COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 3.2.2009
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COMMISSION STAFF WORKING DOCUMENT

Written comments of the Community on the OIE Terrestrial Animal Health Code Commission meeting October 2008 prior to the next Code Commission meeting March 2009 for consideration in the 77th General Session to be held in May 2009

EXPLANATORY MEMORANDUM

The OIE Terrestrial Animal Health Standards Commission met at the OIE Headquarters in Paris from 29 to 10 October 2008 to discuss possible amendments to the Terrestrial Animal Health Code (the Code).

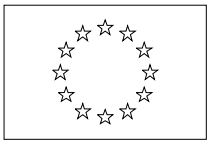
Following this meeting, the OIE has sent to all its 172 members proposals for modifications to the Code for further discussion by the OIE Terrestrial Animal Health Standards Commission in March 2009.

The European Commission held between 16-17 December 2008 a working group with experts from the Member States to consider these proposals and has prepared a report detailing the Community comments.

The European Commission therefore proposes to the Council to authorise the European Commission to present to the OIE, as since 1995, written comments in the annex of this Commission Staff Working Document with a covering letter at annex A, prior to the meeting referred to above.

The European Community comments need to reach the OIE headquarters by mid February 2009 in order to be considered at the next meeting of its Terrestrial Animal Health Standards Commission in March 2009.

ANNEX A



UNION EUROPÉENNE

Bruxelles, le
D(2009) 410136/HB/vb

Object: Meeting of the International Terrestrial Animal Health Code commission – March 2009

Dear Bernard,

Please find attached as an annex to this letter the Community comments on the report of the meeting of Code Commission held in October 2008 with reference to certain Chapters in the OIE Terrestrial Animal Health Code. In order to facilitate the examination of the comments of the Community, they have been incorporated in boxes into the OIE reports. In this context, the Community thanks the OIE for providing the electronic version of the Report.

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

Paola Testori Coggi
Deputy Director General

Enclosures: 1

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

Dr. B. Vallat
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ANNEX

Organisation Mondiale de la Santé Animale
World Organisation for Animal Health
Organización Mundial de Sanidad Animal

Original: English
October 2008

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

Paris, 29 September–10 October 2008

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The OIE Terrestrial Animal Health Standards Commission (the Code Commission) met at the OIE Headquarters in Paris on 29 September–10 October 2008.

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

The Code Commission reviewed the documents identified in the agenda, addressing comments that Members had submitted by 15 August and amended texts in the OIE *Terrestrial Animal Health Code* (the *Code*) where appropriate. The amendments are shown in the usual manner by double underline and ~~strikeout~~ and may be found in the Annexes to the report. In Annexes XXVII, XXVIII, XXX (classical swine fever, West Nile fever, control of hazards of animal health and public health importance in animal feed), amendments made at this meeting (October 2008) are shown with a coloured background to distinguish them from those made prior to the 76th General Session in May 2008.

Members should note that, unless stated otherwise, texts submitted for comment may be proposed for adoption at the 77th General Session. Depending on the comments received on each text, the Code Commission will identify, in the report of its March 2009 meeting, the texts proposed for adoption in May 2009.

The Code Commission strongly encourages Members to participate in the development of the OIE's international standards by submitting comments on this report. It would be very helpful if comments were submitted as specific proposed text changes, supported by a scientific rationale. Proposed deletions should be indicated in '~~strikeout~~' and proposed additions with 'double underline'. Members **should not use the automatic 'track-change' function** provided by word processing software as such changes are lost in the process of collating Members' submissions into the Code Commission's working documents. Comments on this report must reach OIE Headquarters by **30 January 2009** to be considered at the March 2009 meeting of the Code Commission. Comments should be sent to the International Trade Department at: trade.dept@oie.int.

Dr Vallat, Director General of the OIE, welcomed members of the Code Commission to OIE Headquarters. He emphasised the need for collaboration between specialist commissions and proposed to convene a joint meeting of the Code Commission and the Scientific Commission for Animal Diseases (SCAD). Dr Thiermann, President of the Code Commission, welcomed this proposal. He commented that the Code Commission had a heavy workload for this meeting and thanked members for taking the responsibility to lead the discussion on particular agenda items.

The Code Commission acknowledges comments submitted by Argentina, Australia, Canada, Chinese Taipei, the European Union (EU), Guatemala, Japan, New Zealand, Norway, Pakistan, South Africa, Thailand and the United States of America (USA). The comments submitted to the previous meeting from Malaysia, the People's Republic of China, Serbia, Sudan and Switzerland were also noted.

A. JOINT MEETING OF THE CODE COMMISSION AND THE SCIENTIFIC COMMISSION

The Code Commission and the Scientific Commission held a joint meeting, with participation of Dr Vallat, on 2 October and discussed several important points. A summary of these discussions appears below.

1. Inclusion of official disease status questionnaires in the Code

Community comment

The Community can support the inclusion of the questionnaires in the Terrestrial Code.

Dr Vallat indicated that for reasons of transparency and to strengthen the legal basis of decisions granting official status for bovine spongiform encephalopathy (BSE), foot and mouth disease (FMD), rinderpest and contagious bovine pleuropneumonia (CBPP), the relevant OIE questionnaires should be formally adopted by the International Committee and published in the *Code*. Accordingly, the Code Commission agreed to circulate the four existing questionnaires, provided by the Scientific Department, for Member comments.

The Code Commission asked the International Trade Department to review Articles 11.6.23. to 11.6.29. inclusive (BSE risk assessment) to identify any provisions in the questionnaire that are inconsistent with the provisions in these articles.

The questionnaires, which are presented at Annexes XXXII to XXXV of this report, are provided for Member comments.

2. Discussion on buffer zone

The definitions of 'buffer zone' and 'surveillance zone' were discussed and it was proposed that the term 'buffer zone' be replaced by the term 'protection zone' and that there was no need to define the term 'surveillance zone' as this concept is included in the current definition of '*protection zone'*.

The term 'buffer zone' is currently only found in Chapter 8.5. (Foot and mouth disease) and Chapter 12.1. (African horse sickness). The Code Commission reviewed all occurrences of the term in these chapters and decided that 'buffer zone' could be replaced by 'protection zone' in both chapters. No specific changes were made to the text defining the 'protection zone'. The Code Commission requested that the International Trade Department review the entire *Terrestrial Code* and check that this amendment has no unforeseen implications for other chapters.

The term 'surveillance zone' is currently found in Chapter 8.5. (Foot and mouth disease) and Chapter 8.3. (Bluetongue). The Code Commission reviewed all occurrences of the term in these chapters and deleted the definition of 'surveillance zone'. The Code Commission requested that the International Trade Department review the entire *Terrestrial Code* and check that this amendment has no unforeseen implications for other chapters.

Community comments

The Community is concerned about the deletion of "surveillance zone" and wishes the OIE further reflect on the inclusion on implementation guidelines for protection and surveillance zones in the chapter 4.3 on zoning.

3. Disease surveillance in wildlife and classical swine fever

The recommendations of the *ad hoc* Group on Epidemiology, endorsed by SCAD, on these topics were presented to the Code Commission. Surveillance in wildlife is an issue of growing importance and there are many questions concerning the approach and the implication of findings for country status and trade. In the case of classical swine fever, the Code Commission agreed with the *ad hoc* Group's view that it is possible to maintain the disease free status of the domestic pig population with effective biosecurity measures to prevent the spread of infection between wild and domestic pigs.

4. Guidelines on surveillance of vector-borne diseases

It was agreed that guidance on surveillance for vector-borne diseases should be included in the *Code*, at an appropriate level of detail. There was general agreement that more detailed guidance could be provided in another OIE publication, such as the *Handbook on Surveillance for Diseases of Terrestrial Animals*, which is currently under development. The text proposed by the *ad hoc* Group on Climate Change and Vector-borne Disease Surveillance, endorsed by the SCAD, was also discussed by the Code Commission.

B. EXAMINATION OF MEMBERS' COMMENTS AND WORK OF RELEVANT EXPERT GROUPS

1. Glossary

The Community welcomes the idea of the ad hoc group on communication, of a draft proposal for a Chapter on Communication. However, the definitions of "Communication", "Crisis", "Crisis communication" and "Outbreak communication" should be in the draft chapter and the Community refuses that they are already included in the Glossary. In view of this the Community has not made any specific comments on the definitions at this time but does not agree in general with the definitions as proposed. Once a draft chapter including the new definition is proposed, the Community will provide detailed comments.

In some cases, the OIE should work closely with Codex to ensure as far as possible the same definitions throughout. This will apply for the new definition relating to communication, but applies also already for the definitions of risk, risk analysis, risk assessment, risk communication.

The Community is still concerned about the definition of protection zone, which can be confusing, more particularly its implementation and suggests that this concept and its use, as well as that of surveillance zone, is better described in the Chapter on Zoning rather than have just a definition.

Furthermore, the Community reiterates its former comments on the definitions of *Infection* and *Monitoring*, and asks the OIE to further reflect on these comments (here under added at the end this text) for a possible amendment of the definitions.

The Code Commission reviewed comments from Argentina, Australia, Canada, the European Union (EU), Japan, South Africa, the USA, the Comité Veterinario Permanente del CONOSUR (CVP) and an expert. The discussions on 'buffer zone' and 'animal welfare' may be found under the relevant issues elsewhere in this report.

Members commented that 'flock' and 'herd' should be combined in a single definition because these two definitions are similar. The Code Commission reiterated the need to maintain separate definitions because these two terms are used throughout the *Code* in different sections, with different implications. Therefore there is a need to maintain the two definitions in the Glossary.

Following consideration of a Member's comment, the Code Commission decided to revert to the definitions of risk assessment and sanitary measure found in the 2007 edition of the *Code*.

The Code Commission did not agree to delete the reference to animal welfare as a responsibility of the Veterinary Authority, as proposed by one Member, as the OIE considers that Veterinary Authorities should accept responsibility for animal welfare (working in collaboration with other government agencies as appropriate).

After careful consideration of the use of the term 'official veterinary control of live animals' in the *Code* it was found that this term is not always linked to live animals. Therefore the definition was amended to delete 'of live animals' as the specific purpose of the official veterinary control (whether it covers live animals or other aspects) is defined in the text whenever this term is used in the *Code*.

The Code Commission discussed the issue of Members making self declarations of freedom from OIE listed diseases and compared the approach of the *Terrestrial Code* with that of the *Aquatic Code*, which contains a definition of the term 'self declaration'. It was agreed that a definition was not needed in the *Terrestrial Code* as the term is not used in this *Code*. The Code Commission decided to develop a new article (see below) for inclusion in Chapter 1.1. (Notification of Diseases and Epidemiological Information).

New article on self declaration

Members may make a self declaration that a country, zone or compartment is free from a listed disease, based on the implementation of the provisions of the *Terrestrial Code* and the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (the *Terrestrial Manual*). The Veterinary Authority may wish to transmit this information to the OIE Central Bureau, which may publish the information.

Community comment

The Community welcomes this announcement but cannot make any comment before having been submitted a draft text for change of Chapter 1.1.

The revised Glossary, which is presented at Annex III, is provided for Member comments.

2. Criteria for listing diseases (Chapter 1.2.)

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

Dr Ben Jebara joined the Code Commission for this discussion. The Code Commission reviewed Member comments and noted that the list of diseases notifiable to the OIE currently includes disease reports covering both domestic animals and wildlife. Dr Ben Jebara introduced the discussion in the *ad hoc* Group on Wildlife Disease Notification and advised that the OIE Annual Questionnaire on Wildlife will be merged into the WAHIS reporting system.

The Code Commission decided that no amendment to the *Code* was required.

The report of the July 2008 meeting of the *ad hoc* Group on Wildlife Disease Notification is attached in Annex XLI for information of Members.

3. Animal health surveillance (Chapter 1.4.)

Community comments

The Community can accept the proposed draft and thanks the OIE for these very important changes. Nevertheless, there are in the article 1.4.2 definitions which are already in the Code Glossary. If they are identical, it is a mere repetition that could be deleted; if they are not, there can be problems of consistency. Once a definition has been agreed upon, if it is used more than once it should be only in the glossary; if it is used once only, it should only stay in the chapter.

The Code Commission reviewed relevant information in the reports of the September 2008 meeting of the *ad hoc* Group on Epidemiology and the January 2008 meeting of the *ad hoc* Group on Wildlife Disease Surveillance and made some appropriate modifications.

The revised Chapter, which is presented at Annex IV, is provided for Member comments.

4. Horizontal chapters

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

a) Import risk analysis (Chapter 2.2.)

Dr Sarah Kahn updated the Code Commission on the OIE decision to convene an *ad hoc* Group to produce a revised edition of the OIE *Handbook on Risk Analysis*. It is expected that this Group will hold its first meeting in 2009. The Code Commission noted that the Group would review Members' comments on Chapter 2.2. at its first meeting.

Community comment

The Community strongly wishes to be associated in this coming ad hoc group. The notion of Risk analysis is of the utmost importance. See in the text Community's comments regarding definitions.

b) Animal health measures applicable before and at departure (Chapter 5.4.)

Community comment

The Community can only accept the proposed draft if its comments are taken into account.

The Code Commission modified Chapter 5.4. as appropriate.

c) Border posts and quarantine stations in the importing country (Chapter 5.6.)

Community comments

The Community can accept the proposed draft.

The Code Commission modified Chapter 5.6. as appropriate.

The revised Chapters, which are presented at Annex V, are provided for Member comments.

5. Evaluation of Veterinary Services (Chapters 3.1. and 3.2.)

a) Report of the *ad hoc* Group on Evaluation of Veterinary Services

b) Community animal health worker

The Code Commission reviewed the report of the *ad hoc* Group on Evaluation of Veterinary Services and the paper submitted by Prof. A. M. Hassan on the role of 'community animal health workers' (CAHW). The Code Commission noted the particular relevance of CAHW in several African countries and the variability of the tasks and the institutional framework for CAHW from country to country. The Code Commission noted that the *ad hoc* Group recommended against developing a definition of CAHW for inclusion in the *Code*. Noting the important role of CAHW in some countries and that the term 'community animal health worker' is not currently used in the *Code*, the Code Commission proposed to the Director General to convene an expert group to address this issue.

The Code Commission agreed with the *ad hoc* Group's thinking on the current definition of 'veterinary para-professional' and proposed a modified definition, which may be found in Annex III.

The report of the *ad hoc* Group is attached in Annex XXXVII for information of Members.

c) Report of the *ad hoc* Group on communication

The Code Commission reviewed the report of the *ad hoc* Group on Communication and further modified the definition of 'outbreak' by deleting words already included in the definition of 'case'. The new or modified definitions may be found in Annex III.

Community comments

The Community welcomes the report of the ad hoc group on communication but thinks premature the inclusion of the definitions in the Glossary at this stage. A draft chapter on communication is needed first with definitions included.

The report of the *ad hoc* Group is attached in Annex XIL for information of Members.

6. Design and implementation of systems for animal identification and traceability (Chapter 4.2.)

The Code Commission reviewed comments from Argentina, Australia and the EU.

The Code Commission modified the text as appropriate. In response to a Member's comment, the Code Commission noted that items j), k) and l) of point 5 had been deleted from Article 4.2.3., based on advice from the *ad hoc* Group on Identification and Traceability, as reported previously.

Dr Sarah Kahn provided an update on progress in organizing the OIE International Conference on Animal Identification and Traceability. She noted that the dates for the Conference have been changed; it will take place on 23-25 March 2009 in Buenos Aires, Argentina. The Code Commission noted the status report of the Conference.

Community comment

The Community thanks the OIE for the small amendment and can accept the proposed change. The Community recommends to add an Article on the quality and control of data. This could be based on the recommendations of the conference on animal traceability to be held in March 2009 in Buenos Aires, Argentina. The Community wishes that the OIE could work closely with the Codex Alimentarius in order to develop links between animal traceability and traceability of products.

The revised Chapter, which is presented at Annex VI, is provided for Member comments.

7. Zoning and compartmentalisation

a) Zoning and compartmentalisation (Chapter 4.3.)

The Code Commission reviewed comments from the EU, Japan and South Africa.

Community comments

The Community can accept the proposed change. However, the Community wishes the TAHSC takes into account its comments on protection zone and surveillance zone, which implementation should be comprehensively described in this chapter, as it has been done for containment zone. In addition the Community reiterates its comment about the problem of wildlife: it should be clearly stated in this chapter whenever the wildlife and domestic population may be dealt with separately or not as regards zoning.

The Code Commission modified the text as appropriate. Members' comments calling for controls to provide for auditing of animal movements were not accepted as it was felt that this exceeds the OIE's current policies for zoning.

b) Application of compartmentalisation (Chapter 4.4.)

The Code Commission reviewed comments from the EU and Japan.

The Code Commission deleted a paragraph that introduces the use of the glossary on the basis that, since these guidelines have been incorporated in the *Code*, it is not necessary to repeat information relating to the use of the glossary.

The Code Commission accepted comments of Members regarding the inclusion of a reference to HACCP but modified the proposed insertion for clarity.

Member comments on Article 4.4.7. were accepted with modifications for clarity.

Community comments

The Community can accept the proposed draft and thanks the TAHSC for these important changes. However, in the article 4.4.1 the word "goal" is used whereas the word "target" is used in the article 4.3.1. To be consistent, the terms should be the same, "goal" being better. In article 4.4.7 the Community propose a slight modification for better clarity of the objective of this article.

The revised Chapters, which are presented at Annex VII, are provided for Member comments.

8. Surveillance for vector-borne diseases

The Code Commission noted the report of the November 2007 meeting of the *ad hoc* Group on Climate Change and Vector-borne Disease Surveillance, including draft general guidelines for surveillance of arthropod vectors of animal diseases.

The Code Commission provided the existing draft text for Member comments and asked the International Trade Department to reformat the text as required for inclusion in the *Code*. Members' comments will be considered and the reformatted text discussed at the Code Commission's March 2009 meeting.

Community comments

The Community thanks the TAHSC for this proposed draft chapter, which should be given a proper Chapter number. However, it should not be proposed for adoption in 2009.

The new draft text, which is presented as a clean text at Annex VIII, is provided for Member comments.

9. Chapters on semen and embryos (Chapters 4.5., 4.6., 4.7., 4.8., 4.9., 4.10., 4.11.)

The Code Commission reviewed comments from the EU and experts.

The Code Commission reviewed new texts on bovine and porcine semen and embryos that had been provided by experts. The Code Commission noted that the International Trade Department had also restructured the chapters on semen to create a new chapter entitled 'General Hygiene in Semen Collection and Processing Centres'.

The Code Commission noted comments from Members and an expert regarding proposed changes to the categorization of scrapie and porcine reproductive and respiratory syndrome (PRRS) by the International Embryo Transfer Society (IETS) and asked the International Trade Department to forward appropriate requests to the IETS for consideration.

The Code Commission noted comments of experts regarding the lack of detailed information regarding *in vivo* derived embryos of cervids and noted that a further review may be required to address Article 4.7.13.

Community comments

The Community thanks the TAHSC for this proposed draft chapters and generally supports them. However the Community wonders why teschovirus encephalomyelitis has not been deleted as is not a listed disease.

Because of the extensive revisions made, the Chapters 4.5. and 4.6 are presented as a clean text. The revised Chapters, which are presented at Annex IX, are provided for Member comments.

10. Somatic cell nuclear transfer (SCNT) in production livestock and horses (Chapter 4.12.)

The Code Commission reviewed comments from the EU and an expert.

The Code Commission noted the opinion of an expert and accepted the new text with a small modification.

Community comments

The Community can accept the proposed change.

The revised Chapter, which is presented at Annex X, is provided for Member comments.

11. Model certificates

a) General obligations related to certification (Chapter 5.1.)

The Code Commission reviewed comments from Argentina and the EU.

Community comments

The Community can accept the proposed change.

The Code Commission considered the comments and modified point 1 a) of Article 5.1.3. accordingly, taking into account the need to recognize disease free compartments.

b) Certification procedures (Chapter 5.2.)

Community comments

The Community thanks the TAHSC for this important proposed change and has a comment on the article 5.2.3. paragraph 7.

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

c) Model veterinary certificates for international trade in live animals, hatching eggs and products of animal origin (Chapter 5.10.)

The Code Commission noted the comment from Australia. Although the Code Commission agreed that the contents of the certificate, not the format on paper, are paramount, no specific text modifications were recommended and therefore no changes were made to the model veterinary certificates.

The revised Chapters (5.1. and 5.2.), which are presented at Annex XI, are provided for Member comments.

12. The role of the Veterinary Services in food safety (Chapter 6.1.)

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

Community comments

The Community can support the proposed change.

The revised Chapter, which is presented at Annex XII, is provided for Member comments.

13. Salmonellosis

a) The detection, control and prevention of *Salmonella* spp. in poultry (new chapter)

The Code Commission reviewed comments from Argentina, Australia, Canada, Chinese Taipei, the EU, Guatemala, Japan, New Zealand and the USA and made a number of amendments to the text. Some comments of a highly technical nature were forwarded to the *ad hoc* Group for consideration.

In response to a request of a Member, the Code Commission clarified that the new chapter does not cover breeding flocks for the production of pet birds. The same Member requested that the OIE develop recommendations on the inactivation of *Salmonella* spp. in egg products. The Code Commission noted this request but considered that it would be more appropriate for Codex

Alimentarius to address such standards and asked the International Trade Department to raise this matter with Codex.

The revised Chapter, which is presented at Annex XIII, is provided for Member comments.

Community comments

The Community wishes the draft OIE texts on this topic to limit to general recommendations as it is the case for animal health. Detailed guidelines on sampling methodology etc should be edited apart from the Code. It is exactly what is proposed by the TAHSC regarding paratuberculosis, and coherence is needed in this Code, even if the subject and cultures may differ.

b) Hygiene and biosecurity procedures in poultry production (Chapter 6.3.)

