations and other available sources. The objective of a surveillance programme is to determine the geographic distribution and estimation of target population.~~

The design of a monitoring system for wild pigs is dependent on several factors such as the organisation of the *Veterinary Services* and resources available. The geographic distribution and approximate size of wild pig populations need to be assessed as a prerequisite for designing a monitoring system. Sources of information may include wildlife conservation organisations, hunter associations and other available sources. The objective of a surveillance programme is to determine if a given *disease* is present, and if so, at what prevalence ~~the geographic distribution and estimation of a target population~~.

Estimates of wild pig populations can be made using advanced methods (radio tracking, linear transect method, capture/recapture) or traditional methods based on the number of animals that can be hunted to allow for natural restocking (hunting bags).

For implementation of the monitoring programme, it will be necessary to define the limits of the territory over which wild pigs range in order to delineate the *epidemiological units* within the monitoring

programme. It is often difficult to define *epidemiological units* for wild animals. The most practical approach is based on natural and artificial barriers.

The monitoring programme should also include animals found dead, road kills, animals showing abnormal behaviour or exhibiting gross lesions during dressing.

There may be situations where a more targeted surveillance programme can provide additional assurance. The criteria to define high risk areas for targeted surveillance ~~can be~~ include:

a) areas with past history of CSF;

b) sub-regions with high wild pig density;

c) border regions with CSF affected countries or *zones;*

d) ~~areas of contact~~ interface between wild and domestic pig ~~sub~~-populations;

e) picnic and camping areas;

f) ~~around~~ farms with free-ranging pigs;

g) garbage dumps;

h) ~~special~~ other risk areas determined by ~~local~~ the *Veterinary Authorities*~~y~~;.

~~g) garbage dumps.~~

- - - - - - - - - - - - - -
— text deleted

Annex XXI

CHAPTER 2.7.12.

AVIAN INFLUENZA

Community position:

The Community can support the proposed changes, but wishes the OIE to take into account its comments, especially on compartments from which trade should only be possible if they are free from NAI.

Article 2.7.12.1.

1. For the purposes of *international trade*, 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):

   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 the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions, or for breeding or selling these categories of birds as well as pet birds, are not considered to be poultry.

3. For the purposes 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 not impose immediate trade bans in response to a notification of *infection* with HPAI and LPAI virus in birds other than poultry according to Article 2.1.1.3. of the *Terrestrial Code*.

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*.

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.

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~~1. 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~~2. 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 a~~n~~ NAI surveillance programme in accordance with Appendix 3.8.9.

3. consideration of all epidemiological factors for NAI occurrence and their historical perspective.

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 2.7.12.18. or 2.7.12.19. 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:

1. 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

2. 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 a~~n~~ NAI free country, *zone* or *compartment*, *Veterinary Authorities* 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 a~~n~~ NAI free country, zone or compartment since they were hatched or for at least the past 21 days;

3. the required surveillance, in accordance with Appendix 3.8.9., 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.; in that case, the nature of the vaccine used and the date of vaccination should be attached to the certificate ~~relevant information is attached~~.

Article 2.7.12.6.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Authorities* should require:

Community comment:

The word compartment should be deleted.

Export from a compartment should always be from a compartment free of the disease for which it has been designed.

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 within ~~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 or appropriately sanitized *containers*.

If the birds have been vaccinated, the nature of the vaccine used and the date of vaccination ~~relevant information~~ should be attached to the certificate.

Article 2.7.12.7.

When importing from a~~n~~ NAI free country, *zone* or *compartment*, *Veterinary Authorities* should require:

for day-old live poultry

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

1. the poultry were kept in a~~n~~ NAI free country, *zone* or *compartment* since they were hatched;

2. the poultry were derived from parent flocks which had been kept in a~~n~~ 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.; in that case, nature of the vaccine used and the date of vaccination ~~relevant information is~~ should be attached to the certificate.

Article 2.7.12.8.

When importing from a~~n~~ HPNAI free country, *zone* or *compartment*, *Veterinary Authorities* should require:

for day-old live poultry

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

1. the poultry were kept in a~~n~~ HPNAI free country, *zone* or *compartment* since they were hatched;

2. the poultry were derived from parent flocks which had been kept in a~~n~~ 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 or appropriately sanitized *containers*;

4. if the poultry or the parent flocks were vaccinated, vaccination was carried out in accordance with Appendix 3.8.9.; in that case, the nature of the vaccine used and the date of vaccination ~~relevant information is~~ should be attached to the certificate.

Article 2.7.12.8.bis

Regardless of the NAI status of the country, zone or compartment, *Veterinary Authorities* should require:

Community comment:

The word compartment should be deleted.

Export from a compartment should always be from a compartment free of the disease for which it has been designed.

for day-old live birds other than poultry

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

1. the birds showed no clinical signs suggestive of NAI on the day of shipment;

Community comment:

The point 1 above should be in line with point 1 of article 6 and include also the parents of day-old birds:

1. the birds and parents 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 hatched and kept in isolation approved by the *Veterinary Services*;

3. the parent flock birds were subjected to a diagnostic test at the time of the collection of the eggs to demonstrate freedom from infection with NAIV;

4. the birds are transported in new or appropriately sanitized *containers*;

If the birds or parent flocks were vaccinated against NAI, the nature of the vaccine used and the date of vaccination should be attached to the certificate.

Article 2.7.12.9.

When importing from a~~n~~ NAI free country, *zone* or *compartment*, *Veterinary Authorities* should require:

for *hatching eggs* of poultry

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

1. the eggs came from a~~n~~ NAI free country, *zone* or *compartment*;

2. the eggs were derived from parent flocks which had been kept in a~~n~~ 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.; in that case, the nature of the vaccine used and the date of vaccination ~~relevant information is~~ should be attached to the certificate;

4. the eggs are transported in new or appropriately sanitized *containers.*

Article 2.7.12.10.

When importing from a~~n~~ HPNAI free country, *zone* or *compartment*, *Veterinary Authorities* should require:

for *hatching eggs* of poultry

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

1. the eggs came from a~~n~~ HPNAI free country, *zone* or *compartment*;

2. the eggs were derived from parent flocks which had been kept in a~~n~~ 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 sanitized (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.; in that case, the nature of the vaccine used and the date of vaccination ~~relevant information is~~ should be attached to the certificate.

Article 2.7.13.10bis.

Regardless of the NAI status of the country, *zone* or *compartment* origin, *Veterinary ~~Administrations~~ Authorities* should require:

Community comment:

The article should be renumbered 2.7.12.10 bis.

The word *compartment* should be deleted.

Export from a compartment should always be from a compartment free of the disease for which it has been designed.

for *hatching eggs* from birds other than poultry

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

1. the parent flock birds were subjected to a diagnostic test 7 days prior to and at the time of the collection of the eggs to demonstrate freedom from *infection* with NAIV;

Community comment:

In the point 1 above the following words should be added after "the parents flock birds": "showed no clinical sign of infection with a virus which would be considered NAI in poultry and".

2. the eggs have had their surfaces sanitized (in accordance with Article 3.4.1.7.) and are transported in new or appropriately sanitized packing material;

3. the parent flocks have not been vaccinated against NAI; if parent flocks were vaccinated against NAI, the nature of the vaccine used and the date of vaccination should also be attached to the certificate.

Article 2.7.12.11.

When importing from a~~n~~ NAI free country, *zone* or *compartment*, *Veterinary Authorities* should require:

for eggs for human consumption

the presentation of an *international veterinary certificate* attesting that ~~the eggs~~

1. the eggs were produced and packed in ~~come from~~ a NAI free country, *zone* or *compartment*.

2. the eggs are transported in new or appropriately sanitized packaging material.

Article 2.7.12.12.

When importing from a~~n~~ HPNAI free country, *zone* or *compartment*, *Veterinary Authorities* should require:

for eggs for human consumption

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

1. the eggs were produced and packed in ~~come from~~ a~~n~~ HPNAI free country, *zone* or *compartment*;

2. the eggs have had their surfaces sanitis~~z~~ed (in accordance with Article 3.4.1.7.) and are transported in new or appropriately sanitized packing material.

Article 2.7.12.13.

When importing from a~~n~~ NAI free country, *zone* or *compartment*, *Veterinary Authorities* should require:

for egg products

the presentation of an *international veterinary certificate* attesting that the egg products come from, and were processed in, a~~n~~ NAI free country, *zone* or *compartment*.

Article 2.7.12.14.

~~Regardless of the NAI status of the country, *zone* or *compartment* of origin~~ When importing from a country, *zone* or *compartment* not considered free from NAI, *Veterinary Authorities* should require:

Community comment:

In consistency with other articles in the chapter as well as other chapters in the Code, the preious wording should remain:

Regardless of the NAI status of the country, *zone* or *compartment* of origin

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

Community comment:

The reference should not be made to article 10 (hatching eggs) but to article 11 (eggs for human consumption).

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.

4. the eggs are transported in new or appropriately sanitized packaging material.

Community comment:

The article deals with egg products, thus the above point 4 should be deleted.

Article 2.7.12.15.

When importing from a~~n~~ NAI free country, *zone* or *compartment*, *Veterinary Authorities* 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 a~~n~~ 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 a~~n~~ HPNAI free country, *zone* or *compartment*, *Veterinary Authorities* 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 a~~n~~ 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 Authorities* 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~~ within 14 days prior to semen collection and shown to be free of NAI infection.

Article 2.7.12.18.

When importing from a~~n~~ NAI free country, *zone* or *compartment*, *Veterinary Authorities* 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~~ poultry:

1. which have been kept in a~~n~~ 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* in a NAI free country, *zone* or *compartment* and have been subjected to ante-mortem and post-mortem inspections in accordance with Appendix 3.10.1. and have been found free of any signs suggestive of NAI ~~to rule out the presence of NAI with favourable results~~.

Article 2.7.12.19.

When importing from a~~n~~ HPNAI free country, *zone* or *compartment*, *Veterinary Authorities* 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~~ poultry:

1. which have been kept in a~~n~~ 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* in a HPNAI free country, *zone* or *compartment* and have been subjected to ante-mortem and post-mortem inspections in accordance with Appendix 3.10.1 and have been found free of any signs suggestive of NAI ~~to rule out the presence of NAI with favourable results~~.

Article 2.7.12.20.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Authorities* 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 meets 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 avian influenza virus in accordance with Appendix 3.6.5.;

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 Authorities* 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 a~~n~~ 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 avian influenza 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 Authorities* should require:

for feathers and down (~~from~~ of poultry)

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

1. these *commodities* come from poultry which have been kept and processed in a~~n~~ 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 avian influenza 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 Authorities* 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. *commodity* has been processed to ensure the destruction of avian influenza virus (under study);~~

~~2. necessary precautions were taken after processing to avoid contact of the *commodity* with any source of NAI virus.~~

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APPENDIX 3.6.5.

GUIDELINES ~~FOR~~ ON THE INACTIVATION OF THE AVIAN INFLUENZA VIRUS

Community position:

The Community can support the proposed changes.

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	870 seconds
Liquid egg white	56.7	232 seconds
10% salted yolk	62.2	138 seconds
Dried egg white	67	0.83 days
Dried egg white	54.4	21.38 days

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Article 3.6.5.2.

Meat

A procedure which produces a core temperature of 70ºC for 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

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Annex XXI (contd)

APPENDIX 3.8.9.

GUIDELINES ~~FOR~~ ON ~~THE~~ SURVEILLANCE ~~OF~~ FOR AVIAN INFLUENZA

Community position:

The Community can support the proposed changes, but reiterates one comment regarding article 3.8.9.3 point 1.

Article 3.8.9.1.

Introduction

This Appendix defines the principles and provides a guide on the surveillance for notifiable avian influenza (NAI) complementary to ~~in accordance with~~ Appendix 3.8.1., applicable to countries seeking to demonstrate ~~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 is also 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 Members 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 Authority*. 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 Services*. They should be supported directly or indirectly (e.g. through private veterinarians or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. 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 a~~n approved~~ *laboratory* for appropriate tests. 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 a~~n~~ 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 standstill 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.

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, including cases of HPNAI detected in any birds. 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).

Community position:

The Community reiterates its former comment: "HPNAI" is not defined for other birds than poultry, so it should be replaced by "HPAI".

If a Member 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) false 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. Sentinel birds should be used only if no appropriate *laboratory* procedures are available. 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 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 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 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 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.

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 and blocking ELISA tests. For the HA, antibodies are detected in haemagglutination inhibition (HI), ELISA 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. <u>The follow-up procedure in case of positive test results if vaccination is used</u>

   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 NAIV by 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. <u>The follow-up procedure in case of positive test results indicative of infection for determination of infection due to HPNAI or LPNAI virus</u>

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***

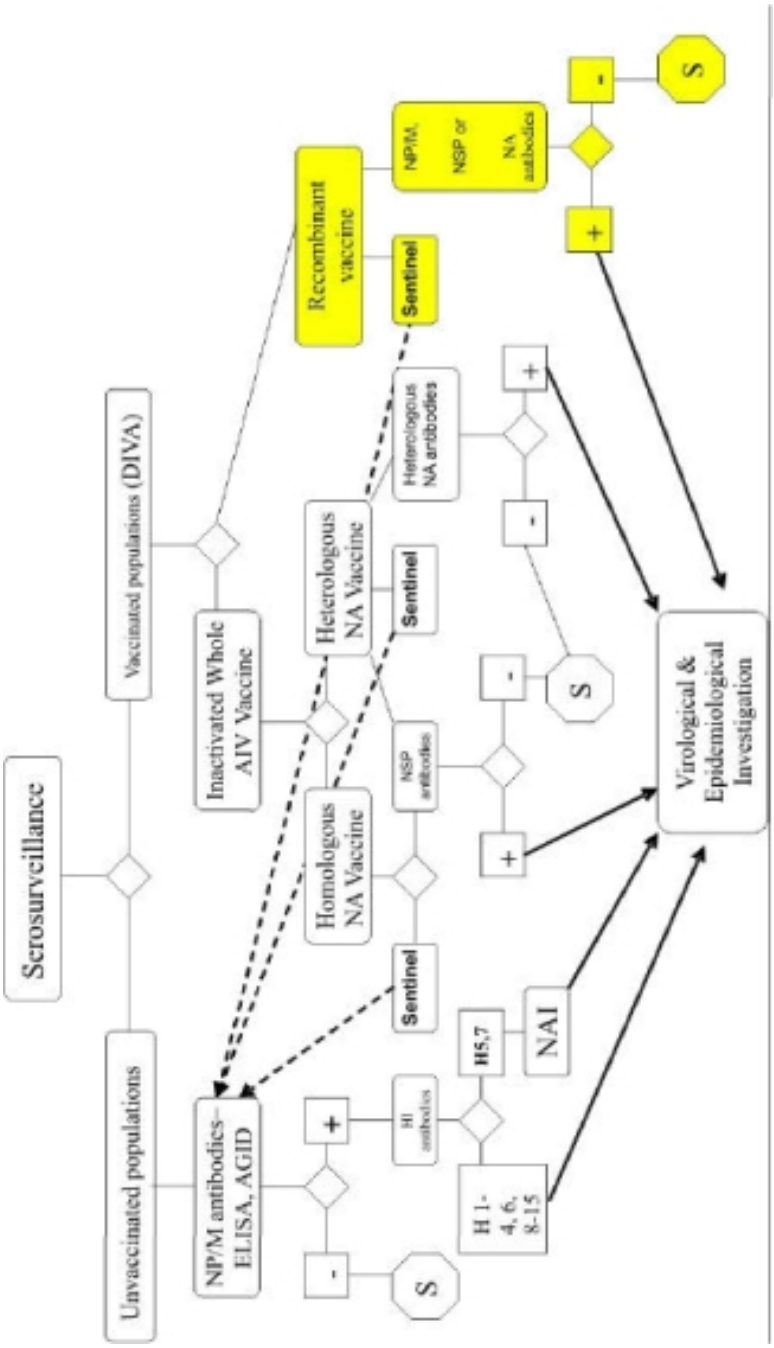
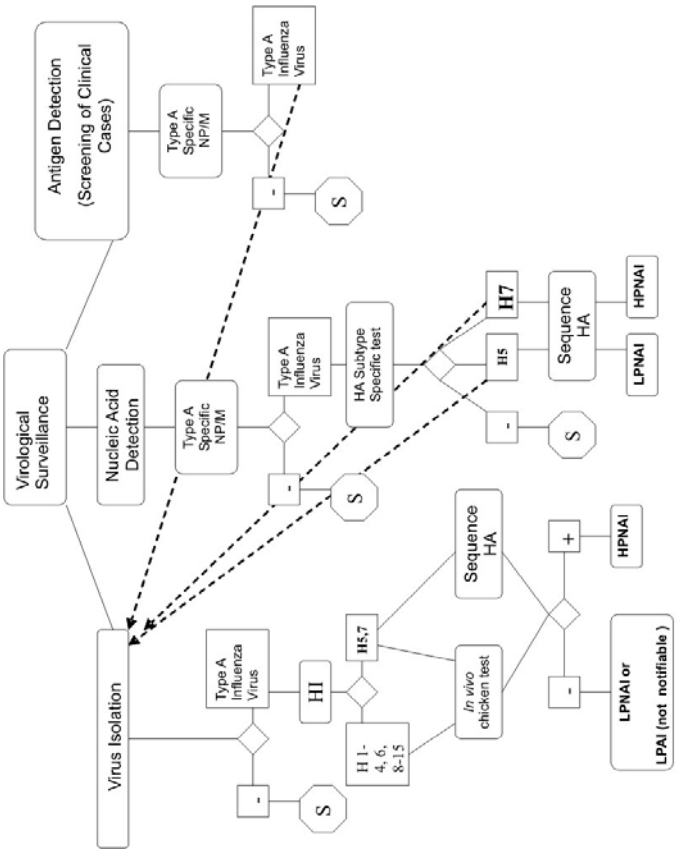


Fig. 2. ***Schematic representation of laboratory tests for determining evidence of NAI infection using virological methods***



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

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Annex XXII

CHAPTER 2.7.13.

NEWCASTLE DISEASE

Community position:

The Community has serious concerns on the proposed changes. On the one hand, it approves and supports the simplification of the definition; but on the other hand it cannot accept that the word "poultry" is again replaced by "birds". Discussions around the adoption of the chapter on AI proved at length the unnecessary trade difficulties that this definition could provoke, especially when it is well known that ND is endemic in the wild birds population throughout the world, and its surveillance as required in Appendix 3.8.X for ND would be impossible.

Thus the words "For the purpose of international trade" should remain, the word "poultry" should replace again the word "birds", and the added sentence at the end of point 1 should be deleted as unnecessary.

In case the OIE cannot accept what is a simple return to a commonly accepted and coherent version, the Community cannot support the changes.

Furthermore, the Community has a few other comments that should be taken into account.

Article 2.7.13.1.

1. ~~For the purposes of the *international trade*,~~ ~~An outbreak of~~ Newcastle ~~D~~disease (ND) ~~for the purpose of the *Terrestrial Code* is defined in the *Terrestrial Manual*~~ is defined as an *infection* of ~~birds~~ ~~poultry~~ birds caused by a virus (NDV) of avian paramyxovirus serotype 1 (APMV-1)~~, termed virulent Newcastle disease virus (vNDV),~~ that meets one of the following criteria for *virulence*:

   a) the virus has an intracerebral pathogenicity index (ICPI) in day-old chicks (*Gallus gallus*) of 0.7 or greater; or

   b) multiple basic amino acids have been demonstrated in the virus (either directly or by deduction) at the C-terminus of the F2 protein and phenylalanine at residue 117, which is the N-terminus of the F1 protein. The term 'multiple basic amino acids' refers to at least three arginine or lysine residues between residues 113 and 116. Failure to demonstrate the characteristic pattern of amino acid residues as described above would require characterisation of the isolated virus by an ICPI test.

   In this definition, amino acid residues are numbered from the N-terminus of the amino acid sequence deduced from the nucleotide sequence of the F0 gene, 113–116 corresponds to residues –4 to –1 from the cleavage site.'

   ~~Viruses classified as APMV-1 are synonymous with Newcastle disease virus (NDV). Those viruses that meet the criteria of virulence to be the cause of ND are termed virulent Newcastle disease virus (vNDV). All other APMV- 1s that do not meet the criteria for vNDV are termed low virulent NDV (loNDV).~~

While findings of ND in all birds are notifiable to the OIE according to Chapter 2.1.1., trade measures should be limited to findings in poultry.

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'. ~~All backyard and game fowl regardless of use will be defined as poultry.~~

   Birds that are kept in captivity for any reason other than those ~~defined as poultry~~ reasons referred to in the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions, ~~or sale~~ or for breeding or selling these categories of birds as well as pet birds, are not considered to be poultry.

3. This chapter ~~only~~ deals with ~~v~~NDV *infection* of ~~birds~~ poultry as defined in point ~~1~~2 above, in the presence or absence of clinical signs. For the purposes of *international trade*, a country should ~~interpret an~~ not impose immediate trade bans in response to reports ~~occurrence~~ of *infection* with ~~v~~NDV in birds other than poultry ~~according to the *Terrestrial Code* and should not impose immediate trade bans, although such infections should be notified~~.

4. ~~The following defines~~ ~~t~~The occurrence of *infection* with ~~v~~NDV is defined as the isolation and identification of~~:~~

   ~~a)~~ ~~v~~NDV ~~has been isolated and identified~~ as such or the detection of viral RNA specific for ~~v~~NDV ~~has been detected~~.

   ~~b)~~5. For the purposes of the *Terrestrial Code*, the *incubation period* for ND shall be 21 days.

   ~~c)~~6. Standards for diagnostic tests, including pathogenicity testing, are described in the *Terrestrial Manual*. When the use of ND vaccines is appropriate, those vaccines should comply with the standards described in the *Terrestrial Manual*.

Article 2.7.13.2.

The ND status of a country, a *zone* or a *compartment* can ~~only~~ be determined ~~and certified~~ on the basis of the following criteria:

1. ND is notifiable in the whole country, an on-going ND awareness programme is in place, and all notified suspect occurrences of ND are subjected to field and, where applicable, laboratory investigations;

2. appropriate surveillance is in place to demonstrate the presence of ~~v~~NDV *infection* in the absence of clinical signs in poultry, this may be achieved through an ND surveillance programme in accordance with Appendix 3.8.X.;

3. consideration of all epidemiological factors for ND occurrence and their historical perspective.

Article 2.7.13.3.

ND free country, zone or compartment

A country, *zone* or *compartment* may be considered free from ND when it has been shown that ~~v~~NDV *infection* has not been present in the country, *zone* or *compartment* for the past 12 months, based on

surveillance in accordance with Appendix 3.8.X. ~~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~~.

Community comment:

The words "in poultry" should be added after the words "NDV infection" in the first sentence above, so that there is no place for misunderstanding.

If *infection* has occurred in a previously free country, *zone* or *compartment*, ND free status can be regained three months after a *stamping-out policy* (including *disinfection* of all affected *establishments)* is applied, providing that surveillance in accordance with Appendix 3.8.X. has been carried out during that three-month period.

Article 2.7.13.4.

When importing from an ND free country, *zone* or *compartment* as defined in Article 2.7.13.3., *Veterinary ~~Administrations~~ Authorities* 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 suggestive of ND on the day of shipment;

2. the poultry were kept in an ND free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;

3. the ~~birds~~ poultry are transported in new or appropriately sanitized *containers*.

~~the poultry have not been vaccinated against ND;~~ If the birds were vaccinated against ND, the nature of the vaccine used and the date of vaccination ~~shall~~ should be attached to the certificate.

Article 2.7.13.5.

Regardless of the ND status of the country, *zone* or *compartment* of origin, *Veterinary ~~Administrations~~ Authorities* should require:

Community comment:

The word "compartment should be deleted (see similar comment of AI chapter).

for live birds other than poultry

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

1. the birds showed no clinical sign suggestive of ND 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 ND in poultry~~ during the isolation period;
3. the birds were subjected to a diagnostic test ~~7 to~~ within 14 days prior to shipment to demonstrate freedom from *infection* with ~~v~~NDV;

~~4.~~ ~~the birds are transported in new or appropriately sanitized containers~~ ~~the birds have not been vaccinated against ND;~~

~~5~~4. ~~the birds have not been vaccinated against ND or if the birds were vaccinated against ND the nature of the vaccine used and the date of vaccination shall also be attached to the certificate~~ the birds are transported in new or appropriately sanitized *containers*.

~~t~~If the birds were vaccinated against ND, the nature of the vaccine used and the date of vaccination ~~shall~~ should also be attached to the certificate

Article 2.7.13.6.

When importing from an ND free country, *zone* or *compartment* as defined in Article 2.7.13.3., *Veterinary ~~Administrations~~ Authorities* should require:

for day-old live poultry

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

1. the poultry were hatched and kept in an ND free country, *zone* or *compartment*;

2. the poultry were derived from parent flocks which had been kept in an ND free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;

3. ~~the poultry have not been vaccinated against ND; if poultry or parent flocks were vaccinated against ND, the nature of the vaccine used and the date of vaccination shall~~ should ~~also be attached to the certificate;~~

~~4.~~ the ~~birds~~ poultry are transported in new or appropriately sanitized *containers*.

~~the poultry have not been vaccinated against ND;~~ If poultry or parent flocks were vaccinated against ND, the nature of the vaccine used and the date of vaccination ~~shall~~ should also be attached to the certificate

~~Article 2.7.13.7.~~

~~Regardless of the ND status of the country, zone or compartment, *Veterinary Administrations Authorities* should require:~~

~~for day-old live birds other than poultry~~

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

~~1. the birds showed no clinical sign suggestive of ND on the day of shipment;~~

~~2. the birds were hatched and kept in isolation approved by the *Veterinary Services*;~~

~~3. the parent flock birds were subjected to a diagnostic test at the time of the collection of the eggs to demonstrate freedom from infection with vNDV;~~

~~4. the birds are transported in new or appropriately sanitized containers;~~

~~5. the birds have not been vaccinated against ND or if the birds or parent flocks were vaccinated against ND the nature of the vaccine used and the date of vaccination shall also be attached to the certificate.~~

Article 2.7.13.7.

Regardless of the ND status of the country, *zone* or *compartment*, *Veterinary Authorities* should require:

Community comment:

The word "compartment should be deleted (see similar comment of AI chapter).

for day-old live birds other than poultry

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

1. the birds showed no clinical sign suggestive of ND on the day of shipment;

2. the birds were hatched and kept in isolation approved by the *Veterinary Services*;

3. the parent flock birds were subjected to a diagnostic test at the time of the collection of the eggs to demonstrate freedom from infection with NDV;

4. the birds are transported in new or appropriately sanitized *containers*;

If the birds or parent flocks were vaccinated against ND, the nature of the vaccine used and the date of vaccination should also be attached to the certificate.

Article 2.7.13.~~8~~78.

When importing from an ND free country, *zone* or *compartment* as defined in Article 2.7.13.3., *Veterinary ~~Administrations~~ Authorities* should require:

for *hatching eggs* ~~from~~ of poultry

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

1. the eggs came from an ND free country, *zone* or *compartment*;

2. the eggs were derived from parent flocks which had been kept in an ND free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;

3. ~~the parent flocks have not been vaccinated against ND; or~~

4. the eggs are transported in new or appropriately sanitized packing material.

If parent flocks were vaccinated against ND, the nature of the vaccine used and the date of vaccination ~~shall~~ should also be attached to the certificate.

Article 2.7.13.~~9~~89.

Regardless of the ND status of the country, *zone* or *compartment* origin, *Veterinary ~~Administrations~~ Authorities* should require:

Community comment:

The word "compartment should be deleted (see similar comment of AI chapter).

for *hatching eggs* from birds other than poultry

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

1. the parent flock birds were subjected to a diagnostic test 7 days prior to and at the time of the collection of the eggs to demonstrate freedom from *infection* with ~~v~~NDV;

2. the ~~birds~~ eggs are transported in new or appropriately sanitized packing material;

Community comment:

As the risk is higher, the eggs should be disinfected, like in the AI chapter. Thus the point 2 above should read:

2. the eggs have had their surfaces sanitized (in accordance with Article 3.4.1.7.) and are transported in new or appropriately sanitized packing material;

~~3. the parent flocks have not been vaccinated against ND;~~

If parent flocks were vaccinated against ND, the nature of the vaccine used and the date of vaccination ~~shall~~ should also be attached to the certificate.

Article 2.7.13.~~10~~910.

When importing from an ND free country, *zone* or *compartment* as defined in Article 2.7.13.3., *Veterinary ~~Administrations~~ Authorities* should require:

for ~~poultry~~ eggs for human consumption

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

1. the eggs were produced and packed in an ND free country, *zone* or *compartment*;

2. the eggs are transported in new or appropriately sanitized packing material.

Article 2.7.13.~~11~~1011.

When importing from an ND free country, *zone* or *compartment* as defined in Article 2.7.13.3., *Veterinary ~~Administrations~~ Authorities* should require:

for ~~poultry~~ egg products

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

1. the egg products come from, and were processed in, an ND free country, *zone* or *compartment*;

2. the egg products are transported in new or appropriately sanitized *containers*.

Article 2.7.13.~~12~~1112.

~~Regardless of the ND status of the country, *zone* or *compartment* of origin~~ When importing from a country, *zone* or *compartment* not considered free from ND, *Veterinary ~~Administrations~~ Authorities* should require:

Community comment:

In consistency with other articles in the chapter as well as other chapters in the Code, the preious wording should remain:

Regardless of the ND status of the country, *zone* or *compartment* of origin

for ~~poultry~~ egg products

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

1. the ~~*commodity is*~~ egg products are processed to ensure the destruction of ~~v~~NDV(under study);

2. the necessary precautions were taken after processing to avoid contact of the ~~*commodity*~~ egg products with any source of ~~v~~NDV;

3. the egg products are transported in new or appropriately sanitized *containers*.

Article 2.7.13.~~13~~1213.

When importing from an ND free country, *zone* or *compartment* as defined in Article 2.7.13.3., *Veterinary ~~Administrations~~ Authorities* should require:

for poultry semen

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

1. showed no clinical sign suggestive of ND on the day of semen collection;

2. were kept in an ND free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

Article 2.7.13.~~14~~1314.

Regardless of the ND status of the country, *zone* or *compartment* of origin, *Veterinary ~~Administrations~~ Authorities* 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 and on the day of semen collection;

2. showed no clinical sign suggestive of *infection* with ~~v~~NDV during the isolation period and on the day of semen collection;

3. were subjected to a diagnostic test ~~7 to~~ within 14 days prior to semen collection to demonstrate freedom from *infection* with ~~v~~NDV.

Article 2.7.13.~~15~~1415.

When importing from an ND free country, *zone* or *compartment* as defined in Article 2.7.13.3., *Veterinary ~~Administrations~~ Authorities* 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~~ poultry:

1. which have been kept ~~and slaughtered~~ in an ND 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* in an ND free country, *zone* or *compartment* and have been subjected to ante-mortem and post-mortem inspections in accordance with Appendix 3.10.1. and have been found free of any sign suggestive of ND.

Article 2.7.13.~~16~~~~15~~16.

When importing from an ND free country, *zone* or *compartment*, *Veterinary Authorities* 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 meets the requirements of Article 2.7.13.~~15~~14. and has been processed in an ND free country, *zone* or *compartment*;

2. the necessary precautions were taken to avoid contact of the *commodity* with any source of ~~v~~NDV.

Article 2.7.13.~~16~~17.

When importing from a country, *zone* or *compartment* not considered free from ND ~~Regardless of the ND status of the country, *zone* or *compartment* of origin~~, *Veterinary ~~Administrations~~ Authorities* should require:

for *meat products* of poultry

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

1. the entire consignment of meat comes from ~~animals~~ poultry which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections in accordance with Appendix 3.10.1. and have been found free of any signs suggestive of ND;

~~1~~2. ~~the *commodity* is derived from *fresh meat* which meet the requirements of Article 2.7.13.15 (fresh meat) and has been processed in an ND free country, zone or compartment; or~~ the *commodity* has been processed to ensure the destruction of ~~v~~NDV (under study);

~~2~~3. the necessary precautions were taken to avoid contact of the *commodity* with any source of ~~v~~NDV.

Article 2.7.13.17.bis

~~When importing from a ND free country, *zone* or *compartment*, *Veterinary Authorities* 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. the *commodities* come from poultry which have been kept and processed in an ND free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;~~

~~2. the necessary precautions were taken to avoid contact of the *commodity* with any source of vNDV.~~

~~Article 2.7.13.17.bis~~

~~When importing from a country, *zone* or *compartment* not considered free from ND~~ ~~Regardless of the ND status of the country, *zone* or *compartment* of origin~~ Regardless of the ND status of the country, *zone* or *compartment* of origin, *Veterinary ~~Administrations~~* *Authorities* 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 and processed in an ND free country, zone or compartment since they were hatched or for at least the past 21 days; or~~ these *commodities* come from poultry which have been kept and processed in an ND 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 ~~v~~NDV (under study);

AND

~~2~~3. the necessary precautions were taken to avoid contact of the *commodity* with any source of ~~v~~NDV.

Article 2.7.13.18.

Regardless of the ND status of the country, *zone* or *compartment* of origin, *Veterinary ~~Administrations~~* *Authorities* should require:

for feathers and down

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

1. these *commodities* come from poultry which have been kept and processed in an ND 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 ~~v~~NDV (under study);

AND

~~2.~~ the necessary precautions were taken to avoid contact of the *commodity* with any source of ~~v~~NDV.