The Code Commission reviewed comments from Australia, Canada, Chinese Taipei, the EU, Guatemala, Japan, New Zealand, Thailand and the USA.

Community comments

The Community strongly wishes to participate in the coming ad hoc group on Salmonellosis.

The Code Commission noted that the *ad hoc* Group on Salmonellosis is scheduled to meet early in 2009 and referred all Member comments to the Group for consideration.

14. Introduction to the recommendations for controlling antimicrobial resistance

The Code Commission noted an introductory text drafted by an expert and decided to incorporate this as appropriate into the *Code*.

Community comments

The Community welcomes the initiative of the OIE and understands that its intention is to propose an introduction chapter to the recommendations for the surveillance and control of use of antimicrobials and of antimicrobial resistance. This could be a good and helpful complement to Chapters 6.5 to 6.8. However, it should not be proposed for adoption before having been discussed in an appropriate expert group.

The new draft Chapter, which is presented as a clean text at Annex XIV, is provided for Member comments.

15. Animal welfare

Community comments:

The Community thanks the OIE Code Commission for its work that improves the Draft Guidelines on Stray Dog Population and appreciates that many of the previous Community comments have been taken into account in the revised Annex. Further Community comments are presented in Annex XV. Furthermore, the Community welcomes the work being carried out on laboratory animals as well as on Animal Welfare and Livestock Production Systems and its initial priorities. The Community also appreciates that the method for killing poultry by the use of gas will be further discussed with appropriate experts.

Nevertheless, the Community does not wish that the Code becomes in itself a complete handbook, or otherwise, the text inflation would jeopardize its strength.

a) Animal welfare definition (Chapter 7.1.)

The Code Commission reviewed comments from Australia, Canada, the EU, Japan and the USA.

The Code Commission noted that Members had submitted comments calling for significant changes to the definition adopted in May 2008. These comments reflected diverse points of view and the Code

Commission had difficulty in reconciling them. The Code Commission also recalled that the definition of animal welfare adopted in May had already been the subject of extensive discussion and reflected a carefully balanced consensus. The Code Commission therefore decided to make no changes to the animal welfare definition.

b) Stray dog population control (new chapter)

The Code Commission reviewed comments from Australia, Canada, the EU, Japan, Kuwait, Malaysia, New Zealand, the People's Republic of China, Serbia, the USA and two NGOs.

A large number of comments had been received and had been considered by the Animal Welfare Working Group (AWWG) at its June 2008 meeting. The Code Commission reviewed the revised text developed by the AWWG and made a number of modifications.

Because of the extensive revisions made, the revised Chapter is presented as a clean text at Annex XV for Member comments.

c) Report of the *ad hoc* Group on the Welfare of Animals used in Research, Testing and Teaching (laboratory animals)

The Code Commission noted that Argentina and the USA had submitted comments on the document circulated after its March meeting. As noted by a Member, this document was incomplete and it had been provided to Members for information only. The *ad hoc* Group will hold a second meeting in December 2008. It is expected that the Group's final report will be circulated for a first round of Member comment early in 2009.

The Code Commission noted a comment from a Member regarding the proposal of the *ad hoc* Group to define 'genetically altered animals' and requested that the International Trade Department consult with the Scientific Department on this issue to ensure that all issues relevant to the OIE mandate were properly addressed in developing such a definition.

d) Report of the *ad hoc* Group on Animal Welfare and Livestock Production Systems

The Code Commission noted the report of the *ad hoc* Group and supported the proposal to work on broiler chickens and dairy cattle as initial priorities.

The report is attached in Annex XXXVI for information of Members.

e) Report of the 7th Meeting of the OIE Animal Welfare Working Group

The Code Commission noted the report of the Working Group.

Concerning modification of the existing Chapters on Animal Welfare in the *Terrestrial Code*, the EU proposed to include a third method for killing poultry by the use of gas. The Code Commission supported the advice of the AWWG and asked the International Trade Department to hold electronic consultations with the appropriate experts on this item.

The report is attached in Annex XXXVI for information of Members.

16. Anthrax (Chapter 8.1.)

The Code Commission reviewed comments from Australia, New Zealand and an expert. Advice from the SCAD was also taken into account.

The Code Commission agreed that the tables cited by a Member could provide a useful basis for advice on the inactivation of anthrax spores and requested that the International Trade Department incorporate relevant information into the *Terrestrial Code*.

The Code Commission reviewed comments of Members and noted an inconsistency between the recommendations in the *Terrestrial Code* and those in the *Terrestrial Manual* regarding the withholding of

cattle from slaughter following vaccination for anthrax. The Code Commission noted advice of the SCAD that concerns about the use of vaccination relate to the use of live vaccine and not to inactivated vaccine.

The Code Commission reviewed Article 8.1.7. in light of the advice of an expert to the effect that, even though the probability that *B. anthracis* is excreted via milk is low, and the number of excreted organisms likely to be low, pasteurisation could not be relied upon to guarantee the inactivation of *B. anthracis* spores in milk. The Code Commission considered that, in any case, the importation of milk and milk products for human consumption from animals showing clinical signs of anthrax at the time of milking was inadvisable and Article 8.1.7. should be modified accordingly.

The Code Commission decided to review additional references with a view to developing recommendations on the inactivation of *B. anthracis* spores in meat and meat products, wool and hair, bristles, animal manure, hides and skins, and milk for animal consumption.

Unfortunately there was not sufficient time to complete the revision. The Code Commission will continue to work on this Chapter at the next meeting.

Community comment

The Community thanks the TAHSC for this work and awaits the results of its further studies on this topic.

17. Bluetongue (Chapter 8.3.)

The Code Commission reviewed comments from the EU, the SCAD and the Biological Standards Commission (BSC).

The Code Commission noted the BSC's advice that the *Terrestrial Manual* chapter on bluetongue had been scheduled for review in 2008-2009. Members' questions on the use of inactivated vaccines were addressed and changes were made accordingly.

Based on advice from the SCAD, the Code Commission modified articles dealing with the northern geographic range of bluetongue.

Community comment

Apart from the comments inserted in the draft text that the Community cannot support, a letter will be sent to the SCAD to assess the issue of maternal transmission of BTV.

The revised Chapter, which is presented at Annex XVI, is provided for Member comments.

18. Foot and mouth disease (Chapter 8.5.)

The Code Commission reviewed comments from Argentina, the EU, Japan, the CVP and an expert. The report of the September 2008 meeting of the *ad hoc* Group on Epidemiology was also taken into consideration.

Most of the comments on Chapter 8.5. related to the concept of the 'buffer zone' and the Code Commission considered that these had been addressed via modification of the definition of 'buffer zone' (see discussion above). The Code Commission modified several articles in Chapter 8.5., to reflect the discussion and agreement of the two Commissions.

Community comments

The Community can support the proposed changes. However, its former comments on articles 8.5.7 and 8.5.21 remain valid. Moreover, for the sake of clarity, the Articles 8.5.2 to 8.5.5 should be re-arranged so so as to have all the "FMD free without vaccination" together and then the same for the "FMD free with vaccination".

The Code Commission also considered that the comments provided by an expert were helpful in establishing general recommendations for the preservation of FMD free status of a country or zone. To

assist Members in understanding the Code Commission's thinking on this issue, the expert's comments are reprinted below:

Introductory comments

A country free from a disease (with or without vaccination) either throughout the country or in a part of the country (a free zone) has the right to take appropriate biosecurity measures to prevent the entry and spread of the relevant pathogen. The country may apply the measures in respect of a country of a different health status (whether that country is contiguous or not) or in respect of a zone of a different health status within its territory.

The objectives of these measures are to:

1. *prevent the entry of the pathogen into the free country/zone;*

2. *facilitate early detection if the pathogen gains entry;*

3. *help the veterinary services to respond quickly and to minimise the spread of the pathogen if it gains entry.*

To meet the first objective, the following measures are relevant:

- *conditions for the import of commodities to prevent the entry of the pathogen from a country /zone of lower health status (whether contiguous or not);*

- *animal movement controls, which may include the exclusion of animals susceptible to the disease in question, in a defined area near the border of the free country/zone. Note: this would apply in the case where there is a contiguous country/zone of lower health status;*

- *reliance on existing physical or geographical barriers. Note: this would apply in the case where there is a contiguous country/zone of lower health status;*

- *implementation of legal and/or administrative procedures (such as border check points).*

The most important activity to address the second objective is increased and/or targeted surveillance near the border of the free country/zone.

To help address the third objective, vaccination could be applied at and/or near the border or throughout the country if the country is free with vaccination.

In the case of a free zone within a country, the national veterinary services are responsible for the implementation and monitoring of these measures as part of the country's management and justification of the free zone. These activities are essential to convince trading partners that the free zone is being effectively maintained.

In the case of a free country that has an agreement with a contiguous country/trading partner of lower health status, the relevant measures could be applied by the veterinary services of the partner i.e. outside the free country. The country that is disease free (or contains the free zone) would be expected to monitor effective application of the measures by its partner.

In the case of a free country that has not established an agreement with a contiguous country/trading partner of lower health status, the relevant measures should be applied by the national veterinary services at the national borders and, as appropriate, within the country. The application of measures such as import restrictions and border check points is a key component of national disease control and eradication programmes and is required to justify claims of disease freedom. These measures are also important to support international trade in animals and animal products.

The Code Commission reviewed the report of the July 2008 meeting of the *ad hoc* Group on Camelidae diseases, which was endorsed by SCAD, and made an appropriate modification to the introduction to Chapter 8.5. (Foot and mouth disease).

The revised Chapter, which is presented at Annex XVII, is provided for Member comments.

The Code Commission intends to include the concept of compartmentalisation into the Chapter on FMD during its next meeting.

The Community does not believe that compartmentalisation is a priority at this stage for FMD until practical experience has been gained in its application for avian influenza.

19. Paratuberculosis (Chapter 8.10.)

The Code Commission reviewed comments from Argentina and Japan.

The Code Commission noted Members' comments but did not consider itself able to amend Chapter 8.10. The Code Commission had no objection to a Member's request that the OIE develop a guidance document (not for inclusion in the *Terrestrial Code*) on the management of paratuberculosis and asked the International Trade Department to refer this request to the Scientific Department for consideration.

Community comment

The Community acknowledges and supports the OIE's decision to separate management guides from the Code, but this should be made in coherence with other topics, as in the case of food safety and animal welfare chapters.

20. Rabies (Chapter 8.11.)

The Code Commission reviewed comments from South Africa and SCAD.

The Code Commission noted that the current focus of the Code is on highlighting the importance of the presence of diseases in domestic animals when providing recommendations relevant to international trade, while at the same time encouraging the reporting of epidemiologic events in wildlife. The Code Commission was of the opinion that the current Chapter on rabies needs to be redrafted in order to consider all viruses capable of causing rabies in mammals, rather than referring to certain (but not all) lyssaviruses. Furthermore, for the purpose of international trade and for determining the status of a country with respect to rabies, the new Chapter should differentiate between the presence of infections in wildlife and infections in domestic animals and man. Therefore, the Code Commission requested the Director General to convene an *ad hoc* Group to draft a new chapter on rabies.

In the interim, the Code Commission agreed with the comment of a Member and decided to modify Article 8.11.2. to provide that the finding of any bat lyssavirus should not affect the rabies free status of a country.

Community comments

The Community can accept the proposed change but is concerned about Lyssavirus genotype one, responsible for around thirty thousand human death each year worldwide. The Commmunity supports the review of this Chapter by a working group and would like to participate.

The revised Chapter, which is presented at Annex XVIII, is provided for Member comments.

21. Rinderpest (Chapter 8.13.)

The Code Commission reviewed comments from the EU.

While no changes were made to Chapter 8.13., the Code Commission recalled that the surveillance provisions for rinderpest had not been adopted at the 76th General Session and decided to propose this text for adoption in 2009.

Community comment: The Community can support the proposed changes.

The revised Chapter, which is presented at Annex XIX, is provided for Member comments.

22. Avian influenza (Chapter 10.4.)

The Code Commission reviewed comments of Australia, Guatemala, the EU, Japan, South Africa and the USA.

The Code Commission made a number of text modifications.

Community comments

The Community can only support the proposed changes, if article 10.4.6, 10.4.9 and 10.4.12 are modified.

The Code Commission considered but did not accept Members' suggestions to change some time periods and other text, as no scientific rationale was provided.

The Code Commission examined but did not accept a request from a Member to change the heading of Article 16 to read 'Regardless of the NAI status of the country, zone or compartment', as provisions for egg products from an NAI free country, zone or compartment are given separately under Article 15.

A Member's recommendation for modifying Article 10.4.21. was not accepted, in the absence of a rationale for the change.

A Member commented regarding the need to modify Article 10.4.23. point 2 (i.e. to remove 'under study') based on the proposal that avian influenza virus can be inactivated using commercial pet food processing methods as specified. The Code Commission noted that this article covers the importation of products of poultry origin intended for use for agricultural and industrial uses as well as for use in animal feed. The Code Commission considered that the data provided on the processing parameters used by the pet food industry should be taken into account in any future work to develop OIE recommendations on pet food.

A Member's request to delete 'under study' from Article 10.4.24. was not accepted by the Code Commission as the Member only provided justification relevant to the processing of feather meal and not to the processing of feathers and down of poultry, which are also covered by this article. However, the Code Commission proposed a new Article 10.4.24.bis 'Recommendations for the importation of feather meal' based on the Member's recommendations.

The Community would be ready to give data to the OIE concerning the inactivation of the AI virus in feathers.

The revised Chapter, which is presented at Annex XX, is provided for Member comments.

23. Newcastle disease (Chapter 10.13.)

The Code Commission reviewed comments from Australia, the EU and South Africa.

The Code Commission made a number of modifications to the text with the goal of harmonizing the approach with that taken to Chapter 10.4. (Avian influenza).

Community comments

The Community can only support the proposed changes, if article 10.3.5, 10.3.7 and 10.3.9 are modified. Moreover, the Community would appreciate to get detailed scientific evidence for the new article 19 bis.

At the request of Members, the Code Commission incorporated into Chapter 10.13. a table showing the time and temperature parameters required to inactivate Newcastle disease virus in eggs, egg products and poultry meat. This information is based on a Member's submission and comments of experts.

The revised Chapter, which is presented at Annex XXI, is provided for Member comments.

24. Bovine spongiform encephalopathy (Chapter 11.6.)

The Code Commission reviewed comments from Canada, the EU, Japan, New Zealand, Pakistan and the USA. Several industry associations also commented on the articles relating to by-products.

The Code Commission considered comments and decided that text changes were only warranted in regard to two specific issues, i.e., point 1. g) of Article 11.6.1. (meat from cattle 30 months of age or less) and Article 11.6.15 (by-products, including gelatine). Several requests for modifications that had been submitted previously and had been resubmitted were reviewed by the Code Commission. The Code Commission decided to adopt no further changes to Chapter 11.6. on the grounds that the Members' recommendations did not address new risks and adoption would not significantly improve the current text.

Community comments

The Community can not support the proposed changes regarding the "30 month rule" for deboned beef and gelatine.

a) Discussion on the '30 month rule'

Although the Code Commission noted that a 30 month age restriction had added an element of safety regarding possible contamination with SRM, a careful examination of the science shows that maintenance of the 30 month age restriction is unwarranted. The Code Commission emphasised that the removal and avoidance of contamination with SRM, as defined in Article 11.6.14., are paramount to manage the human and animal health risks associated with BSE.

The most accurate assessment of the risks to humans from consuming BSE affected cattle can be made by considering the situation in the United Kingdom (UK), where there have been more than 180,000 cases of BSE. (In the rest of the world combined, there have been fewer than 6,000 cases.) It has been estimated that in the UK somewhere between 1.6 and 4 million cattle infected with BSE were consumed. Even though around 45% of Britons are of the genotype considered most susceptible to BSE, fewer than 170 people have died from the disease since 1996. Further, it is now generally accepted that most human exposure to BSE in the UK was through the consumption of mechanically-recovered meat contaminated with central nervous system tissues. That is, humans in the UK were not, in all probabilities, exposed to BSE through eating muscle meat.

Thanks to the proper handling of SRM, including appropriate feed-ban and feed testing provisions, BSE is in decline and is now a rare disease. It is now far less likely that BSE infected cattle will be presented for slaughter than had been the case in the UK through the 1990s. The application of the recommendations in the *Terrestrial Code* (Article 11.6.1.) very significantly reduce the risk of meat being contaminated with central nervous system tissue. While the 30 month restriction may have provided some measures of risk reduction at the peak of the BSE epidemic, these days there can be no significant effect on risk by excluding meat from cattle over 30 months of age, provided the recommendations in this Chapter are properly enforced.

b) Definition of SRM (Article 11.6.14.)

Because scientific knowledge on the infectivity of tissues defined in Article 11.6.14. is very well established and the appropriate management of these tissues provides the most appropriate approach to the control of BSE related risks, the Code Commission decided not to modify this Article.

c) Importation from a country, zone or compartment posing a controlled BSE risk

In point 4 b) of Article 11.6.11. the Code makes reference to cattle over 30 months of age in relation to mechanically separated meat (MSM) from the skull and vertebral column. It is a well established fact that BSE infectivity in the central nervous system manifests, on average, at 30 months of age. On the basis that the disease risk with MSM is associated with nervous tissue, not with meat, the Code Commission decided to maintain this article unchanged.

d) Risk management for gelatine

The OIE received several comments on risk management for gelatine pointing out that the OIE had, at the 76th General Session, adopted more stringent risk management measures than warranted. The Code Commission was of the opinion that gelatine manufactured according to the conditions described in Article 11.6.15. was safe, regardless of the origin of the raw materials, as long as skulls had been removed. The Code Commission failed to find any reason as to why bones from countries with an undetermined risk status for BSE would be riskier than bones from countries with a controlled risk status, as long as the conditions in Article 11.6.12. had been satisfied. Therefore the Code Commission decided to revert to the text proposed for adoption at the 76th General Session.

e) Other comments

The Code Commission noted a comment from an industry organisation and agreed to remove the words 'protein-free' from Article 11.6.1. in order to avoid confusion.

The Code Commission reviewed a comment on point 4 of Article 11.6.20. (cattle subpopulations for surveillance purposes) but did not recognize a need to adopt the proposed text changes. However, the Code Commission added text to Article 11.6.22. advising on surveillance points for small cattle populations, as suggested by a Member.

The revised Chapter, which is presented at Annex XXII, is provided for Member comments.

25. Bovine tuberculosis (Chapter 11.7.)

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

The Code Commission considered comments of Members and made some amendments to Chapter 11.7. The Code Commission reviewed the definition of compartmentalisation, which provides for one or more establishments to be considered as a compartment. The Code Commission deleted 'under study' from Article 11.7.3. and deleted all of Article 11.7.4., based on the view that a free herd should be dealt with as a compartment. Based on this reasoning, the Code Commission also removed the reference to compartment from Article 11.7.7.

Community comments

The Community cannot support the proposed changes. All the bovine tuberculosis surveillance and prophylaxis is based upon the notion of free herds, which cannot be deleted. Compartments are a notion far too new to directly replace herds. Moreover, it is a notion related to trade with specific approval and much too heavy to organise at a global level. And the current proposed article for bovine TB compartments lacks completely from any biosecurity measures, although the role of the herd environment and wildlife is not negligible. There should be a gradation between a free herd and a free compartment, this must be further studied.

In response to Member comment, the Code Commission also reviewed the previous text relating to bovine tuberculosis in farmed cervidae and produced a new draft chapter.

The revised and new chapters, which are presented at Annex XXIII, are provided for Member comments.

26. Contagious bovine pleuropneumonia (Chapter 11.8.)

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

The Code Commission incorporated several comments with a view to clarifying the existing text.

The Code Commission noted the advice from the *ad hoc* Group on Trade in Animal Products on the listing of milk and milk products as safe commodities. It also asked the *ad hoc* Group on Contagious Bovine Pleuropneumonia to provide advice on other products including meat and meat products.

Community comments: The Community can support the proposed draft chapter.

The revised Chapter, which is presented at Annex XXIV, is provided for Member comments.

27. Equine diseases

Community comments

The Community can support the proposed draft chapters but have comments for equine viral arteritis..

a) African horse sickness (Chapter 12.1.)

The Code Commission reviewed comments from the EU and modified the text as appropriate following the advice of SCAD and BSC.

b) Equine influenza (Chapter 12.7.)

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

c) Equine rhinopneumonitis (Chapter 12.9.)

The Code Commission reviewed a comment from New Zealand.

The Member commented that the terminology for equine rhinopneumonitis should be revised to consider Equid herpesvirus 1 (EHV 1) to be the agent of equine abortion and Equid herpesvirus 4 (EHV 4) to be the agent of equine rhinopneumonitis. Based on the BSC advice that the description contained in the *Terrestrial Manual* is accurate, the Code Commission incorporated appropriate text into Article 12.9.1.

d) Equine viral arteritis (Chapter 12.10.)

The Code Commission reviewed comments from the EU, South Africa and an expert.

The Code Commission modified the text as appropriate following the advice of an expert.

The revised Chapters, which are presented at Annex XXV, are provided for Member comments.

28. Scrapie (Chapter 14.9.)

The Code Commission reviewed comments from Argentina, Australia, Canada, the EU, Japan, New Zealand, Norway and the USA.

Community comments

The Community opposes the adoption of this Chapter 14.9 in its present form and regrets that the discussion on the review of the Scrapie Chapter has been stopped.

The Community opposes to the recognition of historical freedom without any requirements related to surveillance. It is suggested that a basis for the minimum level of active surveillance should be laid down. The Chapter on Animal Health Surveillance also states that historical freedom is related to some kind of surveillance.

The Code Commission noted that many comments had been received on Chapter 14.9. and reviewed these carefully. Unlike BSE, scrapie does not pose a human health risk. The management of scrapie is primarily based on preventing contagion at the time of birth and in the period immediately after, and controls over live animals and semen, not via the control of specified risk materials and meat and bone meal, as with BSE. Other approaches to control involve managing the genotype of flocks. The Code Commission therefore decided that the preferred model for the revised chapter on scrapie was Chapter 2.4.8. in the 2007 edition of the *Code*, rather than the BSE chapter in the 2008 edition of the *Code*.

Atypical scrapie is a sporadic degenerative condition occurring in aged sheep and goats. This condition is not thought to be contagious and it is important to distinguish it from classical scrapie in the *Code*, as the trade implications of finding an atypical scrapie case are completely different.

In accordance with Members' recommendations, the Code Commission deleted the reference to cattle in regard to the scope of Chapter 14.9. and replaced 'small ruminant' with 'sheep and goats' throughout. The Code Commission also modified Article 14.9.1. in line with the modification of Article 11.6.1. (BSE) dealing with safe commodities and removed '*in vivo* derived embryos' from the list of products that are safe for trade.

The primary main mode for the transmission of scrapie is from mother to offspring immediately after birth. In response to several Members' comments regarding the lack of evidence for the transmission of scrapie through meat and bone meal, the Code Commission modified the text on meat and bone meal in Article 14.9.2.

Some Members proposed that the OIE provide, in Article 14.9.3., a table showing the number of samples to be tested according to population size. The Code Commission was not in a position to develop such a table but invited Members to submit a draft text for consideration.

Although there is a good scientific consensus that scrapie does not present a human health risk, it has recently been demonstrated that scrapie may be transmitted to lambs in sheep's milk. Therefore, the Code Commission added text (Article 14.9.9.bis) on milk and milk products intended for use in animal feeds.

The revised Chapter, which is presented at Annex XXVI, is provided for Member comments.

29. African swine fever (Chapter 15.1.)

The Code Commission reviewed comments from the EU and South Africa.

The Code Commission acknowledged the requests of Members for advice on surveillance and inactivation procedures for African swine fever virus in swine products, similar to the approach taken in Chapter 15.3. (Classical Swine Fever). The Code Commission is awaiting the provision of advice from the SCAD on these points. In the interim, the Code Commission made no changes to Chapter 15.1.

Community comment

The Community is ready to help in this matter.

30. Classical swine fever (Chapter 15.3.)

The Code Commission reviewed comments from the EU, Japan and South Africa. The Code Commission also took into account the report of the September 2008 meeting of the *ad hoc* Group on Epidemiology.

The Code Commission developed a revised text on classical swine fever (CSF), taking into account the following key considerations:

- For the purposes of international trade, CSF should be considered as an infection of domestic pigs;
- 'Domestic pig' should be defined as including both housed and farmed free range pigs, i.e. all domesticated pigs used for the production of meat for consumption and other commercial products and for breeding these categories of pigs;
- It is important to encourage Members to conduct appropriate surveillance (as defined in the *Terrestrial Code*) and report findings of CSF infection in wild pigs;
- It is possible to establish separation between domestic and wild pig populations and to maintain a distinct CSF status in the two populations;

- The OIE has undertaken to incorporate the concept of compartmentalisation into disease chapters as appropriate to the epidemiology of the disease. This concept can and should be applied in the case of CSF;

- Members should be able to export pigs and pig products from a CSF free domestic population regardless of the presence of CSF in wild pigs, providing that the surveillance, reporting and disease control provisions of the *Terrestrial Code* have been satisfied.

Article 15.3.3. was modified to remove the provision for historical CSF freedom as the Code Commission considered this not to be a disease for which freedom can be maintained without appropriate surveillance.

The Code Commission modified the text of several articles in Chapter 15.3.

Community comments

The Community can support the proposed changes, for which the TAHSC must be congratulated as the chapter is now much more consistent and practical.

There are still some technical comments which should be taken into consideration.

The revised Chapter, which is presented at Annex XXVII, is provided for Member comments.

31. West Nile fever (new Chapter)

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

Following a discussion with the SCAD, the Code Commission relocated Article 2 in front of Article 1.

The Code Commission noted Members' comments regarding the susceptibility of humans, horses and day old poultry to infection with West Nile fever (WNF). While horses and humans are dead end hosts, they are nonetheless susceptible to infection, as are day old poultry. The Code Commission included new text advising that Members should not place trade restrictions on horses on account of WNF. Even though there is a low likelihood of day old poultry being exposed to infection, studies show that they are susceptible to infection and they cannot, therefore, be included on the list of safe commodities.

Some Members called for guidance on surveillance for WNF. The Code Commission agreed that such guidance should be provided and that this would be considered once the SCAD has advised on requirements for surveillance of vector-borne diseases.

Community comments

The Community feels that this Chapter is not mature enough to be voted next May as it needs more scientific input.

The revised Chapter, which is presented at Annex XXVIII, is provided for Member comments.

32. Small hive beetle infestation (Chapter 9.4.) and other bee diseases (Chapters 9.1., 9.2., 9.3., 9.5., 9.6.)

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

Text modifications regarding the responsibility of the Competent Authority will be reflected as appropriate in other Chapters on bee diseases in the *Code*.

Community comment

The Community can support the proposed changes but have technical comments.

The revised Chapters, which are presented at Annex XXIX, are provided for Member comments.

33. The control of hazards of animal health and public health importance in animal feed (new Chapter)

The Code Commission reviewed comments from Canada, the EU, Japan, New Zealand, Switzerland and the USA and modified the text as appropriate.

The revised Chapter, which is presented at Annex XXX, is provided for Member comments.

Community comments

Apart from some comments included in the text, the Community would like to stress that it is important to avoid any confusion or contradictory overlap with the relevant Codex Alimentarius standards dealing with animal feeding, in particular the Code of Good Animal Feeding (CAC/RCP 54-2004) but also others.

The Code Commission discussed representations made by the pet food industry, seeking OIE advice on pet food standards. The Code Commission noted Dr Vallat's advice that the OIE would consider developing specific advice on feed for animals not used for food production (pet animals) in 2009.

34. Swine vesicular disease (Chapter 15.5.)

The Code Commission noted that an *ad hoc* Group has prepared a revised chapter on swine vesicular disease and that the SCAD will further review this text in light of changes made to Chapter 15.3. (CSF).

Community comment

The Community wishes to see the report of this ad hoc group which was not with the report of the SCAD meeting.

35. OIE-FAO Guide to Good Farming Practices

The Code Commission reviewed comments from Argentina and the EU.

The Code Commission noted that the Guide has been finalised and is currently being printed by FAO. The Guide will also be published in the OIE *Bulletin*. Therefore, the Code Commission did not address Members' comments.

C. OTHER ISSUES

36. *Ad hoc* Group on Trade in Animal Products ('Commodities')

The Code Commission reviewed the report of the July 2008 meeting of the *ad hoc* Group on Trade in Animal Products (Commodities). The Code Commission noted the report and agreed that the conclusions were generally sound.

The Code Commission addressed the recommendations of the Group by making a number of amendments to disease chapters in the *Code* (Rift valley fever [|RVF), bovine cysticercosis, Teschen virus encephalomyelitis, contagious bovine pleuropneumonia, equine influenza) in order to emphasise the safety of trade in certain commodities.

The Code Commission also supported a number of recommendations made by the Group for scientific research to be conducted to clarify the effectiveness of various risk management regimes, such as the development of risk management provisions for sheep and goat milk and milk products, the food safety risks associated with RVF virus in milk and dairy products, and the use of deboning, maturing and pH testing of pig meat as a risk management measure for FMD.

The Code Commission addressed a BSE related impediment to trade in commodities with the proposed amendment of the '30-month rule' (Article 11.6.1. item 1 g)) and expressed a strong desire that Members accept this amendment as proposed.

Notwithstanding the good work done by the *ad hoc* Group, the Code Commission expressed some disappointment that it had not provided clear recommendations on a key trade impediment, i.e. the safety of deboned, matured pH-tested bovine meat, regardless of the FMD status of the country/zone from which the cattle came and regardless of whether the cattle were vaccinated against FMD or not. Accordingly, over and above the recommendations of the *ad hoc* Group, the Code Commission recommended that the OIE commission expert studies to demonstrate the scientific rationale for listing deboned, matured pH-tested bovine and porcine products as a safe commodity in regard to FMD, taking into account the recommendations from the *ad hoc* Group, as well as specific scientific publications cited by experts.

The revised Chapters (other than discussed in B. of this report), which are presented at Annex XXXI, are provided for Member comments.

The report of the *ad hoc* Group is attached in Annex XXXVIII for information of Members.

37. Applications for OIE Collaborating Centres and Reference Laboratories

The Code Commission acknowledged two applications for a new Collaborating Centres, one for Animal Feed Safety and Analysis, submitted by the Food and Agricultural Materials Inspection Centre, Saitama (Japan) and another for animal welfare submitted jointly by Universidad Austral de Chile and Universidad de la Republica Oriental del Uruguay. The Code Commission endorsed these submissions and recommended that the International Trade Department forward the applications according to the normal OIE procedure.

38. The Commission's reporting procedures

The Code Commission noted the comments from Australia and the USA. Collaboration between the SCAD and the Code Commission is of critical importance and it was agreed that SCAD meetings should precede Code Commission meetings whenever possible and that there should be a coordination meeting between the two Commissions (or at least the two Presidents) at least once per year.

Pending further discussion within the OIE, no changes were proposed to the schedule of Code Commission meetings.

39. Report of the OIE *ad hoc* Group on Wildlife Disease Notification

Dr Karim Ben Jebara, Director of the Disease Information Department, joined the Code Commission for this discussion.

The Code Commission noted the report of the *ad hoc* Group but did not consider that any modification to the *Code* was warranted at this stage.

The report is attached in Annex XL for information of Members.

40. Future work programme

The updated work programme is shown in Annex XLI.

41. Other business

The next meeting of the Code Commission is scheduled for 2-6 March 2009.

.../Annexes

Annex I

MEETING OF THE OIE

TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 29 September–10 October 2008

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Annex II

MEETING OF THE OIE

TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 29 September – 10 October 2008

Provisional Agenda

1. Welcome and briefing- Director General

2. Update on reports of other commissions and other relevant activities of the OIE - President of the Commission

3. Code revision

A. Examination of Member Countries' comments

Item 1 Glossary

Item 2 Criteria for listing diseases (Chapter 1.2.)

Item 3 Animal health surveillance (Chapter 1.4.)

Item 4 Horizontal chapters

a) Import risk analysis (Chapter 2.2.)

b) Animal health measures applicable before and at departure (Chapter 5.4.)

c) Border posts and quarantine stations in the importing country (Chapter 5.6.)

Item 5 Evaluation of Veterinary Services (Chapter 3.1 and 3.2.)

a) Report of the a*d hoc* Group on Evaluation of Veterinary Services

b) Community animal health worker

c) Report of the a*d hoc* Group on communication

Item 6 Design and implementation of animal systems to achieve animal traceability (Chapter 4.2.)

Item 7 Zoning and compartmentalisation

a) Zoning and compartmentalisation (Chapter 4.3.)

b) Application of compartmentalisation (Chapter 4.4.)

Item 8 Surveillance for vector-borne diseases

Item 9 Semen and embryo chapters (Chapters 4.5., 4.6., 4.7., 4.8., 4.9., 4.10., 4.11.)

Item 10 Somatic cell nuclear transfer in production livestock and horses (Chapter 4.12.)

Item 11 Model certificates

a) General obligations related to certification (Chapter 5.1.)

b) Certification procedures (Chapter 5.2.)

c) Model veterinary certificates for international trade in live animals, hatching eggs and products of animal origin (Chapter 5.10.)

Item 12 The role of the Veterinary Services in food safety (Chapter 6.1.)

Item 13 Salmonellosis

a) The detection, control and prevention of *Salmonella spp.* in poultry (new)

b) Hygiene and biosecurity procedures in poultry production (Chapter 6.3.)

Item 14 Introduction to the recommendations for controlling antimicrobial resistance (new)

Item 15 Animal welfare

a) Animal welfare definition

b) Stray dog population control (new)

c) Report of the *ad hoc* Group on the Welfare of Animals used in Research, Testing and Teaching (laboratory animals)

d) Report of the *ad hoc* Group on Animal Welfare and Livestock Production Systems

e) Report of the 7th Meeting of the OIE Animal Welfare Working Group

Item 16 Anthrax (Chapter 8.1.)

Item 17 Bluetongue (Chapter 8.3.)

Item 18 Foot and mouth disease (Chapter 8.5.)

Item 19 Paratuberculosis (Chapter 8.10.)

Item 20 Rabies (Chapter 8.11.)

Item 21 Rinderpest (Chapter 8.13.)

Item 22 Avian influenza (Chapter 10.4.)

Item 23 Newcastle disease (Chapter 10.13)

Item 24 Bovine spongiform encephalopathy (Chapter 11.6.)

Item 25 Bovine tuberculosis (Chapter 11.7.)

Item 26 Contagious bovine pleuropneumonia (Chapter 11.8.)

Item 27 Equine diseases

a) African horse sickness (Chapter 12.1.)

b) Equine influenza (Chapter 12.7.)

c) Equine rhinopneumonitis (Chapter 12.9.)

d) Equine viral arteritis (Chapter 12.10.)

Item 28 Scrapie (Chapter 14.9.)

Item 29 African swine fever (Chapter 15.1.)

Item 30 Classical swine fever (Chapter 15.3.)

Item 31 West Nile fever (new)

Item 32 Small hive beetle infestation and other bee chapters

Item 33 Guidelines for the control of hazards of animal health and public health importance in animal feed

Item 34 Swine vesicular disease

Item 35 Guide to good farming practices

B. Other issues

Item 36 *Ad hoc* Group on trade in animal products

Item 37 Applications for OIE Collaboration centres / Reference Laboratories

Item 38 The Commission's reporting procedures

Item 39 Ad-hoc Group on wildlife disease notification

Item 40 Future work programme

Item 41 Others

Annex III

GLOSSARY

Community comments

The Community welcomes the idea of the ad hoc group on communication, of a draft proposal for a Chapter on Communication. However, the definitions of "Communication", "Crisis", "Crisis communication" and "Outbreak communication" should be in the draft chapter and the Community refuses that they are already included in the Glossary. In view of this the Community has not made any specific comments on the definitions at this time but does not agree in general with the definitions as proposed. Once a draft chapter including the new definition is proposed, the Community will provide detailed comments.

In some cases, the OIE should work closely with Codex to ensure as far as possible the same definitions throughout. This will apply for the new definition relating to communication, but applies also already for the definitions of risk, risk analysis, risk assessment, risk communication.

The Community is still concerned about the definition of protection zone, which can be confusing, more particularly its implementation and suggests that this concept and its use, as well as that of surveillance zone, is better described in the Chapter on Zoning rather than have just a definition.

Furthermore, the Community reiterates its former comments on the definitions of *Infection* and *Monitoring*, and asks the OIE to further reflect on these comments (here under added at the end this text) for a possible amendment of the definitions.

For the purposes of the *Terrestrial Code*:

~~Buffer~~ Protection zone

means a *zone* established 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*.

Communication

means the discipline of informing, influencing, and motivating individual, institutional and public audiences, preferably on the basis of interactive exchanges, about any issue falling under the mandate of the OIE and the competence of the *Veterinary Services*.

Crisis

means a time of great danger, difficulty or uncertainty when problems related to any issue falling under the mandate of the OIE and the competence of the *Veterinary Services* require immediate action.

Crisis Communication

means the process of providing information of potentially incomplete nature within time constraints that allows an individual, affected and/or interested parties, an entire community or the general public to make best possible decisions and/or accept policy decisions during a crisis.

Official veterinary control ~~of live animals~~

means the operations whereby the *Veterinary Services*, knowing the location of the *animals* and after taking appropriate actions to identify ~~the identity of~~ their owner or responsible keeper, are able to apply appropriate animal health measures, as required. This does not exclude other responsibilities of the *Veterinary Services* e.g. food safety.

Outbreak ~~of disease or infection~~

means the occurrence of one or more *cases* ~~of a *disease* or an *infection*~~ in an *epidemiological unit*.

Outbreak communication

means the process of communicating in the event of an *outbreak*. Outbreak communication includes *notification*.

Risk

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

Risk assessment

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

Risk communication

is the interactive exchange of information ~~on *risk*~~ and opinions throughout the *risk analysis* process concerning *risk*, risk-related factors and *risk* perceptions among *risk* assessors, *risk* managers, *risk* communicators, the general public and other interested parties.

Sanitary measure

means a measure, such as those described in various Chapters of the *Terrestrial Code*, destined to protect animal or human health or life within the territory of the OIE Member from *risks* arising from the entry, establishment ~~and~~ or spread of a *hazard*.

~~***Surveillance zone***~~

~~means a *zone* established within, and along the border of, a *free zone* separating the *free zone* from an *infected zone*.~~

~~The *surveillance zone* should have an intensified degree of *surveillance*.~~

Veterinary para-professional

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

Infection

means the entry and development or multiplication of an infectious agent in the body of humans or *animals*.

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.

Monitoring

means the intermittent performance and analysis of routine measurements, aimed at detecting changes in the environment or health status of a *population*.

The Community wishes to reiterate that 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.

Annex IV

CHAPTER 1.4.

ANIMAL HEALTH SURVEILLANCE

Community comments

The Community can accept the proposed draft and thanks the OIE for these very important changes.

There are in the article 1.4.2 definitions which are already in the Code Glossary. If they are identical, it is a mere repetition that could be deleted; if they are not, there can be problems of consistency. Once a definition has been agreed upon, if it is used more than once it should be only in the glossary; if it is used once only, it should only stay in the chapter.

Article 1.4.1.

Introduction and objectives

1. In general, *surveillance* is aimed at demonstrating the absence of *disease* or *infection*, determining the occurrence or distribution of *disease* or *infection*, while also detecting as early as possible exotic or *emerging diseases*. The type of *surveillance* applied depends on the desired outputs needed to support decision-making. The following recommendations may be applied to all *diseases*, their agents and all susceptible species (including wildlife) as listed in the *Terrestrial Code*, and are designed to assist with the development of *surveillance* methodologies. Except where a specific *surveillance* method for a certain *disease* or *infection* is already described in the *Terrestrial Code*, the recommendations in this Chapter may be used to further refine the general approaches described for a specific *disease* or *infection*. Where detailed *disease*/*infection*-specific information is not available, suitable approaches should be based on the recommendations in this Chapter.

Community comment

The Community supports this principle; however, not all susceptible species are listed in the various Chapters. Thus unless all are listed some will be missed. The Community requests the OIE to have a better and more relevant list.

.

2. Animal health *surveillance* is an essential component necessary to detect *diseases*, to monitor disease trends, to control endemic and exotic diseases, to support claims for freedom from *disease* or *infection*, to provide data to support the *risk analysis* process, for both animal health and/or public health purposes, and to substantiate the rationale for sanitary measures. Both domestic and wild animals are susceptible to certain *diseases*/ *infections*. However, in the presence of appropriate biosecurity measures, *infection*/ *disease* in wild animals does not imply that the same *infection*/ *disease* is necessarily present in domestic animals in the same country or *zone*. *Surveillance* data underpin the quality of disease status reports and should satisfy information requirements for accurate *risk analysis* both for *international trade* as well as for national decision-making. Wildlife may be included because these can serve both as reservoirs and as sensitive indicators of important human and domestic animal *diseases*. Wildlife disease *surveillance* presents specific challenges that may differ importantly from disease *surveillance* in livestock.

Community comment

The Community proposes to delete the words "in the presence of appropriate biosecurity measures" as this implies a conditionality which should not be there in this general statement: infection in wildlife never *implies necessarily* infection in domestic.

3. Essential prerequisites to enable an OIE Member to provide information for the evaluation of its animal health status are:

   a) that the particular Member complies with the provisions of Chapter 3.1. of the *Terrestrial Code* on the quality and evaluation of the *Veterinary Services*;

   b) that, where possible, *surveillance* data be complemented by other sources of information (e.g. scientific publications, research data, documented field observations and other non-survey data);

   c) that transparency in the planning and execution of *surveillance* activities and the analysis and availability of data and information, be maintained at all times, in accordance with Chapter 1.1. of the *Terrestrial Code*.

4. The objectives of this Chapter are to:

   a) provide guidance to the type of outputs that a *surveillance* system should generate;

   b) provide recommendations to assess the quality of disease *surveillance* systems.

Article 1.4.2.

Definitions

The following definitions apply for the purposes of this Chapter:

Bias: A tendency of an estimate to deviate in one direction from a true value.

Case definition: A case definition is a set of criteria used to classify an *animal* or *epidemiological unit* as a *case*.

Confidence: In the context of demonstrating freedom from *infection*, confidence is the probability that the type of *surveillance* applied would detect the presence of *infection* if the population were infected. The confidence depends on, among other parameters, the assumed level of *infection* in an infected population. The term refers to confidence in the ability of the *surveillance* applied to detect *disease*, and is equivalent to the sensitivity of the *surveillance* system.

Early detection system: A system for the timely detection and identification of an incursion or emergence of *disease/infection* in a country, *zone* or *compartment*. An early detection system should be under the control of the *Veterinary Services* and should include the following characteristics:

Community comment

This definition is already in the Glossary.

a) representative coverage of target animal populations by field services;

b) ability to undertake effective *disease* investigation and reporting;

c) access to *laboratories* capable of diagnosing and differentiating relevant *diseases*;

d) a training programme for *veterinarians*, *veterinary para-professionals* and others involved in handling *animals* for detecting and reporting unusual animal health incidents;

e) the legal obligation of private *veterinarians* in relation to the *Veterinary Authority*;

f) timely reporting system of the event to the *Veterinary Services*;

g) a national chain of command.

Outbreak definition: An outbreak definition is a set of criteria used to classify the occurrence of one or more *cases* in a group of *animals* or units as an *outbreak*.

Probability sampling: A sampling strategy in which every unit has a known non-zero probability of inclusion in the sample.

Sample: The group of elements (sampling units) drawn from a population, on which tests are performed or parameters measured to provide *surveillance* information.