~~Article 2.7.13.19.~~

~~Regardless of the ND status of the country, *zone* or *compartment, Veterinary Administrations Authorities* 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 vNDV (under study);~~

~~2. the necessary precautions were taken after processing to avoid contact of the *commodity* with any source of vNDV.~~

- - - - - - - - - - - - - -
— text deleted

Annex XXII (contd)

APPENDIX 3.8.X.

GUIDELINES ON SURVEILLANCE FOR NEWCASTLE DISEASE

Community position:

The Community can support the proposed changes.

Article 3.8.X.1.

Introduction

This Appendix defines the principles and provides a guide on the surveillance for Newcastle ~~D~~disease (ND) as defined in Chapter 2.7.12. and is complementary to ~~in accordance with~~ Appendix 3.8.1.~~,~~ It is applicable to countries seeking to demonstrate ~~recognition for a declared~~ ND 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 ND status is also provided. ~~This Appendix complements Chapter 2.7.13.~~

Surveillance for ND is complicated by the known prevalence of avian paramyxovirus serotype 1 (APMV-1) *infections* in many bird species, both domestic and wild, and the widespread utilization of ND vaccines in domestic poultry. ~~Consequently it is required that APMV-1 isolates synonymous with Newcastle disease vrus virus (NDV) be characterized to differentiate those *infections* of virulent NDV (vNDV) that are notifiable as defined in Chapter 2.7.13. from those of low virulence (loNDV) which are not. Newcastle D~~disease (ND) ~~is described~~ defined in Chapter ~~x.x.x.x~~ 2.7.13 ~~as an infection of birds with APMV-1, however this appendix is only concerned with vNDV infections of poultry).~~

The impact and epidemiology of ND differ widely in different regions of the world and therefore it is not possible to provide specific guidelines for all situations. Therefore surveillance strategies employed for demonstrating freedom from ND 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, production systems and the commingling of different susceptible species require specific surveillance strategies to address each specific situation. It is incumbent upon the country to provide scientific data that explains the epidemiology of ND in the region concerned and also demonstrates how all the risk factors are managed. There is, therefore, considerable latitude available to Members to provide a well-reasoned argument to prove freedom from ~~v~~NDV *infection*.

Surveillance for ND 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 ~~v~~NDV *infection*.

Article 3.8.X.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~~ Authority*. In particular there should be in place:

   a) a formal and ongoing system for detecting and investigating *outbreaks of disease* or ~~v~~NDV *infection*;

b) a procedure for the rapid collection and transport of samples from suspect cases of ND to an ~~*approved*~~ *laboratory* for ND diagnosis as described in the *Terrestrial Manual;*

c) a system for recording, managing and analysing diagnostic and surveillance data.

2. The ND 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 ND 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*~~ *Authority*. All suspected cases of ND should be investigated immediately. As suspicion cannot be resolved by epidemiological and clinical investigation alone, samples should be taken and submitted to a~~n~~ ~~*approved*~~ *laboratory* for appropriate tests. This requires that sampling kits and other equipment are available to those responsible for surveillance. Personnel responsible for surveillance should be able to call for assistance from a team with expertise in ND diagnosis and control;

b) implement, when relevant, regular and frequent clinical, virological and serological surveillance of high risk groups of poultry within the target population, (e.g. those adjacent to an ND infected ~~population~~ country, *zone*, *compartment*, places where birds and poultry of different origins are mixed, or other sources of ~~v~~NDV).

An effective surveillance system may ~~periodically~~ identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is due to ~~v~~NDV *infection*. 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 ~~v~~NDV *infection* should 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.X.3.

Surveillance strategies

1. Introduction

The principles involved in surveillance for *disease* / *infection* are technically well defined. Any surveillance programme requires inputs from professionals competent and experienced in this field and should be thoroughly documented. The design of surveillance programmes to prove the absence of ~~v~~NDV *infection*/circulation needs to be carefully followed to avoid producing results that are either unreliable, or excessively costly and logistically complicated.

If a country wishes to declare freedom from ~~v~~NDV *infection* in a country, *zone* or *compartment,* the subpopulation used for surveillance of the *disease* / *infection* should be representative of all poultry within the country, *zone* or *compartment*. Multiple surveillance methods should be used concurrently to accurately define the true ND status of poultry populations. Active and passive surveillance for ND should be ongoing with the frequency of active surveillance being ~~at least every 6 months~~ appropriate to the *disease* situation in the country. Surveillance should be composed of random and/or targeted approaches, dependent on the local epidemiological situation and using clinical, virological and serological methods as described in the *Terrestrial Manual* ~~(Chapter x.x.x.x)~~. If alternative tests are used they must have been validated as fit-for-purpose in accordance with OIE standards. A country

should justify the surveillance strategy chosen as adequate to detect the presence of ~~v~~NDV *infection* in accordance with Appendix 3.8.1. and the prevailing epidemiological situation.

~~For random surveillance~~ surveys, ~~the design of the sampling strategy will need to~~ incorporate ~~be of an epidemiologically appropriate design to demonstrate the prevalence of vNDV infection~~. In surveys, ~~T~~the sample size selected for testing should ~~to~~ be statistically justified ~~large enough~~ to detect *infection* ~~if it were to occur~~ at a predetermined ~~minimum rate~~ target prevalence. The sample size and expected *disease* prevalence determine the level of confidence in the results of the survey. The survey design and frequency of sampling should be dependent on the historical and current local epidemiological situation. The ~~applicant~~ country ~~must~~ should justify the choice of survey design and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Appendix 3.8.1.

Targeted surveillance (e.g. based on the increased likelihood of *infection* in a population) may be an appropriate strategy.

It may, for example, be appropriate to target clinical surveillance at particular species likely to exhibit clear clinical signs (e.g. unvaccinated chickens). Similarly, virological and serological testing could target species that may not show clinical signs (Article 2.7.13.2.) of ND and are not routinely vaccinated (e.g. ducks). Surveillance may also target poultry populations at specific risk, for example direct or indirect contact with wild birds, multi-age flocks, local trade patterns including live poultry markets, the presence of more than one species on the holding and poor biosecurity measures in place. In situations where wild birds have been shown to play a role in the local epidemiology of ND, surveillance of wild birds may be of value in alerting *Veterinary Services* to the possible exposure of poultry, and in particular, of free ranging poultry.

The sensitivity and specificity of the diagnostic tests are key factors in the choice of survey design, which should anticipate the occurrence of false positive and false negative reactions. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/*infection* history and for the different species in the target population. If the characteristics of the testing system are known, the rate at which these false reactions 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 results of active and passive surveillance are important in providing reliable evidence that no ~~v~~NDV *infection* is present in a country, *zone* or *compartment*.

2. Clinical surveillance

Clinical surveillance aims to detect clinical signs suggestive of ND at the flock level and should not be underestimated as an early indication of *infection*. Monitoring of production parameters (e.g. a drop in feed or water consumption or egg production) is important for the early detection of ~~v~~NDV *infection* in some populations, as there may be no, or mild clinical signs, particularly if they are vaccinated. Any sampling unit within which suspicious animals are detected should be considered as infected until evidence to the contrary is produced. Identification of infected flocks is vital to the identification of sources of ~~v~~NDV.

A presumptive diagnosis of clinical ND in suspect infected populations should always be confirmed by virological testing in an ~~approved~~ *laboratory*. This will enable the molecular, antigenic and other biological characteristics of the virus to be determined.

It is desirable that NDV isolates are sent promptly to an OIE Reference Laboratory for archiving and further characterization if required.

3. Virological surveillance

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

a) monitor at risk populations;

b) confirm suspect clinical cases;

c) follow up positive serological results in unvaccinated populations or sentinel birds;

d) test 'normal' daily mortalities (if warranted by an increased risk e.g. *infection* in the face of vaccination or in *establishments* epidemiologically linked to an *outbreak*).

4. Serological surveillance

Where ~~systematic~~ vaccination is carried out, serological surveillance is of limited value. Serological surveillance cannot be used to discriminate between ~~v~~NDV and other ~~NDV strains~~ APMV-1 ~~aims at the detection of antibodies against NDV but is not diagnostic of the presence of vNDV~~. Test procedures and interpretations of results are as described in ~~Chapter x.x.x of~~ the *Terrestrial Manual*. Positive NDV antibody test results can have ~~four~~ five possible causes:

a) natural *infection* with ~~NDV~~ APMV-1;

b) vaccination against ND ~~(whether intentional or not)~~;

c) exposure to vaccine virus;

~~c~~d) 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~~e) non-specific test reactions.

It may be possible to use serum collected for other survey purposes for ND surveillance. However, the principles of survey design described in these guidelines and the requirement for a statistically valid survey for the presence of NDV should not be compromised.

Discovery of seropositive, unvaccinated flocks must be investigated further by conducting a thorough epidemiological investigation. Since seropositive results are not necessarily indicative of ~~active~~ *infection*, virological ~~surveillance~~ methods should be used to confirm the presence of ~~v~~NDV in such populations. Until validated strategies and tools to differentiate vaccinated animals from those infected with field ~~ND viruses~~ APMV-1 are available, serological tools should not be used to identify NDV *infection* in vaccinated populations.

5. Use of sentinel poultry

There are various applications of the use of sentinel poultry as a surveillance tool ~~in susceptible populations~~ to detect virus circulation ~~by the presence of clinical disease or seroconversion.~~, They may be used to monitor vaccinated populations or species which are less susceptible to the development of clinical *disease* for the circulation of virus. Sentinel poultry should ~~ideally~~ be immunologically naïve and may be used in vaccinated flocks ~~subject to a risk assessment~~. In case of the use of sentinel poultry, the structure and organisation of the poultry sector, t~~T~~he type of vaccine used and local epidemiological factors will determine the type of production systems where sentinels should be placed, the frequency of placement and monitoring of the sentinels.

Sentinel poultry must be in close contact with, but should be identified to be clearly differentiated from, the target population. Sentinel poultry must be observed regularly for evidence of clinical

disease and any *disease* incidents investigated by prompt ~~virological~~ *laboratory* testing. The species to be used as sentinels should be proven to be highly susceptible to *infection* and ideally develop clear signs of clinical *disease*. Where the sentinel poultry do not necessarily develop overt clinical *disease* a programme of regular active testing by virological and serological tests should be used (the development of clinical *disease* may be dependent on the sentinel species used or use of live vaccine in the target population that may infect the sentinel poultry). The testing regime and the interpretation of the results will depend on the type of vaccine used in the target population. Sentinel birds should be used only if no appropriate laboratory procedures are available.

Article 3.8.X.4.

Documentation of ND free status

The requirements for a country, *zone* or *compartment* to declare freedom from ND are given in Article x.x.13.3.

A country declaring freedom of a country, *zone* or *compartment* (with or without vaccination) should report the results of a surveillance programme in which the ND susceptible poultry population undergoes regular surveillance planned and implemented according to the general conditions and methods described in these guidelines.

~~A country, *zone* or *compartment* may be considered free from ND when it has been shown that vNDV infection has not been present in the country, *zone* or *compartment* for the past 12 months, based on surveillance in accordance with Appendix x.x.x. 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, ND free status can be regained three months after a *stamping-out policy* (including *disinfection* of all affected *establishments)* is applied, providing that surveillance in accordance with Appendix x.x.x. has been carried out during that three-month period.~~

1. Countries declaring freedom from ND for the country, *zone* or *compartment*

   In addition to the general conditions described in the *Terrestrial Code,* a Member declaring freedom from ND for the entire country, or a *zone* or a *compartment* should provide evidence for the existence of an effective surveillance programme. The surveillance programme should be planned and implemented according to general conditions and methods described in this Appendix to demonstrate absence of ~~v~~NDV *infection* in poultry during the preceding 12 months. ~~This requires the support of an *approved laboratory* capable of identification of vNDV infection through virus detection and antibody tests described in the *Terrestrial Manual*.~~

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

   Vaccination against ND may be used ~~for risk management (to reduce the risk of introduction and subsequent transmission) or~~ as ~~part~~ a component of a *disease* prevention and 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 used must ~~also~~ comply with the provisions ~~stipulated for ND vaccines in~~ of the *Terrestrial Manual.*

   In ~~all~~ vaccinated populations there is a need to perform surveillance (Article x.x.x.x.) to ensure the absence of ~~v~~NDV circulation. The use of sentinel poultry may provide further confidence of the absence of virus circulation. The surveillance must be repeated at least every 6 months or at shorter

intervals according to the risk in the country, *zone* or *compartment*. , or Ee vidence to show the effectiveness of the vaccination programme should also be is regularly provided.

Article 3.8.X.5.

Countries, zones or compartments regaining freedom from ND following an outbreak

In addition to the general conditions described in Chapter 2.7.13., a A country regaining country, *zone* or *compartment* freedom from vNDV 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 poultry may facilitate the interpretation of surveillance results.

A country declaring freedom of a country, *zone* or *compartment* after an *outbreak* of ND (with or without vaccination) should report the results of an active a surveillance programme in which the ND 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 give at least the same confidence that can be achieved by testing a randomized representative sample of the populations at risk.

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Annex XXIII

~~DRAFT~~ GUIDELINES ON THE DESIGN AND IMPLEMENTATION OF IDENTIFICATION SYSTEMS TO ACHIEVE ANIMAL TRACEABILITY

Community position:

The Community can support the proposed Guidelines, but reiterates some of its previous comments that should to be taken into account in the next Code Commission meeting, as well as by the ad hoc group on identification.

Article 1

Introduction and objectives

These guidelines are based on the general principles presented in Article 3.5.1.1. The Guidelines outline for Member~~ Countrie~~s the basic elements that need to be taken into account in the design and implementation of an *animal identification system* to achieve *animal traceability*. Whatever *animal identification system* the country adopts, it should comply with relevant OIE standards, including Part 4 for animals and animal products intended for export. Each country should design a program in accordance with the scope and relevant performance criteria to ensure that the desired *animal traceability* outcomes can be achieved.

Article 2

~~Definitions~~ Glossary

~~These following definitions apply f~~For the purpose of this Appendix.

Desired outcomes: describe the overall goals of a programme and are usually expressed in qualitative terms, e.g. 'to help ensure that animals and/or animal products are safe and suitable for use'. Safety and suitability for use could be defined in terms such as animal health, food safety, trade and aspects of animal husbandry ~~husbandry aspects~~.

Performance criteria: are specifications for performance of a programme and are usually expressed in quantitative terms, such as 'all animals can be traced to the *establishment* of birth within 48 hours of an enquiry'.

Reporting: means advising the *Veterinary ~~Administration~~ Authority* in accordance with the procedures listed in the programme.

Scope: specifies the targeted species, population and/or production/trade sector within a defined area (country, zone) or compartment that is the subject of the identification and traceability programme.

Transhumance: periodic/seasonal movements of *animals* between different pastures ~~or premises~~ within or between countries.

Article 3

Key elements of the animal identification system

1. Desired outcomes

Desired outcomes should be defined through consultation between the *Veterinary ~~Administration~~ Authority* and other parties, which should include (depending on scope) animal producers and food processors, private sector veterinarians, scientific research organisations and other government agencies. Desired outcomes may be defined in terms of any or all of the following:

a) animal health (e.g. *disease* surveillance and notification; detection and control of *disease*; vaccination programmes);

b) public health (e.g. surveillance and control of zoonotic diseases and food safety);

c) management of emergencies e.g. natural catastrophies or man-made events;

d) trade (support for inspection and certification activities of *Veterinary Services*, as described in Part 4 which reproduces model international veterinary certificates);

e) aspects of animal husbandry ~~aspects (e.g.~~ such as animal performance, and genetic data).

2. Scope

Scope should also be defined through consultation between the *Veterinary ~~Administration~~ Authority* and other parties, as discussed above. The scope of *animal identification systems* is often based on the definition of a species and sector, to take account of particular characteristics of the farming systems e.g. pigs in pork export production; poultry in a defined compartment; cattle within a defined FMD free *zone*. Different systems will be appropriate according to the production systems used in countries and the nature of their industries and trade.

3. Performance criteria

Performance criteria are also designed in consultation with other parties, as discussed above. The performance criteria depend on the desired outcomes and scope of the program. They are usually described in quantitative terms according to the epidemiology of the disease. For example, some countries consider it necessary to trace susceptible animals within 24-48 hours when dealing with highly contagious *diseases* such as FMD and avian influenza. For food safety, animal tracing to support investigation of incidents may also be urgent. For chronic animal *diseases* that are not ~~a~~ zoonos~~i~~es, ~~such as bovine paratuberculosis~~ it may be considered appropriate that animals can be traced over a longer period ~~within 30 days~~.

4. Preliminary studies

In designing *animal identification systems* it is useful to conduct preliminary studies, which should take into account:

a) animal populations, species, distribution, herd management,

b) farming and industry structures, production and location,

c) animal health,

d) public health,

e) trade issues,

f) aspects of animal husbandry,

~~f~~g) zoning and compartmentalisation,

~~g~~h) animal movement patterns (including transhumance),

~~h~~i) information management and communication,

~~i~~j) availability of resources (human and financial),

~~j~~k) social and cultural aspects,

~~k~~l) stakeholder knowledge of the issues and expectations,

~~l~~m) gaps between current enabling legislation and what is needed long term,

~~m~~n) international experience,

~~n~~o) national experience,

~~o~~p) available technology options,

q) existing identification system(s),

r) expected b~~B~~enefits from the *animal identification systems* and *animal traceability* ~~scheme~~ and to whom they accrue.

Pilot projects may form part of the preliminary study to test the *animal identification system* and *animal traceability* and to gather information for the design and the implementation of the programme.

Economic analysis may consider costs, benefits, funding mechanisms and sustainability.

5. Design of the programme

a) General provisions

The programme should be designed in consultation with the stakeholders to facilitate the implementation of the *animal identification system* and *animal traceability*. It should take into account the scope, performance criteria and desired outcomes as well as the results of any preliminary study.

All the specified documentation should be standardised as to format, content and context.

To protect and enhance the integrity of the system, procedures should be incorporated into the design of the programme to prevent, detect and correct errors e.g. use of algorithms to prevent duplication of identification numbers and to ensure plausibility of data ~~in an electronic database~~.

b) Means of animal identification

The choice of a physical animal identifier should ~~take into account~~ consider elements such as the durability, human resources, species and age of the animals to be identified, required period of identification, ~~animal welfare,~~ cultural aspects, animal welfare, technology, compatibility and relevant standards, farming practices, production systems, animal population, climatic conditions, resistance to tampering, trade considerations, cost, and retention and readability of the identification method.

The *Veterinary ~~Administration~~ Authority* is responsible for approving the materials and equipment chosen, to ensure that these means of animal identification comply with technical and field performance specifications, and for the supervision of their distribution. The *Veterinary ~~Administration~~ Authority* is also responsible for ensuring that identifiers are unique and are used in accordance with the requirements of the *animal identification system*.

Community position:

The Community reiterates its previous comment:

The word "materials" should be replaced by "identifiers" (as the Veterinary Authority cannot approve all the materials), and the words "their distribution" by "the distribution of the identifiers" (as the Veterinary Authority cannot supervise the distribution of all the equipments). The word "individual" should be inserted between "ensuring that" and "identifiers", as the same group identifier is applied to all the animals of the group. An alternative would be to replace "identifiers" by "identifying numbers or codes".

The *Veterinary ~~Administration~~ Authority* should establish procedures for *animal identification* and *animal traceability* including:

i) the time period within which an animal born on an *establishment* should be identified;

ii) when a~~A~~nimals are ~~imported~~ introduced into an *establishment*;

iii) when an animal loses its identification or the identifier becomes unusable;

iv) arrangements and rules for the destruction and/or reuse of identifiers.

v) penalties for the tampering and/or removal of official animal identification devices.

Where group identification without a physical identifier is adequate, documentation should be created specifying at least the number of animals in the group, the species, the date of identification, the person legally responsible for the animals and/or establishment. This documentation constitutes a unique group identifier and it should be updated to be traceable if there are any changes.

Where all animals in the group are physically identified with a group identifier, documentation should also specify the unique group identifier.

c) Registration

Procedures need to be incorporated into the design of the programme in order to ensure that relevant events and information are registered in a timely and accurate manner.

Depending on the scope, performance criteria and desired outcomes, records as described below should specify, at least, the species, the unique animal or group identifier, the date of the event, the identifier of the *establishment* where the event took place, and the code for the event itself.

i) Establishments/owners or responsible keeper

Establishments where animals are kept should be identified and registered, including at least their physical location (such as geographical coordinates or street address), the type of *establishment* and the species kept. The register should include the name of the person legally responsible for the animals at the *establishment*.

The types of *establishments* that may need to be registered include holdings (farms), assembly centres (e.g. agriculture shows and fairs, sporting events, transit centres, breeding centres), *markets*, *abattoirs*, rendering plants, dead stock collection points, transhumance areas, centres for necropsy and diagnosis, research centres, zoos, *border posts*, *quarantine stations*.

In cases where the registration of *establishments* is not applicable e.g. some transhumance systems, the animal owner, the owner's place of residence and the species kept should be recorded.

ii) Animals

Animal identification and species should be registered for each *establishment*/owner. Other relevant information about the animals at each *establishment*/owner may also be recorded e.g. date of birth, production category, sex, breed, *animal identification* of the parents.

iii) Movements

The *registration* of animal movements is necessary to achieve *animal traceability*. When an animal is introduced into or leaves an *establishment*, these events constitute a movement.

Some countries classify birth, *slaughter* and *death* of the animal as movements.

The information registered should include the date of the movement, the *establishment* from which the animal or group of animals was dispatched, the number of animals moved, the destination *establishment*, and any *establishment* used in transit ~~*establishment*~~.

When *establishments* are not registered as part of the *animal identification system*, ownership and location changes constitute a movement record. Movement recording may also include means of *transport* and the *vehicle* identifier.

Procedures should be in place to maintain *animal traceability* during *transport* and when animals arrive at and leave an *establishment*.

iv) Events other than movements

The following events may also be *registered*:

- birth, *slaughter* and *death* of the animal (when not classified as a movement),
- attachment of the unique identifier to an animal,
- change of ownership regardless of change of *establishment*,

The Community reiterates its previous comment:

In the indent above, the words "or keeper" should be added after "change of ownership".

- observation of an animal on an *establishment* (testing, health investigation, health certification, etc.),
- animal imported: a record of the *animal identification* from the *exporting country* should be kept and linked with the *animal identification* assigned in the *importing country*,
- animal exported: a record of the *animal identification* from the *exporting country* should be provided to the *Veterinary* ~~*Administration*~~ *Authority* in the *importing country*,
- animal identifier lost or replaced,
- animal missing (lost, stolen, etc.),
- animal identifier retired (at *slaughter*, following loss of the identifier or death of the animal on a farm, at diagnostic laboratories, etc.).

d) Documentation

Documentation requirements should be clearly defined and standardised, according to the scope, performance criteria and desired outcomes and supported by the legal framework.

e) Reporting

Depending on the scope, performance criteria and desired outcomes, relevant information (such as *animal identification*, movement, events, changes in numbers of livestock, *establishments*) should be reported to the *Veterinary ~~Administration~~ Authority* by the person responsible for the animals.

f) Information system

An information system should be designed according to the scope, performance criteria and desired outcomes. This may be paper based or electronic. The system should provide for the collection, compilation, storage and retrieval of information on matters relevant to *registration*. The following considerations are important:

- have the potential for linkage to traceability in the other parts of the food chain;
- minimi~~s~~ze duplication;
- relevant components, including databases, should be compatible;
- confidentiality of data ;
- appropriate safeguards to ~~avoid~~ prevent the loss of data, including ~~backup~~ a system for backing up the data ~~systems~~.

The Veterinary ~~*Administration*~~ *Authority* should have access to this information system as appropriate to meet the scope, performance criteria and desired outcomes.

g) Laboratories

The results of diagnostic tests should record the animal identifier or the group identifier and the *establishment* where the sample was collected.

h) *Abattoirs*, rendering plants, dead stock collection points, markets, assembly centres

Abattoirs, rendering plants, dead stock collection points, *markets* and assembly centres should document arrangements for the maintenance of *animal identification* and *animal traceability* in compliance with the legal framework.

These *establishments* are critical points for control of animal health and food safety.

Animal identification should be recorded on documents accompanying samples collected for analysis.

The components of the *animal identification system* operating within *abattoirs* should complement and be compatible with arrangements for tracking animal products throughout the food chain. At an *abattoir*, *animal identification* should be maintained during the processing of the animal's carcass until the carcass is deemed fit for human consumption.

The *animal identification* and the *establishment* from which the animal was dispatched should be registered by the *abattoir,* rendering plant and dead stock collection points.

Abattoirs, rendering plants and dead stock collection points should ensure that identifiers are collected and disposed of according to the procedures established and regulated within the legal

framework. These procedures should minimize the risk of unauthorized reuse and, if appropriate, should establish arrangements and rules for the reuse of identifiers.

Reporting of movement by *abattoirs*, rendering plants and dead stock collection points should occur according to the scope, performance criteria and desired outcomes and the legal framework.

i) Penalties

Different levels and types of penalties should be defined in the programme and supported by the legal framework

~~j) Commercial arrangements~~

~~An animal identification system requires producers, processors and others (depending on the design of the system) to purchase equipment. There are many possible commercial arrangements that will have a variety of implications for the uptake of the animal identification system.~~

~~k) Transition planning~~

~~Any transition from an existing animal identification system needs to be designed to ensure it is easy for users of the existing system to make the change and to insure that data integrity is maintained during the transition and integrated into the new animal identification system.~~

~~l) Use of incentives~~

~~Depending on the drivers for participation in the animal identification scheme, incentives may be useful to encourage early adoption of the system or to fill capability, capacity or technology gaps.~~

6. Legal framework

The *Veterinary ~~Administration~~ Authority*, with other relevant governmental agencies and in consultation with stakeholders, should establish a legal framework for the implementation and enforcement of *animal identification system* and *animal traceability* in the country. The structure of this framework will vary from country to country.

Animal identification, *animal traceability* and animal movement should be under the responsibility of the *Veterinary ~~Administration~~ Authority*.

This legal framework should address:

i) desired outcomes and scope;

ii) obligations of the *Veterinary ~~Administration~~ Authority* and other parties;

iii) organisational arrangements, including the choice of technologies and methods used for the *animal identification system* and *animal traceability*;

iv) management of animal movement;

v) confidentiality of data;

vi) data access / accessibility;

vii) checking, verification, inspection and penalties;

viii) where relevant, funding mechanisms;

ix) where relevant, arrangements to support a pilot project.

7. Implementation

a) Action plan

For implementing the *animal identification system*, an action plan should be prepared specifying the timetable and including the milestones and performance indicators, the human and financial resources, and checking, enforcement and verification arrangements.

The following activities should be addressed in the action plan:

i) Communication

The scope, performance criteria, desired outcomes, responsibilities, movement and registration requirements and sanctions need to be communicated to all parties.

Communication strategies need to be targeted to the audience, taking into account elements such as the level of literacy (including technology literacy) and spoken languages.

ii) Training programmes

It is desirable to implement training programmes to assist the *Veterinary Services* and other parties.

iii) Technical support

Technical support should be provided to address practical problems.

b) Checking and verification

Checking activities should start at the beginning of the implementation to detect, prevent and correct errors and to provide feedback on programme design.

Verification should begin after a preliminary period as determined by the *Veterinary ~~Administration~~ Authority* in order to determine compliance with the legal framework and operational requirements.

c) Auditing

Auditing should be carried out under the authority of the *Veterinary ~~Administration~~ Authority* to detect any problems with the *animal identification system* and *animal traceability* and to identify *possible* improvements.

d) Review

The programme should be subject to periodic review, taking into account the results of *checking*, verification and auditing activities.

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Annex XXIV

APPENDIX 3.7.1.

INTRODUCTION TO THE GUIDELINES FOR ANIMAL WELFARE

Community comments:

The Community welcomes the work carried out by the OIE Code Commission and the improvement of the definition on animal welfare.

- In the definition the word "innate" should be replaced with the words "species-specific behaviour".

Justification:

Animals should have the opportunity for both innate and learnt behaviours which are covered by the expression of species specific behaviours (those behaviours which are common to all members of a species).

- In the definition, the words "humane transport" should be included between the words "humane handling" and "humane slaughter".

Justification:

Good animal welfare requires also a humane transport.

Article 3.7.1.1

"Animal welfare" means how an animal is coping with the circumstances in which it lives. An animal is in a good state of welfare if (as indicated by scientific evidence) it is healthy, comfortable, well nourished, safe, able to express innate behaviour, able to have normal social contact with others of the same species, and if it is not suffering from unpleasant states such as pain, fear, and distress. Good animal welfare requires disease prevention and veterinary treatment, proper housing, management, nutrition, humane handling and humane slaughter/killing. By scientific convention, "animal welfare" refers to the state of the animal; the treatment that an animal receives is covered by other terms such as animal care, animal husbandry, and humane treatment.

Article 3.7.1.~~1~~2.

Guiding principles for animal welfare

Community comment:

In the first guiding principle, the word "other aspects of" should be included between the words "health" and "animal".

Justification:

The revised definition of good welfare includes health and it is therefore necessary to revise this sentence accordingly.

1. That there is a critical relationship between animal health and animal welfare.

2. That the internationally recognised 'five freedoms' (freedom from hunger, thirst and malnutrition; freedom from fear and distress; freedom from physical and thermal discomfort; freedom from pain, injury and disease; and freedom to express normal patterns of behaviour) provide valuable guidance in animal welfare.

3. That the internationally recognised 'three Rs' (reduction in numbers of animals, refinement of experimental methods and replacement of animals with non-animal techniques) provide valuable guidance for the use of animals in science.

4. That the scientific assessment of animal welfare involves diverse elements which need to be considered together, and that selecting and weighing these elements often involves value-based assumptions which should be made as explicit as possible.

5. That the use of animals in agriculture and science, and for companionship, recreation and entertainment, makes a major contribution to the wellbeing of people.

6. That the use of animals carries with it an ethical responsibility to ensure the welfare of such animals to the greatest extent practicable.

7. That improvements in farm animal welfare can often improve productivity and food safety, and hence lead to economic benefits.

8. That equivalent outcomes based on performance criteria, rather than identical systems based on design criteria, be the basis for comparison of animal welfare standards and guidelines.

Article 3.7.1.2~~2~~3.

Scientific basis for guidelines

1. Welfare is a broad term which includes the many elements that contribute to an animal's quality of life, including those referred to in the 'five freedoms' listed above.

2. The scientific assessment of animal welfare has progressed rapidly in recent years and forms the basis of these guidelines.

3. Some measures of animal welfare involve assessing the degree of impaired functioning associated with injury, disease, and malnutrition. Other measures provide information on animals' needs and affective states such as hunger, pain and fear, often by measuring the strength of animals' preferences, motivations and aversions.

4. Others assess the physiological, behavioural and immunological changes or effects that animals show in response to various challenges.

5. Such measures can lead to criteria and indicators that help to evaluate how different methods of managing animals influence their welfare.

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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 3.7.2.2

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.

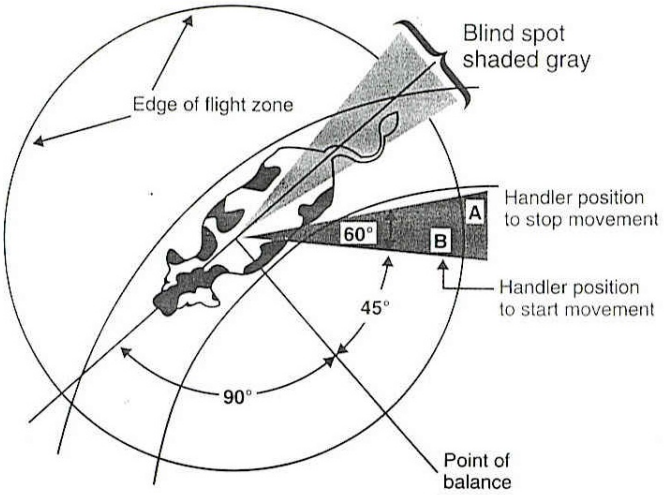
Animals which are likely to be hostile to ~~each~~ other**s** in a group situation should not be mixed.

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*.

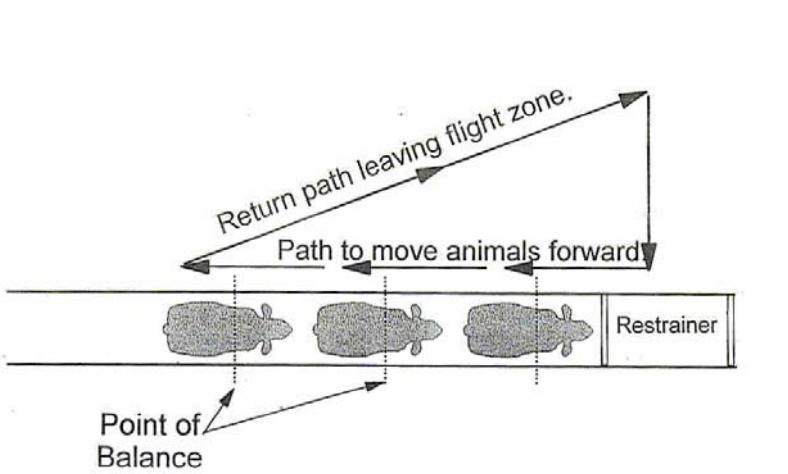
Domestic animals will try to escape if any person approaches closer than a certain distance. This critical distance, which defines the flight zone, varies among species and individuals of the same species, and depends upon previous contact with humans. Animals reared in close proximity to humans (i.e. 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. *Animal handlers* should avoid sudden penetration of the flight zone which may cause a panic reaction which could lead to aggression or attempted escape **and compromise the welfare of the animals.**

Annex XXIV (contd)

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 a wide-angle vision but only have a 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.