Sampling units: The unit that is sampled, either in a random survey or in non-random *surveillance*. This may be an individual *animal* or a group of *animals* (e.g. an *epidemiological unit*). Together, they comprise the sampling frame.

Sensitivity: The proportion of truly positive units that are correctly identified as positive by a test.

Specificity: The proportion of truly negative units that are correctly identified as negative by a test.

Study population: The population from which *surveillance* data are derived. This may be the same as the target population or a subset of it.

Surveillance: The systematic ongoing collection, collation, and analysis of data, and the timely dissemination of information to those who need to know so that action can be taken.

Community comment

This definition is already in the Glossary.

Surveillance system: A method of *surveillance* that may involve one or more component activities that generates information on the health, disease or zoonosis status of animal populations.

Survey: An investigation in which information is systematically collected, usually carried out on a sample of a defined population group, within a defined time period.

Target population: The population about which conclusions are to be inferred.

Test: A procedure used to classify a unit as either positive, negative or suspect with respect to an *infection* or *disease*.

Test system: A combination of multiple tests and rules of interpretation which are used for the same purpose as a test.

Wildlife: Mammals and birds which are not permanently captive or owned free-range. This definition includes the categories of "wild animal" (wild animal genotype living outside of controlling human influence) and "feral animal" (domestic animal genotype living outside of controlling human influence).

Article 1.4.3.

Principles of surveillance

1. Types of surveillance

a) *Surveillance* may be based on many different data sources and can be classified in a number of ways, including:

   i) the means by which data are collected (active versus passive *surveillance*);

   ii) the disease focus (pathogen-specific versus general *surveillance*); and

   iii) the way in which units for observation are selected (structured surveys versus non-random data sources).

b) In this Chapter, *surveillance* activities are classified as being based on:

   EITHER

   i) structured population-based surveys, such as:

      - systematic sampling at *slaughter*;

      - random surveys;

   OR

   ii) structured non-random *surveillance* activities, such as:

      - *disease* reporting or notifications;

      - control programmes/health schemes;

      - targeted testing/screening;

      - ante-mortem and post-mortem inspections;

      - laboratory investigation records;

      - biological specimen banks;

      - sentinel units;

      - field observations;

      - farm production records;

      - wildlife disease data.

c) In addition, all available *surveillance* data should be supported by related information, such as:

Community comment

The wording of "all available" should be replaced by the word "the" as it is only the relevant data that is needed not that dating back many years which is now not important, not relevant or outdated.

   i) data on the epidemiology of the *infection*, including environmental, host population distribution, and climatic information;

   ii) data on animal movements ~~and~~ including transhumance, and natural wildlife migrations;

iii) trading patterns for *animals* and animal products;

~~iii~~iv) national animal health regulations, including information on compliance with them and their effectiveness;

~~iv~~v) history of imports of potentially infected material; and

~~v~~vi) biosecurity measures in place.

d) The sources of evidence should be fully described. In the case of a structured survey, this should include a description of the sampling strategy used for the selection of units for testing. For structured non-random data sources, a full description of the system is required including the source(s) of the data, when the data were collected, and a consideration of any biases that may be inherent in the system.

2. Critical elements

In assessing the quality of a *surveillance* system, the following critical elements need to be addressed over and above quality of *Veterinary Services* (Chapter 3.1.).

a) Populations

Ideally, *surveillance* should be carried out in such a way as to take into account all animal species susceptible to the *infection* in a country, *zone* or *compartment*. The *surveillance* activity may cover all individuals in the population or part of them. When *surveillance* is conducted only on a *subpopulation*, care should be taken regarding the inferences made from the results.

Definitions of appropriate populations should be based on the specific recommendations of the disease Chapters of the *Terrestrial Code*.

b) Epidemiological unit

The relevant *epidemiological unit* for the *surveillance* system should be defined and documented to ensure that it is representative of the population. Therefore, it should be chosen taking into account factors such as carriers, reservoirs, vectors, immune status, genetic resistance and age, sex, and other host criteria.

c) Clustering

Infection in a country, *zone* or *compartment* usually clusters rather than being uniformly or randomly distributed through a population. Clustering may occur at a number of different levels (e.g. a cluster of infected *animals* within a *herd*, a cluster of pens in a building, or a cluster of farms in a *compartment*). Clustering should be taken into account in the design of *surveillance* activities and the statistical analysis of *surveillance* data, at least at what is judged to be the most significant level of clustering for the particular animal population and *infection*.

d) Case and outbreak definitions

Clear and unambiguous case and outbreak definitions should be developed and documented for each pathogen under *surveillance*, using, where they exist, the standards in the *Terrestrial Code*. For wildlife disease *surveillance*, it is essential to correctly identify and report host animal taxonomy (including genus and species).

Community comment

In some cases is impossible to correctly identify and report host animal taxonomy

(including genus and species).... so the Community suggests to change above sentence to read "....wherever possible it is important to correctly identify and report host animal taxonomy (including genus and species)".

e) Analytical methodologies

Surveillance data should be analysed using appropriate methodologies, and at the appropriate organisational levels to facilitate effective decision making, whether it be planning interventions or demonstrating status.

Methodologies for the analysis of *surveillance* data should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. Different methodologies may be needed to accommodate the relevant host species, pathogens, varying production and *surveillance* systems, and types and amounts of data and information available.

The methodology used should be based on the best available information that is in accord with current scientific thinking. The methodology should be in accordance with this Chapter and fully documented, and supported by reference to the scientific literature and other sources, including expert opinion. Sophisticated mathematical or statistical analyses should only be carried out when justified by the proper amount and quality of field data.

Consistency in the application of different methodologies should be encouraged and transparency is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding. The uncertainties, assumptions made, and the effect of these on the final conclusions should be documented.

f) Testing

Surveillance involves the detection of *disease* or *infection* by the use of appropriate case definitions based on the results of one or more tests for evidence of *infection* or immune status. In this context, a test may range from detailed laboratory examinations to field observations and the analysis of production records. The performance of a test at the population level (including field observations) may be described in terms of its sensitivity and specificity and predictive values. Imperfect sensitivity and/or specificity will have an impact on the conclusions from *surveillance*. Therefore, these parameters should be taken into account in the design of *surveillance* systems and analysis of *surveillance* data.

The values of sensitivity and specificity for the tests used should be specified, and the method used to determine or estimate these values should be documented. Alternatively, where values for sensitivity and/or specificity for a particular test are specified in the *Terrestrial Manual*, these values may be used as a guide. For each host species to which a diagnostic test is applied, whenever possible, the tests should be shown to have acceptable sensitivity and specificity for that particular host species.

Samples from a number of *animals* or units may be pooled and subjected to a testing protocol. The results should be interpreted using sensitivity and specificity values that have been determined or estimated for that particular pool size and testing procedure.

g) Quality assurance

Surveillance systems should incorporate the principles of quality assurance and be subjected to periodic auditing to ensure that all components of the system function and provide verifiable documentation of procedures and basic checks to detect significant deviations of procedures from those documented in the design.

h) Validation

Results from animal health *surveillance* systems are subject to one or more potential biases. When assessing the results, care should be taken to identify potential biases that can inadvertently lead to an over-estimate or an under-estimate of the parameters of interest.

i) Data collection and management

The success of a *surveillance* system is dependent on a reliable process for data collection and management. The process may be based on paper records or computerised. Even where data are collected for non-survey purposes (e.g. during disease control interventions, inspections for movement control or during disease eradication schemes), the consistency and quality of data collection and event reporting in a format that facilitates analysis, is critical. Factors influencing the quality of collected data include:

- the distribution of, and communication between, those involved in generating and transferring data from the field to a centralised location; this requires effective collaboration among all stakeholders, such as government ministries, non-governmental agencies, and others, particularly for data involving wildlife;

- the ability of the data processing system to detect missing, inconsistent or inaccurate data, and to address these problems;

- maintenance of disaggregated data rather than the compilation summary data;

- minimisation of transcription errors during data processing and communication.

Article 1.4.4.

Structured population-based surveys

In addition to the principles for *surveillance* discussed above, the following recommendations should be used when planning, implementing and analysing surveys.

1. Types of surveys

Surveys may be conducted on the entire target population (i.e. a census) or on a sample. A sample may be selected in either of the two following ways:

a) non-probability based sampling methods, such as:

i) convenience;

ii) expert choice;

iii) quota;

b) probability based sampling methods, such as:

i) simple random selection;

ii) cluster sampling;

iii) stratified sampling;

iv) systematic sampling.

Non-probability based sampling methods will not be discussed further.

Periodic or repeated surveys conducted in order to document *disease* freedom should be done using probability based sampling methods so that data from the study population can be extrapolated to the target population in a statistically valid manner.

The sources of information should be fully described and should include a detailed description of the sampling strategy used for the selection of units for testing. Also, consideration should be made of any biases that may be inherent in the survey design.

2. Survey design

The population of *epidemiological units* should first be clearly defined; hereafter sampling units appropriate for each stage, depending on the design of the survey, should be defined.

The design of the survey will depend on the size and structure of the population being studied, the epidemiology of the *infection* and the resources available.

Data on wild animal population size often do not exist and should be determined before a survey can be designed. The expertise of wildlife biologists may be sought in the gathering and interpretation of such population data. Historical population data should be updated since these may not reflect current populations.

3. Sampling

The objective of sampling from a population is to select a subset of units from the population that is representative of the population with respect to the object of the study such as the presence or absence of *infection*. Sampling should be carried out in such a way as to provide the best likelihood that the sample will be representative of the population, within the practical constraints imposed by different environments and production systems. In order to detect the presence of an *infection* in a population of unknown disease status, targeted sampling methods that optimise the detection of *infection* can be used. In such cases, care should be taken regarding the inferences made from the results.

4. Sampling methods

When selecting *epidemiological units* from within a population, probability sampling (e.g. simple random selection) should be used. When this is not possible, sampling should provide the best practical chance of generating a sample that is representative of the target population.

In any case, the sampling method used at all stages should be fully documented and justified.

5. Sample size

In general, surveys are conducted either to demonstrate the presence or absence of a factor (e.g. *infection*) or to estimate a parameter (e.g. the prevalence of *infection*). The method used to calculate sample size for surveys depends on the purpose of the survey, the expected prevalence, the level of confidence desired of the survey results and the performance of the tests used.

Article 1.4.5.

Structured non-random surveillance

Surveillance systems routinely use structured non-random data, either alone or in combination with surveys.

1. Common non-random surveillance sources

A wide variety of non-random *surveillance* sources may be available. These vary in their primary purpose and the type of *surveillance* information they are able to provide. Some *surveillance* systems are

primarily established as early detection systems, but may also provide valuable information to demonstrate freedom from *infection*. Other systems provide cross-sectional information suitable for prevalence estimation, either once or repeatedly, while yet others provide continuous information, suitable for the estimate of incidence data (e.g. disease reporting systems, sentinel sites, testing schemes). *Surveillance* systems routinely use structured non-random data, either alone or in combination with surveys.

a) Disease reporting or notification systems

Data derived from *disease* reporting systems can be used in combination with other data sources to substantiate claims of animal health status, to generate data for *risk analysis*, or for early detection. Effective laboratory support is an important component of any reporting system. Reporting systems relying on laboratory confirmation of suspect clinical cases should use tests that have a high specificity. Reports should be released by the laboratory in a timely manner, with the amount of time from *disease* detection to report generation minimized (to hours in the case of introduction of a foreign animal disease).

Whenever the responsibility for disease notification falls outside the scope of the *Veterinary Authority*, for example for *diseases* in wildlife, effective communication and data sharing should be established with the relevant authorities to ensure comprehensive and timely disease reporting.

b) Control programmes / health schemes

Animal *disease* control programmes or health schemes, while focusing on the control or eradication of specific *diseases*, should be planned and structured in such a manner as to generate data that are scientifically verifiable and contribute to structured *surveillance*.

c) Targeted testing / screening

This may involve testing targeted to selected sections of the population (subpopulations), in which *disease* is more likely to be introduced or found. Examples include testing culled and dead *animals*, swill fed *animals*, those exhibiting clinical signs, *animals* located in a defined geographic area and specific age or commodity group.

d) Ante-mortem and post-mortem inspections

Inspections of *animals* at *abattoirs* may provide valuable *surveillance* data. The sensitivity and specificity of the particular *slaughterhouse* inspection system for detecting the presence of infectious agents of *surveillance* interest under the particular inspection arrangements applying in a country should be pre-determined by the *Competent Authority* if the data is to be fully utilised. The accuracy of the inspection system will be influenced by:

i) the level of training and experience of the staff doing the inspections, and the ratio of staff of different levels of training;

ii) the involvement of the *Competent Authorities* in the supervision of ante-mortem and post-mortem inspections;

iii) the quality of construction of the *abattoir*, speed of the slaughter chain, lighting quality, etc.; and

iv) staff morale/motivation for accurate and efficient performance.

Abattoir inspections are likely to provide good coverage only for particular age groups and geographical areas. *Abattoir surveillance* data are subject to obvious biases in relation to target and study populations (e.g. only *animals* of a particular class and age may be slaughtered for human consumption in significant numbers). Such biases need to be recognized when analysing

surveillance data.

Both for traceback in the event of detection of *disease* and for analysis of spatial and *herd*-level coverage, there should be, if possible, an effective identification system that relates each *animal* in the *abattoir* to its locality of origin.

e) Laboratory investigation records

Analysis of laboratory investigation records may provide useful *surveillance* information. The coverage of the system will be increased if analysis is able to incorporate records from national, accredited, university and private sector laboratories. Valid analysis of data from different laboratories depends on the existence of standardised diagnostic procedures and standardized methods for interpretation and data recording. As with *abattoir* inspections, there needs to be a mechanism to relate specimens to the farm of origin.

f) Biological specimen banks

Specimen banks consist of stored specimens, gathered either through representative sampling or opportunistic collection or both. Specimen banks may contribute to retrospective studies, including providing support for claims of historical freedom from *infection*, and may allow certain studies to be conducted more quickly and at lower cost than alternative approaches.

g) Sentinel units

Sentinel units/sites involve the identification and regular testing of one or more of *animals* of known health/immune status in a specified geographical location to detect the occurrence of *disease* (usually serologically). They are particularly useful for *surveillance* of *diseases* with a strong spatial component, such as vector-borne *diseases*. Sentinel units provide the opportunity to target *surveillance* depending on the likelihood of *infection* (related to vector habitats and host population distribution), cost and other practical constraints. Sentinel units may provide evidence of freedom from *infection*, or provide data on prevalence and incidence as well as the distribution of *disease*.

h) Field observations

Clinical observations of *animals* in the field are an important source of *surveillance* data. The sensitivity and specificity of field observations may be relatively low, but these can be more easily determined and controlled if a clear, unambiguous and easy to apply standardised case definition is applied. Education of potential field observers in application of the case definition and reporting is an important component. Ideally, both the number of positive observations and the total number of observations should be recorded.

i) Farm production records

Systematic analysis of farm production records may be used as an indicator of the presence or absence of *disease* at the *herd* or *flock* level. In general, the sensitivity of this approach may be quite high (depending on the *disease*), but the specificity is often quite low.

j) Wildlife data

Specimens from wild animals for disease *surveillance* may be available from sources such as hunters and trappers, road-kills, wild animal meat markets, sanitary inspection of hunted animals,–morbidity and mortality observations by the general public, wildlife rehabilitation centres, wildlife biologists and wildlife agency field personnel, farmers and other landholders, naturalists and conservationists. Wildlife data such as census data, trends over time, and

reproductive success can be used in a manner similar to farm production records for epidemiological purposes.

2. Critical elements for structured non-random surveillance

There is a number of critical factors which should be taken into account when using structured non-random *surveillance* data such as coverage of the population, duplication of data, and sensitivity and specificity of tests that may give rise to difficulties in the interpretation of data. *Surveillance* data from non-random data sources may increase the level of confidence or be able to detect a lower level of prevalence with the same level of confidence compared to structured surveys.

3. Analytical methodologies

Different methodologies may be used for the analysis of non-random *surveillance* data.

Different scientifically valid methodologies may be used for the analysis of non-random *surveillance* data. Where no data are available, estimates based on expert opinions, gathered and combined using a formal, documented and scientifically valid methodology may be used.

4. Combination of multiple sources of data

The methodology used to combine the evidence from multiple data sources should be scientifically valid, and fully documented including references to published material.

Surveillance information gathered from the same country, *zone* or *compartment* at different times may provide cumulative evidence of animal health status. Such evidence gathered over time may be combined to provide an overall level of confidence. For instance, repeated annual surveys may be analysed to provide a cumulative level of confidence. However, a single larger survey, or the combination of data collected during the same time period from multiple random or non-random sources, may be able to achieve the same level of confidence in just one year.

Analysis of *surveillance* information gathered intermittently or continuously over time should, where possible, incorporate the time of collection of the information to take the decreased value of older information into account. The sensitivity, specificity and completeness of data from each source should also be taken into account for the final overall confidence level estimation.

Article 1.4.6.

Surveillance to demonstrate freedom from disease/ infection

1. Requirements to declare a country, zone or compartment free from disease/infection without pathogen specific surveillance

This Article provides general principles for declaring a country, *zone* or *compartment* free from *disease/infection* in relation to the time of last occurrence and in particular for the recognition of historical freedom.

The provisions of this Article are based on the principles described in Article 1.4.3. of this Chapter and the following premises:

- in the absence of *disease* and vaccination, the animal population would become susceptible over a period of time;

- the disease agents to which these provisions apply are likely to produce identifiable clinical signs in susceptible *animals*;

- competent and effective *Veterinary Services* will be able to investigate, diagnose and report disease,

if present;

- *diseases/infections* can affect both wild and domestic animals;

- the absence of *disease/infection* over a long period of time in a susceptible population can be substantiated by effective disease investigation and reporting by a Member.

a) Historically free

Unless otherwise specified in the relevant *disease* Chapter, a country, *zone* or *compartment* may be recognised free from *infection* without formally applying a pathogen-specific *surveillance* programme when:

i) there has never been occurrence of *disease*, or

ii) eradication has been achieved or the *disease/infection* has ceased to occur for at least 25 years, provided that for at least the past 10 years:

iii) it has been a *notifiable disease*;

iv) an early detection system has been in place for all relevant species;

v) measures to prevent *disease/infection* introduction have been in place; no vaccination against the *disease* has been carried out unless otherwise provided in the *Terrestrial Code*;

vi) *infection* is not known to be established in wildlife within the country or *zone* intended to be declared free. (A country or *zone* cannot apply for historical freedom if there is any evidence of *infection* in wildlife. ~~However, specific *surveillance* in wildlife is not necessary.~~)

b) Last occurrence within the previous 25 years

Countries, *zones* or *compartments* that have achieved eradication (or in which the *disease/infection* has ceased to occur) within the previous 25 years, should follow the pathogen-specific *surveillance* requirements in the *Terrestrial Code* if they exist. In the absence of specific requirements for *surveillance* in the *Terrestrial Code*, countries should follow the general recommendations on *surveillance* to demonstrate animal health status outlined in this Chapter provided that for at least the past 10 years:

i) it has been a *notifiable disease*;

ii) an early detection system has been in place;

iii) measures to prevent *disease/infection* introduction have been in place;

iv) no vaccination against the *disease* has been carried out unless otherwise provided in the *Terrestrial Code*;

v) *infection* is not known to be established in wildlife within the country or *zone* intended to be declared free. (A country or *zone* cannot apply for freedom if there is any evidence of *infection* in wildlife. However, specific *surveillance* in wildlife is not necessary.)

2. Recommendations for the discontinuation of pathogen-specific screening after recognition of freedom from infection

A country, *zone* or *compartment* that has been recognised as free from *infection* following the provisions of the *Terrestrial Code* may discontinue pathogen-specific screening while maintaining the infection-free status provided that:

a) it is a *notifiable disease*;

b) an early detection system is in place;

c) measures to prevent *disease*/*infection* introduction are in place;

d) vaccination against the *disease* is not applied;

e) *infection* is known not to be established in wildlife. (~~Specific *surveillance* in wildlife has demonstrated the absence of *infection*.~~ It can be difficult to collect sufficient epidemiological data to prove absence of *infection* in wild animal populations. Therefore, a wide range of supporting evidence should be used to make this assessment.)

3. International recognition of disease/infection free status

For *diseases* for which procedures exist whereby the OIE can officially recognise the existence of a *disease*/*infection* free country, *zone* or *compartment*, a Member wishing to apply for recognition of this status shall, via its Permanent Delegate, send to the OIE all the relevant documentation relating to the country, *zone* or *compartment* concerned. Such documentation should be presented according to the recommendations prescribed by the OIE for the appropriate animal *diseases*.

4. Demonstration of freedom from infection

A *surveillance* system to demonstrate freedom from *infection* should meet the following requirements in addition to the general requirements for *surveillance* outlined in Article 1.4.3. of this Chapter.

Freedom from *infection* implies the absence of the pathogenic agent in the country, *zone* or *compartment*. Scientific methods cannot provide absolute certainty of the absence of *infection*.

Demonstrating freedom from *infection* involves providing sufficient evidence to demonstrate (to a level of confidence acceptable to Members) that *infection* with a specified pathogen is not present in a population. In practice, it is not possible to prove (i.e., be 100% confident) that a population is free from *infection* (unless every member of the population is examined simultaneously with a perfect test with both sensitivity and specificity equal to 100%). Instead, the aim is to provide adequate evidence (to an acceptable level of confidence), that *infection*, if present, is present in less than a specified proportion of the population.

However, finding evidence of *infection* at any level in the target population automatically invalidates any freedom from *infection* claim unless otherwise stated in the relevant *disease* Chapter. The implications of *disease*/*infection* in wildlife for the status of domestic animals in the same country or *zone* should be assessed in each situation, as indicated in the relevant Chapter on each *disease* in the *Terrestrial Code*).