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 noises 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

Design of new *loading* and *unloading* facilities or modification of existing facilities should aim to minimise the potential for distractions that may cause approaching animals to stop, baulk or turn back. 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;

c) animals seeing moving people or equipment up ahead - install solid sides on chutes and races or install shields;

d) dead ends-avoid if possible by curving the passage, or make an illusory passage;

e) chains or other loose objects hanging in chutes or on fences - remove them;

f) 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;

g) sounds of air hissing from pneumatic equipment - install silencers or use hydraulic equipment or vent high pressure to the external environment using flexible hosing;

h) clanging and banging of metal objects - install rubber stops on gates and other devices to reduce metal to metal contact;

i) air currents from fans or air curtains blowing into the face of animals - redirect or reposition equipment.

Article 3.7.2.3.

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. The individual responsibilities of persons involved 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 Community reiterates its previous comment:

In the following 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.

. General considerations

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.

b) Exporters, shipping companies, business or buying/selling agents, and masters of *vessels* are jointly responsible for planning the *journey* to ensure the care of the animals, including:

i) choosing appropriate *vessels* and ensuring that *animal handlers* are available to care for the animals;

The Community reiterates its previous comment:

On the following point (ii) between the word "adverse" and "weather", add the following wording "sea and".

Justification:

In order to clarify the need to plan for adverse sea conditions as well as adverse weather conditions during transport.

ii) developing and keeping up to date contingency plans to address emergencies (including adverse weather conditions) and minimise stress during transport;

iii) correct *loading* of the ship, provision of appropriate food, water, ventilation and protection from adverse weather**,** regular inspections during the *journey* and for appropriate responses to problems arising;

iv) disposal of carcasses according to international law.

c) To carry out the above mentioned responsibilities, the parties involved should be competent regarding transport regulations, equipment usage, and the humane handling and care of animals.

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)~~

Community comment:

In the point b), the following text should be added at the end of the sentence "according to the principle laid down in art 3.7.2.7 point 3 for fitness to travel".

Justification:

The abovementioned amendment would clarify the responsibilities of the owners of animals.

~~e~~b) The responsibilities of the owners of the animals include the selection of animals that are fit to travel based on veterinary recommendations.

~~d~~c) The responsibilities of the business or buying/selling agent include:

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)~~

The Community reiterates its previous comment.

At the following point (d) add: "and to consider adverse weather and sea conditions which can be expected during the journey".

~~f~~d) The responsibilities of masters of *vessels* include the provision of suitable premises for animals on the *vessel*.

~~g~~e) The responsibilities of managers of facilities during *loading* include:

i) providing suitable premises for *loading* the animals;

ii) 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) providing appropriate facilities for emergencies;

v) providing facilities, *veterinarians* or *animal handlers* capable of *killing* animals humanely when required.

~~h~~f) The responsibilities of managers of facilities during *unloading* include:

i) 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) providing *animal handlers* to unload the animals with minimum stress and injury;

iii) minimising the opportunities for *disease* transmission while the animals are in the facilities;

iv) providing appropriate facilities for emergencies;

v) providing facilities, and *veterinarians* or *animal handlers* capable of *killing* animals humanely when required.

~~f~~g) The responsibilities of the *animal handlers* include humane handling and care of the animals, especially during *loading* and *unloading*.

~~g~~h) The responsibilities of the *Competent Authority* of the *exporting country* include:

i) establishing minimum standards for animal welfare, including requirements for inspection of animals before and during their travel, and for certification and record keeping;

ii) approving facilities, *containers*, *vehicles/vessels* for the holding and transport of animals;

iii) setting competence standards for *animal handlers* and managers of facilities;

v) implementation of the standards, including through accreditation of / interaction with other organisations and *Competent Authorities*;

vi) monitor and evaluate health and welfare ~~performance, including the use of any veterinary medications~~ of the animals at the point of loading.

~~h~~i) The responsibilities of the *Competent Authority* of the *importing country* include:

i) establishing minimum standards for animal welfare, including requirements for inspection of animals after their travel, and for certification and record keeping;

ii) approve facilities, *containers*, *vehicles/vessels* for the holding and transport of animals;

iii) setting competence standards for *animal handlers* and managers of facilities;

iv) implementation of the standards, including through accreditation of / interaction with other organisations and *Competent Authorities*;

v) ensuring that the *exporting country* is aware of the required standards for the *vessel* transporting the animals;

i) monitor and evaluate health and welfare of the animals at the point of unloading ~~performance, including the use of any veterinary medications~~;

vii) give animal consignments priority to allow import procedures to be completed without unnecessary delay.

~~l~~j) The responsibilities of *veterinarians* or in the absence of a *veterinarian*, the *animal handlers* travelling on the *vessel* with the animals include:

i) humane handling and treatment of animals during the *journey*, including in emergencies, such as humane killing of the animals;

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.

~~j~~k) The receiving *Competent Authority* should report back to the sending *Competent Authority* on *significant* animal welfare problems which occurred during the *journey*.

Article 3.7.2.4.

Competence

1. All people responsible for animals during *journeys*, should be competent to carry out the relevant responsibilities listed in Article 3.7.2.3. 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 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) responsibilities for the welfare of 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*;

   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.

53. 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 3.7.2.5.

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 *disease*s, *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.

c) *Vessels* should be designed to permit thorough cleaning and *disinfection*, and the management of faeces and urine.

d) *Vessels* and their fittings should be maintained in good mechanical and structural condition.

e) *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.

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.

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.

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.

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.

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 decks of a *vessel*, a road *vehicle* or *container* may require a forced ventilation system of greater capacity than that provided by natural ventilation.

6. Nature and duration of the journey

The maximum duration of a *journey* should be determined 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 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;

i) vessel type used, method of propulsion and risks associated with particular sea 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.

c) Calculations for the *space allowance* for each animal should be carried out in reference to 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 3.7.2.6.

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 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;

   f) *animal identification* to allow *animal traceability* of animals to the premises of departure, and, where possible, to the premises of origin;

   g) details of any animals considered at particular risk of suffering poor welfare during transport (point 3e) of Article 3.7.2.7.);

   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 3.7.2.7.

Pre-journey period

1. General considerations

   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 and risk 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.

      ~~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 3.7.2.12.). 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, 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:

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;

The Community reiterates its previous comment:

The point 3 (c) (vii) should be replaced as follows: "pregnant animals for whom 90% or more of the expected gestation period has already passed, or females who have given birth in the previous week".

Justification:

It is easier to verify and is also important to consider the period after birth where the female is usually weak and can not be considered to be fit for transport.

vii) pregnant animals which would be in the final 10% of their gestation period at the planned time of *unloading*;

viii) animals with unhealed wounds from recent surgical procedures such as dehorning.

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:

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.

Article 3.7.2.8.

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.

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 ease of movement of 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 some animals. Artificial lighting may be required.

3. Goads and other aids

When moving animals, their species specific behaviour should be used (see Article 3.7.2.12.). If goads and other aids are necessary, 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. 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 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) Excessive shouting 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) 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 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.

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.

Travel

1. General considerations

   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 following any incident or situation likely to affect their welfare and in any case within 12 hours of departure.

   b) If necessary and where possible 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.

   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 or injured animals

   a) Sick or injured animals should be segregated.

   b) Sick or injured animals should be appropriately treated or humanely killed, in accordance with a predetermined emergency response plan (Article 3.7.2.5.). 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 instructions.

   c) A record of treatments carried out and their outcomes should be kept.

   d) When humane killing is necessary, the *animal handler* must ensure that it is carried out humanely. Recommendations for specific species are described in Appendix 3.7.6. on killing of animals for *disease* control purposes. Veterinary advice regarding the appropriateness of a particular method of euthanasia should be sought as necessary.

Article 3.7.2.10.

Unloading and post-journey handling

1. General considerations

   a) The required facilities and the principles of animal handling detailed in Article 3.7.2.8. 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 *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 inspections should be completed as quickly as possible.

e) *Unloading* should be supervised by the *Competent Authority* and conducted by *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 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 or injured animals

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.). When necessary, veterinary advice should be sought in the care and treatment of these animals.

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 humanely killed 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.

Article 3.7.2.11.

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 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 health status of the animals with regard to the 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 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 health status of the animals with regard to the 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 3.7.2.12.

Species specific issues

Camelids of the new world 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.

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. Cattle tend to avoid "dead end" in passages.

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.

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.

Pigs have poor eyesight, and may move reluctantly in unfamiliar. 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.

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.

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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 3.7.3.2.

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.

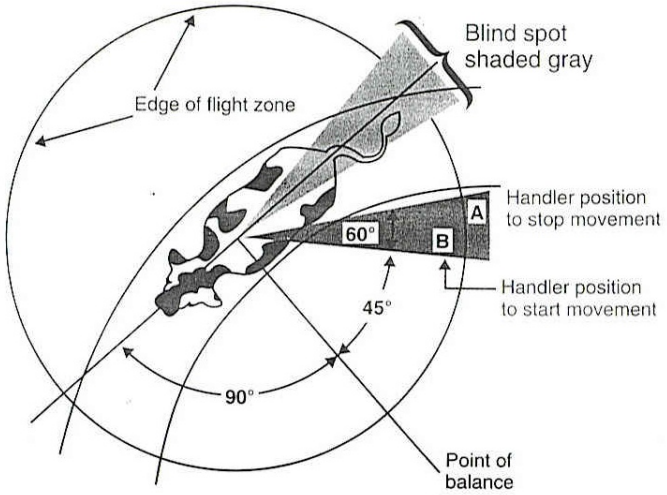
Animals which are likely to harm each other in a group situation should not be mixed.

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*.

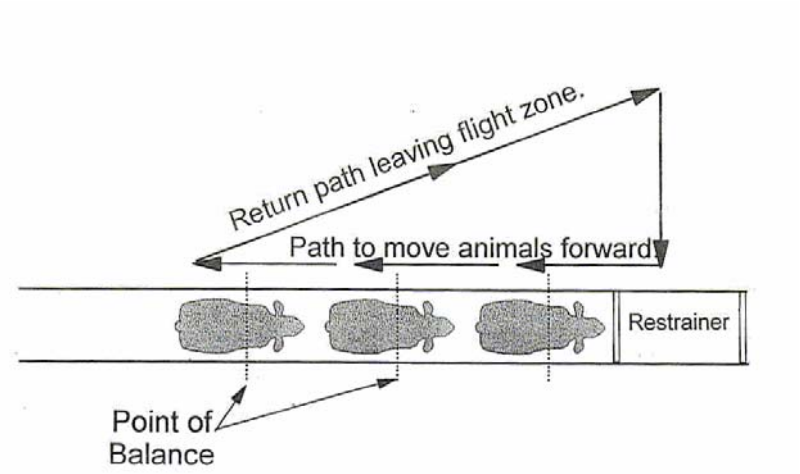
Domestic animals will try to escape if any person approaches closer than a certain distance. This critical distance, which defines the flight zone, varies among species and individuals of the same species, and depends upon previous contact with humans. Animals reared in close proximity to humans (i.e. 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 and compromise the welfare of the animals.

Annex XXIV (contd)

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;

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) dead ends-avoid if possible by curving the passage, or make an illusory passage;

e) chains or other loose objects hanging in chutes or on fences - remove them;

f) 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;

g) sounds of air hissing from pneumatic equipment - install silencers or use hydraulic equipment or vent high pressure to the external environment using flexible hosing;

h) clanging and banging of metal objects - install rubber stops on gates and other devices to reduce metal to metal contact;

i) air currents from fans or air curtains blowing into the face of animals - redirect or reposition equipment.

Article 3.7.3.3.

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. The individual responsibilities of persons involved 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:

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 are responsible for:

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) choosing appropriate *vehicles* for the species transported and the *journey*;

b) ensuring that properly trained staff are available for *loading* / *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;

d) developing and keeping up-to-date contingency plans to address emergencies (including adverse weather conditions) and minimise stress during transport;

e) producing a *journey* plan which includes a *loading* plan, *journey* duration, itinerary and location of resting places;

f) *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 3a) of Article 3.7.3.7.;

g) welfare of the animals during the actual transport.

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, and with protection from adverse weather conditions until further transport, sale or other use (including rearing or *slaughter*);

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) giving 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 3.7.3.4.

Competence

1. All people responsible for animals during *journeys*, should be competent according to their responsibilities listed in Article 3.7.3.3. Competence may be gained through formal training and/or practical experience.

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:

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*;

i) methods of inspecting animals, managing situations frequently encountered during transport such as adverse weather conditions, and dealing with emergencies, including humane killing;

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 3.7.3.5.

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*;

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 take into account animal welfare whenever ~~is~~ possible.

2. Preparation of animals for the journey

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 all animals it is essential ~~extra important~~ that the rest stops during long journeys are long enough to fulfil ~~the needs of the~~ each animal's need for ~~of~~ feed and water. 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. *Animal handlers* should handle and load animals in a manner that reduces their fearfulness and improves their approachability.

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*.

3. Nature and duration of the journey

The maximum duration of a *journey* should be determined taking into account factors, 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 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 for the species, size and weight of the animals to be transported. Special attention should be paid to avoid 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.

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, and the airflow should be adjustable.

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 *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, without being on top of one another , and ~~which~~ allowing~~s~~ necessary thermoregulation.

d) When animals are standing, they should have sufficient space to adopt a balanced position as appropriate to the climate and species transported.

e) The amount of headroom necessary depends on the species of animal. Each animal should be able to assume its natural standing position for transport (including during loading and unloading) without coming into contact with the roof or upper deck of the vehicle, and there should be sufficient headroom to allow adequate airflow over the animals.

f) Calculations for the *space allowance* for each animal should be carried out using the figures given 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) 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) 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. Water and feed should be available 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.

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, 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;

d) medications used prophylactically or therapeutically should be approved by the *Veterinary Authority* of the exporting and *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 3.7.3.6.

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 and an emergency management plan;

b) date, time, and place of *loading* and *unloading*;

c) veterinary certification, when required;

d) animal welfare competencies of the driver; (under study)

e) *animal identification* to allow *animal traceability* to the premises of departure and, where possible, to the premises of origin;

f) details of any animals considered at particular risk of suffering poor welfare during transport (point 3e) of Article 3.7.3.7.);

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 fitness of animals to travel for a particular *journey*.

Article 3.7.3.7.

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;

v) allow for rest, and appropriate water and feed.

c) Consideration should be given to 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 3.7.3.12.

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 allowed.

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 and risk 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 3.7.3.12.). 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 attention ~~treatment~~.

b) Humane and effective arrangements should be made by the owner and the 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;

The Community reiterates its previous comment:

The point 3 (c) (vi) should be replaced as follows: "pregnant animals for whom 90% or more of the expected gestation period has already passed, or females who have given birth in the previous week.

Justification:

It is easier to verify and is important also to consider the period after birth where the female is usually weak and can not be considered to be fit for transport.

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 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 with unhealed wounds from recent surgical procedures 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 3.7.3.12.

Article 3.7.3.8.

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.

b) *Loading* should be supervised and/or conducted by *animal handlers*. The animals are to be loaded quietly and without unnecessary noise, harassment or force. Untrained assistants or spectators 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 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. Loading ramps and other facilities should have a non-slippery flooring.

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

When moving animals, their species specific behaviour should be used (see Article 3.7.3.12.). If goads and other aids are necessary, 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. 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 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) Excessive shouting 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) 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 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.

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 3.7.3.9.

Travel

1. General considerations

a) Drivers 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, especially at rest or refuelling stops or during meal breaks when the *vehicle* is stationary.

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 3.7.3.12.

3. Regulating the environment within vehicles or containers

a) Animals should be protected against harm from hot or cold conditions during travel. Effective ventilation procedures for maintaining the 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.

b) The 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) 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.

f) When killing is necessary, it should be carried out as quickly as possible and assistance should be sought from a veterinarian or other person(s) competent in humane killing 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 3.7.3.12.

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. 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. 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 3.7.3.10.

Unloading and post-journey handling

1. General considerations

a) The required facilities and the principles of animal handling detailed in Article 3.7.3.8. 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

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). 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 killed aboard the *vehicle*. Assistance should be sought from a *veterinarian* or other person(s) competent in humane killing 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.

c) If treatment or humane killing 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 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*.

Article 3.7.3.11.

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 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 health status of the animals with regard to the 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 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) to allow ~~re~~provisioning of the *vehicle* with water and feed as necessary;

b) to provide urgently in writing the reasons for the refusal;

c) to provide urgent access to an independent *veterinarian(s)* to assess the 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) 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 3.7.3.12.

Species specific issues

Camelids of the new world 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.

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. Cattle tend to avoid "dead end" in passages.

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 and can reflect demands for personal space. Housing strange goats together could result in fatalities, either through physical violence, or subordinate goats being refused access to food and water.

Horses in this context include, donkeys, mules and hinnies. 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. Horses are prone to respiratory *disease* if they are restricted by period by tethers that prevent the lowering and lifting of their heads.

Community comment:

In the last sentence the word "for a short period of time" should be inserted between the words" deprivation" and "prior".

Justification:

Pigs are susceptible to motion sickness if transported immediately after being fed and for a short time thereafter until the stomach has emptied.

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. Pigs are susceptible to motion sickness when in transit. Feed deprivation prior to loading may be beneficial to prevent motion sickness.

Sheep are sociable animals with good eyesight, a relatively subtle and undemonstrative behaviour and a tendency 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. Crowding of sheep may lead to damaging aggressive and submissive behaviours as animals try to maintain personal space. Sheep may become agitated if they are singled out for attention, or kept alone, and will strive to rejoin the group. Activities which frighten, injure or cause agitation to sheep should be avoided. They can negotiate steep ramps.

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APPENDIX 3.7.4.

GUIDELINES FOR TRANSPORT OF ANIMALS BY AIR

Article 3.7.4.1.

Livestock containers

1. Design

a) General principles of design

The container should:

– conform to the size of the standard pallet of the aircraft that will be used to transport animals; the common sizes are: 224 x 318 cm (88 x 125 in.) and 244 x 318 cm (96 x 125 in.);

– not be constructed of material that could be harmful to the animals health or welfare;

– allow observation of the animals and be marked on opposite sides with the International Air Transport Association (IATA) symbols which indicate animals and the upright position;

– allow emergency access to animals;

– allow the animal to stand in its normal position without touching the roof of the container or, in the case of open containers, the restraining nets, and provide at least 10 cm (4 in.) clearance above the animal's head when standing in its normal position; in the case of horses, provide sufficient space above the horses head (21 cm, 8 in. recommended) to allow for the movement required to maintain the horses balance;

– protect the animals from adverse weather;

– ensure animals stand on a suitable floor to prevent slipping or injury;

– have adequate strength to ensure the safety of the animals and to prevent the animals from escaping;

– ensure doors can be opened and closed easily, but be secured so that they cannot be opened accidentally;

– be free of any nails, bolts and other protrusions or sharp edges that could cause injuries;

– be designed to minimise the risk of any opening or space entrapping any portion of the animals body;

– if reusable, crates should be constructed of impermeable material that is easily cleaned and disinfected;

– ensure faeces and urine cannot escape from the crate; this requires a minimum upturn of 20 cm but it must not block any ventilation openings;

– if designated for stacking be stable, not block any ventilation space and prevent urine and faeces from leaking into the containers below when stacked;

– allow for a facility for provision of water and possibly food during transportation of longer than 6 hours duration.

b) Ventilation

The container design should:

– provide adequate ventilation taking into consideration the species stocking density, maximum temperature and humidity of the points of departure, destination, and any interim technical stops;

– allow the normal resting or sleeping position to be assumed for certain species and juvenile animals;

– ensure there is no dead air space in the container;

– provide ventilation openings on the walls equal to at least 16% of the wall area; this may be reduced if the container has an open top;

– in the case of two-tiered containers, ventilation in the sides should be for cattle equivalent to not less than 20% of the floor area of each deck, and for pigs and sheep up to 40% of the floor area of each deck;

– have ventilation openings on all four sides of the crate except that two walls may have reduced ventilation space and the other walls have increased space where required by the positioning of the crates during transportation and/or the ventilation pattern of the aircraft;

– ensure that any internal supports or dividers do not block the cross ventilation;

– not have a solid wall above the height of the animal's head in normal resting position;

– in those species where the mouth is normally held near the floor, have at least 25 cm (10 in.) of ventilation space at the level of the animal's head; this opening should be divided in two with a maximum height for any opening of 13 cm; in all containers, there should be a sufficiently large ventilation opening at a height of 25 cm to 30 cm (10 to 11 in.) above floor level on all four sides to allow for circulation;

– have some physical means of ensuring the ventilation space is not blocked, such as the use of cleats (wedges) or allowing space between the outside of the container and the pallet.

2. Species requirements

In general, fractious animals or animals in late pregnancy should not be transported by air (see Article 3.7.4.2.).

a) Horses

Should be transported in containers and be separated from each other if they are more than 145 cm (57 in.) in height.

Crates used to transport horses should:

- be strong enough to prevent unruly horses from breaking or escaping from the container under any circumstances;
- in the case of multi-horse containers, have partitions of sufficient strength and size to separate the horses and to support each horse's weight;
- adjust to allow mare and foal to travel together;
- provide the same percentage of open space for ventilation as required in point 1 above, divided between the two side walls; however, if the access doors are constructed in such a manner that they may be left open during the flight, the door space may be included in the ventilation space;
- be constructed to minimise noise;
- allow access to the head during the flight;
- have the front end notched and padded to accept the neck of the animal;
- have a secure point for attaching restraining devices;
- have a front and rear barrier that will restrict the movement of the horse and will ensure that liquids are deflected into the container;
- ensure horses cannot bite other animals;
- be constructed to resist kicking;
- have no fittings or projections in the area likely to be kicked, metal plates should be covered with a protective material;
- ramps shall be non-skid in nature, have foot battens, and be of a maximum slope of 25 degrees when the container is on a standard 50 cm (20 in.) dolly;
- not have a step up or down of more than 25 cm (10 in.).

b) Swine

- Crate design and shipment planning should recognize that swine are extremely susceptible to high heat and humidity and that they normally carry their head near the floor.
- In the use of multi-tiered crates, special attention should be paid to ensure air can move through the crate, in accordance with the aircraft's ventilation pattern and capacity to remove heat.
- Crate construction should take into consideration the tendency for mature swine to chew.
- Litter should be dust-free, shavings or other non toxic materials may be used but not sawdust.
- Containers for immature swine should only be constructed when flight is imminent, since rapid growth can result in undersized containers if the flight is delayed.
- In order to reduce fighting, swine shipped in group pens should be housed together as a group prior to shipment and not be mixed with other swine before loading on the aircraft.

– Mature boars and incompatible females should be shipped in individual crates.

– Individual crates should be 20 cm (8 in.) longer than the body, 15 cm (6 in.) higher than the loin of the pig and of sufficient width, to allow the pigs to lie on their side.

c) Cattle

Crates used to transport cattle should:

– if multi-tiered or roofed, have at least 33% of the roof and four walls as open space;

– have at least one ventilation opening 20-25 cm (8-10 in.) above the floor which is of such width that it will not cause injuries to the feet.

Adult bulls should be transported separately unless they have been accustomed to each other. Cattle with and without horns should be separated from each other.

d) Other species

– Animals that normally exhibit a herding instinct, including buffalo and deer, can be shipped in group containers providing the mental and physical characteristics of the species are taken into consideration.

– All crates used to move such animals should have a roof or other method of preventing the animals from escaping.

– Animals in which the horns or antler cannot be removed, should be transported individually.

– Deer should not be transported in velvet nor in rut.

Article 3.7.4.2.

Guidelines for pregnant animals

Heavily pregnant animals should not be carried except under exceptional circumstances. Pregnant animals should not be accepted when the last service or exposure to a male prior to departure has exceeded the following time given here for guidance only:

Females	**Maximum number of days since the last service or exposure to a male**
Horses	300
Cows	250
Deer (axis, fallow and sika)	170
(red deer, reindeer)	185
Ewes (sheep)	115
Nannies (goats)	115
Sows (pigs)	90

Where service dates or date of last exposure to a male are not available, the animals should be examined by a veterinarian to ensure that pregnancy is not so advanced that animals are likely to give birth during transport or suffer unnecessarily.

Any animal showing udder engorgement and slackening of the pelvic ligament should be refused.

Article 3.7.4.3.

Stocking density

The current stocking densities agreed by the International Air Transport Association (IATA) should continue to be accepted. However, the graphs giving the space requirements should be extended to take into account animals larger and smaller than those dealt with currently.

1. General considerations

When calculating stocking rates, the following should be taken into account:

a) it is essential that accurate weights of animals are obtained in view of the limitations imposed by the load capabilities of the aircraft and the space required per animal;

b) in narrow bodied aircraft, there is a loss of floor area in the upper tier of two-tier penning due to the contours of the aircraft;

c) space available should be calculated on the inside measurements of the crates or penning system used, not on the floor space of the aircraft;

d) multi-tiered crates, high outdoor temperatures at departure, arrival or stopover points, or extreme length of the trip will require an increase in the amount of space per animal; a 10% decrease in stocking density is recommended for trips in excess of 24 hours;

e) special attention should be paid to the transport of sheep in heavy wool which require an increase in space allotted per animal and to pigs which have limited ability to dissipate heat;

f) animals confined in groups, especially in pens, should be stocked at a high enough density to prevent injuries at take-off, during turbulence and at landing, but not to the extent that individual animals cannot lie down and rise without risk of injury or crushing;

g) in multi-tiered shipments, it should be recognized that the ventilation and cooling capacity of the aircraft is the limiting factor, especially in narrow bodied aircraft. Ventilation capacity varies on each individual aircraft and between aircraft of the same model.

2. Guidelines for stocking densities

The following table gives stocking density guidelines for different domestic species:

Annex XXIV (contd)

Calculation tables
(in kilograms and metres)

Species	Weight	Density	Space/ animal	No. of animals per	Animals per single tier pallet		
	kg	kg/m^2	m^2	10 m^2	2214x2764 cm	2214x3408 cm	234x308 cm
Calves	50	220	0.23	43	264	3128	31
	70	246	0.28	35/6	220	253	25
	80	266	0.30	33	18	21	24
	90	280	0.32	31	17	20	22
Cattle	300	344	0.84	11/12	76	87	8
	500	393	1.27	8	54	65	5
	600	408	1.475	6/7	3/4	54	4/5
	700	400	1.7563	6	3	3/4	4
Sheep	25	147	0.2017	509	312	367	42
	70	196	0.4036	257/8	15	18	20
Pigs	25	172	0.15	67	1137	474	48
	100	196	0.51	20	120	142	14

Article 3.7.4.4.

Preparation for air transport of livestock

1. Health and customs requirements

The legal requirements including animal health, welfare and species conservation, should be ascertained from the country of destination and any in transit countries before the animals are assembled or the transportation is arranged.

Contact the *Veterinary Authorities* in the country of origin regarding veterinary certification.

Planning of the transportation should take into account weekends, holidays and airport closures.

Verify that any proposed intransit stops or alternates will not jeopardise the importing or in transit countries health requirements.

2. Environment

Animals are affected by extremes of temperature. This is especially true of high temperature when compounded by high humidity. Temperature and humidity should therefore be taken into consideration when planning the shipment.

Times of arrival, departure and stopovers should be planned so that the aircraft lands during the coolest hours.

At outside temperatures of below 25°C at the landing point, the aircraft doors should be opened to ensure adequate ventilation. Confirmation should be received from government authorities that animal health legislation does not prevent opening of aircraft doors.

When outside temperatures at any landing point exceed 25°C, prior arrangements should be made to have an adequate air-conditioning unit available when the plane lands.

3. Facilities and equipment

Specific arrangements must be made to ensure that holding and loading facilities including ramps, trucks, and air-conditioning units are available at departure, all in transit and arrival airports. This should include identification of specific staff who are responsible and the method of contacting them, e.g. telephone number and address.

Specific notification must be given to all those responsible for providing facilities or equipment at the destination and in transit stops immediately before departure.

Containers should be loaded so as to ensure access can be made to the animals at all times.

4. Preparation of animals

Vaccination must be done far enough in advance of the departure date to allow for immunity to develop.

Veterinary certification and serological testing must be arranged several weeks in advance of livestock shipment.

Many animals require acclimatisation before they are transported. Animals such as swine and wild herbivores must be separated and held in the groups that will occupy containers. Mixing of such animals immediately before or during transport is extremely stressing and should be avoided.

Incompatible animals should be transported singly.

Article 3.7.4.5.

Disinfection and disinfestation

1. Disinfection

a) Those parts of the interior of the aircraft destined for the carriage of animals should be thoroughly cleaned of all foreign matters using methods acceptable to aircraft management before being loaded.

b) These parts should be sprayed with a disinfectant

i) suitable for the diseases which could be carried by the animals,

ii) that does not cause problems with the aircraft,

iii) that will not leave a residue hazardous to the animals being transported.

If in doubt, the airline should be consulted on the suitability of the disinfectant. A mechanical nebuliser should be used to minimise the amount of disinfectant used.

Suggested disinfectants currently in use are:

iv) 4% sodium carbonate and 0.1% sodium silicate;

v) 0.2% citric acid.

Community comment:

In the following bullet point, the word "removeable" should be replaced by the word "removable".

c) All removeable equipment, penning and containers including loading ramps should be thoroughly cleaned and disinfected in accordance with the requirements of both the *exporting* and *importing countries*.

d) After *disinfection*, all equipment to be replaced in the aircraft should be washed with clean water to remove any traces of disinfectant to avoid any damage to the aircraft structures.

2. Disinfestation

Where *disinfestation* is required, the country requesting the action should be consulted for appropriate procedures.

The World Health Organization (WHO) Recommendations on the Disinsectisation of Aircraft (*WHO Weekly Epidem. Rec.*, No. 7, 1985) are recognised as standard.

Article 3.7.4.6.

Radiation

Radioactive materials must be separated from live animals by a distance of at least 0.5 metre for journeys not exceeding 24 hours, and by a distance of at least 1.0 metre for journeys longer than 24 hours (reference: Technical instructions on storage and loading-separation of the International Civil Aviation Organization - ICAO). Special care should be taken with regard to pregnant animals, semen and embryos/ova.

Article 3.7.4.7.

Tranquilization

Experience has shown that there is considerable risk in sedating animals transported by air. Tranquilizers reduce the ability of the animals to respond to stress during transportation. In addition, the reaction of various species to tranquilization cannot always be foreseen. For these reasons, routine tranquilization is not recommended. Tranquilizers should only be used when a specific problem exists, and should be administered by a veterinarian or by a person who has been instructed in their use. Persons using these drugs should understand the full implications of the effects of the drug in air transport, e.g. certain animals such as horses and elephants should not go down in containers. Drugs should only be administered during the flight with the knowledge and consent of the captain.

In all cases, when tranquilizers are used, a note should be attached to the container stating the weight of the individual animal, the generic name of the drug used, the dose, the method and time of administration.

Article 3.7.4.8.

Destruction of carcasses

In the event of any animal death on board, the competent authority of the airport of destination should be notified in advance of landing.

Carcasses should be disposed of under the supervision of and to the satisfaction of the *Veterinary Authority* of the country the aircraft is in.

The method of disposal should be based on the risk of introducing a controlled disease.

For carcasses which represent a high risk of introducing disease, the following is recommended:

1. destruction by incineration, rendering or deep burial under the supervision of the *Veterinary Authority*;

Community comment:

In the following bullet point, the word "leakproof" should be replaced by the words "leak proof".

2. if removed from the airport site, transportation in a closed, leakproof container.

Article 3.7.4.9.

Emergency slaughter

Emergency slaughter of animals in aircraft should, in general, only occur when the safety of the aircraft, crew or other animals are involved.

Every aircraft transporting animals should have a method of killing the animals with minimum pain and someone trained in that method.

In all cases when horses or other large animals are to be carried, the method of killing should be discussed with the airline during the planning stages. Suitable methods are:

1. Captive bolt stunner, followed by an injection of a lethal chemical

   a) Operator should be trained to use the captive bolt stunner on the species or type of animal being transported.

   b) An expert should determine that the type of captive bolt pistol is adequate for all the animals being transported.

   c) Some airlines and countries may prohibit the carriage of captive bolt pistols.

   d) The user should recognise that the noise associated with the captive bolt may excite other animals.

   e) The requirement that the captive bolt pistol is accurately centered may be difficult to achieve with an excited animal.

2. Injection of a chemical

   a) Various chemicals may be used to sedate, immobilize or kill animals.

   b) Central nervous system depressants such as barbiturate euthanasia solutions must be injected directly into a vein to be effective. This is not normally practical for anyone but an experienced veterinarian or an especially trained and experienced attendant, where the animal is sufficiently fractious to require euthanasia.

   c) Sedatives such as promazine and its derivatives may make the animal more fractious (see Article 3.7.4.7.).

   d) Immobilizing solutions such as succinylcholine are not humane.

3. Firearms

   Airlines do not permit the use of firearms which discharge a free bullet because of the danger to the aircraft.

Article 3.7.4.10.