Evidence from targeted, random or non-random data sources, as stated before, may increase the level of confidence or be able to detect a lower level of prevalence with the same level of confidence compared to structured surveys.

Article 1.4.7.

Surveillance for distribution and occurrence of infection

Surveillance to determine distribution and occurrence of *infection* or of other relevant health related events is widely used to assess progress in the control or eradication of selected *diseases* and pathogens and as an aid to decision making. It has, however, relevance for the international movement of *animals* and products when movement occurs among infected countries.

In contrast to *surveillance* to demonstrate freedom from *infection*, *surveillance* used to assess progress in

control or eradication of selected *diseases* and pathogens is usually designed to collect data about a number of variables of animal health relevance, for example:

1. prevalence or incidence of *infection*;

2. morbidity and mortality rates;

3. frequency of *disease/infection risk* factors and their quantification;

4. frequency distribution of *herd* sizes or the sizes of other *epidemiological units*;

5. frequency distribution of antibody titres;

6. proportion of immunised *animals* after a vaccination campaign;

7. frequency distribution of the number of days elapsing between suspicion of *infection* and *laboratory* confirmation of the diagnosis and/or to the adoption of control measures;

8. farm production records~~, etc~~.

9. Role of wildlife in maintenance or transmission of the *infection*.

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Annex V

CHAPTER 2.2.

GUIDELINES FOR IMPORT RISK ANALYSIS

Community comments

The Community can accept the proposed draft. The Community strongly wishes to be associated in the coming ad hoc group on import risk analysis.

Article 2.2.1.

Introduction

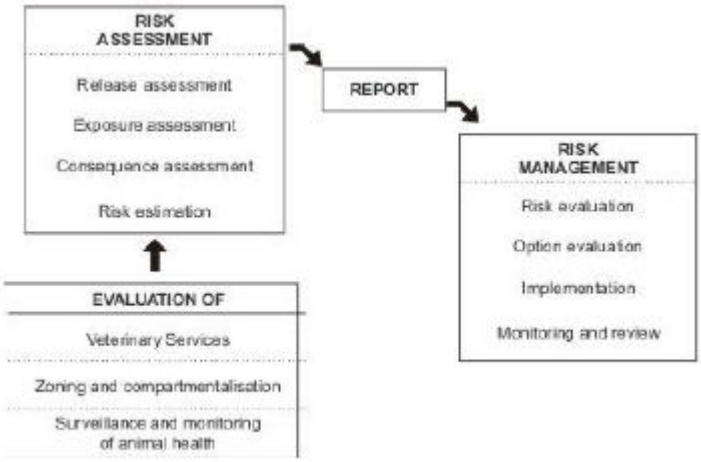
An import *risk analysis* begins with a description of the *commodity* proposed for import and the likely annual quantity of trade. It must be recognised that whilst an accurate estimate of the anticipated quantity of trade is desirable to incorporate into the risk estimate, it may not be readily available, 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 2.2.2.

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 2.2.3.

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. Although quantitative analysis is recognised as being able to provide deeper insights into a particular problem, qualitative methods may be more relevant when available data are limited.

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 2.2.4.

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 and compartmentalisation 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* 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 2.2.5.

Principles of risk management

1. *Risk management* is the process of deciding upon and implementing measures to achieve the Member's appropriate level of protection, whilst at the same time ensuring that negative effects on trade are minimized. The objective is to manage *risk* appropriately to ensure that a balance is achieved between a country's desire to minimize 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 2.2.6.

Risk management components

1. Risk evaluation - the process of comparing the *risk* estimated in the *risk assessment* with the Member'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 order to bring it into line with the Members 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 2.2.7.

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.

Annex V (contd)

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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CHAPTER 5.4.

ANIMAL HEALTH MEASURES APPLICABLE BEFORE AND AT DEPARTURE

Community comments

The Community can only accept the proposed draft if the following wording for the second sentence in Article 5.4.1. point 3 is taken into account:

- The words "or a certifying official approved by the importing country" should be deleted and replaced by the words "of the exporting country"

- The words "if required" should be placed before the word "disinfected".

This is to ensure:

- that there is no certification established in the exporting country under the responsibility of the importing country or even that the importing country uses its own personnel to certify as this is not acceptable; if trade takes place it means that the competent authorities of the importing country agrees on the certification system of the exporting country;

- and that the word "required" only refers to the disinfection of the vehicle. The vehicle should always be cleaned but may not be necessary to disinfect it every time.

Moreover, in Article 5.4.3 the word "establishment" should be in italic.

Article 5.4.1.

Animals for breeding, rearing or slaughter

1. Countries should only authorise the exportation from their territory of *animals for breeding or rearing* or *animals for 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*~~ of the health status agreed by the *importing* and *exporting countries* by an *Official Veterinarian* or by an official of the *Competent Authority* or a certifying official approved by the *importing country*, during the period of observation, the *animals* should be transported to the *place of shipment* in specially constructed *vehicles*, previously cleansed and disinfected if required. 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 5.4.2.

Semen, embryo/ ova, hatching eggs

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 5.4.3.

Notification

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 an establishment ~~point at which the shipment is assembled of 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 5.4.4.

Certificate

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 Chapters 5.10. to 5.12. 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 5.4.5.

Live animals

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* as agreed by the *importing* and *exporting countries*;
   b) avoid entry into the *vehicle* of possible vectors or causal agents of *infection*.

Article 5.4.6.

Products of animal origin

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 Chapters 5.10. to 5.12. 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 Chapters 5.10. to 5.12. of the *Terrestrial Code*).

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CHAPTER 5.6.

BORDER POSTS AND QUARANTINE STATIONS IN THE IMPORTING COUNTRY

Community comments

The Community can accept the proposed draft.

Article 5.6.1.

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 5.6.2.

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 5.6.3.

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 contact between animals of different health status and the *risk* of introducing *diseases* transmitted by insects.

Article 5.6.4.

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 5.7.1. to 5.7.4.;

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 VI

CHAPTER 4.2.

DESIGN AND IMPLEMENTATION OF IDENTIFICATION SYSTEMS TO ACHIEVE ANIMAL TRACEABILITY

Community comments

The Community thanks the OIE for the small amendment and can accept the proposed change.

The Community recommends to add an Article on the quality and control of data. This could be based on the recommendations of the conference on animal traceability to be held in March 2009 in Buenos Aires, Argentina.

Article 4.2.1.

Introduction and objectives

These recommendations are based on the general principles presented in Article 4.1.1. The recommendations outline for Members 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 Chapters 5.10. to 5.12. for *animals* and animal products intended for export. Each country should design a programme in accordance with the scope and relevant performance criteria to ensure that the desired *animal traceability* outcomes can be achieved.

Article 4.2.2.

Glossary

For the purpose of this Chapter:

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.

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 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 within or between countries.

Article 4.2.3.

Key elements of the animal identification system

1. Desired outcomes

   Desired outcomes should be defined through consultation between the *Veterinary 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 Chapters 5.10. to 5.12. which reproduce model international veterinary certificates);

   e) aspects of animal husbandry such as animal performance, and genetic data.

2. Scope

   Scope should also be defined through consultation between the *Veterinary 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 programme. 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 *zoonoses*, it may be considered appropriate that *animals* can be traced over a longer period.

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,

g) zoning and compartmentalisation,

h) animal movement patterns (including transhumance),

i) information management and communication,

j) availability of resources (human and financial),

k) social and cultural aspects,

l) stakeholder knowledge of the issues and expectations,

m) gaps between current enabling legislation and what is needed long term,

n) international experience,

o) national experience,

p) available technology options,

q) existing *identification system(s)*,

r) expected benefits from the *animal identification systems* and *animal traceability* 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.

b) Means of animal identification

The choice of a physical animal identifier should consider elements such as the durability, human resources, species and age of the *animals* to be identified, required period of identification, 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 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 Authority* is also responsible for ensuring that identifiers are unique and are used in accordance with the requirements of the *animal identification system*.

The *Veterinary 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 *animals* are 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 keepers

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.

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 owner~~ship~~ or keeper regardless of change of establishment,
- 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 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.).

Annex VI (contd)

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 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;
- minimize duplication;
- relevant components, including databases, should be compatible;
- confidentiality of data;
- appropriate safeguards to prevent the loss of data, including a system for backing up the data.

The *Veterinary 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 and 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.

6. Legal framework

The *Veterinary 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 Authority*.

This legal framework should address:

i) desired outcomes and scope;

ii) obligations of the *Veterinary 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.

Annex VI (contd)

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 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 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 VII

CHAPTER 4.3.

ZONING AND COMPARTMENTALISATION

Community comments
The Community can accept the proposed change.
However, in the article 4.3.1 the word "target" is used whereas the word "goal" is used in the article 4.4.1. To be consistent, the terms should be the same, "goal" being better.
Moreover the Community reiterates its comment on article 4.3.3 point 5 on movement documentation.
The Community wishes the TAHSC takes into account its comments on protection zone and surveillance zone, which implementation should be comprehensively described in this chapter, as it has been done for containment zone.
In addition the Community reiterates its comment about the problem of wildlife: it should be clearly stated in this chapter whenever the wildlife and domestic population may be dealt with separately or not as regards zoning.

Article 4.3.1.

Introduction

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

Establishing and maintaining a disease free-status throughout the country should be the final target for OIE Members. However, gGiven the difficulty of establishing and maintaining a *disease* free status for an entire territory, 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 Member 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. 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 compartmentalisation 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 4.3.2.

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 a distinct *animal health status* for the given *zone* or *compartment* 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 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 *animal 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 4.3.3.

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 stands till of movement of *animals* and *commodities* upon notification of suspicion of the specified *disease* and the demonstration that the *outbreaks* 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 Chapter 8.5. 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*.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.

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.*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*.

4. 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 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*.

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 opinion that the movements of identified animals should be documented in order for their history to be audited. Thus the words"and their movements documented" should be included between "should be identified" and "in such a way that etc. "

6. 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.

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CHAPTER 4.4.

APPLICATION OF COMPARTMENTALISATION

Community comments
The Community can accept the proposed draft and thanks the TAHSC for these important changes.
However, in the article 4.4.1 the word "goal" is used whereas the word "target" is used in the article 4.3.1. To be consistent, the terms should be the same, "goal" being better.
In article 4.4.7 the Community propose a slight modification for better clarity of the objective of this article.

Article 4.4.1.

Introduction and objectives

The recommendations in this Chapter provide a structured framework for the application and recognition of *compartments* within countries or *zones*, based on the provisions of Chapter 4.3. 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 throughout the country should be final goal for OIE Member. However, e~~E~~stablishing 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 have traditionally applied the concept of zoning to establish and maintain an animal *subpopulation* with a different animal health status within national boundaries.

~~The Glossary of the *Terrestrial Code* defines a *compartment* as "an animal *subpopulation* contained in one or more *establishments* under a common biosecurity management system 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 *subpopulations*.

For example, 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 infected countries or *zones*, compartmentalisation may be used to facilitate trade.

For the purpose of *international trade*, *compartments* must be under the responsibility of the *Veterinary Authority* in the country. For the purposes of this Chapter, compliance by the Members with Chapters 1.1. and 3.1. is an essential prerequisite.

Article 4.4.2.

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*.

Article 4.4.3.

Separation of a compartment from potential sources of infection

The management of a *compartment* must provide to the *Veterinary Authority* documented evidence on the following:

1. 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:

   a) disease status in adjacent areas and in areas epidemiologically linked to the *compartment*;

   b) 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:

      i) *flocks* or *herds* with a different health status in close proximity to the *compartment*, including wildlife and their migratory routes;

      ii) *slaughterhouses*, rendering plants or feed mills;

      iii) *markets*, fairs, agricultural shows, sporting events, zoos, circuses and other points of animal concentration.

2. Infrastructural factors

   Structural aspects of the *establishments* within a *compartment* contribute to the effectiveness of its Biosecurity. Consideration should be given to:

   a) fencing or other effective means of physical separation;

   b) facilities for people entry including access control, changing area and showers;

   c) *vehicle* access including washing and *disinfection* procedures;

d) *unloading* and *loading* facilities;

e) isolation facilities for introduced *animals*;

f) facilities for the introduction of material and equipment;

g) infrastructure to store feed and veterinary products;

h) disposal of carcasses, manure and waste;

i) water supply;

j) measures to prevent exposure to living mechanical or biological vectors such as insects, rodents and wild birds;

k) air supply;

l) feed supply/source.

More detailed recommendations for certain *establishments* can be found in Sections 4 and 6 of the *Terrestrial Code*.

3. 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:

a) 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;

b) the critical control points for each pathway;

c) measures to mitigate exposure for each critical control point;

d) standard operating procedures including:

   i) implementation, maintenance, monitoring of the measures,

   ii) application of corrective actions,

   iii) verification of the process,

   iv) record keeping;

e) contingency plan in the event of a change in the level of exposure;

f) reporting procedures to the *Veterinary Authority*;

g) the programme for educating and training workers to ensure that all persons involved are knowledgeable and informed on biosecurity principles and practices;

h) the *surveillance* programme in place.

Annex VII (contd)

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 should be structured in line with the principles of Hazard Analysis and Critical Control Point (HACCP). 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*.

4. 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 Authority* should provide sufficient assurance of *traceability*.

All animal movements into and out of the *compartment* should be 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 4.4.4.

Documentation

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 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 Authority*.

Article 4.4.5.

Surveillance for the agent or disease

The *surveillance* system should comply with Chapter 1.4. on Surveillance and the specific recommendations 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. At the same time, biosecurity measures in place should be reassessed and increased if necessary.

1. Internal surveillance

   Surveillance should involve the collection and analysis of *disease/infection* data so that the *Veterinary Authority* can certify that the animal *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 *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.

2. 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 Chapter 1.4., 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 4.4.6.

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 *laboratory* for the specific *disease*.

Each *laboratory* that conducts testing should have systematic procedures in place for rapid reporting of *disease* results to the *Veterinary Authority*. Where appropriate, results should be confirmed by an OIE Reference Laboratory.

Article 4.4.7.

Emergency response and notification

Early detection, diagnosis and notification of *disease* are critical to minimize 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.

In case of an occurrence of any infectious *disease* not present according to the baseline animal health report of the *compartment* referred to in Article 4.4.4., the management of the *compartment* should notify the *Veterinary Authority*, and initiate a review to determine whether there has been a breach in the biosecurity measures. If a significant breach in biosecurity, even in the absence of *outbreak*, ~~was~~ is detected, export certification of the free *compartment* should be suspended. ~~Trade~~ Free status of the *compartment* may only be ~~resumed~~ reinstated after the *compartment* has adopted the necessary measures to re-establish the original biosecurity level and the *Veterinary Authority* re-approves the status of the *compartment* ~~for trade~~.

Community comment

In the above second sentence of the third paragraph, the words "export certification <u>of the free *compartment*</u> should be suspended" should be replaced by "export certification <u>as a free *compartment*</u> should be suspended" or "<u>the free status of the *compartment*</u> should be suspended". Indeed, the objective is not to stop all trade but to suspend the approval until the biosecurity has been reinstated.

<u>In the event of a *compartment* being in close proximity to an *outbreak of the disease* for which the *compartment* was defined, the *Veterinary Authority* should re-evaluate without delay the biosecurity measures applied to ensure that the integrity of the *compartment* has been maintained.</u>

Article 4.4.8.

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 *Terrestrial Code*, to provide confidence in the integrity of the *compartment*.

The *Veterinary Authority* has the final authority in granting, suspending and revoking the status of a *compartment*. The *Veterinary Authority* should continuously supervise compliance with all the requirements critical to the maintenance of the *compartment* status described in this Chapter 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 VIII

CHAPTER 3.X.X.

GENERAL GUIDELINES FOR SURVEILLANCE OF ARTHROPOD VECTORS OF ANIMAL DISEASES

Community comments

The Community thanks the TAHSC for this proposed draft chapter, which should be given a proper Chapter number. However, it should not be proposed for adoption in 2009, as it is not complete especially as:.- The suggested definition should be replaced by a practical definition of "vector" (and after should be included in the Code Glossary), which should differentiate between active and passive vectors and should not include waste i.e. mechanical transfer;- the decision tree to which the last sentence of point 1 refers is not included in this draft neither is the figure mentioned.

1. Introduction

Vector-borne diseases are of increasing importance economically and to human and animal health.

Environmental (including climate change), sociological and economical changes may affect the distribution and impact of these diseases.

Improved understanding of the distribution and population dynamics of the vectors is a key element for assessing and managing the risks associated with vector-borne animal and zoonotic diseases.

The OIE *Terrestrial Animal Health Code* contains guidelines for the surveillance of several vector-borne diseases.

The need has arisen to complement these general surveillance guidelines with additional general guidelines for the surveillance of vectors themselves. This Appendix only addresses surveillance for arthropod vectors.

Community comment

The Community proposes to replace the word "general" by "disease specific".

Indeed, the guidelines contained in the OIE *Terrestrial Animal Health Code* are specific of the related vector-borne diseases.

For the purpose of trade, it must be noted that there is no conclusive relationship between the presence of a vector(s) and the *disease* status of a country/zone, and also that the apparent absence of a vector(s) does not by itself confirm vector-free status.

A vector may be broadly defined as:

> *", in infectious disease epidemiology, an insect or any living carrier that transports an infectious agent from an infected individual or its wastes to a susceptible individual or its food or immediate surroundings. The organism may or may not pass through a development cycle within the vector". (Dictionary of Epidemiology, John M. last, 4th Edition 2001)*

A Decision Tree with respect to vector surveillance is reflected in Figure 2.

2. Objectives

The objective of these *Guidelines* is to provide methods for:

- gathering up-to-date information on the spatial and temporal distribution and abundance of vectors of the arthropod-borne OIE-listed diseases and emerging diseases;
- monitoring changes in the spatial and temporal distribution and abundance of these vectors;
- collecting relevant data to inform risk assessment (including vector competency) and risk management of these vector-borne diseases.

3. Sampling methodology

a) Sampling plan

i) The state of existing knowledge should be assessed to determine whether or not historical data on the vector or the disease exist for the country or zone.

ii) The sampling plan should consider the following:

- the known aspects of the biology and ecology of the vector(s),
- the presence, distribution and abundance of the vectors' host animal populations,
- the environmental, ecological and topographic conditions of relevance to vector ecology.

iii) Sampling should be aimed at:

- establishing vector presence in the country or zone,
- describing the distribution of the vector(s) within the country or zone,
- providing additional information on vector density and spatial/temporal variability (both over the short- and the long-term).

iv) The sampling plan should be designed to provide representative estimates, with a minimum of bias, of the indicators listed in item 3 above. Consideration should be given to the following:

The recommended general approach to sampling is via a three-stage hierarchy:

- Stratification based on ecological criteria (where possible),
- subdivision of strata into spatial sampling units, and
- establishment of actual sampling sites within selected spatial sampling units.

If adequate historical data and/or expert opinion are available, the sampling plan may be further refined or targeted by defining strata which are as homogenous as possible with respect to the following known or suspected risk-factors:

- domestic or wild populations of host animals preferred by the vector,
- vector habitat suitability,

- climatic patterns (including seasonal),
- areas endemically and/or epidemically affected by the disease of concern,
- areas of known vector occurrences,
- fringe zone(s) around areas of known vector occurrences,
- areas in which the disease(s) or vector(s) of concern have not been reported currently or historically,
- each stratum (or the whole country or zone, if not stratified) should be divided into spatial sampling units according to standard methodologies such as a grid system,
- the number and size of the spatial sampling units should be defined to provide representative estimates of the indicators listed in item 3 above,
- the number and location of actual sampling sites within each spatial sampling unit also should be defined to provide representative estimates of the indicators listed in item 3 above,
- different levels of sampling intensity (spatial sampling unit size, number of units sampled, number of sites sampled within units, and sampling frequency) may be applied to different strata into which the country or zone has been divided. For example, more intensive sampling might be carried out in strata where vector presence seems most likely, based on biological or statistical criteria.

b) Sampling methods

Many sampling methods have been developed for the capture of vector arthropods, and these differ according to the disease/vector system under consideration.

i) The collection methods used should be adapted as required to ensure reasonable confidence of collecting the vector(s) of concern.

ii) Collection methods should secure the various developmental stages (such as eggs, larvae, nymphs, adults) and adult age categories, as appropriate to the species in question, required to estimate population survival rates and population dynamics in relation to disease transmission.

iii) Different collection methods may be required to secure samples from a single vector species, depending on the life stage or place of capture (such as from the environment or from the host animals). The collection method must be appropriate to the species and life stage of interest.

The collection methods should preserve the vector(s) to allow for subsequent complete taxonomic analysis (using both morphological and molecular techniques) and detection and/or isolation of pathogenic agent(s).

c) Data management, analysis and interpretation

Data management and analytical methodologies should be done in accordance with Chapter 1.4.).

Annex IX

CHAPTER 4.5.

COLLECTION AND PROCESSING OF BOVINE, SMALL RUMINANT AND PORCINE SEMEN

Community comments

The Community thanks the TAHSC for this proposed draft chapter.

However teschovirus encephalomyelitis should be deleted here as this is not a listed disease. (The same comment applies for the chapter 15.6.) The Code Commissions justification for deletion of Enterovirus encephalomyelitis was (page 496 of Appendix XXVIII in the Report of the Meeting of the OIE Terrestrial Animal Health Standards Commission, 17 - 28 January 2005): "Enterovirus encephalomyelitis (Teschen/Talfan disease) – The clinical form (Teschen disease) does not seem to occur anymore. Talfan and Teschen viruses are indistinguishable from other type 1 enteroviruses which are very common in the pig population. Serological cross-reactions occur. The morbidity and mortality are not significant. The disease should be excluded from the list."

Moreover, in the last paragraph of the chapter, the words "official seal" should be changed to "numbered seal", as there is a confusion with the official seal apposed to certificates: here it is a numbered seal whose number is reported on the certificate.

Article 4.5.1.

General considerations

The purposes of official sanitary control of semen production are to:

1. maintain the health of *animals* on an *artificial insemination centre* at a level which permits the international distribution of semen with a negligible *risk* of infecting other *animals* or humans with pathogens transmissible by semen;

2. ensure that semen is hygienically collected, processed and stored.

Artificial insemination centres should comply with recommendations in Chapter 4.6.

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

Article 4.5.2.

Conditions applicable to testing of bulls and teaser animals

Bulls and teaser animals should only enter an *artificial insemination centre* if they fulfil the following requirements.

1. Pre-quarantine

   The *animals* should comply with the following requirements prior to entry into isolation at the *quarantine station*.

   a) Bovine brucellosis

The *animals* should comply with point 3 or 4 of Article 11.3.5.

b) Bovine tuberculosis

The *animals* should comply with point 3 or 4 of Article 11.7.5.

c) Bovine viral diarrhoea-mucosal disease (BVD-MD)

The *animals* should be subjected to the following tests:

i) a virus isolation test or a test for virus antigen, with negative results;

ii) a serological test to determine the serological status of every *animal*.

d) Infectious bovine rhinotracheitis-infectious pustular vulvovaginitis

If the *artificial insemination centre* is to be considered as infectious bovine rhinotracheitis-infectious pustular vulvovaginitis free (IBR/IPV), the *animals* should either:

i) come from an IBR/IPV free *herd* as defined in Article 11.12.3.; or

ii) be subjected, with negative results, to a serological test for IBR/IPV on a blood sample.

e) Bluetongue

The *animals* should comply with Articles 8.3.5., 8.3.6. or 8.3.7., depending on the bluetongue status of the country of origin of the *animals*.

2. Testing in the quarantine station prior to entering the semen collection facilities

Prior to entering the semen collection facilities of the *artificial insemination centre*, bulls and teaser animals should be kept in a *quarantine station* for at least 28 days. The *animals* should be subjected to diagnostic tests as described below a minimum of 21 days after entering the *quarantine station*, except for *Campylobacter fetus* subsp. *venerealis* and *Trichomonas foetus*, for which testing may commence after 7 days in quarantine. All the results should be negative except in the case of BVD-MD antibody serological testing (see point 2b)i) below).

a) Bovine brucellosis

The *animals* should be subjected to a serological test with negative results.

b) BVD-MD

i) All *animals* should be tested for viraemia as described in point 1c) above.

Only when all the *animals* in quarantine test negative for viraemia, may the *animals* enter the semen collection facilities upon completion of the 28-day quarantine period.

ii) After 21 days in quarantine, all *animals* should be subjected to a serological test to determine the presence or absence of BVD-MD antibodies.

iii) Only if no sero-conversion occurs in the *animals* which tested seronegative before entry into the *quarantine station*, may any *animal* (seronegative or seropositive) be allowed entry into the semen collection facilities.

iv) If sero-conversion occurs, all the *animals* that remain seronegative should be kept in quarantine over a prolonged time until there is no more seroconversion in the group for a

period of 3 weeks. Serologically positive *animals* may be allowed entry into the semen collection facilities.

c) *Campylobacter fetus* subsp. *venerealis*

i) *Animals* less than 6 months old or kept since that age only in a single sex group prior to quarantine should be tested once on a preputial specimen, with a negative result.

ii) *Animals* aged 6 months or older that could have had contact with females prior to quarantine should be tested three times at weekly intervals on a preputial specimen, with a negative result in each case.

d) *Trichomonas foetus*

i) *Animals* less than 6 months old or kept since that age only in a single sex group prior to quarantine, should be tested once on a preputial specimen, with a negative result.

ii) *Animals* aged 6 months or older that could have had contact with females prior to quarantine should be tested three times at weekly intervals on a preputial specimen, with a negative result in each case.

e) IBR-IPV

If the *artificial insemination centre* is to be considered as IBR/IPV free, the *animals* should be subjected, with negative results, to a diagnostic test for IBR/IPV on a blood sample. If any *animal* tests positive, the *animal* should be removed immediately from the *quarantine station* and the other *animals* of the same group should remain in quarantine and be retested, with negative results, not less than 21 days after removal of the positive *animal*.

f) Bluetongue

The *animals* should comply with Articles 8.3.5., 8.3.6. or 8.3.7., depending on the bluetongue status of the country of origin of the *animals*.

3. Testing for BVD-MD prior to the initial dispatch of semen from each serologically positive bull

Prior to the initial dispatch of semen from BVD-MD serologically positive bulls, a semen sample from each *animal* should be subjected to a virus isolation or virus antigen test for BVD-MD. In the event of a positive result, the bull should be removed from the centre and all of its semen destroyed.

4. Testing of frozen semen for IBR/IPV in artificial insemination centres not considered as IBR/IPV free

Each aliquot of frozen semen should be tested as per Article 11.12.7.

5. Testing programme for bulls and teasers resident in the semen collection facilities

All bulls and teasers resident in the semen collection facilities should be tested at least annually for the following *diseases*, with negative results, where the country of origin is not free:

a) Bovine brucellosis

b) Bovine tuberculosis

c) BVD-MD

Animals negative to previous serological tests should be retested to confirm absence of antibodies.

Should an *animal* become serologically positive, every ejaculate of that *animal* collected since the last negative test should be either discarded or tested for virus with negative results.

d) *Campylobacter fetus* subsp. *venerealis*

i) A preputial specimen should be cultured.

ii) Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay off of more than 6 months should be tested not more than 30 days prior to resuming production.

e) Bluetongue

The *animals* should comply with the provisions referred to in Articles 8.3.5., 8.3.6. or 8.3.7., depending on the bluetongue status of the country of origin of the *animals*.

f) *Trichomonas foetus*

i) A preputial specimen should be cultured.

ii) Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay off of more than 6 months should be tested not more than 30 days prior to resuming production.

g) IBR-IPV

If the *artificial insemination centre* is to be considered as IBR/IPV free, the *animals* should comply with the provisions in point 2)c) of Article 11.12.3.

Article 4.5.3.

Conditions applicable to testing of rams/ bucks and teaser animals

Rams/bucks and teaser animals should only enter an *artificial insemination centre* if they fulfil the following requirements.

1. Pre-quarantine

The *animals* should comply with the following requirements prior to entry into isolation at the *quarantine station*.

a) Caprine and ovine brucellosis

The *animals* should comply with Article 14.1.6.

b) Ovine epididymitis

The *animals* should comply with Article 14.7.3.

c) Contagious agalactia

The *animals* should comply with points 1 and 2 of Article 14.3.1.

d) Peste des petits ruminants

The *animals* should comply with points 1, 2, and 4 or 5 of Article 14.8.7.

e) Contagious caprine pleuropneumonia

The *animals* should comply with Article 14.4.5. or Article 14.4.7., depending on the contagious caprine pleuropneumonia status of the country of origin of the *animals*.

f) Paratuberculosis

The *animals* should be free from clinical signs for the past 2 years.

g) Scrapie

If the *animals* do not originate from a scrapie free country or zone as defined in Article 14.9.3., the *animals* should comply with Article 14.9.6.

h) Maedi-visna

The *animals* should comply with Article 14.6.2.

i) Caprine arthritis/encephalitis

In the case of goats, the *animals* should comply with Article 14.2.2.

j) Bluetongue

The *animals* should comply with Articles 8.3.5., 8.3.6. or 8.3.7., depending on the bluetongue status of the country of origin of the *animals*.

k) Tuberculosis

In the case of goats, the *animals* should be subject to a single or comparative tuberculin test, with negative results.

l) Border disease

The *animals* should be subject to a viral agent isolation test with negative results.

2. Testing in the quarantine station prior to entering the semen collection facilities

Prior to entering the semen collection facilities of the *artificial insemination centre*, rams/bucks and teasers should be kept in a *quarantine station* for at least 28 days. The *animals* should be subjected to diagnostic tests as described below a minimum of 21 days after entering the *quarantine station*, with negative results.

a) Caprine and ovine brucellosis

The *animals* should be subject to testing as described in point 1c) of Article 14.1.8.

b) Ovine epididymitis

The *animals* and semen should be subject to testing as described in points 1d) and 2 of Article 14.7.4.

c) Maedi-visna and caprine arthritis/encephalitis

The *animals* and semen should be subjected to a serological test.

d) Bluetongue

The *animals* should comply with the provisions referred to in Articles 8.3.5., 8.3.6. or 8.3.7., depending on the bluetongue status of the country of origin of the *animals*.

3. Testing programme for rams/bucks and teasers resident in the semen collection facilities

All rams/bucks and teasers resident in the semen collection facilities should be tested at least annually for the following *diseases*, with negative results, where the country of origin is not free:

a) caprine and ovine brucellosis;

b) ovine epididymitis;

c) Maedi-visna and caprine arthritis/encephalitis;

d) tuberculosis (for goats only);

e) bluetongue.

Article 4.5.4

Conditions applicable to testing of boars

Boars should only enter an *artificial insemination centre* if they fulfil the following requirements.

1. Pre-quarantine

The *animals* should be clinically healthy, physiologically normal and comply with the following requirements within 30 days prior to entry into isolation at the *quarantine station*.

a) Porcine brucellosis

The *animals* should comply with Article 15.4.3.

b) Foot and mouth disease

The *animals* should comply with Article 8.5.10., 8.5.11. or 8.5.12.

c) Aujeszky's disease

The *animals* should comply with Article 8.2.8. or 8.2.9.

d) Teschovirus encephalomyelitis

The *animals* should comply with Article 15.6.5. or 15.6.7.

e) Transmissible gastroenteritis

The *animals* should comply with Article 15.7.2.

f) Swine vesicular disease

The *animals* should comply with Article 15.5.5. or 15.5.7.

g) African swine fever

The *animals* should comply with Article 15.1.5. or 15.1.6.

h) Classical swine fever

The *animals* should comply with Article 15.3.7., 15.3.8. or 15.3.9.

i) Porcine reproductive and respiratory syndrome

The *animals* should be subject to the test complying with the standards in the *Terrestrial Manual*.

2. Testing in the quarantine station prior to entering the semen collection facilities

Prior to entering the semen collection facilities of the *artificial insemination centre,* boars should be kept in a *quarantine station* for at least 28 days. The animals should be subjected to diagnostic tests as described below a minimum of 21 days after entering the *quarantine station*, with negative results.

a) Porcine brucellosis

The *animals* should comply with Article 15.4.5.

b) Foot and mouth disease

The *animals* should comply with Article 8.5.13., 8.5.14., 8.5.15. or 8.5.16.

c) Aujeszky's disease

The *animals* should comply with Article 8.2.12., 8.2.13. or 8.2.14.

d) Teschovirus encephalomyelitis

The *animals* should comply with Article 15.6.9. or 15.6.10.

Community comment

Teschovirus encephalomyelitis should be deleted here as is not a listed disease.

e) Transmissible gastroenteritis

The *animals* should comply with Article 15.7.4.

f) Swine vesicular disease

The *animals* should comply with Article 15.5.9. or 15.5.10.

g) African swine fever

The *animals* should comply with Article 15.1.8. or 15.1.9.

h) Classical swine fever

The *animals* should comply with Article 15.3.11., 15.3.12. or 15.3.13.

i) Porcine reproductive and respiratory syndrome

The *animals* should be subject to the test complying with the standards in the *Terrestrial Manual*.

3. Testing programme for boars resident in the semen collection facilities

All boars resident in the semen collection facilities should be tested at least annually for the following diseases, with negative results, where the *compartment/zone* or country is not free:

a) Porcine brucellosis

The *animals* should comply with Article 15.4.5.

b) Foot and mouth disease

The *animals* should comply with Article 8.5.13., 8.5.14., 8.5.15. or 8.5.16.

c) Aujeszky's disease

The *animals* should comply with Article 8.2.12., 8.2.13. or 8.2.14. regarding testing every four months.

d) Teschovirus encephalomyelitis

The *animals* should comply with Article 15.6.9. or 15.6.10.

e) Transmissible gastroenteritis

The *animals* should comply with Article 15.7.4.

f) Swine vesicular disease

The *animals* should comply with Article 15.5.9. or 15.5.10.

g) African swine fever

The *animals* should comply with Article 15.1.8. or 15.1.9. Routine test to be applied at least every six months.

h) Classical swine fever

The *animals* should comply with Article 15.3.11., 15.3.12. or 15.3.13.

i) Porcine reproductive and respiratory syndrome

The *animals* should be subject to the test complying with the standards in the *Terrestrial Manual*.

Article 4.5.5.

General considerations for hygienic collection and handling of semen

Observation of the recommendations described in the Articles below will very significantly reduce the likelihood of the semen being contaminated with common bacteria which are potentially pathogenic.

Article 4.5.6.

Conditions applicable to the collection of semen

1. The floor of the mounting area should be easy to clean and to disinfect. A dusty floor should be avoided.

2. The hindquarters of the teaser, whether a dummy or a live teaser animal, should be kept clean. A dummy should be cleaned completely after each period of collection. A teaser animal should have its hindquarters cleaned carefully before each collecting session. The dummy or hindquarters of the teaser animal should be sanitized after the collection of each ejaculate. Disposable plastic covers may be used.

3. The hand of the person collecting the semen should not come into contact with the *animal*'s penis. Disposable gloves should be worn by the collector and changed for each collection.

4. The artificial vagina should be cleaned completely after each collection where relevant. It should be dismantled, its various parts washed, rinsed and dried, and kept protected from dust. The inside of the body of the device and the cone should be disinfected before re-assembly using approved *disinfection* techniques such as those involving the use of alcohol, ethylene oxide or steam. Once re-assembled, it should be kept in a cupboard which is regularly cleaned and disinfected.

5. The lubricant used should be clean. The rod used to spread the lubricant should be clean and should not be exposed to dust between successive collections.

6. The artificial vagina should not be shaken after ejaculation, otherwise lubricant and debris may pass down the cone to join the contents of the collecting tube.

7. When successive ejaculates are being collected, a new artificial vagina should be used for each mounting. The vagina should also be changed when the *animal* has inserted its penis without ejaculating.

8. The collecting tubes should be sterile, and either disposable or sterilised by autoclaving or heating in an oven at 180°C for at least 30 minutes. They should be kept sealed to prevent exposure to the environment while awaiting use.

9. After semen collection, the tube should be left attached to the cone and within its sleeve until it has been removed from the collection room for transfer to the laboratory.

Annex IX (contd)

Article 4.5.7.

Conditions applicable to the handling of semen and preparation of semen samples in the laboratory

1. Diluents

   a) All receptacles used should have been sterilised.

   b) Buffer solutions employed in diluents prepared on the premises should be sterilized by filtration (0.22 µm) or by autoclaving (121°C for 30 minutes) or be prepared using sterile water before adding egg yolk (if applicable) or equivalent additive and antibiotics.

   c) If the constituents of a diluent are supplied in commercially available powder form, the water used must have been distilled or demineralised, sterilized (121°C for 30 minutes or equivalent), stored correctly and allowed to cool before use.

   d) Whenever milk, egg yolk or any other animal protein is used in preparing the semen diluent, the product must be free of pathogens or sterilised; milk heat-treated at 92°C for 3-5 minutes, eggs from SPF flocks when available. When egg yolk is used, it should be separated from eggs using aseptic techniques. Alternatively, commercial egg yolk prepared for human consumption or egg yolk treated by, for example, pasteurisation or irradiation to reduce bacterial contamination, may be used. Other additives must also be sterilized before use.

   e) Diluent should not be stored for more than 72 hours at +5°C before use. A longer storage period is permissible for storage at -20°C. Storage vessels should be stoppered.

   f) A mixture of antibiotics should be included with a bactericidal activity at least equivalent to that of the following mixtures in each ml of frozen semen: gentamicin (250 µg), tylosin (50 µg), lincomycin-spectinomycin (150/300 µg); penicillin (500 IU), streptomycin (500 µg), lincomycin-spectinomycin (150/300 µg); or amikacin (75µg), divekacin (25µg).

      The names of the antibiotics added and their concentration should be stated in the *international veterinary certificate*.

2. Procedure for dilution and packing

   a) The tube containing freshly collected semen should be sealed as soon as possible after collection, and kept sealed until processed.

   b) After dilution and during refrigeration, the semen should also be kept in a stoppered container.

   c) During the course of filling receptacles for dispatch (such as insemination straws), the receptacles and other disposable items should be used immediately after being unpacked. Materials for repeated use should be disinfected with alcohol, ethylene oxide, steam or other approved *disinfection* techniques.

   d) If sealing powder is used, care should be taken to avoid its being contaminated.

3. Conditions applicable to the storage of semen

   Semen for export should be stored separately from other genetic material not meeting these recommendations in fresh liquid nitrogen in sterilised/sanitised flasks before being exported.

Semen straws should be sealed and code marked in line with the international standards of the International Committee for Animal Recording (ICAR)[1].

Prior to export, semen straws or pellets should be identified and placed into new liquid nitrogen in a new or sterilised flask or container under the supervision of an *Official Veterinarian*. The contents of the container or flask should be verified by the *Official Veterinarian* prior to sealing with an official numbered seal before export and accompanied by an *international veterinary certificate* listing the contents and the number of the official seal.

Community comment

The words "official seal" should be changed to "numbered seal", as there is a confusion with the official seal apposed to certificates: here it is a numbered seal whose number is reported on the certificate.

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1 The ICAR international standards on straws are contained in *Recording Guidelines* – Appendices to the international agreement of recording practices. Section 9, Appendix B relating to semen straw identification.

The text of this document is available at the following web site: www.icar.org

CHAPTER 4.6.

GENERAL HYGIENE IN SEMEN COLLECTION AND PROCESSING CENTRES

Community comments

The Community can support this proposed draft chapter.

Article 4.6.1.

General considerations

Observation of the recommendations described in the Articles below will very significantly reduce the likelihood of the semen being contaminated with common bacteria which are potentially pathogenic.

Article 4.6.2.

Conditions applicable to artificial insemination centres

1. The *artificial insemination centre* is comprised of:

   a) animal accommodation areas (including one isolation facility for sick *animals*) and a semen collection room, these two premises hereon designated as semen collection facilities; accommodation areas should be species specific where relevant;

   b) a semen laboratory and semen storage areas;

   c) administration offices.

   A *quarantine station* may also be attached to the centre, provided that it is on a different location from that of those two first parts.

2. The centre should be officially approved by the *Veterinary Authority*.

3. The centre should be under the supervision and control of the *Veterinary Services* which will be responsible for regular audits, at an interval of no more than 6 months, of protocols, procedures and prescribed records on the health and *welfare* of the *animals* in the centre and on the hygienic production, storage and dispatch of semen.

4. The centre should be under the direct supervision and control of an *official veterinarian*.

5. Only swine associated with semen production should be permitted to enter the centre. Other species of livestock may exceptionally be resident on the centre, provided that they are kept physically apart from the swine.

6. Swine on the centre should be adequately isolated from farm livestock on adjacent land or buildings for instance by natural or artificial means.

7. The entry of visitors should be strictly controlled. Personnel at a centre should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms. Protective clothing and footwear for use only on the centre should be provided.

8. Individual semen containers and storage rooms should be capable of being disinfected.

Article 4.6.3.

Conditions applicable to semen collection facilities

1. The semen collection facilities should include separate and distinct areas for accommodating resident *animals*, for semen collection, for feed storage, for manure storage, and for the isolation of *animals* suspected of being infected.

2. Only *animals* associated with semen production should be permitted to enter the semen collection facilities. Other species of *animals* may be resident at the centre, if necessary for the movement or handling of the donors and teasers or for security, but contact with the donors and teasers should be minimised. All *animals* resident at the semen collection facilities must meet the minimum health requirements for donors.

3. The donors and teasers should be adequately isolated to prevent the transmission of *diseases* from farm livestock and other *animals*. Measures should be in place to prevent the entry of wild *animals* susceptible to ruminant and swine *diseases* transmissible via semen.

4. Personnel at the centre should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms. Special protective clothing and footwear for use only at the semen collection facilities should be provided and worn at all times inside.

5. Visitors to the semen collection facilities should be kept to a minimum, and visits should be subject to formal authorisation and control. Equipment for use with the livestock should be dedicated to the semen collection facilities or disinfected prior to entry. All equipment and tools brought on to the premises must be examined and treated if necessary to ensure that they cannot introduce *disease*.

6. *Vehicles* used for transport of *animals* to and from the semen collection facilities should not be allowed to enter the facilities.

7. The semen collection area should be cleaned daily after collection. The *animals*' accommodation and semen collection areas should be cleaned and disinfected at least once a year.

8. Fodder introduction and manure removal should be done in a manner which poses no significant animal health risk.

Article 4.6.4.

Conditions applicable to semen laboratories

1. The semen laboratory should be physically separated from the semen collection facilities, and include separate areas for artificial vagina cleaning and preparation, semen evaluation and processing, semen pre-storage and storage. Entry to the laboratory should be prohibited to unauthorised personnel.

2. The laboratory personnel should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms during semen evaluation, processing and storage.

3. Visitors to the laboratory should be kept to a minimum, and visits should be subject to formal authorisation and control.

4. The laboratory should be constructed with materials that permit effective cleaning and *disinfection*.

5. The laboratory should be regularly cleaned. Work surfaces for semen evaluation and processing should be cleaned and disinfected at the end of each workday.

6. The laboratory should be treated against rodents and insects on a regular basis as needed to control these pests.

7. The storage rooms and individual semen containers should be easy to clean and disinfect.

8. Only semen collected from donors having a health status equivalent to or better than the donors at the semen collection facilities should be processed in the laboratory.

Article 4.6.5.

Conditions applicable to the management of bulls, rams, bucks and boars

The objective is to keep the *animals* in a satisfactory state of cleanliness, particularly of the lower thorax and abdomen.

1. Whether on pasture or housed, the *animal* should be kept under hygienic conditions. If housed, the litter must be kept clean and renewed as often as necessary.