Handling of food and waste material

Waste material which contains anything of animal origin including food, litter, manure, or animal feed should be handled, collected and disposed of in a manner that ensures it will not be fed to livestock. It should be collected in specified areas, and stored and transported in closed, leakproof containers.

Some *importing countries*' legislation may prohibit or restrict the use of hay or straw during the transportation period. Unloading of hay, straw, other animal feed and litter may be restricted or prohibited by in transit countries.

Article 3.7.4.11.

Disposal of food and waste material

Recommended methods of disposal are:

a) incineration to an ash;

b) heating at an internal temperature of at least of 100°C for 30 minutes, then disposal in a land fill site;

c) controlled burial in a land fill site.

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— text deleted

APPENDIX 3.7.5.

GUIDELINES FOR THE SLAUGHTER OF ANIMALS

Community speaking position:

The Community welcomes the work carried out by the OIE Code Commission and supports the amendments of the text.

However, as regards the analysis of handling and restraining methods and the associated animal welfare issues as referred to in Article 3.7.5.6, the Community asks that the OIE Code Commission again looks at the need to retain the rotary stunning pen.

Article 3.7.5.1.

General principles

1. Object

These guidelines address the need to ensure the welfare of food animals during pre-*slaughter* and *slaughter* processes, until they are dead.

These guidelines apply to the *slaughter* in *slaughterhouses* of the following domestic animals: cattle, buffalo, bison, sheep, goats, camelids, deer, horses, pigs, ratites, rabbits and poultry. Other animals, wherever they have been reared, and all animals slaughtered outside *slaughterhouses* should be managed to ensure that their *transport*, *lairage*, *restraint* and *slaughter* is carried out without causing undue stress to the animals; the principles underpinning these guidelines apply also to these animals.

2. Personnel

Persons engaged in the *unloading*, moving, *lairage*, care, *restraint*, *stunning*, *slaughter* and bleeding of animals play an important role in the welfare of those animals. For this reason, there should be a sufficient number of personnel, who should be patient, considerate, competent and familiar with the guidelines outlined in the present Appendix and their application within the national context.

Competence may be gained through formal training and/or practical experience. This competence should be demonstrated through a current certificate from the *Competent Authority* or from an independent body accredited by the *Competent Authority*.

The management of the *slaughterhouse* and the *Veterinary Services* should ensure that *slaughterhouse* staff are competent and carry out their tasks in accordance with the principles of animal welfare.

3. 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.

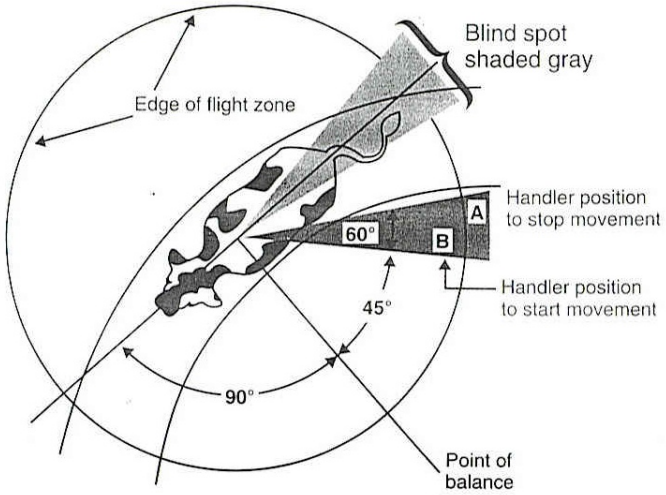
Most domestic livestock are kept in herds and follow a leader by instinct.

Animals which are likely to harm each other in a group situation should not be mixed at *slaughterhouses*.

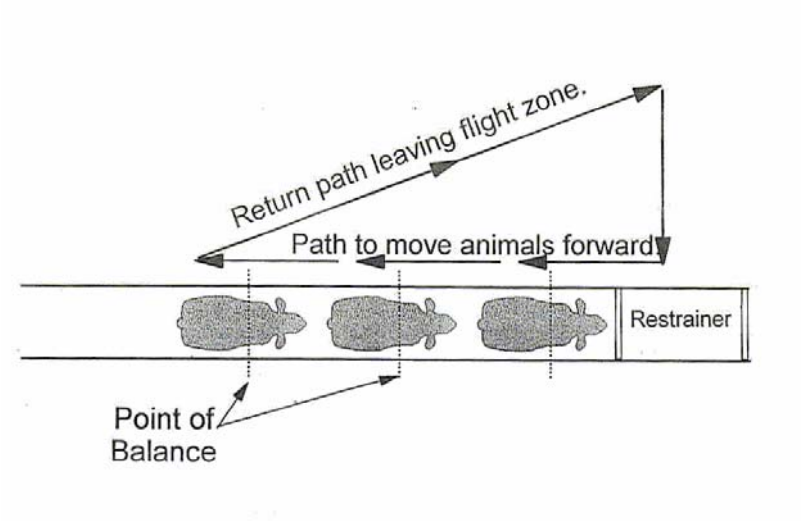
The desire of some animals to control their personal space should be taken into account in designing facilities.

Domestic animals will try to escape if 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 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 react in different ways to the smells of *slaughterhouses*. Smells which cause fear or other negative responses should be taken into consideration when managing animals.

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.

4. Distractions and their removal

Distractions that may cause approaching animals to stop, baulk or turn back should be designed out from new facilities or removed from existing ones. Below are examples of common distractions and methods for eliminating them:

a) reflections on shiny metal or wet floors - move a lamp or change lighting;

b) dark entrances to chutes, races, stun boxes or conveyor restrainers - illuminate with indirect lighting which does not shine directly into the eyes of approaching animals;

c) animals seeing moving people or equipment up ahead - install solid sides on chutes and races or install shields;

d) dead ends-avoid if possible by curving the passage, or make an illusory passage;

e) chains or other loose objects hanging in chutes or on fences - remove them;

f) uneven floors or a sudden drop in floor levels at the entrance to conveyor restrainers – avoid uneven floor surfaces or install a solid false floor under the restrainer to provide an illusion of a solid and continuous walking surface;

g) sounds of air hissing from pneumatic equipment - install silencers or use hydraulic equipment or vent high pressure to the external environment using flexible hosing;

h) clanging and banging of metal objects - install rubber stops on gates and other devices to reduce metal to metal contact;

i) air currents from fans or air curtains blowing into the face of animals - redirect or reposition equipment.

Article 3.7.5.2.

Moving and handling animals

1. General considerations

Animals should be transported to *slaughter* in a way that minimises adverse animal health and welfare outcomes, and the transport should be conducted in accordance with the OIE guidelines for the transportation of animals (Appendices 3.7.2. and 3.7.3.).

The following principles should apply to *unloading* animals, moving them into *lairage* pens, out of the *lairage* pens and up to the *slaughter* point:

a) The conditions of the animals should be assessed upon their arrival for any animal welfare and health problems.

b) Injured or sick animals, requiring immediate *slaughter*, should be killed humanely and without delay, ~~at the site where they are found~~ in accordance with the OIE guidelines. ~~for the killing of animals for *disease* control purposes (Appendix 3.7.6.).~~

The Community reiterates its previous comment:

In paragraph (c) the following two changes should be introduced:

(1) In the second sentence, after the words "Performance standards" the word "should" should be replaced by "could".

(2) The wording "99% of" should be deleted.

Justification:

(1) Performance standards could be useful to improve animal welfare conditions but are not always necessary.

(2) As an objective no animals should be falling from animal welfare point of view.

c) Animals should not be forced to move at a speed greater than their normal walking pace, in order to minimise injury through falling or slipping. Performance standards should be established where numerical scoring of the prevalence of animals slipping or falling is used to evaluate whether animal moving practices and/or facilities should be improved. In properly designed and constructed facilities with competent *animal handlers*, it should be possible to move 99% of animals without their falling.

d) Animals for *slaughter* should not be forced to walk over the top of other animals.

e) Animals should be handled in such a way as to avoid harm, distress or injury. Under no circumstances should *animal handlers* resort to violent acts to move animals, such as crushing or breaking tails of animals, grasping their eyes or pulling them by the ears. *Animal handlers* should never apply an injurious object or irritant substance to animals and especially not to sensitive areas such as eyes, mouth, ears, anogenital region or belly. 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.

f) When using goads and other aids, the following principles should apply:

   i) 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.

   ii) 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.

iii) 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 rattles; they should be used in a manner sufficient to encourage and direct movement of the animals without causing undue stress.

iv) 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.

v) Excessive shouting 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.

vi) 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 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.

vii) Conscious animals should not be thrown, dragged or dropped.

The Community reiterates its previous comment:

SAME AS 3.7.5.2. (1) (c)

In paragraph (viii), first sentence, after the words "Performance standards", the word "should" should be replaced by "could".

Justification:

Performance based standards are useful but not always necessary.

viii) Performance standards should be established to evaluate the use of such instruments. Numerical scoring may be used and to measure the percentage of animals moved with an electric instrument and the percentage of animals slipping or falling at a point in the *slaughterhouse.* Any risk of compromising animal welfare, for example slippery floor, should be investigated immediately and the defect rectified to eliminate the problem.

2. Provisions relevant to animals delivered in containers

a) *Containers* in which animals are transported should be handled with care, and should not be thrown, dropped or knocked over. Where possible, they should be horizontal while being loaded and unloaded mechanically, and stacked to ensure ventilation. In any case they should be moved and stored in an upright position as indicated by specific marks.

b) Animals delivered in *containers* with perforated or flexible bottoms should be unloaded with particular care in order to avoid injury. Where appropriate, animals should be unloaded from the *containers* individually.

c) Animals which have been transported in *containers* should be slaughtered as soon as possible; mammals and ratites which are not taken directly upon arrival to the place of *slaughter* should have drinking water available to them from appropriate facilities at all times. Delivery of poultry for *slaughter* should be scheduled such that they are not deprived of water at the premises for longer than 12 hours. Animals which have not been slaughtered within 12 hours of their arrival should be fed, and should subsequently be given moderate amounts of food at appropriate intervals.

3. Provisions relevant to restraining and containing animals

The Community reiterates its previous comment:

The following text should be added under this section:

"(a) Appropriate restraint shall be applied to the animals before they are stunned or immediately killed. In particular individual restraint is necessary when captive-bolt is used or when animals are slaughtered without prior stunning."

Justification:

The use of the above-mentioned methods of stunning or slaughter needs to be applied with high accuracy by the operator and can not be performed correctly under commercial conditions without individual restraint.

a) Provisions relevant to restraining animals for *stunning* or *slaughter* without *stunning*, to help maintain animal welfare, include:

   i) provision of a non-slippery floor;

   ii) avoidance of excessive pressure applied by restraining equipment that causes struggling or vocalisation in animals;

   iii) equipment engineered to reduce noise of air hissing and clanging metal;

   iv) absence of sharp edges in restraining equipment that would harm animals;

   v) avoidance of jerking or sudden movement of restraining device.

b) Methods of *restraint* causing avoidable suffering should not be used in conscious animals. Such methods include the following:

   i) suspending or hoisting animals (other than poultry) by the feet or legs;

   ii) indiscriminate and inappropriate use of *stunning* equipment;

   iii) mechanical clamping of the legs or feet of the animals (other than shackles used in poultry and ostriches) as the sole method of *restraint*;

   iv) breaking legs, cutting leg tendons or blinding animals in order to immobilise them;

   v) severing the spinal cord, for example using a puntilla or dagger, to immobilise animals using electric currents to immobilise animals, except for proper *stunning*.

Article 3.7.5.3.

Lairage design and construction

1. General considerations

The *lairage* should be designed and constructed to hold an appropriate number of animals in relation to the throughput rate of the *slaughterhouse* without compromising the welfare of the animals.

In order to permit operations to be conducted as smoothly and efficiently as possible without injury or undue stress to the animals, the *lairage* should be designed and constructed so as to allow the animals to move freely in the required direction, using their behavioural characteristics and without undue penetration of their flight zone.

The following guidelines may help to achieve this.

2. Design of *lairages*

a) The *lairage* should be designed to allow a one-way flow of animals from *unloading* to the point of *slaughter*, with a minimum number of abrupt corners to negotiate.

b) In red meat *slaughterhouses*, pens, passageways and races should be arranged in such a way as to permit inspection of animals at any time, and to permit the removal of sick or injured animals when considered to be appropriate, for which separate appropriate accommodation should be provided.

c) Each animal should have room to stand up and lie down and, when confined in a pen, to turn around, except where the animal is reasonably restrained for safety reasons (e.g. fractious bulls). Fractious animals should be slaughtered as soon as possible after arrival at the *slaughterhouse* to avoid welfare problems. The *lairage* should have sufficient accommodation for the number of animals intended to be held. Drinking water should always be available to the animals, and the method of delivery should be appropriate to the type of animal held. Troughs should be designed and installed in such a way as to minimise the risk of fouling by faeces, without introducing risk of bruising and injury in animals, and should not hinder the movement of animals.

d) Holding pens should be designed to allow as many animals as possible to stand or lie down against a wall. Where feed troughs are provided, they should be sufficient in number and feeding space to allow adequate access of all animals to feed. The feed trough should not hinder the movement of animals.

e) Where tethers, ties or individual stalls are used, these should be designed so as not to cause injury or distress to the animals and should also allow the animals to stand, lie down and access any food or water that may need to be provided.

f) Passageways and races should be either straight or consistently curved, as appropriate to the animal species. Passageways and races should have solid sides, but when there is a double race, the shared partition should allow adjacent animals to see each other. For pigs and sheep, passageways should be wide enough to enable two or more animals to walk side by side for as long as possible. At the point where passageways are reduced in width, this should be done by a means which prevents excessive bunching of the animals.

g) *Animal handlers* should be positioned alongside races and passageways on the inside radius of any curve, to take advantage of the natural tendency of animals to circle an intruder. Where one-way gates are used, they should be of a design which avoids bruising. Races should be horizontal but where there is a slope, they should be constructed to allow the free movement of animals without injury.

h) There should be a waiting pen, with a level floor and solid sides, between the holding pens and the race leading to the point of *stunning* or *slaughter*, to ensure a steady supply of animals for *stunning* or *slaughter* and to avoid having *animal handlers* trying to rush animals from the holding pens. The waiting pen should preferably be circular, but in any case, so designed that animals cannot be trapped or trampled.

i) Ramps or lifts should be used for *loading* and *unloading* of animals where there is a difference in height or a gap between the floor of the *vehicle* and the *unloading* area. Unloading ramps should be designed and constructed so as to permit animals to be unloaded from *vehicles* on the level or at the minimum gradient achievable. Lateral side protection should be available to prevent animals escaping or falling. They should be well drained, with secure footholds and adjustable to facilitate easy movement of animals without causing distress or injury.

3. Construction of lairages

a) *Lairages* should be constructed and maintained so as to provide protection from unfavourable climatic conditions, using strong and resistant materials such as concrete and metal which has been treated to prevent corrosion. Surfaces should be easy to clean. There should be no sharp edges or protuberances which may injure the animals.

b) Floors should be well drained and not slippery; they should not cause injury to the feet of the animals. Where necessary, floors should be insulated or provided with appropriate bedding. Drainage grids should be placed at the sides of pens and passageways and not where animals would have to cross them. Discontinuities or changes in floor patterns or texture which could cause baulking in the movement of animals should be avoided.

c) *Lairages* should be provided with adequate lighting, but care should be taken to avoid harsh lights and shadows, which frighten the animals or affect their movement. The fact that animals will move more readily from a darker area into a well-lit area might be exploited by providing for lighting that can be regulated accordingly.

d) *Lairages* should be adequately ventilated to ensure that waste gases (e.g. ammonia) do not build up and that draughts at animal height are minimised. Ventilation should be able to cope with the range of expected climatic conditions and the number of animals the *lairage* will be expected to hold.

e) Care should be taken to protect the animals from excessively or potentially disturbing noises, for example by avoiding the use of noisy hydraulic or pneumatic equipment, and muffling noisy metal equipment by the use of suitable padding, or by minimising the transmission of such a noise to the areas where animals are held and slaughtered.

f) Where animals are kept in outdoor *lairages* without natural shelter or shade, they should be protected from the effects of adverse weather conditions.

Article 3.7.5.4.

Care of animals in lairages

Animals in *lairages* should be cared for in accordance with the following guidelines:

1. As far as possible, established groups of animals should be kept together. Each animal should have enough space to stand up, lie down and turn around. Animals hostile to each other should be separated.

2. Where tethers, ties or individual stalls are used, they should allow animals to stand up and lie down without causing injury or distress.

3. Where bedding is provided, it should be maintained in a condition that minimises risks to the health and safety of the animals, and sufficient bedding should be used so that animals do not become soiled with manure.

4. Animals should be kept securely in the *lairage*, and care should be taken to prevent them from escaping and from predators.

5. Suitable drinking water should be available to the animals on their arrival and at all times to animals in *lairages* unless they are to be slaughtered without delay.

6. If animals are not to be slaughtered as soon as possible, suitable feed should be available to the animals on arrival and at intervals appropriate to the species. Unweaned animals should be slaughtered as soon as possible.

7. In order to prevent heat stress, animals subjected to high temperatures, particularly pigs and poultry, should be cooled by the use of water sprays, fans or other suitable means. However, the potential for water sprays to reduce the ability of animals to thermoregulate (especially poultry) should be considered in any decision to use water sprays. The risk of animals being exposed to very cold temperatures or sudden extreme temperature changes should also be considered.

8. The *lairage* area should be well lit in order to enable the animals to see clearly without being dazzled. During the night, the lights should be dimmed. Lighting should also be adequate to permit inspection of all animals. Subdued lighting, and for example blue light, may be useful in poultry *lairages* in helping to calm birds.

9. The condition and state of health of the animals in a *lairage* should be inspected at least every morning and evening by a *veterinarian* or, under the *veterinarian's* responsibility, by another competent person, such as an *animal handler*. Animals which are sick, weak, injured or showing visible signs of distress should be separated, and veterinary advice should be sought immediately regarding treatment ~~or euthanasia,~~ or the animals should be humanely killed immediately if necessary.

10. Lactating dairy animals should be slaughtered as soon as possible. Dairy animals with obvious udder distension should be milked to minimise udder discomfort.

11. Animals which have given birth during the *journey* or in the *lairage* should be slaughtered as soon as possible or provided with conditions which are appropriate for suckling, for their welfare and the welfare of the newborn. Under normal circumstances, animals which are expected to give birth during a *journey* should not be transported.

12. Animals with horns, antlers or tusks capable of injuring other animals, if aggressive, should be penned separately.

Recommendations for specific species are described in detail in Articles 3.7.5.5. to 3.7.5.9.

Article 3.7.5.5.

Management of foetuses during slaughter of pregnant animals

Under normal circumstances, pregnant animals that would be in the final 10% of their gestation period at the planned time of *unloading* at the *slaughterhouse* should be neither transported nor slaughtered. If such an event occurs, an *animal handler* should ensure that females are handled separately and the specific procedures described below are applied. In all cases, the welfare of foetuses and dams during *slaughter* should be safeguarded.

1. Foetuses should not be removed from the uterus sooner than five minutes after the maternal neck or chest cut, to ensure absence of consciousness. A foetal heartbeat will usually still be present and foetal movements may occur at this stage, but these are only a cause for concern if the exposed foetus successfully breathes air.

2. If a live mature foetus is removed from the uterus, it should be prevented from inflating its lungs and breathing air (e.g. by clamping the trachea).

3. When uterine, placental or foetal tissues, including foetal blood, are not to be collected as part of the post-slaughter processing of pregnant animals, all foetuses should be left inside the unopened uterus until they are dead. When uterine, placental or foetal tissues are to be collected, where practical, foetuses should not be removed from the uterus until at least 15-20 minutes after the maternal neck or chest cut.

4. If there is any doubt about consciousness, the foetus should be killed with a captive bolt of appropriate size or a blow to the head with a suitable blunt instrument.

The above guidelines do not refer to foetal rescue. Foetal rescue, the practice of attempting to revive foetuses found alive at evisceration of the dam, should not be attempted during normal commercial *slaughter* as it may lead to serious welfare complications in the newborn animal. These include impaired brain function resulting from oxygen shortage before rescue is completed, compromised breathing and body heat production because of foetal immaturity, and an increased incidence of *infections* due to a lack of colostrums.

The Community reiterates its position:

(on following Article 3.7.5.6)

The use of rotating box (i.e. restraining by inversion for cattle) should not be recommended. Therefore the rows referring to restraining by inversion should be deleted in the table.

Justification:

The use of rotating box has raised serious and well founded welfare concerns among scientists while alternative methods are available which provide better welfare conditions without additional costs.

See p. 25 European Food Safety Authority - AHAW/04-027 "Welfare aspects of stunning and killing methods" Scientific report of the Scientific Panel for Animal Health and Welfare".

http://www.efsa.europa.eu/en/science/ahaw/ahaw_opinions/495.html

Annex XXIV (contd)

Article 3.7.5.6.

Summary analysis of handling and restraining methods and the associated animal welfare issues

	Presentation of animals	Specific procedure	Specific purpose	AW concerns/implications	Key AW requirements	Applicable species
No restraint	Animals are grouped	Group container	Gas stunning	Specific procedure is suitable only for gas stunning	Competent animal handlers in lairage; facilities; stocking density	Pigs, poultry
		In the field	Free bullet	Inaccurate targeting and inappropriate ballistics not achieving outright kill with first shot	Operator competence	Deer
		Group stunning pen	Head-only electrical Captive bolt	Uncontrolled movement of animals impedes use of hand operated electrical and mechanical stunning methods	Competent animal handlers in lairage and at stunning point	Pigs, sheep, goats, calves
	Individual animal confinement	Stunning pen/box	Electrical and mechanical stunning methods	Loading of animal; accuracy of stunning method, slippery floor and animal falling down	Competent animal handlers	Cattle, buffalo, sheep, goats, horses, pigs, deer, camelids, ratites
Restraining methods	Head restraint, upright	Halter/ head collar/bridle	Captive bolt Free bullet	Suitable for halter-trained animals; stress in untrained animals	Competent animal handlers	Cattle, buffalo, horses, camelids
	Head restraint, upright	Neck yoke	Captive bolt Electrical-head-only Free bullet Slaughter without stunning	Stress of loading and neck capture; stress of prolonged restraint, horn configuration; unsuitable for fast line speeds, animals struggling and falling due to slippery floor, excessive pressure	Equipment; competent animal handlers, prompt stunning or slaughter	Cattle
	Leg restraint	Single leg tied in flexion (animal standing on 3 legs)	Captive bolt Free bullet	Ineffective control of animal movement, misdirected shots	Competent animal handlers	Breeding pigs (boars and sows)

Summary analysis of handling and restraining methods and the associated animal welfare issues (contd)

	Presentation of animals	Specific procedure	Specific purpose	AW concerns/implications	Key AW requirements	Applicable species
Restraining methods (contd)	Upright restraint	Beak holding	Captive bolt Electrical-head-only	Stress of capture	Sufficient competent-animal handlers	Ostriches
		Head restraint in electrical stunning box	Electrical-head-only	Stress of capture and positioning	Competent animal handlers	Ostriches
	Holding body upright- manual	Manual restraint	Captive bolt Electrical-head-only Slaughter without stunning	Stress of capture and restraint; accuracy of stunning/slaughter	Competent animal handlers	Sheep, goats, calves, ratites, small camelids, poultry
	Holding body upright mechanical	Mechanical clamp / crush / squeeze/ V-restrainer (static)	Captive bolt Electrical methods Slaughter without stunning	Loading of animal and overriding; excessive pressure	Proper design and operation of equipment	Cattle, buffalo, sheep, goats, deer, pigs, ostriches
	Lateral restraint – manual or mechanical	Restrainer/cradle/ crush	Slaughter without stunning	Stress of restraint	Competent animal handlers	Sheep, goats, calves, camelids, cattle
	Upright restraint mechanical	Mechanical straddle (static)	Slaughter without stunning Electrical methods Captive bolt	Loading of animal and overriding	Competent animal handlers	Cattle, sheep, goats, pigs
	Upright restraint – manual or mechanical	Wing shackling	Electrical	Excessive tension applied prior to stunning	Competent animal handlers	Ostriches

Annex XXIV (contd)

Summary analysis of handling and restraining methods and the associated animal welfare issues (contd)

	Presentation of animals	Specific procedure	Specific purpose	AW concerns/implications	Key AW requirements	Applicable species
Restraining and /or conveying methods	Mechanical – upright	V-restrainer	Electrical methods Captive bolt Slaughter without stunning	Loading of animal and overriding; excessive pressure, size mismatch between restrainer and animal	Proper design and operation of equipment	Cattle, calves, sheep, goats, pigs
	Mechanical-upright	Mechanical straddle – band restrainer (moving)	Electrical methods Captive bolt Slaughter without stunning	Loading of animal and overriding, size mismatch between restrainer and animal	Competent animal handlers, proper design and layout of restraint	Cattle, calves, sheep, goats, pigs
	Mechanical – upright	Flat bed/deck Tipped out of *containers* on to conveyors	Presentation of birds for shackling prior to electrical stunning Gas stunning	Stress and injury due to tipping in dump-module systems Height of tipping conscious poultry Broken bones and dislocations	Proper design and operation of equipment	Poultry
	Suspension and/or inversion	Poultry shackle	Electrical stunning Slaughter without stunning	Inversion stress; pain from compression on leg bones	Competent animal handlers; proper design and operation of equipment	Poultry
	Suspension and/or inversion	Cone	Electrical – head-only Captive bolt Slaughter without stunning	Inversion stress	Competent animal handlers; proper design and operation of equipment	Poultry
	Upright restraint	Mechanical leg clamping	Electrical – head-only	Stress of resisting restraint in ostriches	Competent animal handlers; proper equipment design and operation	Ostriches

Summary analysis of handling and restraining methods and the associated animal welfare issues (contd)

	Presentation of animals	Specific procedure	Specific purpose	AW concerns/implications	Key AW requirements	Applicable species
Restraining by inversion	Rotating box	Fixed side(s) (e.g. Weinberg pen)	Slaughter without stunning	Inversion stress; stress of resisting restraint, prolonged restraint, inhalation of blood and ingesta. Keep restraint as brief as possible	Proper design and operation of equipment	Cattle
		Compressible side(s)	Slaughter without stunning	Inversion stress, stress of resisting restraint, prolonged restraint Preferable to rotating box with fixed sides Keep restraint as brief as possible	Proper design and operation of equipment	Cattle
Body restraint	Casting/ hobbling	Manual	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; animal temperament; bruising. Keep restraint as short as possible	Competent animal handlers	Sheep, goats, calves, small camelids, pigs
Leg restraints		Rope casting	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; prolonged restraint, animal temperament; bruising Keep restraint as short as possible	Competent animal handlers	Cattle, camelids
		Tying of 3 or 4 legs	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; prolonged restraint, animal temperament; bruising Keep restraint as short as possible	Competent animal handlers	Sheep, goats, small camelids, pigs

Article 3.7.5.7.

Stunning methods

1. General considerations

The competence of the operators, and the appropriateness, and effectiveness of the method used for *stunning* and the maintenance of the equipment are the responsibility of the management of the *slaughterhouse*, and should be checked regularly by a *Competent Authority*.

Persons carrying out *stunning* should be properly trained and competent, and should ensure that:

a) the animal is adequately restrained;

b) animals in *restraint* are stunned as soon as possible;

c) the equipment used for *stunning* is maintained and operated properly in accordance with the manufacturer's recommendations, in particular with regard to the species and size of the animal;

d) the instrument is applied correctly;

e) stunned animals are bled out (slaughtered) as soon as possible;

f) animals should not be stunned when slaughter is likely to be delayed; and

g) backup *stunning* devices are available for immediate use if the primary method of *stunning* fails.

In addition, such persons should be able to recognise when an animal is not correctly stunned and should take appropriate action.

Community comment:

Since free bullet is mentioned as a method of slaughter in Article 3.7.5.8 the corresponding details applicable for free bullet that are laid down in the guidelines for killing for disease control purposes should be inserted here as well.

2. Mechanical stunning

A mechanical device should be applied usually to the front of the head and perpendicular to the bone surface. The following diagrams illustrate the proper application of the device for certain species.

Cattle

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

The optimum position for cattle is at the intersection of two imaginary lines drawn from the rear of the eyes to the opposite horn buds.

Pigs

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

The optimum position for pigs is on the midline just above eye level, with the shot directed down the line of the spinal cord.

Sheep

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

The optimum position for hornless sheep and goats is on the midline.

Goats

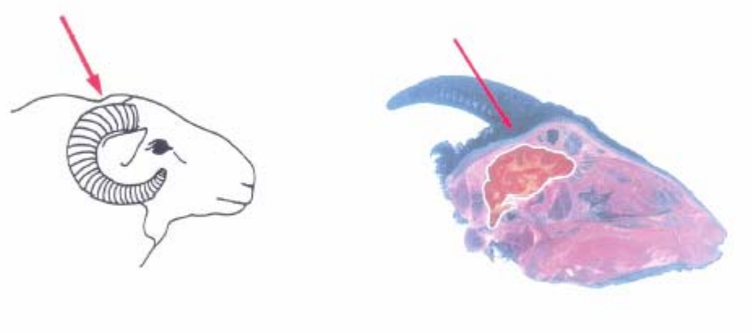


Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

The optimum position for heavily horned sheep and horned goats is behind the poll, aiming towards the angle of the jaw.

Horses

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

The optimum position for horses is at right angles to the frontal surface, well above the point where imaginary lines from eyes to ears cross.

Signs of correct *stunning* using a mechanical instrument are as follows:

a) the animal collapses immediately and does not attempt to stand up;

b) the body and muscles of the animal become tonic (rigid) immediately after the shot;

c) normal rhythmic breathing stops; and

d) the eyelid is open with the eyeball facing straight ahead and is not rotated.

3. Electrical stunning

a) General considerations

An electrical device should be applied to the animal in accordance with the following guidelines.

Electrodes should be designed, constructed, maintained and cleaned regularly to ensure that the flow of current is optimal and in accordance with manufacturing specifications. They should be placed so that they span the brain. The application of electrical currents which bypass the brain is unacceptable unless the animal has been stunned. The use of a single current leg-to-leg is unacceptable as a *stunning* method.

If, in addition, it is intended to cause cardiac arrest, the electrodes should either span the brain and immediately thereafter the heart, on the condition that it has been ascertained that the animal is adequately stunned, or span brain and heart simultaneously.

Electrical *stunning* equipment should not be applied on animals as a means of guidance, movement, *restraint* or immobilisation, and shall not deliver any shock to the animal before the actual *stunning* or *killing*.

Electrical *stunning* apparatus should be tested prior to application on animals using appropriate resistors or dummy loads to ensure the power output is adequate to stun animals.

The electrical *stunning* apparatus should incorporate a device that monitors and displays voltage (true RMS) and the applied current (true RMS) and that such devices are regularly calibrated at least annually.

Appropriate measures, such as removing excess wool or wetting the skin only at the point of contact, can be taken to minimise impedance of the skin and facilitate effective *stunning*.

The Community reiterates its previous comment:

The following sentence should be added here:

"In all cases electrodes should be applied rapidly and firmly and appropriate pressure maintained to facilitate proper contact and effective stunning ".

Justification:

Correct operator technique in applying the electrodes is very important to achieve effective stunning. When electrodes are not applied in the correct manner there may be a risk of injury, pain and suffering to the animal.

The *stunning* apparatus required for electrical *stunning* should be provided with adequate power to achieve continuously the minimum current level recommended for *stunning* as indicated in the table below:

Species	Minimum current levels for head-only stunning
Cattle	1.5 amps
Calves (bovines of less than 6 months of age)	1.0 amps
Pigs	1.25 amps
Sheep and goats	1.0 amps
Lambs	0.7 amps
Ostriches	0.4 amps

In all cases, the correct current level shall be attained within one second of the initiation of stun and maintained at least for three seconds and in accordance with the manufacturer's instructions.

b) Electrical stunning of birds using a waterbath

There should be no sharp bends or steep gradients in the shackle line and the shackle line should be as short as possible consistent with achieving acceptable line speeds, and ensuring that birds have settled by the time they reach the water bath. A breast comforter can be used effectively to reduce wing flapping and calm birds. The angle at which the shackle line approaches the entrance to the water bath, and the design of the entrance to the water bath, and the draining of excess 'live' water from the bath are all important considerations in ensuring birds are calm as they enter the bath, do not flap their wings, and do not receive pre-stun electric shocks.

In the case of birds suspended on a moving line, measures should be taken to ensure that the birds are not wing flapping at the entrance of the stunner. The birds should be secure in their shackle, but there should not be undue pressure on their shanks.

Community comment:

In the following sentence, the word "waterbaths" should be replaced by the words "water baths".

Waterbaths for poultry should be adequate in size and depth for the type of bird being slaughtered, and their height should be adjustable to allow for the head of each bird to be immersed. The electrode immersed in the bath should extend the full length of the waterbath. Birds should be immersed in the bath up to the base of their wings.

The waterbath should be designed and maintained in such a way that when the shackles pass over the water, they are in continuous contact with the earthed rubbing bar.

The control box for the waterbath stunner should incorporate an ammeter which displays the total current flowing through the birds.

The shackle-to-leg contact should be wetted preferably before the birds are inserted in the shackles. In order to improve electrical conductivity of the water it is recommended that salt be added in the waterbath as necessary. Additional salt should be added regularly as a solution to maintain suitable constant concentrations in the waterbath.