2. The coat of the *animal* should be kept clean.

3. For bulls, the length of the tuft of hairs at the preputial orifice, which is invariably soiled, should be cut to about 2 cm. The hair should not be removed altogether, because of its protective role. If cut too short, irritation of the preputial mucosa may result because these hairs aid the drainage of urine.

4. The *animal* should be brushed regularly, and where necessary on the day before semen collection, paying special attention to the underside of the abdomen.

5. In the event of obvious soiling, there should be careful cleaning, with soap or a detergent, of the preputial orifice and the adjoining areas, followed by thorough rinsing and drying.

6. When the *animal* is brought into the collection area, the technician must make sure that it is clean, and that it is not carrying any excessive litter or particles of feed on its body or its hooves, for such materials are always heavily contaminated.

CHAPTER 4.7.

COLLECTION AND PROCESSING OF *IN VIVO* DERIVED EMBRYOS

Community comments

The Community can support this proposed draft chapter.

Article 4.7.1.

Aims of control

The purpose of official sanitary control of *in vivo* derived embryos intended for movement internationally is to ensure that specific pathogenic organisms, which could be associated with embryos, are controlled and transmission of *infection* to recipient animals and progeny is avoided.

Article 4.7.2.

Conditions applicable to the embryo collection team

The embryo collection team is a group of competent technicians, including at least one veterinarian, to perform the collection, processing and storage of embryos. The following conditions should apply:

1. The team should be supervised by a team veterinarian.

2. The team veterinarian is responsible for all team operations which include verification of donor health status, sanitary handling and surgery of donors and *disinfection* and hygienic procedures.

3. The team veterinarian should be specifically approved for this purpose by an *Official Veterinarian*.

4. Team personnel should be adequately trained in the techniques and principles of disease control. High standards of hygiene should be practiced to preclude the introduction of *infection*.

5. The collection team ~~must~~ should have adequate facilities and equipment for:

   a) collecting embryos;

   b) processing and treatment of embryos at a permanent site or mobile laboratory;

   c) storing embryos.

   These facilities need not necessarily be at the same location.

6. The collection team ~~must~~ should keep a record of its activities, which ~~must~~ should be maintained for inspection by the approving authority for a period of at least 2 years after the embryos have been exported.

7. The collection team should be subjected to regular inspection at least once a year by an *Official Veterinarian* to ensure compliance with procedures for the sanitary collection, processing and storage of embryos.

~~8. The collection team must not operate in an *infected zone* with regard to foot and mouth disease (except for the collection of *in vivo* derived bovine embryos), rinderpest, peste des petits ruminants, contagious~~

Article 4.7.3.

Conditions applicable to the processing laboratories

The processing laboratory used by the embryo collection team may be mobile or permanent. It is a facility in which embryos are recovered from collection media, examined and subjected to any required treatments such as washing before freezing, storage and quarantine, pending results of diagnostic procedures.

A permanent laboratory may be part of a specifically designed collection and processing unit, or a suitably adapted part of an existing building. It may be on the premises where the donor animals are kept. In either case, the laboratory should be physically separated from animals. Both mobile and permanent laboratories should have a clear separation between dirty areas (animal handling) and the clean processing area.

Additionally:

1. The laboratory should be under the direct supervision of the team veterinarian and regularly inspected by an *Official Veterinarian*.

2. While embryos for export are being handled prior to their storage in ampoules, vials or straws, no embryos of a lesser health status should be processed.

3. The laboratory should be protected against rodents and insects.

4. The processing laboratory should be constructed with materials which permit its effective cleansing and *disinfection*. This should be done following each occasion on which embryos are processed.

~~5. The laboratory must not be situated in an *infected zone* with regard to foot and mouth disease (except for the collection of *in vivo* derived bovine embryos), rinderpest, peste des petits ruminants, contagious bovine pleuropneumonia, African horse sickness, African swine fever and classical swine fever.~~

Article 4.7.4.

Conditions applicable to ~~the introduction of~~ donor animals

1. Donor animals

   a) The *Veterinary Authority* should have knowledge of, and authority over, the *herd/flock* ~~of origin of~~ from which the donor animals have been sourced.

   ~~b) At the time of collection, donor animals should be clinically inspected by a veterinarian responsible to the team veterinarian and certified to be free of clinical signs of *diseases* not included in Category 1 of the IETS classification[1].~~

   ~~c~~b) The ~~*herd* of origin must~~ donor animals should not be situated in a *herd* subject to veterinary restrictions for ~~an *infected zone* for~~ in the 30 days (60 days in the case of camelids) before and after embryo collection, with regard to ~~foot and mouth disease (except for the collection of *in vivo* derived bovine embryos), rinderpest, peste des petits ruminants, contagious bovine pleuropneumonia, African horse sickness, African swine fever and classical swine fever~~ OIE listed pathogens for relevant species, other than those that are in IETS Category 1 for the species of embryos being collected.

~~d~~c) At the time of collection, t~~T~~he donor animals should ~~not have been imported from another country during the previous 60 days and should have been in the *herd* of origin for at least 30 days prior to collection~~ be clinically inspected by a veterinarian responsible to the team veterinarian and certified to be free of clinical signs of *diseases* ~~other than those included in Category 1 of the IETS classification[1] for the species of embryos being collected~~.

2. Semen donors

a) Semen used to inseminate donor animals artificially should have been produced and processed in accordance with the provisions of Chapter 4.5. ~~or Chapter 4.6., as relevant.~~

b) When the donor of the semen used to inseminate donor females for embryo production is ~~no longer living~~ dead, and when the health status of the semen donor concerning a particular infectious *disease* or *diseases* of concern was not known at the time of semen collection, additional tests may be required of the inseminated donor female after embryo collection to verify that these infectious *diseases* were not transmitted. An alternative may be to subject an aliquot of semen from the same collection date to testing.

c) Where natural service or fresh semen is used, donor sires should meet the ~~same~~ health ~~requirements as donor females.~~ conditions set out in Chapter 4.5, as appropriate to the species.

Article 4.7.5.

Risk management

With regard to *disease* transmission, transfer of *in vivo* derived embryos is a very low risk method for moving animal genetic material. Irrespective of animal species, there are three phases in the embryo transfer process that determine the final level of risk:

1. The first phase, which is applicable to *diseases* not included in Category 1 of the IETS classification[1], comprises the potential for embryo contamination and depends on:

a) the disease situation in the *exporting country* and/or *zone*;

b) the health status of the *herds/flocks* and the donors from which the embryos are collected;

c) the pathogenic characteristics of the specified disease agents.

2. The second phase covers *risk* mitigation by use of internationally accepted procedures for processing of embryos which are set out in the IETS Manual[2]. These include the following:

a) The embryos must be washed at least ten times with at least 100-fold dilutions between each wash, and a fresh pipette for transferring the embryos through each wash.

b) Only embryos from the same donor should be washed together.

c) Sometimes, for example when inactivation or removal of certain virus (e.g. bovine herpesvirus-1, and Aujeszky's disease virus) is required, the standard washing procedure should be modified to include additional washes with the enzyme trypsin, as described in the IETS Manual[2].

d) The zona pellucida of each embryo, after washing, must be examined over its entire surface area at not less than 50X magnification to ensure that it is intact and free of adherent material.

[NOTE: All shipments of embryos must be accompanied by a statement signed by the team veterinarian certifying that these embryo processing procedures have been completed.]

3. The third phase, which is applicable to *diseases* not included in Category 1 of the IETS classification, encompasses the *risk* reductions resulting from:

a) post-collection *surveillance* of the donors and donor *herds* based on the recognized *incubation periods* of the *diseases* of concern to determine retrospectively the health status of donors whilst the embryos are stored (in species where effective cryopreservation is possible) in the *exporting country*;

b) testing of embryo-collection (flushing) fluids and non-viable embryos, or other samples such as blood, for presence of specified disease agents.

Article 4.7.6.

Conditions applicable to the collection and storage of embryos

1. Media

Any biological product of animal origin used in the media and solutions for collection, processing, washing or storage of embryos should be free of pathogenic micro-organisms. Media and solutions used in the collection, freezing and storage of embryos should be sterilized by approved methods according to the IETS Manual[2] and handled in such a manner as to ensure that sterility is maintained.

Antibiotics should be added to collection, processing, washing and storage media as recommended in the IETS Manual[2].

2. Equipment

a) All equipment used to collect, handle, wash, freeze and store embryos should be sterilized prior to use as recommended in the IETS Manual[2].

b) Used equipment should be transferred between countries for re-use by the embryo collection team only if cleaning and *disinfection* procedures appropriate to the *disease risk* concerned are followed.

Article 4.7.7.

Optional tests and treatments

1. The ~~examination~~ testing of embryos and collection or washing fluids can be requested by an *importing country*. ~~Tests may be carried out on these samples~~ to confirm the absence of pathogenic organisms that may be transmitted via *in vivo* embryos, or to help assess whether the degree of quality control of the collection team (with regard to adherence to procedures as described in the IETS Manual[2]) is at an acceptable level:

a) Embryos/oocytes

Where the viable, zona pellucida intact embryos are intended for export, all non-fertilized oocytes and degenerated or zona pellucida compromised embryos collected from a donor should be washed according to the IETS Manual[2] and pooled for possible testing. Only embryos/oocytes from one donor should be processed simultaneously.

b) Collection fluids

The collection fluid should be placed in a sterile, closed container and, if there is a large amount, it should be allowed to stand undisturbed for one hour. The supernatant fluid should then be removed and the bottom 10-20 ml, along with accumulated debris, decanted into a sterile bottle. If a filter is used in the collection of embryos/oocytes then any debris that is retained on the filter must be rinsed into the retained fluid.

c) Washing fluids

The last four washes of the embryos/oocytes (washes 7, 8, 9 and 10) should be pooled (IETS Manual[2]).

d) Samples

The samples referred to above should be stored at 4°C and tested within 24 hours. If this is not possible, then samples should be stored frozen at -70°C or lower.

2. When treatment of the viable embryos is modified to include additional washings with the enzyme trypsin (see paragraph 2c) in Article 4.7.5.), the procedure should be carried out according to the IETS Manual[2] and only when pathogens for which the IETS recommends additional treatment (such as with trypsin) may be present. It should be noted that such enzymatic treatment is not necessarily always beneficial and it should not be regarded as a general disinfectant. It may also have adverse effects on embryo viability, for instance in the case of equine embryos where the embryonic capsule could be damaged by the enzyme.

Article 4.7.8.

Conditions applicable to the storage~~, quarantine~~ and transport of embryos

1. Embryos should be frozen in fresh liquid nitrogen and then stored in fresh liquid nitrogen in cleaned and disinfected tanks or containers.

2. The embryos should be stored in sealed sterile ampoules, vials or straws under strict hygienic conditions at a storage place approved by the *Veterinary Authority* of the *exporting country* where there is no risk of contamination of the embryos.

3. In case of ruminants, ~~O~~only embryos from the same donor should be stored together in the same ampoule, vial or straw.

4. Ampoules, vials or straws must be sealed at the time of freezing (or prior to export where cryopreservation is not possible), and they should be clearly identified by labels according to the standardised system recommended in the IETS Manual[2].

5. Liquid nitrogen containers should be sealed under the supervision of the *Official Veterinarian* prior to shipment from the *exporting country*.

6. Embryos must not be exported until the appropriate veterinary ~~certification documents~~ certificates are completed.

Article 4.7.9.

Specific conditions applicable to porcine embryos

The *herd* of origin should be free of clinical signs of swine vesicular disease, brucellosis and pathogenic Teschovirus encephalomyelitis.

[NOTE: The development of effective cryopreservation methods for zona pellucida-intact porcine embryos is still at a very early stage.]

Article 4.7.10.

Specific conditions applicable to ovine/ caprine embryos

The *herd* of origin should be free of clinical signs of sheep pox, goat pox, brucellosis and bluetongue.

Article 4.7.11.

Specific conditions applicable to equine embryos

The recommendations apply principally to embryos from animals continuously resident in national equine populations and therefore may be found to be unsuitable for those from equines routinely involved in events or competitions at the international level. For instance, in appropriate circumstances horses travelling with an *international veterinary certificate* (e.g. competition horses) may be exempt from this condition where mutually agreed upon on a bilateral basis between the respective *Veterinary Authorities*.

Article 4.7.12.

Specific conditions applicable to camelid embryos

South American camelid embryos recovered from the uterine cavity by the conventional non-surgical flushing technique at 6.5 to 7 days post-ovulation are almost invariably at the hatched blastocyst stage, and thus the zona pellucida has already been shed. Since the embryos do not enter the uterus and cannot be recovered before 6.5 to 7 days, it would be unrealistic to stipulate for South American camelids that only zona pellucida-intact embryos can be used in *international trade*. It must also be noted that pathogen interaction studies with South American camelid embryos have not yet been carried out.

The ~~*herd* of origin~~ donor animals should be free of clinical signs of foot and mouth disease, vesicular stomatitis, bluetongue, brucellosis and tuberculosis.

[NOTE: The development of cryopreservation methods for camelid embryos is still at a very early stage.]

Article 4.7.13.

Specific conditions applicable to cervid embryos

The recommendations apply principally to embryos derived from animals continuously resident in national domestic or ranched cervid populations and therefore may be found to be unsuitable for those from cervids in feral or other circumstances related to biodiversity or germplasm conservation efforts.

The *herd* of origin should be free of clinical signs of brucellosis and tuberculosis.

Article 4.7.14.

Recommendations regarding the risk of disease transmission via *in vivo* derived embryos

The IETS has categorised the following *diseases* and pathogenic agents into four categories, which applies only to *in vivo* derived embryos.

1. Category 1

   a) 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 Manual[1].

   b) The following *diseases* or pathogenic agents are in category 1:

      - Aujeszky's disease (pseudorabies) (swine): trypsin treatment required
      - Bluetongue (cattle)
      - Bovine spongiform encephalopathy (cattle)
      - *Brucella abortus* (cattle)
      - Enzootic bovine leukosis
      - Foot and mouth disease (cattle)
      - Infectious bovine rhinotracheitis: trypsin treatment required.

2. Category 2

   a) 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 Manual[1], but for which additional transfers are required to verify existing data.

   b) The following *diseases* are in category 2:

      - Bluetongue (sheep)
      - Caprine arthritis/encephalitis
      - Classical swine fever (hog cholera)
      - Scrapie (sheep).

Annex IX (contd)

3. Category 3

a) 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 Manual[1], but for which additional *in vitro* and *in vivo* experimental data are required to substantiate the preliminary findings.

b) 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)
- 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.

4. Category 4

a) Category 4 *diseases* or pathogenic agents are those for which studies have been done, or are in progress, that indicate:

i) that no conclusions are yet possible with regard to the level of transmission *risk*; or

ii) the *risk* of transmission via embryo transfer might not be negligible even if the embryos are properly handled according to the IETS Manual[1] between collection and transfer.

b) 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
- *Chlamydia psittaci* (cattle, sheep)
- Contagious equine metritis
- Enterovirus (cattle, swine)
- Equine rhinopneumonitis
- *Escherichia coli* 09:K99 (cattle)
- *Leptospira borgpetersenii* serovar *hardjobovis* (cattle)
- *Leptospira* sp. (swine)
- *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 Based on available research and field information, the Research Subcommittee of the International Embryo Transfer Society (IETS) has categorised some diseases based on their relative risk of dissemination by properly processed and handled *in vivo* derived embryos. This Chapter contains the list of IETS categorised diseases.

2 Manual of the International Embryo Transfer Society ~~(1998)~~.

CHAPTER 4.8.

COLLECTION AND PROCESSING OF *IN VITRO* FERTILISED BOVINE EMBRYOS / *IN VITRO* MATURING BOVINE OOCYTES

Community comments

The Community can support this proposed draft chapter.

Article 4.8.1.

Aims of control

The purpose of official sanitary control of *in vitro* fertilised bovine embryos intended for movement internationally is to ensure that specific pathogenic organisms, which could be associated with embryos, are controlled and transmission of *infection* to recipient animals and progeny is avoided.

Article 4.8.1.bis

Conditions applicable to the embryo ~~collection~~ production team

The embryo production team is a group of competent technicians, including at least one veterinarian, to perform the collection and processing of bovine ovaries/oocytes and the production and storage of *in vitro* fertilised (IVF) bovine embryos. The following conditions should apply:

1. The team should be supervised by a team veterinarian.

2. The team veterinarian is responsible for all team operations which include hygienic collection of ovaries and oocytes and all other procedures involved in the production of embryos intended for international movement.

3. The team veterinarian should be specifically approved for this purpose by an *official Veterinarian*.

4. Team personnel should be adequately trained in the techniques and principles of disease control. High standards of hygiene should be practised to preclude the introduction of *infection*.

5. The production team ~~must~~ should have adequate facilities and equipment for:

   a) collecting oocytes;

   b) processing of oocytes and embryos at a permanent site or mobile laboratory;

   c) storing embryos.

   These facilities need not necessarily be at the same location.

6. The collection team ~~must~~ should keep a record of its activities, which ~~must~~ should be maintained for inspection by the approving authority for a period of at least 2 years after the embryos have been exported.

Annex IX (contd)

7. The production team should be subjected to regular inspection by an *Official Veterinarian* to ensure compliance with procedures for the sanitary collection and processing of oocytes, and the production and storage of embryos.

8. The production team ~~must~~ should not operate in an *infected zone* for foot and mouth disease, contagious bovine pleuropneumonia, bluetongue or ~~and~~ rinderpest.

Article 4.8.2.

Conditions applicable to the processing laboratories

The processing laboratory ~~is a premises~~ may be mobile or permanent. It is a facility in which oocytes which have been recovered from ovaries are then matured and fertilised, and embryos are further cultured *in vitro*. It may be contiguous with the oocyte recovery area or may be at a separate location.

Embryos so produced may also be subjected to any required treatments such as washing before freezing, storage and quarantine in this laboratory.

Additionally:

1. The laboratory should be under the direct supervision of the team veterinarian and regularly inspected by an *Official Veterinarian*.

2. While embryos for export are being produced prior to their storage in ampoules, vials or straws, no oocyte/embryo of a lesser health status should be recovered or processed in the laboratory.

3. The laboratory should be protected against rodents and insects.

4. The processing laboratory should be constructed with materials which permit its effective cleansing and *disinfection*. This should be done following each occasion on which embryos are processed.

5. The laboratory ~~must~~ should not be situated in an *infected zone* for foot and mouth disease, contagious bovine pleuropneumonia, bluetongue or rinderpest.

Article 4.8.3.

Conditions applicable to ~~the introduction of~~ donor animals

Oocytes for the production of IVF embryos are obtained from donors in one of two ways: individual collection or batch collection. The recommended sanitary conditions for these differ.

Individual collection usually involves the aspiration of oocytes from the ovaries of live animals on the farm where the donor animal resides or at the laboratory. Occasionally oocytes may also be recovered from individual live donors by aspiration from surgically excised ovaries. ~~When oocytes are recovered from individual live animals, the procedures for these donors should follow the recommendations set out in Article 4.7.4.~~

Cleaning and sterilisation of equipment is especially important and must be carried out between each donor in accordance with the requirements of the Procedures Manual of the International Embryo Transfer Society (IETS) [2].

Batch collection usually involves the removal of ovaries from slaughtered animals at an *abattoir* but may alternatively involve the surgical removal of ovaries from live donors; these ovaries are then transported to the laboratory where oocytes are removed by aspiration. Batch collection involving *abattoir* derived ovaries has the disadvantage that it is usually impractical to relate ovaries which are transported to the laboratory to the donors which were slaughtered at the *abattoir*. Nevertheless, it is critical to ensure that only healthy tissues are obtained and that they are removed from the donors in a hygienic manner.

Additionally:

1. The *Veterinary Authority* should have knowledge of, and authority over, the *herd(s)* ~~of origin of~~ from which the donor animals have been sourced.

2. The donor females should not originate from an *infected zone* for foot and mouth disease, contagious bovine pleuropneumonia, bluetongue or rinderpest and the removal of any tissue should not take place in an *infected zone* for foot and mouth disease, contagious bovine pleuropneumonia, bluetongue or rinderpest.

3. In the case of oocyte recovery from individual animals or batch collection from live donors, post-collection surveillance of the donors and donor *herds* based on the recognized *incubation periods* of the *diseases* of concern to determine retrospectively the health status of donors should be conducted.

~~3~~4. The *abattoir* should be officially approved and under the supervision of a veterinarian whose responsibility it is to ensure that ante-mortem and post-mortem inspections of potential donor animals are carried out, and to certify them to be free of clinical signs of ~~contagious~~ *diseases* ~~of concern transmissible to cattle~~ that may be transmissible by bovine semen or embryos.

~~4~~5. The donor females should not have been designated for compulsory *slaughter* for a *notifiable disease* and other animals of a lesser health status ~~must~~ should not be slaughtered at the same time as donors from which ovaries and other tissues will be removed.

~~5~~6. Records of the identities and origins of all donors ~~must be kept~~ should be maintained for inspection by the approving authority for a period of at least 2 years after the embryos have been exported.

~~6~~7. Batches of ovaries should not be transported to the processing laboratory before confirmation has been obtained that ante and post-mortem inspection of donors has been satisfactorily completed.

~~7~~8. Equipment for removal and transport of ovaries and other tissues should be cleaned and sterilized before use and exclusively used for these purposes.

Article 4.8.4.

Testing of oocytes, embryos, semen and culture media

The main approach for ensuring IVF embryos are free of pathogenic organisms is the testing of non-viable oocytes/embryos and associated co-culture cells, fluid and media.

Tests may also be used to assess whether quality control procedures being applied in the processing laboratory are acceptable.

Tests may be carried out on the following materials to confirm the absence of pathogenic organisms that may be transmissible by bovine semen or embryos and that ~~which~~ are of concern to the *importing country*.