Community comment:

In the last sentence of the previous paragraph as well as in the first sentence of the following paragraph, the word "waterbaths" should be replaced by the words "water baths".

Using waterbaths, birds are stunned in groups and different birds will have different impedances. The voltage should be adjusted so that the total current is the required current per

bird as shown in the table hereafter, multiplied by the number of birds in the waterbath at the same time. The following values have been found to be satisfactory when employing a 50 Hertz sinusoidal alternating current.

Birds should receive the current for at least 4 seconds.

Species	Current (milliamperes per bird)
Broilers	100
Layers (spent hens)	100
Turkeys	150
Ducks and Geese	130

While a lower current may also be satisfactory, the current shall in any case be such as to ensure that unconsciousness occurs immediately and lasts until the bird has been killed by cardiac arrest or by bleeding. When higher electrical frequencies are used, higher currents may be required.

Frequency (Hz)	Chickens	Turkeys
< 200 Hz	100 mA	250 mA
From 200 to 400 Hz	150 mA	400 mA
From 400 to 1500 Hz	200 mA	400 mA

Every effort shall be made to ensure that no conscious or live birds enter the scalding tank.

In the case of automatic systems, until fail-safe systems of *stunning* and bleeding have been introduced, a manual back-up system should be in place to ensure that any birds which have missed the waterbath stunner and/or the automatic neck-cutter are immediately stunned and/or killed immediately, and they are dead before entering scald tank.

To lessen the number of birds that have not been effectively stunned reaching neck cutters, steps should be taken to ensure that small birds do not go on the line amongst bigger birds and that these small birds are stunned separately.

4. Gas stunning (under study)

a) Stunning of pigs by exposure to carbon dioxide (CO_2)

The concentration of CO_2 for *stunning* should be preferably 90% by volume but in any case no less than 80% by volume. After entering the *stunning* chamber, the animals should be conveyed to the point of maximum concentration of the gas as rapidly as possible and be kept until they are dead or brought into a state of insensibility which lasts until *death* occurs due to bleeding. Ideally, pigs should be exposed to this concentration of CO_2 for 3 minutes. Sticking should occur as soon as possible after exit from the gas chamber.

In any case, the concentration of the gas should be such that it minimises as far as possible all stress of the animal prior to loss of consciousness.

The chamber in which animals are exposed to CO_2 and the equipment used for conveying them through it shall be designed, constructed and maintained in such a way as to avoid injury or unnecessary stress to the animals. The animal density within the chamber should be such to avoid stacking animals on top of each others.

The conveyor and the chamber shall be adequately lit to allow the animals to see their surroundings and, if possible, each other.

The Community reiterates its previous comment:

At the end of the sentence, the text "and to have access to the animals in emergency cases" should be deleted.

Justification:

Access to animals in a gas chamber is of little interest from a welfare point of view, as, due to safety reason, operators will not be in a position to intervene in this particular area.

It should be possible to inspect the CO_2 chamber whilst it is in use, and to have access to the animals in emergency cases.

The chamber shall be equipped to continuously measure and display register at the point of *stunning* the CO_2 concentration and the time of exposure, and to give a clearly visible and audible warning if the concentration of CO_2 falls below the required level.

Emergency stunning equipment should be available at the point of exit from the *stunning* chamber and used on any pigs that do not appear to be dead or completely stunned.

b) Inert gas mixtures for stunning pigs

Inhalation of high concentrations of carbon dioxide is aversive and can be distressing to animals. Therefore, the use of non-aversive gas mixtures is being developed.

Such gas mixtures include:

i) a maximum of 2% by volume of oxygen in argon, nitrogen or other inert gases, or

ii) a maximum of 30% by volume of carbon dioxide and a maximum of 2% by volume of oxygen in mixtures with carbon dioxide and argon, nitrogen or other inert gases.

Exposure time to the gas mixtures should be sufficient to ensure that no pigs regain consciousness before *death* supervenes through bleeding or cardiac arrest is induced.

c) Gas stunning of poultry

The main objective of gas *stunning* is to avoid the pain and suffering associated with shackling conscious poultry under water bath *stunning* and *killing* systems. Therefore, gas *stunning* should be limited to birds contained in crates or on conveyors only. The gas mixture should be non-aversive to poultry.

Gas *stunning* of poultry in their transport *containers* will eliminate the need for live bird handling at the processing plant and all the problems associated with the electrical *stunning*. Gas *stunning* of poultry on a conveyor eliminates the problems associated with the electrical water bath *stunning*.

Live poultry should be conveyed into the gas mixtures either in transport crates or on conveyor belts.

The following gas procedures have been properly documented for chickens and turkeys but do not necessarily apply for other domestic birds. In any case the procedure should be designed as to ensure that all animals are properly stunned without unnecessary suffering.

i) Gas mixtures used for *stunning* poultry include:

– a minimum of 2 minutes exposure to 40% carbon dioxide, 30% oxygen and 30% nitrogen, followed by a minimum of one minute exposure to 80% carbon dioxide in air; or

– a minimum of 2 minutes exposure to any mixture of argon, nitrogen or other inert gases with atmospheric air and carbon dioxide, provided that the carbon dioxide concentration does not exceed 30% by volume and the residual oxygen concentration does not exceed 2% by volume; or

– a minimum of 2 minutes exposure to argon, nitrogen, other inert gases or any mixture of these gases in atmospheric air with a maximum of 2% residual oxygen by volume; or

– a minimum of 2 minutes exposure to a minimum of 55% carbon dioxide in air.

ii) Requirements for effective use are as follows:

– Compressed gases should be vaporised prior to administration into the chamber and should be at room temperature to prevent any thermal shock. Under no circumstances, should solid gases with freezing temperatures enter the chamber.

– Gas mixtures should be humidified.

– Appropriate gas concentrations of oxygen and carbon dioxide should be monitored and displayed continuously at the level of the birds inside the chamber to ensure that anoxia ensues.

Under no circumstances, should birds exposed to gas mixtures be allowed to regain consciousness. If necessary, the exposure time should be extended.

5. Bleeding

From the point of view of animal welfare, animals which are stunned with a reversible method should be bled without delay. Maximum stun-stick interval depends on the parameters of the *stunning* method applied, the species concerned and the bleeding method used (full cut or chest stick when possible). As a consequence, depending on those factors, the *slaughterhouse* operator should set up a maximum stun-stick interval that ensures that no animals recover consciousness during bleeding. In any case the following time limits should be applied.

Stunning method	**Maximum delay for bleeding to be started**
Electrical methods and non penetrating captive bolt	20 seconds
CO_2	60 seconds (after leaving the chamber)

All animals should be bled out by incising both carotid arteries, or the vessels from which they arise (e.g. chest stick). However, when the *stunning* method used cardiac arrest, the incision of all of these *vessels* is not necessary from the point of view of animal welfare.

It should be possible for staff to observe, inspect and access the animals throughout the bleeding period. Any animal showing signs of recovering consciousness should be re-stunned.

After incision of the blood vessels, no scalding carcass treatment or dressing procedures should be performed on the animals for at least 30 seconds, or in any case until all brain-stem reflexes have ceased.

Annex XXIV (contd)

Article 3.7.5.8.

Summary analysis of stunning methods and the associated animal welfare issues

Method	Specific method	AW concerns/implications	Key AW requirements applicable	Species	Comment
Mechanical	Free bullet	Inaccurate targeting and inappropriate ballistics	Operator competence, achieving outright kill with first shot	Cattle, calves, buffalo, deer, horses, pigs (boars and sows)	Personnel safety
	Captive bolt - penetrating	Inaccurate targeting, velocity and diameter of bolt	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, buffalo, sheep, goats, deer, horses, pigs, camelids, ratites	(Unsuitable for specimen collection from TSE suspects). A back-up gun should be available in the event of an ineffective shot
	Captive bolt - non-penetrating	Inaccurate targeting, velocity of bolt, potentially higher failure rate than penetrating captive bolt	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats, deer, pigs, camelids, ratites	Presently available devices are not recommended for young bulls and animals with thick skull. This method should only be used for cattle and sheep when alternative methods are not available.
	Manual percussive blow	Inaccurate targeting; insufficient power; size of instrument	Competent animal handlers; restraint; accuracy. Not recommended for general use	Young and small mammals, ostriches and poultry	Mechanical devices potentially more reliable. Where manual percussive blow is used, unconsciousness should be achieved with single sharp blow delivered to central skull bones
Electrical	Split application: 1. across head then head to chest; 2. across head then across chest	Accidental pre-stun electric shocks; electrode positioning; application of a current to the body while animal conscious; inadequate current and voltage	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats and pigs, ratites and poultry	Systems involving repeated application of head-only or head-to-leg with short current durations (<1 second) in the first application should not be used.
	Single application: 1. head only; 2. head to body; 3. head to leg	Accidental pre-stun electric shocks; inadequate current and voltage; wrong electrode positioning; recovery of consciousness	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats, pigs, ratites, poultry	
	Waterbath	Restraint, accidental pre-stun electric shocks; inadequate current and voltage; recovery of consciousness	Competent operation and maintenance of equipment	Poultry only	

Annex XXIV (contd)

Summary analysis of stunning methods and the associated animal welfare issues (contd)

Method	Specific method	AW concerns/implications	Key AW requirements applicable	Species	Comment
Gaseous	CO_2 air/O_2 mixture; CO_2 inert gas mixture	Aversiveness of high CO_2 concentrations, respiratory distress; inadequate exposure	Concentration; duration of exposure; design, maintenance and operation of equipment; stocking density management	Pigs, poultry	
	Inert gases	Recovery of consciousness	Concentration; duration of exposure; design, maintenance and operation of equipment; stocking density management	Pigs, poultry	
Bleeding out by severance of blood vessels in the neck without stunning	Full frontal cutting across the throat	Failure to cut both common carotid arteries; occlusion of cut arteries; pain during and after the cut.	High level of operator competency. A very sharp blade or knife, of sufficient length so that the point of the knife remains outside the incision during the cut; the point of the knife should not be used to make the incision. An incision which does not close over the knife during the throat cut.	Cattle, buffalo, horses, camelids, sheep, goats, poultry, ratites	No further procedure should be carried out before the bleeding out is completed (i.e. at least 30 ~~60~~ seconds for mammals) The practice to remove hypothetical blood clots just after the bleeding should be discouraged since this may increase animal suffering.

Annex XXIV (contd)

Article 3.7.5.9.

Summary analysis of slaughter methods and the associated animal welfare issues

Slaughter methods	Specific method	AW concerns / implications	Key requirements	Species	Comments
Bleeding with prior stunning	Full frontal cutting across the throat	Failure to cut both common carotid arteries; occlusion of cut arteries; pain during and after the cut.	A very sharp blade or knife, of sufficient length so that the point of the knife remains outside the incision during the cut; the point of the knife should not be used to make the incision. An incision which does not close over the knife during the throat cut.	Cattle, buffalo, horses, camelids, sheep, goats,	
	Neck stab followed by forward cut	Ineffective stunning; failure to cut both common carotid arteries; impaired blood flow; delay in cutting after reversible stunning	Prompt and accurate cutting	Camelids, sheep, goats, poultry, ratites	
	Neck stab alone	Ineffective stunning; failure to cut both common carotid arteries; impaired blood flow; delay in cutting after reversible stunning	Prompt and accurate cutting	Camelids, sheep, goats, poultry, ratites	
	Chest stick into major arteries or hollow-tube knife into heart	Ineffective stunning; Inadequate size of stick wound inadequate length of sticking knife; delay in sticking after reversible stunning	Prompt and accurate sticking	Cattle, sheep, goats, pigs	
	Neck skin cut followed by severance of vessels in the neck	Ineffective stunning; Inadequate size of stick wound; Inadequate length of sticking knife; delay in sticking after reversible stunning	Prompt and accurate cutting of vessels	Cattle	

Annex XXIV (contd)

Article 3.7.5.9.

Summary analysis of slaughter methods and the associated animal welfare issues (contd)

Slaughter methods	Specific method	AW concerns / implications	Key requirements	Species	Comments
Bleeding with prior stunning (contd)	Automated mechanical cutting	Ineffective stunning; failure to cut and misplaced cuts. Recovery of consciousness following reversible stunning systems	Design, maintenance and operation of equipment; accuracy of cut; manual back-up	Poultry only	
	Manual neck cut on one side	Ineffective stunning; recovery of consciousness following reversible stunning systems	Prior non-reversible stunning	Poultry only	N.B. slow induction of unconsciousness under slaughter without stunning
	Oral cut	Ineffective stunning; recovery of consciousness following reversible stunning systems	Prior non-reversible stunning	Poultry only	N.B. slow induction of unconsciousness in non-stun systems
Other methods without stunning	Decapitation with a sharp knife	Pain due to loss of consciousness not being immediate		Sheep, goats, poultry	This method is only applicable to Jhatka slaughter
	Manual neck dislocation and decapitation	Pain due to loss of consciousness not being immediate; difficult to achieve in large birds	Neck dislocation should be performed in one stretch to sever the spinal cord	Poultry only	Slaughter by neck dislocation should be performed in one stretch to sever the spinal cord. Acceptable only when slaughtering small numbers of small birds
Cardiac arrest in a waterbath electric stunner	Bleeding by evisceration		Induction of cardiac arrest	Quail	
	Bleeding by neck cutting			Poultry	

Annex XXIV (contd)

Article 3.7.5.10.

Methods, procedures or practices unacceptable on animal welfare grounds

1. The restraining methods which work through immobilisation by injury such as breaking legs, leg tendon cutting, and severing the spinal cord (e.g. using a puntilla or dagger) cause severe pain and stress in animals. Those methods are not acceptable in any species.

2. The use of the electrical *stunning* method with a single application leg to leg is ineffective and unacceptable in any species.

3. The *slaughter* method of brain stem severance by piercing through the eye socket or skull bone without prior *stunning*, is not acceptable in any species.

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— text deleted

APPENDIX 3.7.6.

GUIDELINES FOR THE KILLING OF ANIMALS FOR DISEASE CONTROL PURPOSES

Community speaking position:

The Community welcomes the work carried out by the OIE Code Commission and supports the amendments of the text.

The Community reiterates its wishes to have included a third method for controlled atmosphere killing (Containerised Gassing Units) which has been tested in the UK, as referred to in the detailed written comments to Article 3.7.6.12.

The Community delegation is available for further exchange of scientific background to the abovementioned third method.

Article 3.7.6.1.

General principles

These guidelines are based on the premise that a decision to kill the animals has been made, and address the need to ensure the welfare of the animals until they are dead.

1. All personnel involved in the humane *killing* of animals should have the relevant skills and competencies. Competence may be gained through formal training and/or practical experience.

2. As necessary, operational procedures should be adapted to the specific circumstances operating on the premises and should address, apart from animal welfare, aesthetics of the method of euthanasia, cost of the method, operator safety, biosecurity and environmental aspects, aesthetics of the method of euthanasia and cost of the method.

3. Following the decision to kill the animals, *killing* should be carried out as quickly as possible and normal husbandry should be maintained until the animals are killed.

4. The handling and movement of animals should be minimised and when done, it should be done in accordance with the guidelines described below.

5. Animal *restraint* should be sufficient to facilitate effective *killing*, and in accordance with animal welfare and operator safety requirements; when *restraint* is required, *killing* should follow with minimal delay.

The Community reiterates its previous comment:

The paragraph 6 should be amended in the following way:

"6. When animals are killed for disease control purposes, methods used should result in immediate death or immediate loss of consciousness lasting until death; when loss of consciousness is not immediate, induction of unconsciousness should be non-aversive or as least aversive as possible and should not cause avoidable anxiety, pain, distress or suffering in the animals.

Justification:

Total non-aversiveness is technically difficult to guarantee especially under disease control situation. Furthermore some killing methods which may be slightly aversive for a short period of time may cause overall lower levels of stress and better welfare overall than a less aversive killing methods which requires higher levels of handling stress. E.g. killing chickens by exposure to a lethal gas mixture either held in crates or in their accommodation compared with catching, crating and hanging birds by their legs before killing using electricity.

6. When animals are killed for *disease* control purposes, methods used should result in immediate death or immediate loss of consciousness lasting until death; when loss of consciousness is not immediate, induction of unconsciousness should be non-aversive and should not cause anxiety, pain, distress or suffering in the animals.

7. For animal welfare considerations, young animals should be killed before older animals; for biosecurity considerations, infected animals should be killed first, followed by in-contact animals, and then the remaining animals.

8. There should be continuous monitoring of the procedures by the *Competent Authorities* to ensure they are consistently effective with regard to animal welfare, operator safety and biosecurity.

9. When the operational procedures are concluded, there should be a written report describing the practices adopted and their effect on animal welfare, operator safety and biosecurity.

10. These general principles should also apply when animals need to be killed for other purposes such as after natural disasters or for culling animal populations.

Article 3.7.6.2.

Organisational structure

Community comment:

In the second last sentence of the following paragraph, the word "is" should be replaced by the word "are".

Disease control contingency plans should be in place at a national level and should contain details of management structure, *disease* control strategies and operational procedures; animal welfare considerations should be addressed within these disease control contingency plans. The plans should also include a strategy to ensure that an adequate number of personnel competent in the humane *killing* of animals is available. Local level plans should be based on national plans and be informed by local knowledge.

Disease control contingency plans should address the animal welfare issues that may result from animal movement controls.

The operational activities should be led by an *official veterinarian* who has the authority to appoint the personnel in the specialist teams and ensure that they adhere to the required animal welfare and biosecurity standards. When appointing the personnel, he/she should ensure that the personnel involved have the required competencies.

The *official veterinarian* should be responsible for all activities across one or more affected premises and should be supported by coordinators for planning (including communications), operations and logistics to facilitate efficient operations.

The *official veterinarian* should provide overall guidance to personnel and logistic support for operations on all affected premises to ensure consistency in adherence to the OIE animal welfare and animal health guidelines.

A specialist team, led by a team leader answerable to the *official veterinarian*, should be deployed to work on each affected premises. The team should consist of personnel with the competencies to conduct all required operations; in some situations, personnel may be required to fulfil more than one function. Each team should contain a *veterinarian* or have access to veterinary advice at all times.

In considering the animal welfare issues associated with the *killing* of animals, the key personnel, their responsibilities and competencies required are described in Article 3.7.6.3.

Article 3.7.6.3.

Responsibilities and competencies of the specialist team

1. Team leader

    a) Responsibilities:

        i) plan overall operations on ~~an~~ affected premises;

        ii) determine and address requirements for animal welfare, operator safety and biosecurity;

        iii) organise, brief and manage team of people to facilitate humane *killing* of the relevant animals on the premises in accordance with national regulations and these guidelines;

        iv) determine logistics required;

        v) monitor operations to ensure animal welfare, operator safety and biosecurity requirements are met;

        vi) report upwards on progress and problems;

        vii) provide a written report at the conclusion of the *killing*, describing the practices adopted and their effect on the animal welfare, operator safety and biosecurity outcomes.

    b) Competencies

        i) appreciation of normal animal husbandry practices;

        ii) appreciation of animal welfare and the underpinning behavioural, anatomical and physiological processes involved in the *killing* process;

        iii) skills to manage all activities on premises and deliver outcomes on time;

        iv) awareness of psychological effects on farmers, team members and general public;

        v) effective communication skills;

        vi) appreciation of the environmental impacts caused by their operation.

2. Veterinarian

    a) Responsibilities

i) determine and supervise the implementation of the most appropriate *killing* method to ensure that animals are killed without avoidable pain and distress;

ii) determine and implement the additional requirements for animal welfare, including the order of *killing*;

Community comment:

In the following bullet point, the word "animals" should be replaced by the word "animals' ".

iii) ensure that confirmation of animals deaths is carried out by competent persons at appropriate times after the *killing* procedure;

iv) minimise the *risk* of *disease* spread within and from the premises through the supervision of biosecurity procedures;

v) continuously monitor animal welfare and biosecurity procedures;

vi) in cooperation with the leader, prepare a written report at the conclusion of the *killing*, describing the practices adopted and their effect on animal welfare.

b) Competencies

i) ability to assess animal welfare, especially the effectiveness of *stunning* and *killing*, and to correct any deficiencies;

ii) ability to assess biosecurity risks.

3. Animal handlers

a) Responsibilities

i) review on-site facilities in terms of their appropriateness;

ii) design and construct temporary animal handling facilities, when required;

iii) move and restrain animals;

iv) continuously monitor animal welfare and biosecurity procedures.

b) Competencies

i) animal handling in emergency situations and in close confinement is required;

ii) an appreciation of biosecurity and containment principles.

4. Animal killing personnel

a) Responsibilities

Humane *killing* of the animals through effective *stunning* and *killing* should be ensured.

b) Competencies

i) when required by regulations, licensed to use necessary equipment;

ii) competent to use and maintain relevant equipment;

iii) competent to use techniques for the species involved;

iv) competent to assess effective *stunning* and *killing*.

5. Carcass disposal personnel

a) Responsibilities

An efficient carcass disposal (to ensure *killing* operations are not hindered) should be ensured.

b) Competencies

The personnel should be competent to use and maintain available equipment and apply techniques for the species involved.

6. Farmer/owner/manager

a) Responsibilities

i) assist when requested.

b) Competencies

i) specific knowledge of his/her animals and their environment.

Article 3.7.6.4.

Considerations in planning the humane killing of animals

Many activities will need to be conducted on affected premises, including the humane *killing* of animals. The team leader should develop a plan for humanely *killing* animals on the premises which should include consideration of:

1. minimising handling and movement of animals;

2. *killing* the animals on the affected premises; however, there may be circumstances where the animals may need to be moved to another location for *killing*; when the *killing* is conducted at an *abattoir*, the guidelines in Appendix 3.7.5. on *slaughter* of animals should be followed;

3. the species, number, age and size of animals to be killed, and the order of *killing* them;

4. methods of *killing* the animals, and their cost;

5. housing, husbandry, location of the animals, as well as accessibility of the farm;

6. the availability and effectiveness of equipment needed for *killing* of the animals, as well as the time necessary to kill the required number of animals using such methods;

7. the facilities available on the premises that will assist with the *killing* including any additional facilities that may need to be brought on and then removed from the premises;

8. biosecurity and environmental issues;

9. the health and safety of personnel conducting the *killing*;

10. any legal issues that may be involved, for example where restricted veterinary drugs or poisons may be used, or where the process may impact on the environment;

11. the presence of other nearby premises holding animals;

12. possibilities for removal, disposal and destruction of carcasses.

The plan should minimise the negative welfare impacts of the *killing* by taking into account the different phases of the procedures to be applied for *killing* (choice of the *killing* sites, *killing* methods, etc.) and the measures restricting the movements of the animals.

Competences and skills of the personnel handling and killing animals.

In designing a *killing* plan, it is essential that the method chosen be consistently reliable to ensure that all animals are humanely and quickly killed.

Annex XXIV (contd)

Article 3.7.6.5.

Table summarising killing methods described in Articles 3.7.6.6.-3.7.6.17.

Species	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
Cattle	all	free bullet	no	non-lethal wounding	3.7.6.6.
	all except neonates	captive bolt - penetrating, followed by pithing or bleeding	yes	ineffective stunning	3.7.6.7.
	adults only	captive bolt - non-penetrating, followed by bleeding	yes	ineffective stunning, regaining of consciousness before killing	3.7.6.8.
	calves only	electrical, two stage application	yes	pain associated with cardiac arrest after ineffective stunning	3.7.6.10.
	calves only	electrical, single application (method 1)	yes	ineffective stunning	3.7.6.11.
	all	injection with barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	3.7.6.15.
Sheep and goats	all	free bullet	no	non-lethal wounding	3.7.6.6.
	all except neonates	captive bolt - penetrating, followed by pithing or bleeding	yes	ineffective stunning, regaining of consciousness before death	3.7.6.7.
	all except neonates	captive bolt - non-penetrating, followed by bleeding	yes	ineffective stunning, regaining of consciousness before death	3.7.6.8.
	neonates	captive bolt - non-penetrating	yes	non-lethal wounding	3.7.6.8.
	all	electrical, two stage application	yes	pain associated with cardiac arrest after ineffective stunning	3.7.6.10.
	all	electrical, single application (Method 1)	yes	ineffective stunning	3.7.6.11.
	neonates only	CO_2 / air mixture	yes	slow induction of unconsciousness, aversiveness of induction	3.7.6.12.
	neonates only	nitrogen and/or inert gas mixed with CO_2	yes	slow induction of unconsciousness, aversiveness of induction	3.7.6.13.

Annex XXIV (contd)

Table summarising killing methods described in Articles 3.7.6.6.-3.7.6.17. (Contd)

Species	Age range	Procedure	Restraint Necessary	Animal welfare concerns with inappropriate application	Article reference
Sheep and goats (cont)	neonates only	nitrogen and/or inert gases	yes	slow induction of unconsciousness	3.7.6.14.
	all	injection of barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	3.7.6.15.
Pigs	all, except neonates	free bullet	no	Non-lethal wounding	3.7.6.6.
	all except neonates	captive bolt - penetrating, followed by pithing or bleeding	yes	ineffective stunning, regaining of consciousness before death	3.7.6.7.
	neonates only	captive bolt - non-penetrating	yes	Non-lethal wounding	3.7.6.8.
	all §	electrical, two stage application	yes	pain associated with cardiac arrest after ineffective stunning	3.7.6.10.
	all	electrical, single application (Method 1)	yes	ineffective stunning	3.7.6.11.
	neonates only	CO_2 / air mixture	yes	slow induction of unconsciousness, aversiveness of induction	3.7.6.12.
	neonates only	nitrogen and/or inert gas mixed with CO_2	yes	slow induction of unconsciousness, aversiveness of induction	3.7.6.13.
	neonates only	nitrogen and/or inert gases	yes	slow induction of unconsciousness,	3.7.6.14.
	all	injection with barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	3.7.6.15.
Poultry	adults only	captive bolt - non-penetrating	yes	ineffective stunning	3.7.6.8.
	day-olds and eggs only	Maceration	no	non-lethal wounding, non- immediacy;	3.7.6.9.
	adults only	electrical single application (Method 2)	yes	ineffective stunning	3.7.6.11.
	adults only	electrical single application, followed by killing (Method 3)	yes	ineffective stunning; regaining of consciousness before death	3.7.6.11.

Annex XXIV (contd)

Table summarising killing methods described in Articles 3.7.6.6.-3.7.6.17. (Contd)

Species	Age range	Procedure	Restraint Necessary	Animal welfare concerns with inappropriate application	Article reference
Poultry (cont)	all	CO_2 / air mixture Method 1 Method 2	 yes no	slow induction of unconsciousness, aversiveness of induction	3.7.6.12.
	all	nitrogen and/or inert gas mixed with CO_2	yes	slow induction of unconsciousness, aversiveness of induction	3.7.6.13.
	all	nitrogen and/or inert gases	yes	slow induction of unconsciousness	3.7.6.14.
	all	injection of barbiturates and other drugs	yes	Non-lethal dose, pain associated with injection site	3.7.6.15.
	adults only	addition of anaesthetics to feed or water, followed by an appropriate killing method	no	ineffective or slow induction of unconsciousness	3.7.6.16.

- The methods are described in the order of mechanical, electrical and gaseous, not in an order of desirability from an animal welfare viewpoint.

§ The only preclusion against the use of this method for neonates is the design of the stunning tongs that may not facilitate their application across such a small-sized head/body.

Article 3.7.6.6.

Free bullet

1. Introduction

   a) A free bullet is a projectile fired from a shotgun, rifle, handgun or purpose-made humane killer.

   b) The most commonly used firearms for close range use are:

      i) humane killers (specially manufactured/adapted single-shot weapons);

      ii) shotguns (12, 16, 20, 28 bore and .410);

      iii) rifles (.22 rimfire);

      iv) handguns (various calibres from .32 to .45).

   c) The most commonly used firearms for long range use are rifles (.22, .243, .270 and .308).

   d) A free bullet used from long range should be aimed to penetrate the skull or soft tissue at the top of the neck of the animal (high neck shot), to cause irreversible concussion and death and should only be used by properly trained and competent marksmen.

2. Requirements for effective use

a) The marksman should take account of human safety in the area in which he/she is operating. Appropriate vision and hearing protective devices should be worn by all personnel involved.

b) The marksman should ensure that the animal is not moving and in the correct position to enable accurate targeting and the range should be as short as possible (5 –50 cm for a shotgun) but the barrel should not be in contact with the head of the animal.

c) The correct cartridge, calibre and type of bullet for the different species age and size should be used. Ideally the ammunition should expand upon impact and dissipate its energy within the cranium.

d) Shot animals should be checked to ensure the absence of brain stem reflexes.

Figure 1. The optimum shooting position for cattle is at the intersection of two imaginary lines drawn from the rear of the eyes to the opposite horn buds.

Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire,AL4 8AN, United Kingdom (www.hsa.org.uk).

Figure 2. The optimum position for hornless sheep and goats is on the midline, with the shot aiming at the angle of the jaw.

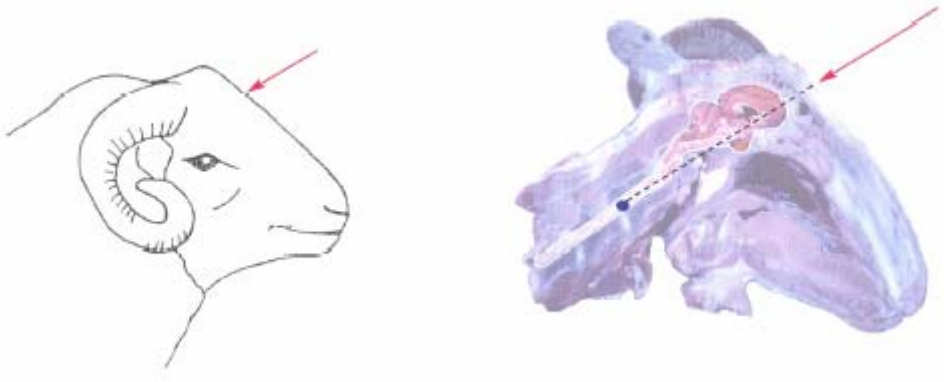

Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire,AL4 8AN, United Kingdom (www.hsa.org.uk).

Annex XXIV (contd)

Figure 3. The optimum shooting position for heavily horned sheep and horned goats is behind the poll aiming towards the angle of the jaw.

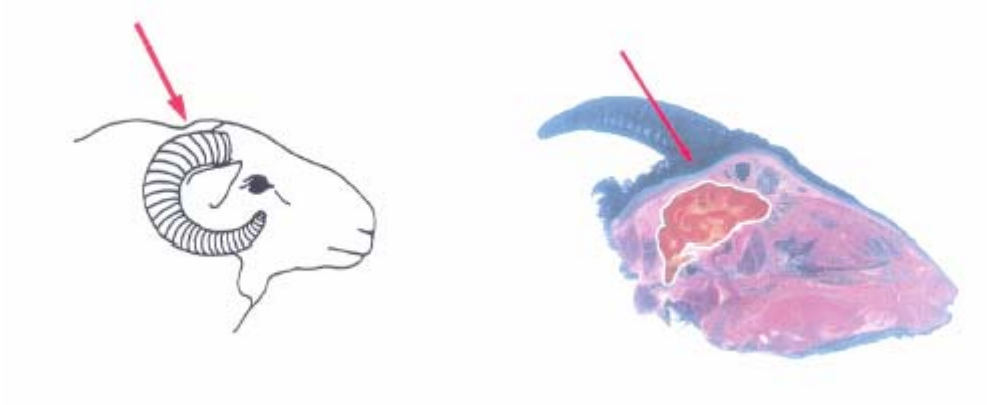

Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire,AL4 8AN, United Kingdom (www.hsa.org.uk).

Figure 4. The optimum shooting position for pigs is just above eye level, with the shot directed down the line of the spinal cord.

Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire,AL4 8AN, United Kingdom (www.hsa.org.uk).

3. Advantages

a) Used properly, a free bullet provides a quick and effective method for *killing*.

b) It requires minimal or no *restraint* and can be use to kill from a distance by properly trained and competent marksmen.

c) It is suitable for *killing* agitated animals in open spaces.

4. Disadvantages

a) The method is potentially dangerous to humans and other animals in the area.

b) It has the potential for non-lethal wounding.

c) Destruction of brain tissue may preclude diagnosis of some *diseases*.

d) Leakage of bodily fluids may present a biosecurity *risk*.

e) Legal requirements may preclude or restrict use.

f) There is a limited availability of competent personnel.

5. Conclusions

The method is suitable for cattle, sheep, goats and pigs, including large animals in open spaces.

Article 3.7.6.7.

Penetrating captive bolt

1. Introduction

A penetrating captive bolt is fired from a gun powered by either compressed air or a blank cartridge. There is no free projectile.

The captive bolt should be aimed on the skull in a position to penetrate the cortex and mid-brain of the animal. The impact of the bolt on the skull produces unconsciousness. Physical damage to the brain caused by penetration of the bolt may result in death, however pithing or bleeding should be performed as soon as possible after the shot to ensure the death of the animal.

2. Requirements for effective use

a) For cartridge powered and compressed air guns, the bolt velocity and the length of the bolt should be appropriate to the species and type of animal, in accordance with the recommendations of the manufacturer.

b) Captive bolt guns should be frequently cleaned and maintained in good working condition.

c) More than one gun may be necessary to avoid overheating and a back-up gun should be available in the event of an ineffective shot.

d) Animals should be restrained; at a minimum they should be penned for cartridge powered guns and in a race for compressed air guns.

e) The operator should ensure that the head of the animal is accessible.

f) The operator should fire the captive bolt at right angles to the skull in the optimal position (see figures 1, 3 & 4. The optimum shooting position for hornless sheep is on the highest point of the head, on the midline and aim towards the angle of the jaw).

g) To ensure the death of the animal, pithing or bleeding should be performed as soon as possible after *stunning*.

h) Animals should be monitored continuously after *stunning* until death to ensure the absence of brain stem reflexes.

3. Advantages

a) Mobility of cartridge powered equipment reduces the need to move animals.

b) The method induces an immediate onset of a sustained period of unconsciousness.

4. Disadvantages

a) Poor gun maintenance and misfiring, and inaccurate gun positioning and orientation may result in poor animal welfare.

b) Post stun convulsions may make pithing difficult and hazardous.

c) The method is difficult to apply in agitated animals.

d) Repeated use of a cartridge powered gun may result in over-heating.

e) Leakage of bodily fluids may present a biosecurity risk.

f) Destruction of brain tissue may preclude diagnosis of some *diseases*.

5. Conclusions

The method is suitable for cattle, sheep, goats and pigs (except neonates), when followed by pithing or bleeding.

Article 3.7.6.8.

Captive bolt – non-penetrating

1. Introduction

A non-penetrating captive bolt is fired from a gun powered by either compressed air or a blank cartridge. There is no free projectile.

Community comment:

A condition should be added such as follows:

"The method should only be used in poultry and neonate sheep, goats and pigs up to a maximum live weight of 10 kg."

Justification

Non penetrative captive bolt is unreliable on cattle, calves and adult sheep and should not be used (see EFSA recommendations 2.1.2 and 3.1.2).

EFSA reference: The EFSA Journal (2004) 45, 1-29, Welfare aspects of the main systems of stunning and killing the main commercial species of animals.

The gun should be placed on the front of the skull to deliver a percussive blow which produces unconsciousness in cattle (adults only), sheep, goats and pigs, and death in poultry and neonate sheep, goats and pigs. Bleeding should be performed as soon as possible after the blow to ensure the death of the animal.

2. Requirements for effective use

a) For cartridge powered and compressed air guns, the bolt velocity should be appropriate to the species and type of animal, in accordance with the recommendations of the manufacturer.

b) Captive bolt guns should be frequently cleaned and maintained in good working condition.

c) More than one gun may be necessary to avoid overheating and a back-up gun should be available in the event of an ineffective shot.

d) Animals should be restrained; at a minimum mammals should be penned for cartridge powered guns and in a race for compressed air guns; birds should be restrained in cones, shackles, crushes or by hand.

e) The operator should ensure that the head of the animal is accessible.

f) The operator should fire the captive bolt at right angles to the skull in the optimal position (figures 1-4).

g) To ensure death in non-neonate mammals, bleeding should be performed as soon as possible after *stunning*.

h) Animals should be monitored continuously after *stunning* until death to ensure the absence of brain stem reflexes.

3. Advantages

a) The method induces an immediate onset of unconsciousness, and death in birds and neonate mammals.

b) Mobility of equipment reduces the need to move animals.

4. Disadvantages

a) As consciousness can be regained quickly in non-neonate mammals, they should be bled as soon as possible after *stunning*.

b) Laying hens in cages have to be removed from their cages and most birds have to be restrained.

c) Poor gun maintenance and misfiring, and inaccurate gun positioning and orientation may result in poor animal welfare.

d) Post stun convulsions may make bleeding difficult and hazardous.

e) Difficult to apply in agitated animals; such animals may be sedated in advance of the *killing* procedure.

f) Repeated use of a cartridge powered gun may result in over-heating.

g) Bleeding may present a biosecurity risk.

5. Conclusions

Community comment

A condition should be added such as follows:

"The method should only be used in poultry and neonate sheep, goats and pigs up to a maximum live weight of 10 kg."

Justification

Non penetrative captive bolt is unreliable on cattle, calves and adult sheep and should not be used (see EFSA recommendations 2.1.2 and 3.1.2).

EFSA reference: The EFSA Journal (2004) 45, 1-29, Welfare aspects of the main systems of stunning and killing the main commercial species of animals

The method is suitable for *killing* poultry, and neonate sheep, goats and pigs up to a maximum weight of 10 kg.

Article 3.7.6.9.

Maceration

1. Introduction

Maceration, utilising a mechanical apparatus with rotating blades or projections, causes immediate fragmentation and death in day-old poultry and embryonated eggs.

2. Requirements

a) Maceration requires specialised equipment which should be kept in excellent working order.

b) The rate of introducing the birds should not allow the equipment to jam, birds to rebound from the blades or the birds to suffocate before they are macerated.

3. Advantages

a) Procedure results in immediate death.

b) Large numbers can be killed quickly.

4. Disadvantages

a) Specialised equipment is required.

b) Macerated tissues may present ~~a~~ biosecurity or human health risks.

c) The cleaning of the equipment can be a source of contamination.

5. Conclusion

The method is suitable for *killing* day-old poultry and embryonated eggs.

Article 3.7.6.10.

Electrical – two-stage application

1. Introduction

A two stage application of electric current comprises firstly an application of current to the head by scissor-type tongs, immediately followed by an application of the tongs across the chest in a position that spans the heart.

The application of sufficient electric current to the head will induce 'tonic/clonic' epilepsy and unconsciousness. Once the animal is unconscious, the second stage will induce ventricular fibrillation (cardiac arrest) resulting in death. The second stage (the application of low frequency current across the chest) should only be applied to unconscious animals to prevent unacceptable levels of pain.

Figure 5. Scissor-type stunning tongs.

2. Requirements for effective use

a) The stunner control device should generate a low frequency (AC sine wave 50 Hz) current with a minimum voltage and current as set out in the following table:

Animal	Minimum voltage (V)	Minimum current (A)
Cattle	220	1.5
Sheep	220	1.0
Pigs > 6 weeks	220	1.3
Pigs < 6 weeks	125	0.5

b) Appropriate protective clothing (including rubber gloves and boots) should be worn.

c) Animals should be restrained, at a minimum free-standing in a pen, close to an electrical supply.

d) Two team members are required, the first to apply the electrodes and the second to manipulate the position of the animal to allow the second application to be made.

e) A *stunning* current should be applied via scissor-type stunning tongs in a position that spans the brain for a minimum of ~~3~~ 10 seconds; immediately following the application to the head, the electrodes should be transferred to a position that spans the heart and the electrodes applied for a minimum of 3 seconds.

f) Electrodes should be cleaned regularly and after use, to enable optimum electrical contact to be maintained.

g) Animals should be monitored continuously after *stunning* until death to ensure the absence of brain stem reflexes.

h) Electrodes should be applied firmly for the intended duration of time and pressure not released until the stun is complete.

3. Advantages

a) The application of the second stage minimises post-stun convulsions and therefore the method is particularly effective with pigs.

b) Non-invasive technique minimises biosecurity risk.

4. Disadvantages

a) The method requires a reliable supply of electricity.

b) The electrodes must be applied and maintained in the correct positions to produce an effective stun and kill.

c) Most stunner control devices utilise low voltage impedance sensing as an electronic switch prior to the application of high voltages; in unshorn sheep, contact impedance may be too high to switch on the required high voltage (especially during stage two).

d) The procedure may be physically demanding, leading to operator fatigue and poor electrode placement.

5. Conclusion

The method is suitable for calves, sheep and goats, and especially for pigs (over one week of age).

Article 3.7.6.11.

Electrical – single application

1. Method 1

Method 1 comprises the single application of sufficient electrical current to the head and back, to simultaneously stun the animal and fibrillate the heart. Provided sufficient current is applied in a position that spans both the brain and heart, the animal will not recover consciousness.

a) Requirements for effective use

i) The stunner control device should generate a low frequency (30 – 60 Hz) current with a minimum voltage of 250 volts true RMS under load.

ii) Appropriate protective clothing (including rubber gloves and boots) should be worn.

iii) Animals should be individually and mechanically restrained close to an electrical supply as the maintenance of physical contact between the stunning electrodes and the animal is necessary for effective use.

iv) The rear electrode should be applied to the back, above or behind the heart, and then the front electrode in a position that is forward of the eyes, with current applied for a minimum of ~~3~~ 10 seconds.

v) Electrodes should be cleaned regularly between animals and after use, to enable optimum electrical contact to be maintained.

vi) Water or saline may be necessary to improve electrical contact with sheep.

vii) An effective stun and kill should be verified by the absence of brain stem reflexes.

b) Advantages

i) Method 1 stuns and kills simultaneously.

ii) It minimises post-stun convulsions and therefore is particularly effective with pigs.

iii) A single team member only is required for the application.

iv) Non-invasive technique minimises biosecurity risk.

c) Disadvantages

i) Method 1 requires individual mechanical animal *restraint*.

ii) The electrodes must be applied and maintained in the correct positions to produce an effective stun and kill.

iii) Method 1 requires a reliable supply of electricity.

d) Conclusion

Method 1 is suitable for calves, sheep, goats, and pigs (over 1 week of age).

2. Method 2

Method 2 stuns and kills by drawing inverted and shackled poultry through an electrified waterbath stunner. Electrical contact is made between the 'live' water and earthed shackle and, when sufficient current is applied, poultry will be simultaneously stunned and killed.

a) Requirements for effective use

i) A mobile waterbath stunner and a short loop of processing line are required.

ii) A low frequency (50-60 Hz) current applied for a minimum of 3 seconds is necessary to stun and kill the birds.

iii) Poultry need to be manually removed from their cage, house or yard, inverted and shackled onto a line which conveys them through a waterbath stunner with their heads fully immersed.

iv) The required minimum currents to stun and kill dry birds are:

- Quail - 100 mA/bird
- Chickens – 160 mA/bird
- Ducks & Geese – 200 mA/bird
- Turkeys – 250 mA/bird.

A higher current is required for wet birds.

v) An effective stun and kill should be verified by the absence of brain stem reflexes.

b) Advantages

i) Method 2 stuns and kills simultaneously.

ii) It is capable of processing large numbers of birds reliably and effectively.

iii) This non-invasive technique minimises biosecurity risk.

c) Disadvantages

i) Method 2 requires a reliable supply of electricity.

ii) Handling, inversion and shackling of birds are required.

d) Conclusion

Method 2 is suitable for large numbers of poultry.

3. Method 3

Method 3 comprises the single application of sufficient electrical current to the head of poultry in a position that spans the brain, causing unconsciousness; this is followed by a *killing* method (Article 3.7.6.17.).

a) Requirements for effective use

i) The stunner control device should generate sufficient current (more than 600 mA/ duck, more than 300 mA/bird) to stun.

ii) Appropriate protective clothing (including rubber gloves and boots) should be worn.

iii) Birds should be restrained, at a minimum manually, close to an electrical supply.

iv) A *stunning* current should be applied in a position that spans the brain for a minimum of ~~3~~ 7 seconds; immediately following this application, the birds should be killed (Article 3.7.6.17.).

v) Electrodes should be cleaned regularly and after use, to enable optimum electrical contact to be maintained.

vi) Birds should be monitored continuously after *stunning* until death to ensure the absence of brain stem reflexes.

b) Advantages

Non-invasive technique (when combined with cervical dislocation) minimises biosecurity risk.

c) Disadvantages

i) Method 3 requires a reliable supply of electricity and is not suitable for large-scale operations.

ii) The electrodes must be applied and maintained in the correct position to produce an effective stun.

iii) Birds must be individually restrained.

iv) It must be followed by a *killing* method.

d) Conclusion

Method 3 is suitable for small numbers of poultry.

Article 3.7.6.12.
(under study)

CO_2 / air mixture

1. Introduction

The Community reiterates its previous comment:

The following paragraph should be changed by the following text:

Controlled atmosphere killing is performed by exposing animals to a predetermined gas mixture, either by placing them in a gas-filled container or apparatus (Method 1) or by the gas being introduced into a poultry house (Method 2) or by placing birds in transport modules and placing them in a gas tight container and introducing a gas mixture(method 3 – under study) Method 2 should be used whenever possible, as it eliminates welfare issues resulting from the need to manually remove live birds Method 3 (under study) requires only handling and crating of the birds and reduces stress of manually moving birds to containers and immersion in gas mixture used for method 1.

Inhalation of carbon dioxide (CO2) induces respiratory and metabolic acidosis and hence reduces the pH of cerebrospinal fluid (CSF) and neurones thereby causing unconsciousness and, after prolonged exposure, death.

Justification:

This method 3 has been tested in the UK and has provided improved welfare for the animals as they are handled under usual conditions. Furthermore, another advantage of this method is that there are usually staff and equipment available for this type of handling birds.

Controlled atmosphere *killing* is performed by exposing animals to a predetermined gas mixture, either by placing them in a gas-filled *container* or apparatus (Method 1) or by the gas being introduced into a poultry house (Method 2). Method 2 should be used whenever possible, as it eliminates welfare issues resulting from the need to manually remove live birds.

Inhalation of carbon dioxide (CO_2) induces respiratory and metabolic acidosis and hence reduces the pH of cerebrospinal fluid (CSF) and neurones thereby causing unconsciousness and, after prolonged exposure, death.

2. Method 1

The animals are placed in a gas-filled *container* or apparatus.

a) Requirements for effective use in a *container* or apparatus

i) *Containers* or apparatus should allow the required gas concentration to be maintained and accurately measured.

ii) When animals are exposed to the gas individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the animals and allow them to be observed.

iii) Animals can also be introduced to low concentrations [as low concentrations are not aversive] and the concentration could be increased afterwards and the animals then held in the higher concentration until death is confirmed.

iv) Team members should ensure that there is sufficient time allowed for each batch of animals to die before subsequent ones are introduced into the *container* or apparatus.

iv) *Containers* or apparatus should not be overcrowded and measures are needed to avoid animals suffocating by climbing on top of each other.

b) Advantages

i) CO_2 is readily available.

ii) Application methods are simple.

c) Disadvantages

i) The need for properly designed *container* or apparatus.

ii) The aversive nature of high CO_2 concentrations.

iii) No immediate loss of consciousness.

iv) The risk of suffocation due to overcrowding.

v) Difficulty in verifying death while the animals are in the *container* or apparatus.

d) Conclusion

Method 1 is suitable for use in poultry and neonatal sheep, goats and pigs.

3. <u>Method 2</u>

The gas is introduced into a poultry house.

a) Requirements for effective use in a poultry house

i) Prior to introduction of the CO_2 the poultry house should be appropriately sealed to allow control over the gas concentration.

ii) The house should be gradually filled with CO_2 so that all birds are exposed to a concentration of >40% until they are dead; a vaporiser may be required to prevent freezing.

iii) Devices should be used to accurately measure the gas concentration at the maximum height accommodation of birds.

b) Advantages

i) Applying gas to birds *in situ* eliminates the need to manually remove live birds.

ii) CO_2 is readily available.

iii) Gradual raising of CO_2 concentration minimises the aversiveness of the induction of unconsciousness.

c) Disadvantages

i) It is difficult to determine volume of gas required to achieve adequate concentrations of CO_2 in some poultry houses.

ii) It is difficult to verify death while the birds are in the poultry house.

d) Conclusion

Method 2 is suitable for use in poultry in closed-environment sheds.

The Community reiterates its previous comment:

The following text should be added

Method 3. (under study)

The birds are placed in crates and loaded into a container and gas is introduced into the container.

a) Requirements for effective use of containerised gassing units (CGU)

i) Each CGU consists of a purpose-built, gas-tight steel chamber with a lockable access door, large enough to accommodate industry standard poultry transport modules and fitted with gas lines and diffusers, with silencers to a portable gas supply. Either an oxygen meter is used to ensure that the level of Oxygen is less than 2% or a carbon dioxide meter can be used to ensure a concentration of at least 40 % carbon dioxide is reached.

. ii) The birds are caught and placed in crates used for the transport modules of appropriate size and at appropriate stocking densities to allow all birds to sit down and such that the will not be subject to thermal stress.

iii) The time taken for each batch of animals to die may be readily assessed by the cessation of sound before the door is opened. A check is made that all the birds have died by examining each module.

b) Advantages

i) The gas is introduced quickly and quietly resulting in less disturbance of the birds Gradual raising of CO2 concentration minimises the aversiveness of the induction of unconsciousness

ii) This use of transport modules minimises handling. Birds should be handled by trained, experienced catching teams at the time of depopulation of the poultry house and placed into crates, which are then loaded into the modules. The modules are loaded mechanically into the CGU and a lethal mixture of gas is rapidly introduced into the chamber immediately after sealingCO2 is readily available.

iii) When birds are placed in a container as used for method 1 they frequently flap and move quickly so disrupting other birds. Birds sitting transport modules are likely to have fewer disturbances.

iv) The units are operated in tandem for optimum capacity, and throughputs per pair of up to 4,000 chickens per hour are possible .The main limiting factors are speed of catching and availability of gas.

v) The volume of gas required can be readily calculated and as the units are operated outdoors the gas is dispersed quickly at the end of each cycle by opening the door

vi) The system used the skilled catching teams and catching methods and equipment in daily use by the industry available and readily cleansed and disinfected.

c) Disadvantages

i) Requires trained operators, trained catchers, transport modules and fork lift suitable area with hard surface but such equipment is usually available at large poultry units.

d) Conclusion

i) Method 3 is suitable for use in poultry in a wide range of poultry systems which have access to vehicles to carry containers and handling equipment.

ii) Animals should be introduced into the container or apparatus, which is then sealed and filled as quickly as possible thereafter with the required gas concentrations (with ≥2% O2) or more than 40% CO2 and held in this atmosphere until death is confirmed;

Article 3.7.6.13.

Nitrogen and/or inert gas mixed with CO_2

1. Introduction

The Community reiterates its comment:

As the previous method can be used for both mixtures of gas the following text should be amended as follows:

CO2 may be mixed in various proportions with nitrogen or an inert gas (e.g., argon), and the inhalation of such mixtures leads to hypercapnic-hypoxia and death when the oxygen concentration by volume is ≤2%. This method involves either the introduction of animals into a container or apparatus containing the gases or the use of a containerised gassing unit (See Article 3.7.6.12. for details) in which birds are placed on transport modules and then into a container which is sealed and a gas mixture added. Mixtures of CO2 with nitrogen or an inert gas do not induce immediate loss of consciousness, therefore the aversiveness of various gas mixtures containing high concentrations of CO2 and the respiratory distress occurring during the induction phase, are important animal welfare considerations.

CO_2 may be mixed in various proportions with nitrogen or an inert gas (e.g. argon), and the inhalation of such mixtures leads to hypercapnic-hypoxia and death when the oxygen concentration by volume is ≤2%. This method involves the introduction of animals into a *container* or apparatus containing the gases. Such mixtures do not induce immediate loss of consciousness, therefore the aversiveness of various gas mixtures containing high concentrations of CO_2 and the respiratory distress occurring during the induction phase, are important animal welfare considerations.

Pigs and poultry appear not to find low concentrations of CO_2 strongly aversive, and a mixture of nitrogen or argon with ≤30% CO_2 by volume and ≤2% O_2 by volume can be used for *killing* poultry and neonatal sheep, goats and pigs.

2. Requirements for effective use

The Community reiterates its previous comment:

For sake of consistency the following section should be amended as follows:

Requirements for effective use

a) Containers or apparatus should allow the required gas concentrations to be maintained, and the O2 and/or CO2 concentrations accurately measured during the killing procedure.

b) When animals are exposed to the gases individually or in small groups in a container or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the animals and allow them to be observed.

c) Either:

i) Method 1 Animals should be introduced into the container or apparatus after it has been filled with the required gas concentrations (with ≤2% O2), and held in this atmosphere until death is confirmed; or

ii) Method 2 (under study) Animals should be introduced into the container gassing unit (CGU) , which is then sealed and filled as quickly as possible thereafter with the required gas concentrations (with ≥2% O2) and held in this atmosphere until death is confirmed);

d) For method 1 Team members should ensure that there is sufficient time allowed for each batch of animals to die before subsequent ones are introduced into the container or apparatus. Containers or apparatus should not be overcrowded and measures are needed to avoid animals suffocating by climbing on top of each other.

e) For method 2 (under study) Team members should ensure that there is sufficient time allowed for each batch of animals to die before the door is opened and then all the birds should be checked for death by examining each module.

3. Advantages

a) Low concentrations of CO2 cause little aversiveness and, in combination with nitrogen or an inert gas, produces a fast induction of unconsciousness.

b) The advantages of using CGUS are described in artcle3.7.6.12. For details) .

c) Using mixtures of CO2 and inert gases renders then easier to use than using 100% CO2 which requires specific measures to prevent blockages due to freezing of pipes due to vaporisation of the gas.

4. Disadvantages

a) A properly designed container or apparatus is needed.

b) It is difficult to verify death while the animals are in the container or apparatus.

c) There is no immediate loss of consciousness.

d) Exposure times required to kill are considerable.

e) The disadvantages of using CGUS are described in artcle3.7.6.12. for details)

5. Conclusion

Methods using Nitrogen and/or inert gas mixed with CO2 by either introducing animals to a container or using CGUS are suitable for poultry and neonatal sheep, goats and pigs.

a) *Containers* or apparatus should allow the required gas concentrations to be maintained, and the O_2 and CO_2 concentrations accurately measured during the *killing* procedure.

b) When animals are exposed to the gases individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the animals and allow them to be observed.

c) Animals should be introduced into the *container* or apparatus after it has been filled with the required gas concentrations (with ≤2% O_2), and held in this atmosphere until death is confirmed.

d) Team members should ensure that there is sufficient time allowed for each batch of animals to die before subsequent ones are introduced into the *container* or apparatus.

e) *Containers* or apparatus should not be overcrowded and measures are needed to avoid animals suffocating by climbing on top of each other.

3. Advantages

Low concentrations of CO_2 cause little aversiveness and, in combination with nitrogen or an inert gas, produces a fast induction of unconsciousness.

4. Disadvantages

a) A properly designed *container* or apparatus is needed.

b) It is difficult to verify death while the animals are in the *container* or apparatus.

c) There is no immediate loss of consciousness.

d) Exposure times required to kill are considerable.

5. Conclusion

The method is suitable for poultry and neonatal sheep, goats and pigs.

Article 3.7.6.14.

Nitrogen and/or inert gasses

1. Introduction

This method involves the introduction of animals into a *container* or apparatus containing nitrogen or an inert gas such as argon. The controlled atmosphere produced leads to unconsciousness and death from hypoxia.

Research has shown that hypoxia is not aversive to pigs and poultry, and it does not induce any signs of respiratory distress prior to loss of consciousness.

2. Requirements for effective use

a) *Containers* or apparatus should allow the required gas concentrations to be maintained, and the O_2 concentration accurately measured.

b) When animals are exposed to the gases individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the animals and allow them to be observed.

c) Animals should be introduced into the *container* or apparatus after it has been filled with the required gas concentrations (with ≤2% O_2), and held in this atmosphere until death is confirmed.

d) Team members should ensure that there is sufficient time allowed for each batch of animals to die before subsequent ones are introduced into the *container* or apparatus.

e) *Containers* or apparatus should not be overcrowded and measures are needed to avoid animals suffocating by climbing on top of each other.

3. Advantages

Animals are unable to detect nitrogen or inert gases, and the induction of hypoxia by this method is not aversive to animals.

4. Disadvantages

a) A properly designed *container* or apparatus is needed.

b) It is difficult to verify death while the animals are in the *container* or apparatus.

c) There is no immediate loss of consciousness.

d) Exposure times required to kill are considerable.

5. Conclusion

The method is suitable for poultry and neonatal sheep, goats and pigs.

Article 3.7.6.15.

Lethal injection

1. Introduction

A lethal injection using high doses of anaesthetic and sedative drugs causes CNS depression, unconsciousness and death. In practice, barbiturates in combination with other drugs are commonly used.

2. Requirements for effective use

a) Doses and routes of administration that cause rapid loss of consciousness followed by death should be used.

b) Prior sedation may be necessary for some animals.

c) Intravenous administration is preferred, but intraperitoneal or intramuscular administration may be appropriate, especially if the agent is non-irritating.

d) Animals should be restrained to allow effective administration.

e) Animals should be monitored to ensure the absence of brain stem reflexes.

3. Advantages

a) The method can be used in all species.

b) Death can be induced smoothly.

4. Disadvantages

a) *Restraint* and/or sedation may be necessary prior to injection.

b) Some combinations of drug type and route of administration may be painful, and should only be used in unconscious animals.

c) Legal requirements and skill/training required may restrict use to *veterinarians*.

d) Contaminated carcasses may present a risk to other wild or domestic animals.

5. Conclusion

The method is suitable for *killing* small numbers of cattle, sheep, goats, pigs and poultry.

Article 3.7.6.16.

Addition of anaesthetics to feed or water

1. Introduction

An anaesthetic agent which can be mixed with poultry feed or water may be used to kill poultry in houses. Poultry which are only anaesthetised need to be killed by another method such as cervical dislocation.

2. Requirements for effective use

a) Sufficient quantities of anaesthetic need to be ingested rapidly for effective response.

b) Intake of sufficient quantities is facilitated if the birds are fasted or water is withheld.

c) Must be followed by *killing* (see Article 3.7.6.17.) if birds are anaesthetised only.

3. Advantages

a) Handling is not required until birds are anaesthetised.

b) There may be biosecurity advantages in the case of large numbers of diseased birds.

4. Disadvantages

a) Non-target animals may accidentally access the medicated feed or water when provided in an open environment.

b) Dose taken is unable to be regulated and variable results may be obtained.

c) Animals may reject adulterated feed or water due to illness or adverse flavour.

d) The method may need to be followed by *killing*.

e) Care is essential in the preparation and provision of treated feed or water, and in the disposal of uneaten treated feed/water and contaminated carcasses.

5. Conclusion

The method is suitable for *killing* large numbers of poultry in houses.

Article 3.7.6.17.

Cervical dislocation and decapitation

1. Cervical dislocation (manual and mechanical)

a) Introduction

Unconscious poultry may be killed by either manual cervical dislocation (stretching) or mechanical neck crushing with a pair of pliers. Both methods result in death from cerebral anoxia due to cessation of breathing and/or blood supply to the brain.

When the number of birds to be killed is small, and other methods of killing are not available, or are impracticable, conscious birds of less than 3 kilograms may be killed using cervical dislocation in a way that the blood vessels of the neck are severed and death is instantaneous.

~~However, conscious birds of less than 3 kilograms in case of small numbers of birds where other methods are not available or impracticable, may be killed using cervical dislocation in a way that the blood vessels of the neck are severed and death is instantaneous.~~

b) Requirements for effective use

i) *Killing* should be performed either by manually or mechanically stretching the neck to sever the spinal cord or by using mechanical pliers to crush the cervical vertebrae with consequent major damage to the spinal cord.

ii) Consistent results require strength and skill so team members should be rested regularly to ensure consistently reliable results.

iii) Birds should be monitored continuously until death to ensure the absence of brain stem reflexes.

Community comment:

The following requirement shall be added in order to be consistent with the introduction:

"The method should not be used in any case on conscious birds over 3 kg of live weight".

Justification:

p. 195 EFSA report

c) Advantages

i) It is a non-invasive *killing* method.

ii) It can be performed manually on small birds.

d) Disadvantages

i) Operator fatigue.

ii) The method is more difficult in larger birds.

iii) Requires trained personnel to perform humanely.

iv) Human health and safety concerns due to handling of the birds.

v) Additional stress to the animals from handling.

2. Decapitation

The Community reiterates its previous comment:

The method should only be used for unconscious animals as previously recommended.

Justification:

There is no clear scientific evidence that this method induces immediate loss of consciousness.

a) Introduction

Decapitation results in death by cerebral ischaemia using a guillotine or knife.

b) Requirements for effective use

The required equipment should be kept in good working order.

c) Advantages

The technique is effective and does not require monitoring.

d) Disadvantages

The working area is contaminated with body fluids, which increases biosecurity risks.

Article 3.7.6.18.

Pithing and bleeding

1. Pithing

a) Introduction

Pithing is a method of *killing* animals which have been stunned by a penetrating captive bolt, without immediate death. Pithing results in the physical destruction of the brain and upper regions of the spinal cord, through the insertion of a rod or cane through the bolt hole.

b) Requirements for effective use

i) Pithing cane or rod is required.

ii) An access to the head of the animal and to the brain through the skull is required.

iii) Animals should be monitored continuously until death to ensure the absence of brain stem reflexes.

c) Advantages

The technique is effective in producing immediate death.

d) Disadvantages

i) A delayed and/or ineffective pithing due to convulsions may occur.

ii) The working area is contaminated with body fluids, which increases biosecurity risks.

2. Bleeding

a) Introduction

Bleeding is a method of *killing* animals through the severance of the major blood vessels in the neck or chest that results in a rapid fall in blood pressure, leading to cerebral ischaemia and death.

b) Requirements for effective use

i) A sharp knife is required.

ii) An access to the neck or chest of the animal is required.

iii) Animals should be monitored continuously until death to ensure the absence of brain stem reflexes.

c) Advantages

The technique is effective in producing death after an effective *stunning* method which does not permit pithing.

d) Disadvantages

a) A delayed and/or ineffective bleeding due to convulsions may occur.

b) The working area is contaminated with body fluids, which increases biosecurity risks.

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Annex XXV

CHAPTER 2.9.X.

AETHINA TUMIDA (SMALL HIVE BEETLE) INFESTATION OF HONEY BEES

Community position:

The Community reiterates its previous comment: if Bombus spp must be considered to be susceptible of infestation and a possible way of transmission to Apis mellifera, since it is the object of a growing international trade, notably for use in the greenhouses, it should be included. Thus the title should only be AETHINA TUMIDA (SMALL HIVE BEETLE), and the risk mitigation articles 5, 6 and 7 should include the bumble bees.

The Community is ready to share its experience on inactivation of A. tumida and to help the OIE in further elaborating the chapter and annexes related to that pest.

Article 2.9.X.1.

For the purposes of this chapter, small hive beetle (SHB) is an *infestation* of bee colonies by the beetle *Aethina tumida,* which is ~~an ectoparasite~~ a free-living predator and scavenger affecting populations of the honey bee *Apis mellifera* L. It can also parasitise bumble bee *Bombus terrestris* colonies under experimental conditions, and although *infestation* has not been demonstrated in wild populations, *Bombus* spp. must also be considered to be susceptible to *infestation.*

The adult beetle is attracted to bee colonies to reproduce, although it can survive and reproduce independently in other natural environments, using other food ~~supplies as its nutritional~~ sources, including certain types of fruit. Hence once it is established within a localised environment, it is extremely difficult to eradicate.

The life cycle of *A~~rthina~~. tumida* begins with the adult beetle laying eggs within infested *hives*. These are usually laid in irregular masses in ~~*hive*~~ crevices or brood combs. After 2-6 days, the eggs hatch and the emerging larvae begin to feed ~~vociferously~~ voraciously on brood comb, bee eggs, pollen and honey within the *hive*. The SHB has a high reproductive potential. Each female can produce about 1,000 eggs in its four to six months of life. At maturation (approximately 10-29 days after hatching), the larvae exit the *hive* and burrow into soil around the *hive* entrance. Adult beetles emerge after an average of 3-4 weeks, although pupation can take between 8 and 60 days depending on temperature and moisture levels ~~(usually takes 3 to 4 weeks)~~.

The life span of an adult beetle depends on environmental conditions such as temperature and humidity but, in practice, adult beetles can live for at least 6 months and, in favourable reproductive conditions, the female is capable of laying new egg batches every 5-12 weeks. The beetle is able to survive at least two weeks without food and 50 days on brood combs.

Early signs of *infestation* may go unnoticed, but the growth in the beetle population is rapid, leading to high mortality in the *hive*. Because *A~~rthina~~. tumida* can be found and can thrive within the natural environment, and can fly up to ~~a distance of~~ 6-13km from its nest site, it is capable of dispersing rapidly and directly colonising *hives*. ~~This~~ Dispersal includes following or accompanying swarms. ~~It also does not require direct contact between adult bees to spread *infestation*~~ Spread of infestation does not require contact between adult bees. However, the movement of adult bees, honeycomb and other apiculture products and used

equipment associated with bee-keeping may all cause *infestations* to spread to previously unaffected colonies.

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

Article 2.9.X.2.

The *Aethina tumida* status of a country or *zone* can only be determined after considering the following criteria:

1. a *risk assessment* has been conducted, identifying all potential factors for *Aethina tumida* occurrence and their historic perspective, including *disease*/pest incidence data from permanent official sanitary surveillance of *apiaries* programme;

2. *Aethina tumida* infestation should be notifiable in the whole country, and all clinical signs suggestive of *Aethina tumida* infestation should be subjected to field and laboratory investigations;

3. on-going awareness and training programmes should be in place to encourage reporting of all *cases* suggestive of *Aethina tumida* infestation;

4. the *Veterinary Competent Authority* or other competent authority with responsibility for the health of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the country.

Community comment:

The Competent authority has not the responsibility for the health of the bees, but for the control of their status or possible diseases. Thus in point 3 above, the word "health" should be replaced by "control of diseases".

Article 2.9.X.3.

Country or zone free from *Aethina tumida*

1. Historically free status

   A country or *zone* may be considered free from the *disease* pest after conducting a *risk assessment* as referred to in Article 2.9.X.2. but without formally applying a specific surveillance programme if the country or *zone* complies with the provisions of Article 3.8.1.26.

2. Free status as a result of an eradication programme

   A country or *zone* which does not meet the conditions of point 1 above may be considered free from *Aethina tumida* infestation after conducting a *risk assessment* as referred to in Article 2.9.X.2. and when:

   a) the *Veterinary Competent Authority* or other competent authority with responsibility for the health of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or *zone*;

   b) *Aethina tumida* infestation is notifiable in the whole country or *zone*, and any clinical *cases* suggestive of *Aethina tumida* infestation are subjected to field and laboratory investigations; a contingency plan is in place describing controls and inspection activities;

   c) for the 5 years following the last reported *case* of *Aethina tumida* infestation, an annual survey supervised by the *Veterinary Competent Authority*, with negative results, have has been carried out

on a representative sample of *apiaries* in the country or *zone* to provide a confidence level of at least 95% of detecting *Aethina tumida* infestation if at least 1% of the *apiaries* were infested at a within-*apiary* prevalence rate of at least 5% of the *hives*; such surveys may be targeted towards areas with a higher likelihood of *infestation*;

d) to maintain free status, an annual survey supervised by the *Veterinary Competent Authority*, with negative results, is carried out on a representative sample of *apiaries* in the country or *zone* to indicate that there has have been no new *cases*; such surveys may be targeted towards areas with a higher likelihood of *infestation*;

e) all equipment associated with previously infested *apiaries* has been destroyed, or cleaned and sterilised to ensure the destruction of *Aethina tumida* spp., in conformity with one of the procedures referred to in Appendix X.X.X. (under study);

f) the soil and undergrowth in the immediate vicinity of all infested *apiaries* has been treated with a soil drench or similar suitable treatment that is efficacious in destroying incubating *Aethina tumida* larvae and pupae;

g) the importation of the *commodities* listed in this Chapter into the country or *zone* is carried out, in conformity with the recommendations of this Chapter.

Article 2.9.X.4.

Regardless of the status of the *exporting country* with regard to *Aethina tumida* infestation, *Veterinary Competent Authorities* should authorise without restriction the import or transit through their territory of the following *commodities*:

1. honey bee semen and honey bee venom;

2. packaged extracted honey, refined or rendered beeswax, propolis and frozen or dried royal jelly.

Article 2.9.X.5.

Veterinary Competent Authorities of *importing countries* should require:

for individual consignments containing a single live queen honey bee, accompanied by a small number of associated attendants (a maximum of 20 attendants per queen)

Community comment:

The words "or queen bumble bee" should be added after the words "queen honey bee".

the presentation of an *international veterinary certificate* attesting that the bees come from a country or *zone* officially free from *Aethina tumida* infestation

OR

the presentation of an *international veterinary certificate* including an attestation from the *eCompetent aAuthority* of the exporting third country stating that:

1. the bees come from *hives* or colonies which were inspected immediately prior to dispatch and show no clinical signs or suspicion of the presence of *Aethina tumida* or its eggs, larvae or pupae; and

2. come from an area of at least 100 km radius where no *apiary* has been subject to any restrictions associated with the occurrence of *Aethina tumida* for the previous 6 months; and

3. the bees and accompanying packaging presented for export have been thoroughly and individually inspected and do not contain *Aethina, tumida* or its eggs, larvae or pupae; and

4. the consignment of bees is covered with fine mesh through which a live beetle cannot enter.

Community comment:

This point 4 should be also stated in article 6 and 7 as it is intended to protect the consignment from infestation.

Article 2.9.X.6.

Veterinary Competent Authorities of *importing countries* should require:

for live worker bees, drone bees or bee colonies with or without associated brood combs

Community comments:

The words "or for live bumble bees" should be added at the end of the above line.

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

1. come from a country or *zone* officially free from *Aethina, tumida* infestation,

and AND

2. the bees and accompanying packaging presented for export have been inspected and do not contain *Aethina, tumida* or its eggs, larvae or pupae.

Article 2.9.X.7.

Veterinary Competent Authorities of *importing countries* should require:

for eggs, larvae and pupae of honey bees

Community comments:

The words "or bumble bees" should be added after the words "honey bees".

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

1. were sourced from a free country or *zone* (under study);

Community comment:

The point 1 above should read: "were sourced from a country or zone free from Aethina tumida infestation".

OR

2. have been isolated from queens in a *quarantine station*; and

3. are from *hives* or come from *hives* or colonies which were inspected immediately prior to entry into the *quarantine station* and show no clinical signs or suspicion of the presence of *Aethina, tumida* or its eggs or larvae or pupae then and during the quarantine period.

Community comment:

The certificate should be amended to be based upon risk management measures at source rather than in a quarantine station (which something difficult to apprehend for bees). Thus points 2 and 3 should be replaced by the following:

2. have been bred and kept under a controlled environment within a recognised establishment which is supervised and controlled by the competent authority,

3. the establishment referred to above was inspected immediately prior to dispatch and all eggs, larvae and pupae show no clinical signs or suspicion of the presence of *Aethina tumida* or its eggs or larvae or pupae and

4. the packaging material, containers, accompanying products and food are new and all precautions have been taken to prevent contamination with *Aethina tumida* or its eggs, larvae or pupae.

Article 2.9.X.8.

~~*Veterinary*~~ *Competent Authorities* of *importing countries* should require:

for used equipment associated with beekeeping

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

1. the equipment:

   EITHER

   a) comes from a country or *zone* free from *A~~ethina~~. tumida* infestation; and

   b) contains no live honey bees or bee brood;

   OR

   c) contains no live honey bees or bee brood;and

   d) has been thoroughly cleaned, and treated to ensure the destruction of *A~~ethina~~. tumida* spp., in conformity with one of the procedures referred to in Appendix XXX (under study); and

2. all precautions have been taken to prevent *infestation*/contamination.

Article 2.9.X.9.

~~*Veterinary*~~ *Competent Authorities* of *importing countries* should require:

for honey-bee collected pollen and beeswax (in the form of honeycomb)

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

1. the products:

   EITHER

   a) comes from a country or *zone* free from *A~~ethina~~. tumida* infestation; and

   b) contains no live honey bees or bee brood;

   OR

c) contains no live honey bees or bee brood; and

d) has been thoroughly cleaned, and treated to ensure the destruction of *Aethina. tumida* spp., in conformity with one of the procedures referred to in Appendix X.X.X. (under study); and

2. all precautions have been taken to prevent *infestation*/contamination.

Article 2.9.X.10.

Veterinary Competent Authorities of *importing countries* should require:

for comb honey

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

1. comes from a country or *zone* free from *Aethina. tumida* infestation; and

2. contains no live honey bees or bee brood.

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Annex XXVI

APPENDIX 3.X.X.

GUIDELINES FOR SOMATIC CELL NUCLEAR TRANSFER IN PRODUCTION LIVESTOCK AND HORSES

Community position:

The Community can support the proposed Appendix, but has one comment.

This draft was not presented to the former Code Commission meetings, and it is extremely difficult to have a sound opinion in such a short period of time. This document should have been proposed for comments.

PREFACE

Following the first meeting of the OIE *ad hoc* Group on Biotechnology held from 3 to 5 April 2006, the Biological Standards Commission suggested restricting the mandate "to develop guidelines on the animal health risks arising from somatic cell nuclear transfer (SCNT) cloning of production animals, including criteria for assessing the health of embryos and animals derived from such cloning." The following document is a starting point for identifying, characterising and providing a basis for discussion on the animal health risks associated with SCNT cloning technology.

Overview

At the first meeting of the *ad hoc* Group on Biotechnology, it was recommended that the Subgroup on Reproductive Animal Biotechnologies should draft guidelines on risk analysis, based on the life-cycle approach, for biotechnology-derived animals. The definition of 'Reproductive Animal Biotechnology' was proposed as "the generation of animals through the use of assisted reproductive technologies (ART), which range from artificial insemination through to technologies involving a significant *in-vitro* component, such as *in-vitro* fertilisation, embryo transfer, embryo splitting and including asexual reproduction such as nuclear transfer". The following ~~draft~~ text is restricted to SCNT and is based on a risk analysis approach to biotechnology-derived animals categorised according to the life-cycle approach consisting of: i) embryos, ii) recipients, iii) offspring, and iv) progeny of animal clones.

Scope

These guidelines address animal health aspects of production animals derived from some reproductive biotechnologies.

Recognising the mandate of the OIE and the suggestion of the Biological Standards Commission, it is the recommendation of the *ad hoc* Group on Biotechnology to identify risk analysis parameters for animal health and their implication for environmental safety and food and feed safety. These guidelines will focus initially on the scientific basis for the risk assessment aspects, prevention measures and guidance for production livestock and horses derived from ~~ART~~ SCNT cloning. This is without prejudice to the addition of any relevant issue at a later stage. At present, these guidelines include the following:

- Identification of animal health risks and recommendations for management of those risks in embryos, recipients, animal clones and progeny of clones;

- Risk and prevention measures related with SCNT cloning technology;
- Some welfare issues related to animal health.

Recognising further that the following issues have been discussed or may be addressed by other bodies or instruments, or that they may be addressed at a later stage by the OIE, the document does not address:

- Safety and nutritional aspects of food derived from ART, for example transgenics (addressed by Codex);
- Risks related to the environmental release of animal clones;
- Risks related to transgenic animals that have not involved SCNT or other cloning technology;
- Non-reproductive animal biotechnologies;
- Risks related to animals produced for xenotransplantation or organ donors;
- Technologies related to stem cells;
- Risk related to aquatic animal health, including fish clones;
- Risks related to other terrestrial animals, such as wild mammals and non-mammals, including avian species and insects

Background

Risk analysis– general principles

Risk analysis in general includes hazard identification, risk assessment, risk management and risk communication. The risk assessment is the component of the analysis that estimates the risks associated with a *hazard* (~~OIE *Terrestrial Animal Health Code* [*Terrestrial Code*], 2006,~~ see Chapter 1.3.1.). These principles are routinely used by regulators in making decisions about experimental or commercial releases. These analyses can then be used to determine whether the outcomes require management or regulation. Risk management is the process by which risk managers evaluate alternative actions or policies in response to the result(s) of the risk assessment taking into consideration the various social, economic, and legal considerations that form the environment in which such activities occur.

For animal diseases, particularly those listed in the ~~OIE~~ *Terrestrial Code*, there is broad agreement concerning the likely risks and these risks can be qualitative or quantitative (~~OIE *Terrestrial Code*,~~ see Chapter 1.3.1). In disease scenarios it is more likely that a qualitative risk assessment is all that is required. Qualitative assessments do not require mathematical modelling to carry out routine decision-making. Quantitative or semi-quantitative risk assessments assign magnitudes to the risks in numerical (e.g. 1/1,000,000) or ~~verbal~~ descriptive (high/medium/low) terms.

In the context of animal cloning, two broad categories of risk assessments are considered: absolute risk assessment and comparative risk assessments. Absolute risk assessments characterise risk independent of a comparator (e.g. the likelihood of an animal transmitting a specific livestock disease). A comparative risk assessment (or relative risk assessment) puts the risk in the context of a comparator. For example the degree to which an animal produced by one reproductive technology can transmit a particular disease to another animal of the same species compared with the degree to which a similar animal produced by another reproductive technology transmits the same disease to another animal of same species.

Regardless of the methodology used, hazard identification is an early step in all science-based risk assessments. In the context of assessing the risks associated with animal cloning (SCNT) and starting with the embryo and moving on through animal clone development and subsequent progeny, it is important to be clear at this juncture that only a comparative semi-quantitative risk assessment can be completed. A

systematic, absolute, quantitative risk assessment of potential risks is difficult, due to the relative newness of the technology, and the variability in outcomes among laboratories and species cloned. Furthermore, with the technology of SCNT there is no introduced hazard from the insertion of novel genes (which may potentially happen in transgenesis). Thus, to analyse what factors contribute to animal health risks, the existing baseline must be analysed.

In short, the specific points where the risk assessment needs to be focused need to be identified. As illustrated in the accompanying diagram – the focus is to look at the basics of creating an embryo – using current terminology, starting from the selection of donor of oocyte and the cells to the creation of an embryo by the cloning methodology. The second phase will focus on the recipient of the embryo clone and the animal health and care considerations for the animals. The actual embryo clone that is born as an offspring is the third part of the paradigm that needs clear guidelines for assessment, and the next generation, either the progeny of the animal clone (which is a result of normal sexual reproduction) or animals produced by recloning (clones of clones) is the fourth and final stage.

Managing Animal Health Risks associated with embryos

Embryo production by *in-vitro* techniques has been applied for many years. Although the additional steps involved in cloning add a new dimension to this procedure, many of the risks associated with SCNT have previously been identified for established ART (~~OIE *Terrestrial Code*~~, see Appendix 3.3.2.). An analysis of SCNT methodology allows the procedural details to be categorised into:

i) Oocytes (obtained from the abattoir, recovered from trans-vaginal ultrasound-guided procedures or by laparotomy procedures).

   The primary risks are associated with the health status of the animal from which the ovaries are harvested and the quality of the oocytes.

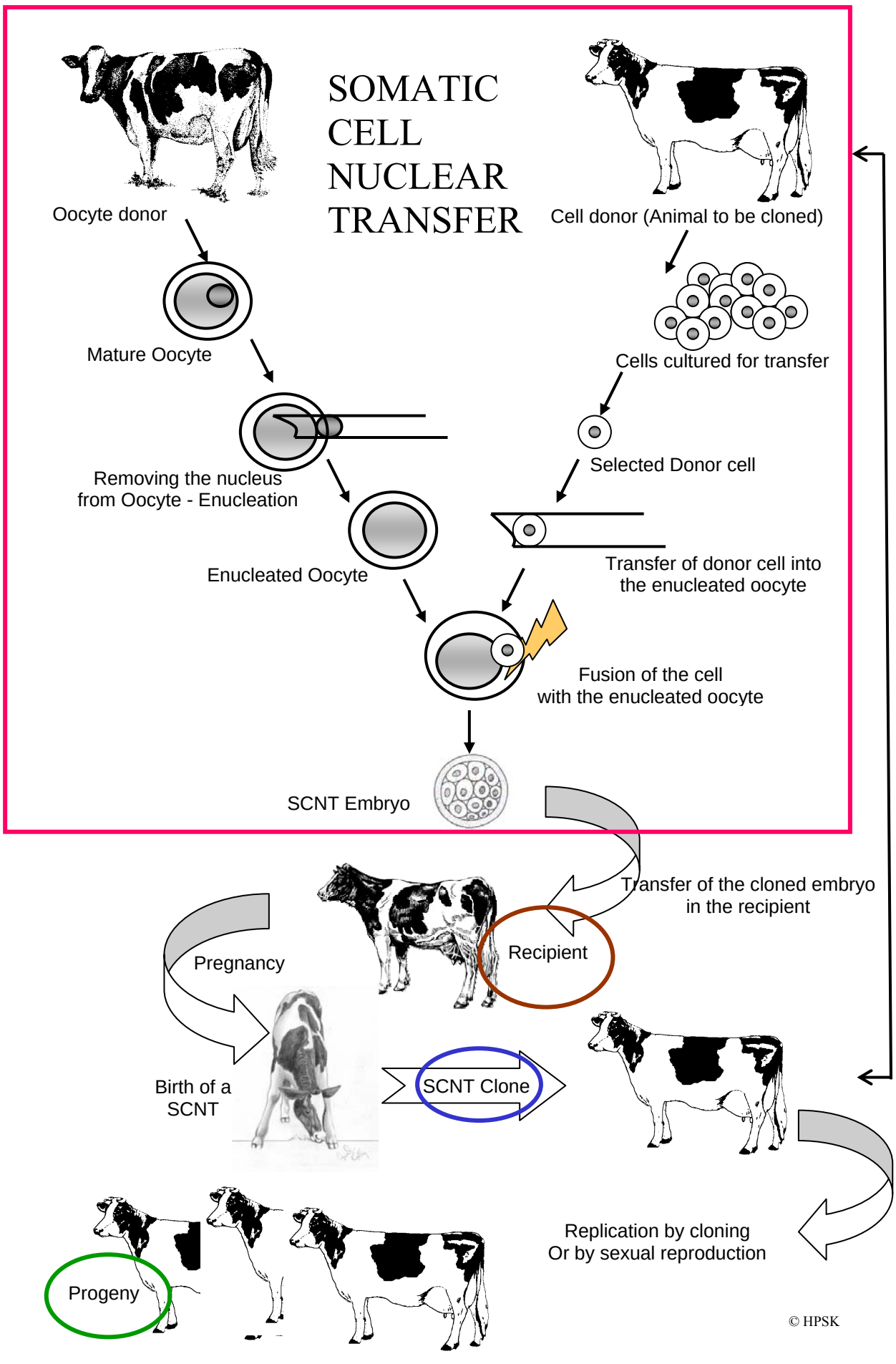
ii) Donor cells (cells obtained from animals chosen to be cloned – by biopsy, harvesting at slaughter or after death).

   Currently there are no specific new risks identified with SCNT cloning. There is a proposed risk related to activation of endogenous retroviruses during cell transfer procedures, however, this may be more theoretical than practical. In some current experimental procedures, the donor cell may be treated with chemicals to modify its composition, for example cell cycle inhibitors or chromatin modifiers.

iii) *In-vitro* culture of reconstructed embryos (procedure used to fuse the donor and recipient material and to culture the reconstructed embryo).

   Risks associated with the method of fusing donor cells with enucleated recipient oocytes and with culture conditions.

In addition, the practitioner should ensure that the clone pregnancy is compatible to the surrogate dam's breed, anatomy and physiology.


SOMATIC CELL NUCLEAR TRANSFER
Oocyte donor
Cell donor (Animal to be cloned)
Mature Oocyte
Cells cultured for transfer
Selected Donor cell
Removing the nucleus from Oocyte - Enucleation
Enucleated Oocyte
Transfer of donor cell into the enucleated oocyte
Fusion of the cell with the enucleated oocyte
SCNT Embryo
Transfer of the cloned embryo in the recipient
Recipient
Pregnancy
Birth of a SCNT
SCNT Clone
Progeny
Replication by cloning Or by sexual reproduction
© HPSK

Oocytes

- The laboratory or the producer should establish a detailed record of ovaries – their origin, health of the animal from which the ovaries are obtained, details of any systemic lesion on the animal and proper herd data. This is particularly useful where the pooling of ovaries may provide cross-contamination of ovarian tissue.

- Follicular fluids may carry various infectious agents like bovine viral diarrhoea virus (BVDV) and can contaminate pooled follicular fluid from healthy animals. Furthermore, the technique for collecting oocytes, such as aspiration or slicing of the ovarian follicles, determines the extent of blood contamination or extraneous material. A representative sample to demonstrate the absence of infectious biological material should be done with each pooled batch.

- Oocytes are matured as cumulus oocyte complexes (COCs) and then matured in most instances in the culture/maturation media. Care and efforts should be taken to carefully select and mature the oocytes from the pools that are morphologically good; also the media used should have been quality tested. Use of serum or protein components from an undefined or untested source should be avoided. Addition of proper and safe antibiotics in the culture media to control opportunistic bacteria should be encouraged.

- Use of proper sanitary and disinfection procedures is of utmost importance and should be emphasised in any *in-vitro* fertilisation (IVF) laboratory. Proper handling and following sanitary protocols during the maturation and further culture of embryos should be encouraged.

Donor cells

In order to minimise risks

- Donor cells should be properly harvested from the animal and cultured under proper sanitary conditions using good laboratory practices.

- When applicable, the passaging of the cells used for the cloning procedure should be documented and at different stage sampling may be warranted to look at the chromosomal component of the cell lines. If possible, procedures should be in place for regular sampling of the cells for morphological and other characteristics.

- Master cell lines (to be used for cloning at a later stage) should be stored under conditions found to be optimal for maintaining viability. Freedom from extraneous agents should be established by testing for bacteria, fungi, mycoplasmas or viruses, using appropriate tests (IETS Manual~~, 1998~~). –

Cloning procedures/ reconstruction

- The cloning procedure that employs the use of chemicals or other reagents should be carefully evaluated, in terms of the quality of embryos and overall efficiency.

- During the fusion of recipient and donor material by chemical or physical means care and control should be employed. The optimisation of the procedure based on the laboratory protocols or published reports should be determined to avoid early embryonic mortalities.

- If co-culture of the cell is used for the culture procedure after reconstruction of embryos, proper screening of the co-culture cells should be done. A sample of each batch may be tested for the bacterial, fungal, mycoplasmal or viral component.

- Embryos should be cultured and harvested for an appropriate time and stage to transfer them or to cryo-preserve them for later use. Proper procedures based on the international standards (IETS Codes of Practice) for washing and preservation of the embryos should be followed.

- Care should be taken with regard to grading the embryos before transfer (~~*OIE Terrestrial Code*~~, Appendices 3.3.1 and 3.3.2).

Managing animal health risks related to the recipients (surrogate dams)

1. Animal health risks to the surrogate dams

Currently, when compared with *in-vitro* produced embryos, SCNT has a higher rate of pregnancy failure and, in some species, placental abnormalities. Loss due to defects in the embryo or failure to implant in the uterus of the surrogate dam does not pose a hazard to the dam. Rather, the surrogate dam simply resorbs any embryonic tissue and returns to cycling. Mid- and late-term spontaneous abortions may be hazardous to surrogates if they are unable to expel the fetus and its associated membranes. Most abortions in natural service and artificial insemination (AI) pregnancies in cattle remain undiagnosed due to the expense of laboratory work and the low profit margin in both the beef and dairy industry. Producers and veterinarians become concerned when the rate of abortion exceeds 3–5% in a herd. The same potential impact of external influences should be considered with pregnancy evaluation with SCNT and other reproductive technologies. Disease, under-nutrition, and severe environmental conditions are stressors known to interfere with animal fertility and embryo survival. Under these circumstances, the risk to the pregnancy is directly related to stress factors and not to the technology used.

To date, a species-specific effect has been seen. Abnormalities in clones may result from incomplete reprogramming of the donor nucleus. Epigenetic reprogramming occurs at different times in embryos in different species. Many of the abnormalities reported in cattle and sheep pregnancies have not been noted in goats or swine carrying SCNT clones. The amount of *in-vitro* manipulation of an embryo inversely correlates to the chances for successful pregnancy outcomes. This has been observed in both SCNT embryos and *in-vitro* produced fertilised embryos. Unlike other forms of other reproductive technologies SCNT pregnancy losses occur at all stages of gestation in cattle. Clone pregnancies have been lost during the second and third trimesters and have been accompanied by reports of hydrops, enlarged umbilicus, and abnormal placentation.

2. Animal health risks posed by the surrogate dam to the clone embryos

No new animal health risks have been identified for the developing clone fetus from the surrogate dam compared with conventional pregnancies. The latter include vertically transmitted diseases and abnormalities due to metabolic or physiological stress.

With respect to the animal health risks associated with the surrogate dam, it is difficult to document the relative frequency of early stage losses of SCNT embryos compared with early stage losses of other pregnancies as these abortions are not typically diagnosed with other reproductive technologies. Additionally, external stressors will similarly impact SCNT pregnancies.

Veterinarians should monitor the progress of pregnancy as the common gestational anomalies seen in other assisted reproductive technologies may be exhibited and diagnosed during the physical examination. A database of commonly encountered problems in clone pregnancies would be useful if available to animal health experts.

- Care should be taken to assess the general health of the recipient dam before selection to carry the embryo clones. The general health status of the recipient should be determined in terms of freedom from infection and disease, proper vaccination and follow up, and, if applicable, proof of earlier uneventful pregnancies, absence of birthing problems, and proper post-pregnancy recovery.

- Pregnancy loss is greatest with SCNT embryos prior to 60 days' gestation in cattle. This is similar to the pattern seen with other reproductive technologies. However, in clones, high pregnancy losses during this time of placental formation (between 45–60 days) suggest that embryonic death may be a consequence of faulty placentation. Abnormal placentation may lead to a build up of wastes in the fetus and associated membranes, or inadequate transfer of nutrients and oxygen from the dam to the fetus. Care should be taken to monitor the recipient dam during pregnancy. Once the pregnancy is established and confirmed, regular veterinary assessments and monitoring of animal health status is desirable up to the birth of the offspring.

- To ensure that the recipient is pregnant and to monitor its health during the first trimester, it is useful to perform ultrasonographic assessments, determine hormonal profiles and assess the general physiological parameters. Based on these profiles, proper attention should be paid to aid in the proper establishment of pregnancy by providing proper husbandry conditions and nutrition.

- The animals should be observed carefully for the signs of labour nearing the time of birth. In some species, one of the more common problems is uterine inertia and the absence of contractions. The absence of contractions may result in prolonged pregnancies with associated sequellae that may require assistance with deliveries.

- A surgical intervention should be decided and should be available for the near term animal if the situation so warrants. Proper procedures should be employed to ascertain the proper handling of the offspring and the surrogate dam.

- Health concerns may arise as a result of surgical procedures, excessive traction, or other complications such as retained fetal membranes. In these cases *post-partum* care may be necessary.

Managing animal health risks of animal clones

The health problems of individual clones can be observed *in utero* and *post-partum*. These appear to be the same as observed in other ART, but they may be more common in clones. It is important to determine whether the abnormalities are of genetic or epigenetic origin. Large offspring syndrome (LOS) and placental abnormalities are particularly observed in sheep and cattle.

Community comment:

The Community propose the following wording for the last sentence or the above paragraph:

Large offspring syndrome (LOS), probably in relation to placental abnormalities rather than fetal abnormalities, have been particularly observed in cloned cattle and sheep following suboptimal in vitro handling.However, these pathologies are becoming less frequent in small ruminants (yet seen in less than 50% of cloved cattle with hydro allantois).

Rationale: see attached ref 1, 2 and 3.

- Appropriate husbandry practices are important to the health of animal clones. Care should be taken to provide colostrums and a clean and hygienic environment, supervision for the first few weeks after birth should be practiced.

- The animal clones must be checked routinely for the most common phenotypic anomalies, such as atresia anii, umblical hernia, flexor muscle contractions, respiratory or cardiac insufficiency, and failure to suckle. This will allow proper treatment and care of the newborn and increase the survival of the young one.

- To consolidate current understanding of the health status of animal clones, a comprehensive veterinary examination should be performed to monitor the progress of the clone, as unexplained fatalities or fatalities arising from systemic complications have been reported. It is encouraged to follow the health profile of the animals to at least the reproductive maturity stage, and to record the ability to reproduce (fertility index).

- Animal welfare concerns ranging from LOS to serious abnormalities are notable in the debates pertaining to cloning technology. Proper research and peer-reviewed data should be generated. The animal clones should undergo species-specific basic welfare assessments. If welfare concerns are detected at initial screening, a more extensive characterisation of that phenotype should be performed to document the animal welfare concerns.

- Proper monitoring of the animal population during different stages of life from birth to puberty should be documented to address and validate the genomic potential of the animal clones.

Managing animal health risks related to sexually reproduced progeny of clones

Presently there is no evidence of an increased health risk if sexual reproduction is used for obtaining progeny. Some data indicate that the reprogramming errors during the cloning process may actually be corrected during the natural mating and reproduction process.

- Characterisation of the health profile, including health status and data on animal welfare, would consolidate the knowledge of sexually reproduced progeny.

- Monitoring the reproductive performance of sexually reproduced progeny of clones would be useful to assess their reproductive capacity in comparison with their conventional counterparts.

Managing animal health risks associated with re-cloning/clones of clones

Information on recloning is only beginning to appear. It is therefore necessary to follow the approach below:

- The health profile (health status and data on animal welfare) should be characterised to consolidate the knowledge.

- The reproductive performance of clones of clones should be monitored to assess the capacity of the animals to perform in comparison with their conventional counterparts.

Review of guidelines

The goal of these guidelines is to provide a scientific basis and recommendations on animal health and welfare risks to animals involved in SCNT cloning compared with other ART. These guidelines will focus initially on the scientific basis for the risk assessment aspects, prevention measures and guidance for production livestock and horses, derived from ~~ART~~ SCNT cloning and should be reviewed in light of new scientific information.

~~***Glossary:***~~

~~**Hazard: (as defined in OIE)**~~

~~Hazard means a biological, chemical or physical agent, or a condition of, an animal or animal product with the potential to cause an adverse health effect.~~

~~A hazard is an element or event that poses potential harm; an adverse event or adverse outcome. A hazard is identified by describing what might go wrong and how that might happen. Covello and Merkhofer defined a hazard as a (potential) source of risk that does not necessarily produce risk. A hazard produces risk only if an exposure pathway exists and if exposures create that possibility of adverse consequences.~~

~~Hazard identification is the process of identifying new agents in sources of risk. Risk sources may release risk agents into the environment.~~

~~**Risk:**~~

~~Risk means the likelihood of the occurrence and likely the magnitude of consequences of an adverse event to animal or human health during a specified time period, as a result of hazard.~~

~~The likelihood of the occurrence and the magnitude of the consequences of an adverse event; a measure of the probability of harm and the severity of impact of a hazard. Objective measurement and scientific repeatability are hallmarks of risk. In risk studies it is common, especially in oral communication, to use "risk" synonymously with the likelihood (probability or frequency) of occurrence of a hazardous event. In such instances, the magnitude of the event is assumed to be significant.~~

~~**Risk analysis:**~~

~~Risk analysis means the process composed of hazard identification, risk assessment, risk management and risk communication.~~

~~The process of risk analysis includes risk assessment, risk management and risk communication.~~

~~**Risk Assessment:**~~

~~Risk assessment means the evaluation of the likelihood and biological and economic consequences of entry, establishment, or spread of a pathogenic agent.~~

~~The process of identifying a hazard and evaluating the risk of a specific hazard, either in absolute or relative terms. The risk assessment process involves four interrelated assessment steps: release assessment, exposure assessment, consequence assessment and risk estimation. It includes estimates of uncertainty in process, and is an objective, repeatable, scientific process. Quantitative risk assessment characterises the risk in numerical representations. Qualitative risk assessment characterises the outputs on the likelihood of the outcome or the magnitude of the consequences in qualitative terms such as "high", "medium", "low" or "negligible".~~

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Annex XXVII

APPENDIX 3.3.5.

CATEGORISATION OF DISEASES AND PATHOGENIC AGENTS BY THE INTERNATIONAL EMBRYO TRANSFER SOCIETY

Community position:

The Community can support the proposed changes, but has one comment on scrapie, that could be reassessed and possibly moved to category 1.

Article 3.3.5.1.

In 2004, the Research Subcommittee of the International Embryo Transfer Society (IETS) Health and Safety Advisory Committee again reviewed available research and field information on infectious diseases which have been studied regarding the risk of their transmission via in vivo derived embryos. As a result of this review, the IETS has categorised the following diseases and pathogenic agents into four categories. Please note that this categorisation applies only to in vivo derived embryos.

The following methodology is used by the Research Subcommittee to categorise infectious diseases with regard to the risk of their transmission:

1. Research procedures used to handle and process the embryos will comply with criteria that have been set out by A. Bielanksi and W.C.D. Hare in Appendix A of the IETS Manual1.

2. The data used by the Subcommittee to categorise or re-categorise diseases will have been published in peer-reviewed articles in reputable scientific journals. This is to ensure that scientific procedures and results, as well as the interpretation of results, have undergone another level of review.

3. Decisions regarding disease categorisation are based on a consensus judgement which is taken annually by the Subcommittee. The names of members of the Subcommittee who are present when the decisions are made are recorded, as are the names of any others whose opinions were solicited in the decision making process.

4. Questions considered in the decision-making process include the following:

    a) What is the nature of the disease? For example, is the causal agent a uterine pathogen? Does it occur in blood? Does it persist in blood? Do asymptomatic shedders occur? What is the minimum infective dose?

    b) Has the causal agent been found in the ovarian/oviductal/uterine (OOU) environment?

    c) Is the causal agent's presence in the OOU environment incidental or is it a consequence of the pathogenesis of the disease?

d) Is the causal agent's presence in the OOU environment consistent with obtaining viable embryos?

e) Has the causal agent been found in flushing fluids?

f) Has the causal agent been found to penetrate or cross the intact zona pellucida (ZP)?

g) Has the causal agent been found to adhere to the ZP?

h) Is the causal agent removed by washing the embryo?

i) Will special treatments (e.g. with trypsin) remove or inactivate the causal agent?

j) How many embryos have been transferred with or without disease transmission?

k) What is the accumulated evidence for non-transmission of the disease by embryo transfer?

l) What evidence is there that the disease could be transmitted by embryo transfer?

m) Have negative (or positive) results been duplicated by the same or different investigators?

n) Has evidence been accumulated for different animal species as well as for a range of different types and strains of the causal agent?

Article 3.3.5.2.

Category 1

Category 1 diseases or pathogenic agents are those for which sufficient evidence has accrued to show that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual1.

The following diseases or pathogenic agents are in category 1:

- Bluetongue (cattle)
- Bovine spongiform encephalopathy (cattle)
- Brucella abortus (cattle)
- Enzootic bovine leukosis
- Foot and mouth disease (cattle)
- Infectious bovine rhinotracheitis: trypsin treatment required
- Aujeszky's disease (pseudorabies) (swine): trypsin treatment required.

Article 3.3.5.3.

Category 2

Category 2 diseases are those for which substantial evidence has accrued to show that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual1, but for which additional transfers are required to verify existing data.

The following diseases are in category 2:

- Bluetongue (sheep)
- Caprine arthritis/encephalitis
- Classical swine fever (hog cholera)
- Scrapie (sheep).

Community comment:

As more and more relevant data and sufficient evidence show that scrapie do not present risk of transmission through ET, the category of this disease should be reassessed to evaluate its move to category 1.

Article 3.3.5.4.

Category 3

Category 3 diseases or pathogenic agents are those for which preliminary evidence indicates that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual1, but for which additional in vitro and in vivo experimental data are required to substantiate the preliminary findings.

The following diseases or pathogenic agents are in category 3:

- Bovine immunodeficiency virus
- Bovine spongiform encephalopathy (goats)
- Bovine viral diarrhea virus (cattle)
- Campylobacter fetus (sheep)
- ~~Caprine arthritis/encephalitis~~
- Foot and mouth disease (swine, sheep and goats)
- Haemophilus somnus (cattle)
- Maedi-visna (sheep)
- Mycobacterium paratuberculosis (cattle)
- Neospora caninum (cattle)
- Ovine pulmonary adenomatosis
- Porcine reproductive and respiratory disease syndrome (PRRS)
- Rinderpest (cattle)
- Swine vesicular disease.

Article 3.3.5.5.

Category 4

Category 4 diseases or pathogenic agents are those for which studies have been done, or are in progress, that indicate:

1. that no conclusions are yet possible with regard to the level of transmission risk; or

2. the risk of transmission via embryo transfer might not be negligible even if the embryos are properly handled according to the IETS Manual1 between collection and transfer.

The following diseases or pathogenic agents are in category 4:

- African swine fever
- Akabane (cattle)
- Bovine anaplasmosis
- Bluetongue (goats)
- Border disease (sheep)
- Bovine herpesvirus-4
- Contagious equine metritis
- Chlamydia psittaci (cattle, sheep)
- Enterovirus (cattle, swine)
- Escherichia coli 09:K99 (cattle)
- Equine rhinopneumonitis
- Leptospira borgpetersenii serovar hardjobovis (cattle)
- Leptospira sp. (swine)
- ~~Maedi-visna (sheep)~~
- Mycobacterium bovis (cattle)
- Mycoplasma spp. (swine)
- Ovine epididymitis (Brucella ovis)
- Parainfluenza-3 virus (cattle)
- Parvovirus (swine)
- Porcine circovirus (type 2) (pigs)
- Scrapie (goats)
- Trichomonas foetus (cattle)
- Ureaplasma/Mycoplasma spp. (cattle, goats)
- Vesicular stomatitis (cattle, swine).

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1 Manual of the International Embryo Transfer Society ~~(1998)~~.

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Annex XXVIII

THE ROLE OF THE VETERINARY SERVICES IN FOOD SAFETY

Community position:

The Community can support the proposed paper, which should have a numbering.

The purpose of this paper is to provide guidance to OIE Members in regard to the role and responsibilities of *Veterinary Services* in food safety, to assist them in meeting the food safety objectives laid down in national legislation and the requirements of importing countries.

Definitions

The following definitions, from the *Terrestrial Animal Health Code* (the *Code*) (1), are relevant to this paper. Throughout the paper, terms that are defined in the *Code* appear in italics.

Veterinarian means a person registered or licensed by the relevant *veterinary statutory body* to practice veterinary medicine/science in that country.
Veterinary Services means the governmental and non-governmental organisations that implement animal health and welfare measures and other standards and guidelines in the OIE Terrestrial Animal Health Code (*Terrestrial Code*) and Aquatic Animal Health Code (*Aquatic Code*) in the country. The *Veterinary Services* are under the overall control and direction of the *Veterinary Authority*. Private veterinary organisations are normally accredited or approved to deliver functions by the *veterinary authority*.

Veterinary Authority means the governmental authority of a Member Country, comprising *veterinarians*, other professionals and paraprofessionals, having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and guidelines in the *Terrestrial Code* in the whole country.

The *Veterinary Statutory Body* is an autonomous authority regulating *veterinarians* and veterinary para-professionals.

Zoonosis means any disease or infection that is naturally transmissible from animals to man.

Background

Historically, the *Veterinary Services* were set up to control livestock diseases at the farm level. There was an emphasis on prevention and control of the major epizootic diseases of livestock and of diseases that could affect man (zoonotic diseases). As countries begin to bring the serious diseases under control, the scope of official animal health services normally increases to address production diseases of livestock, where control leads to more efficient production and/or better quality animal products.

The role of the *Veterinary Services* has traditionally extended from the farm to the slaughterhouse, where *veterinarians* have a dual responsibility – epidemiological surveillance of animal diseases and ensuring the safety and suitability of meat. The education and training of *veterinarians*, which includes both animal health (including zoonoses) and food hygiene components, makes them uniquely equipped to play a central role in ensuring food safety, especially the safety of foods of animal origin. As described below, in addition to *veterinarians*, several other professional groups are involved in supporting integrated food safety approaches throughout the food chain. In many countries the role of the *Veterinary Services* has been extended to include subsequent stages of the food chain in the "farm to fork" continuum (2, 3).

Approaches to food safety

The concept of the food production continuum

Food safety and quality are best assured by an integrated, multidisciplinary approach, considering the whole of the food chain. Eliminating or controlling food hazards at source, i.e. a preventive approach, is more effective in reducing or eliminating the risk of unwanted health effects than relying on control of the final product, traditionally applied via a final 'quality check' approach. Approaches to food safety have evolved in recent decades, from traditional controls based on good practices (Good Agricultural Practice, Good Hygienic Practice, etc), via more targeted food safety systems based on hazard analysis and critical control points (HACCP) to risk-based approaches using food safety risk analysis (4).

Risk-based management systems

The development of risk-based systems has been heavily influenced by the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement"). This Agreement stipulates that signatories shall ensure that their sanitary and phytosanitary measures are based on an assessment of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by relevant international organizations. Risk assessment, the scientific component of risk analysis, should be functionally separated from risk management to avoid interference from economic, political or other interests. The SPS Agreement specifically recognises as the international benchmarks the standards developed by the OIE for animal health and zoonoses and by the Codex Alimentarius Commission for food safety. In recent decades there has also been a trend towards a redefinition of responsibilities. The traditional approach, whereby food operators were primarily held responsible for food quality while regulatory agencies were charged with assuring food safety, has been replaced by more sophisticated systems that give food operators primary responsibility for both the quality and the safety of the foods they place on the market. The role of the supervisory authorities is to analyse scientific information as a basis to develop appropriate food safety standards (both processing and end product standards) and monitoring to ensure that the control systems used by food operators are appropriate, validated and operated in such a way that the standards are met. In the event of non-compliance, regulatory agencies are responsible to ensure that appropriate sanctions are applied.

The *Veterinary Services* play an essential role in the application of the risk analysis process and the implementation of risk based recommendations for regulatory systems, including the extent and nature of veterinary involvement in food safety activities throughout the food chain, as outlined below. Each country should establish its health protection objectives, for animal health and public health, through consultation with stakeholders (especially livestock producers, processors and consumers) in accordance with the social, economic, cultural, religious and political contexts of the country. These objectives should be put into effect through national legislation and steps taken to raise awareness of them both within the country and to trading partners.

Functions of Veterinary Services

The *Veterinary Services* contribute to the achievement of these objectives through the direct performance of some veterinary tasks and through the auditing of animal and public health activities conducted by other government agencies, private sector *veterinarians* and other stakeholders. In addition to *veterinarians*, several other professional groups are involved in ensuring food safety throughout the food chain, including analysts, epidemiologists, food technologists, human and environmental health professionals, microbiologists and toxicologists. Irrespective of the roles assigned to the different professional groups and stakeholders by the administrative system in the country, close cooperation and effective communication between all involved is imperative to achieve the best results from the combined resources. Where veterinary or other professional tasks are delegated to individuals or enterprises outside the *Veterinary Authority*, clear information on regulatory requirements and a system of checks should be established to monitor and verify performance of the delegated activities. The *Veterinary Authority* retains the final responsibility for satisfactory performance of delegated activities.

At the farm level

Through their presence on farms and appropriate collaboration with farmers, the *Veterinary Services* play a key role in ensuring that animals are kept under hygienic conditions and in the early detection, surveillance and treatment of animal diseases, including conditions of public health significance. The *Veterinary Services* may also provide livestock producers with information, advice and training on how to avoid, eliminate or control food safety hazards (e.g. drug and pesticide residues, mycotoxins and environmental contaminants) in primary production, including through animal feed. Producers' organisations, particularly those with veterinary advisors, are in a good position to provide awareness and training as they are regularly in contact with farmers and are well placed to understand their priorities. Technical support from the *Veterinary Services* is important and both private *veterinarians* and employees of the *Veterinary Authority* can assist. The *Veterinary Services* play a central role in ensuring the responsible and prudent use of biological products and veterinary drugs, including antimicrobials, in animal husbandry. This helps to minimise the risk of developing antimicrobial resistance and unsafe levels of veterinary drug residues in foods of animal origin. Section 3.9.3 of the OIE *Terrestrial Code* contains guidelines on the use of antimicrobials.

Meat inspection

Slaughterhouse inspection of live animals (*ante-mortem*) and the carcase (*post-mortem*) plays a key role in both the surveillance network for animal diseases and zoonoses and ensuring the safety and suitability of meat and by-products for their intended uses. Control and/or reduction of biological hazards of animal and public health importance by *ante-* and *post-mortem* meat inspection is a core responsibility of the *Veterinary Services* and they should have primary responsibility for the development of relevant inspection programmes.

Wherever practicable, inspection procedures should be risk-based. Management systems should reflect international norms and address the significant hazards to both human and animal health in the livestock being slaughtered. The Codex Alimentarius Code of Hygienic Practice for Meat (CHPM) (5) constitutes the primary international standard for meat hygiene and incorporates a risk-based approach to application of sanitary measures throughout the meat production chain. Section 3.10 of the *Terrestrial Code* contains guidelines for the control of biological hazards of animal health and public health importance through *ante-* and *post-mortem* meat inspection, which complement the CHPM.

Traditionally, the primary focus of the OIE Codes was on global animal health protection and transparency. Under its current mandate, the OIE also addresses animal production food safety risks. The Code includes several standards and guidelines aimed at protecting public health (such as Appendix 3.10.1 on the Control of Biological Hazards of Animal Health and Public Health Importance through Ante- and Post- Mortem Meat Inspection) and work is underway developing new standards to prevent the contamination of animal products by Salmonella spp. and Campylobacter spp. The OIE and Codex collaborate closely in the development of standards to ensure seamless coverage of the entire food production continuum. The recommendations of the OIE and the Codex Alimentarius Commission on the production and safety of animal commodities should be read in conjunction.

The *Veterinary Authority* should provide for flexibility in the delivery of meat inspection service. Countries may adopt different administrative models, involving degrees of delegation to officially recognised competent bodies operating under the supervision and control of the *Veterinary Authority*. If personnel from the private sector are used to carry out *ante-* and *post-mortem* inspection activities under the overall supervision and responsibility of the *Veterinary Authority,* the *Veterinary Authority* should specify the competency requirements for all such persons and verify their performance. To ensure the effective implementation of *ante-* and *post-mortem* inspection procedures, the *Veterinary Authority* should have in place systems for the monitoring of these procedures and the exchange of information gained. Animal identification and animal traceability systems should be integrated in order to be able to trace slaughtered animals back to their place of origin, and products derived from them forward in the meat production chain.

Certification of animal products for international trade

Another important role of the *Veterinary Services* is to provide health certification to international trading partners attesting that exported products meet both animal health and food safety standards. Certification in relation to animal diseases, including zoonoses, and meat hygiene should be the responsibility of the *Veterinary Authority*. Certification may be provided by other professions (a sanitary certificate) in connection with food processing and hygiene (e.g. pasteurisation of dairy products) and conformance with product quality standards.

Other roles of the *Veterinary Services*

Most reported outbreaks of foodborne disease are due to contamination of foods with zoonotic agents, often during primary production. The *Veterinary Services* play a key role in the investigation of such outbreaks all the way back to the farm and in formulating and implementing remedial measures once the source of the outbreak has been identified. This work should be carried out in close collaboration with human and environmental health professionals, analysts, epidemiologists, food producers, processors and traders and others involved.

In addition to the roles mentioned above, *veterinarians* are well equipped to assume important roles in ensuring food safety in other parts of the food chain, for example through the application of HACCP-based controls and other quality assurance systems during food processing and distribution. The *Veterinary Services* also play an important role in raising the awareness of food producers, processors and other stakeholders of the measures required to assure food safety.

Optimising the contribution of the *Veterinary Services* to food safety

In order for *Veterinary Services* to make the best possible contribution to food safety, it is important that the education and training of *veterinarians* in the roles outlined in this paper meets high standards and that there are national programmes for ongoing professional development. The *Veterinary Services* should comply with the OIE fundamental principles of quality given in Section 1.3.3 of the Terrestrial *Code*. Guidelines for the evaluation of *Veterinary Services* are provided in Section 1.3.4 of the *Terrestrial Code* and in the OIE Tool for the Evaluation of Performance of *Veterinary Services* (the OIE PVS Tool).

There should be a clear and well documented assignment of responsibilities and chain of command within the *Veterinary Services*. The national *Competent Authority* should provide an appropriate institutional environment to allow the *Veterinary Services* to develop and implement the necessary policies and standards and adequate resources for them to carry out their tasks in a sustainable manner. In developing and implementing policies and programmes for food safety the *Veterinary Authority* should collaborate with other responsible agencies to ensure that food safety risks are addressed in a coordinated manner.

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Annex XXIX

CHAPTER 2.1.1.

NOTIFICATION CRITERIA FOR LISTING DISEASES

Community position:

The Community can support the proposed changes, but would like to introduce general comments.

For some diseases there are unclear or different definitions between the Code and the Manual and this is also applicable to the disease cards which need updating. This can lead to difficulties in notification by the OIE Members.

As for diseases affecting wild life it is not clear whether they are included or not and what should be the procedure. The Community suggests the ad hoc group on epidemiology look at this, together with the ad hoc group on wild life disease surveillance and working group on wildlife diseases.

Article 2.1.1.1.

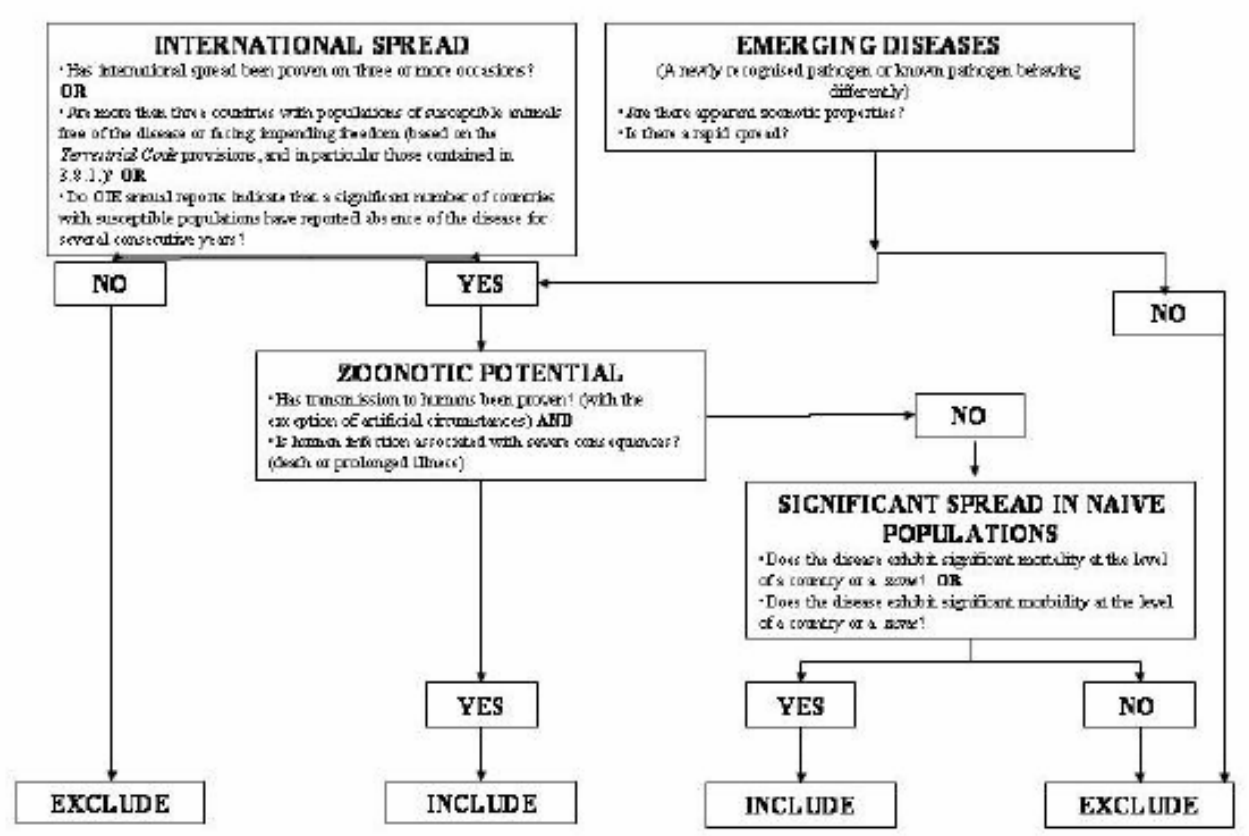
The criteria for the inclusion of a disease in the OIE List are as follows:

Basic criteria	**Parameters (at least one 'yes' answer means that the criterion has been met)**
International Spread	Has international spread been proven on three or more occasions? **OR** Are more than three countries with populations of susceptible animals free of the disease or facing impending freedom (based on the relevant provisions of the *Terrest rial Code*, and in particular those contained in Appendix 3.8.1.)? **OR** Do OIE annual reports indicate that a significant number of countries with susceptible populations have reported absence of the disease for several consecutive years?
Zoonotic Potential	Has transmission to humans been proven? (with the exception of artificial circumstances) **AND** Is human infection associated with severe consequences? (death or prolonged illness)

Significant Spread within Naïve Populations	Does the disease exhibit significant mortality at the level of a country or a *zone*? **OR** Does the disease exhibit significant morbidity at the level of a country or a *zone*?
Emerging Diseases	Are there apparent zoonotic properties or is there a rapid spread?

Article 2.1.1.2.

The criteria in Article 2.1.1.1. above are applied according to the decision-making model shown below:



Article 2.1.1.3.

The following diseases are included in the OIE List.

1. The following diseases are included within the category of multiple species diseases:

   - Anthrax
   - Aujeszky's disease

- Bluetongue
- Brucellosis (*Brucella abortus*)
- Brucellosis (*Brucella melitensis*)
- Brucellosis (*Brucella suis*)
- Crimean Congo haemorrhagic fever
- Echinococcosis/hydatidosis
- Epizootic haemorrhagic disease (EHD)
- Equine encephalomyelitis (Eastern)
- Foot and mouth disease
- Heartwater
- Japanese encephalitis
- Leptospirosis
- New world screwworm (*Cochliomyia hominivorax*)
- Old world screwworm (*Chrysomya bezziana*)
- Paratuberculosis
- Q fever
- Rabies
- Rift Valley fever
- Rinderpest
- Surra (*Trypanosoma evansi*)
- Trichinellosis
- Tularemia
- Vesicular stomatitis
- West Nile fever.

2. The following diseases are included within the category of cattle diseases:
   - Bovine anaplasmosis
   - Bovine babesiosis
   - Bovine genital campylobacteriosis
   - Bovine spongiform encephalopathy
   - Bovine tuberculosis
   - Bovine viral diarrhoea
   - Contagious bovine pleuropneumonia
   - Enzootic bovine leukosis
   - Haemorrhagic septicaemia
   - Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
   - Lumpy skin disease
   - ~~Malignant catarrhal fever (Wildebeest only)~~

- Theileriosis
- Trichomonosis
- Trypanosomosis (tsetse-transmitted).

3. The following diseases are included within the category of sheep and goat diseases:
   - Caprine arthritis/encephalitis
   - Contagious agalactia
   - Contagious caprine pleuropneumonia
   - Enzootic abortion of ewes (ovine chlamydiosis)
   - Maedi–visna
   - Nairobi sheep disease
   - Ovine epididymitis (*Brucella ovis*)
   - Peste des petits ruminants
   - Salmonellosis (*S.* abortusovis)
   - Scrapie
   - Sheep pox and goat pox.

4. The following diseases are included within the category of equine diseases:
   - African horse sickness
   - Contagious equine metritis
   - Dourine
   - ~~Equine encephalomyelitis (Eastern)~~
   - Equine encephalomyelitis (Western)
   - Equine infectious anaemia
   - Equine influenza
   - Equine piroplasmosis
   - Equine rhinopneumonitis
   - Equine viral arteritis
   - Glanders
   - ~~Surra (*Trypanosoma evansi*)~~
   - Venezuelan equine encephalomyelitis.

5. The following diseases are included within the category of swine diseases:
   - African swine fever
   - Classical swine fever
   - Nipah virus encephalitis
   - Porcine cysticercosis
   - Porcine reproductive and respiratory syndrome
   - Swine vesicular disease

- Transmissible gastroenteritis.

6. The following diseases are included within the category of avian diseases:
   - Avian chlamydiosis
   - Avian infectious bronchitis
   - Avian infectious laryngotracheitis
   - Avian mycoplasmosis (*Mycoplasma gallisepticum*)
   - Avian mycoplasmosis (*Mycoplasma synoviae*)
   - Duck virus hepatitis
   - Fowl cholera
   - Fowl typhoid
   - Highly pathogenic avian influenza in birds and low pathogenicity notifiable avian influenza in poultry as defined in Chapter 2.7.12.
   - Infectious bursal disease (Gumboro disease)
   - Marek's disease
   - Newcastle disease
   - Pullorum disease
   - Turkey rhinotracheitis.
7. The following diseases are included within the category of lagomorph diseases:
   - Myxomatosis
   - Rabbit haemorrhagic disease.
8. The following diseases are included within the category of bee diseases:
   - Acarapisosis of honey bees
   - American foulbrood of honey bees
   - European foulbrood of honey bees
   - Small hive beetle infestation (*Aethina tumida*)
   - *Tropilaelaps* infestation of honey bees
   - Varroosis of honey bees.
9. The following diseases are included within the category of other diseases:
   - Camelpox
   - Leishmaniosis.

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Annex XXX

CHAPTER 1.4.5.

INTERNATIONAL TRANSFER AND LABORATORY CONTAINMENT OF ANIMAL PATHOGENS

Community position:

The Community can support the proposed changes.

Article 1.4.5.1.

Object

To prevent the introduction and spread of animal diseases caused by pathogens.

Article 1.4.5.2.

Introduction

1. The consequences of the introduction into a country of an infectious disease or an animal pathogen or new strain of animal pathogen from which it is currently free, are potentially very serious. This is because animal health, human health, the agricultural economy and trade may all be adversely affected to a greater or a lesser degree. Countries will already have in place a range of measures, such as requirements for pre-import testing and quarantine, to prevent such introductions through the importation of live animals or their products.

2. However, there is also the risk that disease may occur as a result of the accidental release of animal pathogens from laboratories that are using them for various purposes such as research, diagnosis or the manufacture of vaccines. Such pathogens may already occur in the country or they may have been imported deliberately or inadvertently. It is therefore necessary to have in place measures to prevent their accidental release. These measures may be applied either at national borders by prohibiting or controlling the importation of specified pathogens or their carriers ~~(see Article 1.4.5.7.)~~ or within national boundaries by specifying the conditions under which laboratories must handle them. In practice, a combination of external and internal controls is likely to be applied depending on the risk to animal health posed by the pathogen in question.

Article 1.4.5.3.

Classification of pathogens

Pathogens should be categorised according to the risk they pose to both human and animal health. They are grouped into four risk categories. Detailed information is provided in the *Terrestrial Manual.*

~~Article 1.4.5.3.~~

~~**Purpose**~~

~~1) To provide guidance on the laboratory containment of animal pathogens according to the risk they pose to animal health and the agricultural economy of a country, particularly when the disease they cause is not enzootic.~~

~~2) To provide guidance on the import conditions applicable to animal pathogens.~~

~~3) Where animal pathogens also pose a risk to human health, guidance on their laboratory containment should be sought from the *Terrestrial Manual* and other relevant published documents.]~~

Article 1.4.5.4.

Importation of animal pathogens

1. The importation of any animal pathogen, *pathological material* or organisms carrying the pathogen should be permitted only under an import licence issued by the relevant authority. The import licence should contain conditions appropriate to the risk posed by the pathogen and, in relation to air transport, the appropriate standards of the International Air Transport Association concerning the packaging and transport of hazardous substances. The import licence for risk groups 2, 3 or 4 should only be granted to a laboratory that is licensed to handle the particular pathogen as in Article 1.4.5.5.

2. When considering applications to import *pathological material* from other countries, the authorities should have regard to the nature of the material, the animal from which it is derived, the susceptibility of that animal to various diseases and the animal health situation of the country of origin. It may be advisable to require that material is pre-treated before import to minimise the risk of inadvertent introduction of a pathogen.

~~Article 1.4.5.4.~~

~~**Classification of animal pathogens**~~

~~1) Animal pathogens should be categorised on the risk they pose to animal health, should they be introduced into a country or accidentally released from a laboratory. In categorising pathogens into four groups according to containment requirements, the following factors should be taken into account: the organism's pathogenicity, the biohazard it presents, its ability to spread, the economic aspects and the availability of prophylactic and therapeutic treatments.~~

~~2) Some pathogens need to be transmitted by specific vectors or require intermediate hosts to complete their life cycles before they can infect animals and cause disease. In countries where such vectors or intermediate hosts do not occur, or where climatic or environmental factors mitigate against their survival, the pathogen poses a lower risk to animal health than in countries where such vectors or intermediate hosts occur naturally or could survive.~~

~~3) When categorising animal pathogens into specific groups, the following criteria should be taken into account:~~

~~a) Group 1 animal pathogens~~

~~Disease producing organisms which are enzootic but not subject to official control.~~

~~b) Group 2 animal pathogens~~

~~Disease producing organisms which are either exotic or enzootic but subject to official control and which have a low risk of spread from the laboratory.~~

~~i) They do not depend on vectors or intermediate hosts for transmission.~~

~~ii) There is a very limited or no transmission between different animal species.~~

~~iii) Geographical spread if released from the laboratory is limited.~~

~~iv) Direct animal to animal transmission is relatively limited.~~

v) The need to confine diseased or infected non-diseased animals is minimal.

vi) The disease is of limited economic and/or clinical significance.

c) Group 3 animal pathogens

Disease producing organisms which are either exotic or enzootic but subject to official control and which have a moderate risk of spread from the laboratory.

i) They may depend on vectors or intermediate hosts for transmission.

ii) Transmission between different animal species may readily occur.

iii) Geographical spread if released from the laboratory is moderate.

iv) Direct animal to animal transmission occurs relatively easily.

v) The statutory confinement of diseased, infected and in-contact animals is necessary.

vi) The disease is of severe economic and/or clinical significance.

vii) Prophylactic and/or therapeutic treatments are not readily available or of limited benefit.

d) Group 4 animal pathogens

Disease producing organisms which are either exotic or enzootic but subject to official control and which have a high risk of spread from the laboratory.

i) They may depend on vectors or intermediate hosts for transmission.

ii) Transmission between different animal species may occur very readily.

iii) Geographical spread if released from the laboratory is widespread.

iv) Direct animal to animal transmission occurs very easily.

v) The statutory confinement of diseased, infected and in-contact animals is necessary.

vi) The statutory control of animal movements over a wide area is necessary.

vii) The disease is of extremely severe economic and/or clinical significance.

viii) No satisfactory prophylactic and/or therapeutic treatments are available.

Article 1.4.5.5.

Containment levels

~~1) The principal purpose of containment is to prevent the escape of the pathogen from the laboratory into the national animal population. Some animal pathogens can infect man. In these instances the risk to human health may demand additional containment than would otherwise be considered necessary from purely animal health considerations.~~

~~2) The level of physical containment and biosecurity procedures and practices should be related to the group into which the pathogen has been placed, and the detailed requirements should be appropriate to the type of organism (i.e. bacterium, virus, fungus or parasite). The lowest containment level will be required for pathogens in group 1 and the highest level for those in group 4. Guidance on the containment requirements for groups 2, 3 and 4 is provided in Table 1.~~

~~3) Arthropods may be pathogens or vectors for pathogens. If they are a vector for a pathogen being used in the laboratory, the appropriate containment level for the pathogen will be necessary in addition to the containment facilities for the arthropod.~~

~~Article 1.4.5.6.~~

~~**Possession and handling of animal pathogens]**~~

Article 1.4.5.5.

Laboratory containment of animal pathogens

1. Guidance on the laboratory containment of animal pathogens and on the import conditions applicable to animal pathogens is found in the Chapter I.1.6. of the *Terrestrial Manual*. Additional guidance on human safety is also found in this chapter.

~~1~~2. A laboratory should be allowed to possess and handle animal pathogens in group 3 or 4 only if it can satisfy the relevant authority that it can provide containment facilities appropriate to the group. However, depending on the particular circumstances of an individual country, the authority might decide that the possession and handling of certain pathogens in group 2 should also be controlled. The authority should first inspect the facilities to ensure they are adequate and then issue a licence specifying all relevant conditions. There should also be a requirement for appropriate records to be kept and for the authority to be notified if it is suspected that a material being handled contains a pathogen not covered by the licence. The authority should visit the laboratory periodically to ensure compliance with the licence conditions. It is important that authority staff carrying out the visit should not have any contact with species susceptible to the pathogens being handled at the laboratory for a specified period after visiting the laboratory. The length of this period will depend on the pathogen.

~~2~~3. Licences should specify:

a) how the pathogen is to be transported and the disposal of the packaging;

b) the name of the person responsible for the work;

c) whether the pathogen may be used *in vivo* (and if so whether in laboratory animals or other animals) and/or only *in vitro*;

d) how the pathogen and any experimental animals should be disposed of when the work is completed;

e) limitations on contact by laboratory staff with species susceptible to the pathogens being used;

f) conditions for the transfer of pathogens to other laboratories;

g) specific conditions relating to the appropriate containment level and biosecurity procedures and practices.

Article 1.4.5.7.

Importation of animal pathogens

1. The importation of any animal pathogen, *pathological material* or organisms carrying the pathogen should be permitted only under an import licence issued by the relevant authority. The import licence should contain conditions appropriate to the risk posed by the pathogen and, in relation to air transport, the appropriate standards of the International Air Transport Association concerning the packaging and transport of hazardous substances. The import licence for group 2, 3 or 4 should only be granted to a laboratory that is licensed to handle the particular pathogen as in Article 1.4.5.6.

2. When considering applications to import *pathological material* from other countries, the authorities should have regard to the nature of the material, the animal from which it is derived, the susceptibility of that animal to various diseases and the animal health situation of the country of origin. It may be advisable to require that material is pre treated before import to minimise the risk of inadvertent introduction of a pathogen.

Table 1. Guidance on the laboratory requirements for the different containment groups

-	**CONTAINMENT GROUP**		
REQUIREMENTS OF THE LABORATORY	**2**	**3**	**4**
A)Laboratory siting and structure	-	-	-
1.Not next to known fire hazard	Yes	Yes	Yes
2.Workplace separated from other activities	Yes	Yes	Yes
3.Personnel access limited	Yes	Yes	Yes
4.Protected against entry/exit of rodents and insects	Yes	Yes	Yes
5.Liquid effluent must be sterilised	-	Yes and monitored	Yes and monitored
6.Isolated by airlock. Continuous internal airflow	-	Yes	Yes
7.Input and extract air to be filtered using HEPA or equivalent	-	Single on extract	Single for input, double for extract
8.Mechanical air supply system with fail-safe system	-	Yes	Yes
9.Laboratory sealable to permit fumigation	-	Yes	Yes
10.Incinerator for disposal of carcasses and waste	Available	Yes	Yes on site
B)Laboratory facilities			
11.Class 1/2/3 exhaust protective cabinet available	Yes	Yes	Yes
12.Direct access to autoclave	Yes	Yes with double doors	Yes with double doors
13.Specified pathogens stored in laboratory	Yes	Yes	Yes
14.Double ended dunk tank required	-	Preferable	Yes
15.Protective clothing not worn outside laboratory	Yes	Yes	Yes
16.Showering required before exiting laboratory	-	-	Yes
17.Safety Officer responsible for containment	Yes	Yes	Yes
18.Staff receive special training in the requirements needed	Yes	Yes	Yes
C)Laboratory discipline	-	-	-
19.Warning notices for containment area	Yes	Yes	Yes

-	CONTAINMENT GROUP		
REQUIREMENTS OF THE LABORATORY	2	3	4
20.Laboratory must be lockable	Yes	Yes	Yes
21.Authorised entry of personnel	Yes	Yes	Yes
22.On entering all clothing removed and clean clothes put on	-	Yes	Yes
23.On exiting all laboratory clothes removed, individual must wash and transfer to clean side	-	Yes	-
24.Individual must shower prior to transfer to clean side	-	-	Yes
25.All accidents reported	Yes	Yes	Yes
D)Handling of specimens	-	-	-
26.Packaging requirements to be advised prior to submission	Yes	Yes	Yes
27.Incoming packages opened by trained staff	Yes	Yes	Yes
28.Movement of pathogens from an approved laboratory to another requires a licence	Yes	Yes	Yes
29.Standard Operating Procedures covering all areas must be available	Yes	Yes	Yes

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