Annex IX (contd)

a) non-viable oocytes/embryos: all non-viable oocytes/embryos at any stage of the production line from batches intended for export should be pooled for testing;

b) *in vitro* maturation medium prior to mixing the oocytes with semen for the fertilisation process;

c) embryo culture medium taken immediately prior to embryo storage.

These samples should be stored at 4°C and tested within 24 hours. If this is not possible, then the samples should be stored frozen at -70°C or lower.

~~In the case of oocyte recovery from individual animals or batch collection from live donors, monitoring of clinical health status and post collection testing of donors for *diseases* of concern may be considered.~~

Additionally:

1. Semen used to fertilise oocytes *in vitro* should meet the health requirements and standards set out in Chapter 4.5 as appropriate to the species.

   When the donor of the semen used to fertilise the oocytes is no longer living, and when the health status of the semen donor concerning a particular infectious *disease* or *diseases* of concern was not known at the time of semen collection, additional tests on the spare IVF embryos may be required to verify that these infectious *diseases* were not transmitted. An alternative may be to subject an aliquot of semen from the same collection date to testing.

2. Any biological product of animal origin, including co-culture cells and media constituents, used in oocyte recovery, maturation, fertilisation, culture, washing and storage should be free of living pathogen~~ic micro-organisms~~s. Media should be sterilised by approved methods according to the IETS Manual[2] and handled in such a manner as to ensure that sterility is maintained. Antibiotics should be added to all fluids and media as recommended in the IETS Manual[2].

3. All equipment used to recover, handle, culture, wash, freeze and store oocytes/embryos should be cleaned and sterilised prior to use as recommended in the IETS Manual[2].

Article 4.8.5.

Conditions applicable to the processing, storage~~, quarantine~~ and transport of embryos/ ova

1. After the culture period is finished but prior to freezing, storage and transport, the embryos should be subjected to washing and other treatments similar to those specified for *in vivo* derived embryos in accordance with the IETS Manual[2].

2. Only embryos from the same donor, in the case of individual animal recovery, or from the same batch collection, should be washed together.

3. The zona pellucida of each embryo ~~must~~ should be examined over its entire surface area at not less than 50X magnification and certified to be intact.

4. The IVF embryos should be stored in sealed sterile ampoules, vials or straws and then frozen in fresh liquid nitrogen or other cryoprotectant in cleaned and sterilised containers under strict hygienic conditions at a storage place, approved by the *Veterinary Authority* of the *exporting country*, ~~where no risk of~~ to avoid contamination of the embryos ~~can occur~~.

5. Only embryos from the same individual donor or batch collection should be stored together in the same ampoule, vial or straw.

6. Ampoules, vials or straws must be sealed at the time of freezing and should be labelled according to the IETS Manual[2].

7. Liquid nitrogen containers should be sealed prior to shipment from the *exporting country*.

8. Embryos must not be exported until the appropriate veterinary ~~certification documents~~ certificates are completed.

Article 4.8.6.

Procedure for micromanipulation

When micromanipulation of the embryos is to be carried out, this should be done after completion of the treatments described in Article 4.8.5. and conducted in accordance with Chapter 4.7.

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1 Where transportation of *in vitro* maturing (IVM) oocytes is intended, the conditions outlined in this Chapter are also applicable.

2 Manual of the International Embryo Transfer Society ~~(1998)~~.

~~An up-to-date list of relevant scientific publications is available on the IETS Website Homepage at http://www.iets.uiuc.edu where the link entitled 'Embryo-Pathogen Research and Reference Lists' may be visited.~~

CHAPTER 4.9.

COLLECTION AND PROCESSING OF MICROMANIPULATED BOVINE EMBRYOS

Community comments

The Community can support this proposed draft chapter.

Article 4.9.1.

Introduction

Chapter 4.7. recommends official sanitary control measures for the international movement of intact, *in vivo* derived ~~bovine~~ embryos, and ~~likewise~~ Chapter 4.8. recommends measures for *in vitro* fertilized bovine embryos/*in vitro* maturing bovine oocytes. Neither of those Chapters covers embryos which have been subjected to biopsy, splitting, transgene injection, intracytoplasmic sperm injection (ICSI), nuclear transplantation or other micromanipulations which breach the integrity of the zona pellucida. Such embryos are subsequently referred to here as 'micromanipulated embryos'.

It should be noted that complete removal of granulosa cells prior to micromanipulation of oocytes, zygotes and embryos is necessary to avoid lowering their health status.

To bring micromanipulated embryos within the scope of the above mentioned Chapters, the following conditions ~~shall~~ should apply:

Article 4.9.2.

1. Prior to any micromanipulation which involves breaching the zona pellucida, all embryos/oocytes ~~must~~ should be collected and processed according to the sanitary conditions laid down in Chapter 4.7. *in vivo* derived embryos) or produced according to the sanitary conditions laid down in Chapter 4.8. (*in vitro* fertilised bovine embryos/*in vivo* maturing bovine oocytes).

2. Responsibility for the embryos/oocytes ~~must~~ remains with the embryo collection team (*in vivo* derived embryos) or with the embryo production team (*in vitro* fertilised bovine embryos), and all processing involving micromanipulation should be carried out in an approved processing laboratory under supervision of an approved team veterinarian (see Articles 4.7.2. and 4.7.3., and Articles 4.8.1. and 4.8.2., as relevant).

3. Donor animals ~~must~~ should comply with the conditions laid down in Article 4.7.4. (*in vivo* derived embryos) or Article 4.8.3. (*in vitro* fertilised bovine embryos/*in vivo* maturing bovine oocytes), whichever is appropriate. The criteria for testing samples to ensure that embryos are free of pathogenic organisms are laid down in Article 4.7.5. and Article 4.8.4. respectively, and these should be followed.

4. All embryos to be micromanipulated ~~must~~ should be washed according to the protocols laid down in the IETS Manual ~~(1998)~~[1] and they ~~must~~ should be observed to have an intact zona pellucida before and after washing. Only embryos from the same donor, or, in the case of some *in vitro* produced embryos (see Chapter 4.8.) from the same batch collection, should be washed together at the same time. After washing, but before micromanipulation, the zona pellucida of each embryo should be examined over its entire surface area at not less than 50X magnification and certified to be intact and free of adherent material.

5. If surrogate zonae are used, they should be of bovine origin and the embryos/oocytes from which they are obtained should be treated in the same manner as if they were *in vivo* derived or *in vitro* produced embryos intended for international movement.

Article 4.9.3.

Procedures for micromanipulation

The term 'micromanipulation' covers several different procedures and a variety of specialized microsurgical instruments and other equipment may be used. However, from the standpoint of animal health, any cutting, penetrating or breaching of the integrity of the zona pellucida is an action that can alter the health status of an embryo. To maintain health status during and after micromanipulation, the following conditions should apply:

1. Media

   Any product of animal origin, including co-culture cells and media constituents, used in the collection of embryos, oocytes or other cells, and in their micromanipulation, culture, washing and storage should be free of pathogenic micro-organisms (including transmissible spongiform encephalopathy agents, sometimes called prions). All media and solutions should be sterilized by approved methods according to the IETS Manual[1] and handled in such a manner as to ensure that sterility is maintained. Antibiotics should be added to all fluids and media as recommended in the IETS Manual[1].

2. Equipment

   Equipment (e.g. microsurgical instruments which have direct contact with embryos) should either be of the single-use type (disposed of after each embryo) or should be effectively sterilised between embryos in accordance with recommendations in the IETS Manual[1].

3. Nuclei for transfer

   a) Where it is intended to transplant nuclei derived from pre-hatching stage (i.e. zona pellucida intact) embryos, the parent embryos from which those nuclei are derived should fulfil the conditions of this Chapter. Where nuclei derived from other types of donor cell (e.g. post-hatching stage embryos, embryonic, fetal and adult cells, including spermatozoa/spermatids for ICSI) are to be transplanted, the parent embryo, fetus or animal from which those donor cells originate, and the methods whereby they are derived, including cell culture, should comply with the relevant animal health standards recommended elsewhere in this *Terrestrial Code* and in the *Terrestrial Manual*.

   b) Where it is intended to transplant a nucleus into an oocyte (for ICSI), or into an enucleated oocyte (for nuclear transfer), those oocytes should be collected, cultured and manipulated according to the recommendations in this Chapter and/or in Chapter 4.7.

Article 4.9.4.

Optional tests and treatments

The *importing country* may request that tests[2] be carried out on certain samples or that embryos are treated to ensure that specified pathogenic organisms are absent.

1. Samples

   Samples to be tested may include those referred to in Article 4.7.7. and/or in Article 4.8.4. Where cells other that from zona pellucida-intact embryos (e.g. somatic or sperm cells) are used as donors of nuclei for transplantation, then samples or cultures of those donor cells may also be tested.

2. Treatments

   Treatments of embryos with the enzyme trypsin or other substances proven to inactivate or remove pathogenic organisms~~, and which are harmless to the embryo,~~ may be requested when pathogens that are not removed by ~~routine~~ washing may be present. ~~, but t~~These also should be applied prior to any micromanipulation, and according to the IETS Manual[1].

Article 4.9.5.

Conditions applicable to storage, quarantine and transport

Micromanipulated embryos should be stored, quarantined and transported according to the conditions laid down in Article 4.7.8. or in points 4, 5, 6, 7 and 8 of Article 4.8.5. Veterinary certification documents should identify all micromanipulations, where and when they were carried out.

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1 Manual of the International Embryo Transfer Society ~~(1998)~~.

~~2 If the samples mentioned above in point 1. of Article 4.9.4. are to be tested for pathogenic agents, then the microbiological techniques in current use for those agents would be appropriate.~~

CHAPTER 4.10.

COLLECTION AND PROCESSING OF LABORATORY RODENT AND RABBIT EMBRYOS / OVA

Community comments

The Community can support this proposed draft chapter.

Article 4.10.1.

Conditions applicable to the maintenance of laboratory animal colonies

Maintenance of laboratory animal colonies of specific genotypes requires intensive breeding management within specialised premises. They may be kept in a gnotobiotic environment, in either a 'germfree' system or a 'barrier' room (usually with defined flora), in a conventional colony, or under undefined conditions. In both the germfree and barrier systems, the animals are raised in a controlled environment according to protocols that attempt to eliminate potential sources of microbiological contamination. The primary difference is that the barrier maintained animals have been inoculated with known (defined) microbes[1] using a cocktail of non-pathogenic flora, whereas germfree animals are kept free from both pathogenic and non-pathogenic microbes.

A second category is where laboratory animals are kept in closed, conventional colonies within which known pathogens may exist. Here, less rigid colony management protocols are used to control potential sources of contamination, but implementation of simple aseptic precautions (e.g. autoclaving of feed and bedding) should allow animals to be maintained in a microbiologically defined system. Finally, laboratory animals may live in environments with undefined microbiological conditions (e.g. non-restricted colonies, free-ranging animals).

Disease testing and donor animal/embryo handling requirements can therefore be considered as being of three distinct types, depending on the type of colony being dealt with, i.e. defined floral, conventional and undefined. The health status of all colonies should be confirmed quarterly by bacteriological, virological, parasitological, serological and immunohistochemical tests on pre-designated sentinel animals or other representative animals of the colony (e.g. older breeding males which have sired multiple litters).

Article 4.10.2.

Conditions applicable to the embryo production team/ laboratory

1. The embryo production team ~~must~~ should be composed of competent technicians supervised by an experienced ~~embryologist~~ professional ~~holding a graduate academic degree (e.g. M.S., Ph.D., D.V.M.)~~.

2. Team personnel should be trained in the principles of *disease* control and the use of aseptic techniques in embryo handling. Laboratory sanitary procedures must conform with requirements in the IETS Manual[2].

Annex IX (contd)

3. The embryo production team ~~must~~ should use all necessary precautions to protect the animals, animal facilities, laboratory and equipment against microbiological contamination. In particular, the zoonotic potential of specific pathogens should be identified and understood by staff members to avoid contamination of colonies via human vectors, or vice versa. Restrictions should be established to prevent free access of personnel into the embryo handling laboratory after their exposure to other animal facilities.

4. Proper records ~~must~~ should be maintained for inspection by the ~~chief embryologist (i.e.~~ supervisor~~)~~.

   Until standardised record sheets are developed for laboratory animals, it is the responsibility of each laboratory to maintain complete animal and embryo records (i.e. embryo collection, cryopreservation data). Information of the type shown in standard IETS record sheets[2] for livestock species should be incorporated, where applicable, and data such as embryo quality grading system, morphological stage at cryopreservation and genotypic identification of the donors should be clearly given in the records.

5. It is the responsibility of the ~~chief embryologist (i.e.~~ laboratory supervisor~~)~~ to ensure that the embryos are properly stored in sterile, sealed containers (e.g. ampules or straws). In addition, the containers must be correctly identified using a standard format which includes embryo species/genotype, cryopreservation date, number and stage of embryos, container number and indication of any specialised procedure (e.g. *in vitro* fertilisation, micromanipulation) or condition (e.g. germfree, microbiologically defined).

Article 4.10.3.

Conditions applicable to the embryo team/ institute veterinarian

1. The veterinarian, certified in laboratory animal care or laboratory animal accredited, must ensure that the required colony health profiling procedures are implemented, and the results are reviewed and properly recorded before shipment of embryos. He/she is also responsible for confirming that proper animal management/sanitation conditions have been maintained.

2. The veterinarian is responsible for certifying that the embryo handling procedures and laboratory conditions were maintained in accordance with the IETS Manual[2].

3. The veterinarian must supervise all quarantine practices to protect against unwanted contamination and spread of *disease*, and to ensure that valid results are generated.

4. The veterinarian must authorise all embryo shipments, ensuring that the correct veterinary certification documents and embryo collection records are completed and included in the shipments.

Article 4.10.4.

Test programmes for donor animals

Sentinel animals in each donor colony should be subjected to routine monthly microbial screening. Testing for specific pathogens is species dependent and will undoubtedly also be influenced by geographic location. Recommendations regarding specific microbial agents to be tested for in mice, rats, cotton rats, hamsters, guinea pigs, gerbils and rabbits have been published elsewhere[3].

Article 4.10.5.

Conditions applicable to the embryo/ animal handling

1. Defined microbial conditions

   a) Germfree and microbiologically defined, barrier maintained animals represent the cleanest sources of gametes, and the embryos recovered from these can be regarded as pathogen free.

   b) Since the animals themselves are pathogen free or possess defined flora (usually based on random, monthly testing of sentinel animals), dissection of the reproductive tract and embryo isolation procedures can be performed under aseptic laboratory conditions, and do not require the use of a biological safety cabinet.

   c) Strict aseptic procedures should nevertheless be followed and, while embryo washing is not essential to safeguard against any possible air-borne contamination in the laboratory, it is recommended that embryos undergo at least a 3-step washing procedure. In each wash, embryos should be gently agitated in the medium, and the wash volume must constitute at least a one hundred-fold dilution of the volume in which the embryos are transferred.

   d) Microbial testing of flush or washing media is not required.

   e) Cryopreserved embryos should be designated, in the appropriate records, as coming from a germfree or microbiologically defined, barrier maintained colony, thus indicating that additional safeguards for pathogen removal are not necessary. Isolation and health status monitoring of the embryo recipients should be considered but the need to quarantine them is a decision for the importing laboratory.

2. Conventional conditions

   a) Animals maintained under these conditions generally represent closed colonies whose health status is routinely ~~profiled~~ monitored. They may have been exposed to various pathogens, resulting in the isolation of infectious agents, positive antibody titres or even active clinical *disease*. However, prior to embryo collection there should be familiarity with the pathogen(s) of particular concern in the colony.

   b) Reproductive tracts (uteri, oviducts and/or ovaries) should be removed at a separate site and then taken into the embryo laboratory. These procedures should be performed by separate technicians or, at the very minimum, their protective clothing should be changed between locations. If the animals are to be handled in the laboratory, the tracts should be dissected out within a biological safety cabinet. This will help protect against the possible shedding of pathogens into the laboratory itself.

   c) Once the reproductive tracts have been removed, embryo recovery should be performed under aseptic conditions. Embryos must be inspected (>100x) for the presence of cracks in the zona pellucida and only zona-intact embryos should be kept. They must then be washed using the standard ~~10-step~~ procedure~~,~~ described in the IETS Manual[2]. ~~This recommendation could be waived in the future if sufficient research evidence from embryo-pathogen interaction studies warranted it.~~

d) Embryos derived from animals that have positive antibody titres or other evidence of specific pathogens should only be transferred into a new colony via a quarantine system, using microbiologically defined recipient females. As an additional safeguard, if there is any uncertainty about the donor or disease status of the embryos, quarantining of recipients should be applied. In certain situations where embryos might have been exposed to bacterial infection (e.g. mycoplasma), they should be cultured in a medium containing an appropriate antibiotic for 24 h pre-freezing, or post-thawing and prior to transfer.

e) If the embryos were not handled in the recommended manner, this must be indicated on the shipment records, and mandatory quarantining of the recipient dam and offspring should be imposed by the recipient institution until their health status is confirmed. The recipient dam should then be tested post-weaning for pathogens, and introduction of the progeny into the colony should only take place if test results are satisfactory.

3. Undefined microbial conditions

a) These animals are derived from either the wild or from colonies of unknown health status and embryos from them require maximum precautions. The health status of breeder males and donor females should be determined 15 days before and on the day of breeding (for males) or at embryo collection (for females). Alternatively, the animals could be incorporated into a conventional colony, where, over time, a health history can be documented to reduce the strict monitoring and embryo handling requirements.

b) A biological safety cabinet should be used for all animal, tissue and embryo handling.

c) An aliquot of flush fluid from each donor, or a pooled sample, should be tested for the presence of specific pathogens of concern to the *importing country* and laboratory.

d) Embryos must be washed in accordance with the protocols in the IETS Manual[2] (i.e. the 10-step wash, possibly including trypsin treatment in the case of certain herpesviruses) and an aliquot of media from the last four (pooled) washes should be tested for pathogens.

e) Cryopreserved embryos must be stored in the exporting laboratory until such time as the necessary *disease* screening of tissues and fluids is completed. All embryos from these animals must be transferred into a colony via a quarantine system, as discussed above. In addition to testing the recipient dam, all offspring should be tested at 12 weeks of age and/or individuals from successive generations should be tested before their introduction into breeding colonies outside the quarantine facility.

Article 4.10.6.

Special experimental circumstances

If embryos are to be cryopreserved following specialised micromanipulation procedures that involve penetration of the zona pellucida, they must undergo the required washing steps (depending on colony status) before treatment. In the case of *in vitro* fertilisation, to minimise possible pathogen exposure, it is also advised that only washed sperm should be used. Embryos should be washed again before cryopreservation.

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1 **Recommendations for the health monitoring of mouse, rat, hamster, guineapig and rabbit breeding colonies**.- Report of the Federation of European Laboratory Animal Science Associations (FELASA), Working Group on Animal Health accepted by the FELASA Board of Management, November 1992.

2 Manual of the International Embryo Transfer Society ~~(1998)~~.

3 Schiewe M.C., Hollifield V.M., Kasbohm L.A. & Schmidt P.M. (1995) - Embryo importation and cryobanking strategies for laboratory animals and wildlife species. *Theriogenology*, **43**, 97-104.

Annex IX (contd)

CHAPTER 4.11.

CATEGORISATION OF DISEASES AND PATHOGENIC AGENTS

Article 4.11.1.

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 Manual[1].

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?

Annex IX (contd)

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 4.11.2.

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 Manual[1].

The following *diseases* or pathogenic agents are in category 1:

- Aujeszky's disease (pseudorabies) (swine): trypsin treatment required
- Bluetongue (cattle)
- Bovine spongiform encephalopathy (cattle)
- *Brucella abortus* (cattle)
- Enzootic bovine leukosis
- Foot and mouth disease (cattle)
- Infectious bovine rhinotracheitis: trypsin treatment required.

Article 4.11.3.

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 Manual[1], 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).

~~Article 4.11.4.~~

~~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 Manual[1], 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)~~
- ~~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 4.11.5.~~

~~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 Manual[1] between collection and transfer.~~

~~The following *diseases* or pathogenic agents are in category 4:~~

- ~~African swine fever~~
- ~~Akabane (cattle)~~

Annex IX (contd)

- ~~Bovine anaplasmosis~~
- ~~Bluetongue (goats)~~
- ~~Border disease (sheep)~~
- ~~Bovine herpesvirus 4~~
- ~~*Chlamydia psittaci* (cattle, sheep)~~
- ~~Contagious equine metritis~~
- ~~Enterovirus (cattle, swine)~~
- ~~Equine rhinopneumonitis~~
- ~~*Escheridhia coli* 09:K99 (cattle)~~
- ~~*Leptospira borgpetersenii* serovar *hardjobovis* (cattle)~~
- ~~*Leptospira* sp. (swine)~~
- ~~*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.~~

Annex X

CHAPTER 4.12.

SOMATIC CELL NUCLEAR TRANSFER IN PRODUCTION LIVESTOCK AND HORSES

Community comments

The Community can accept the proposed change.

Article 4.12.1.

Preface

Following the first meeting of the OIE *ad hoc* Group on Biotechnology held from 3 to 5 April 2006, the OIE Biological Standards Commission suggested restricting the mandate "to develop recommendations 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 Articles are a starting point for identifying, characterising and providing a basis for discussion on the animal health *risks* associated with SCNT cloning technology.

Article 4.12.2.

Overview

At the first meeting of the *ad hoc* Group on Biotechnology, it was recommended that the Subgroup on Reproductive Animal Biotechnologies should draft recommendations 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 recommendations are restricted to SCNT and are 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.

Article 4.12.3.

Scope

These recommendations address animal health aspects of production *animals* derived from some reproductive biotechnologies.

Recognising the mandate of the OIE and the suggestion of the OIE 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 recommendations will focus initially on the scientific basis for the *risk assessment* aspects, prevention measures and guidance for production livestock and horses derived from SCNT cloning. This is without prejudice to the addition of any relevant issue at a later stage. At present, these recommendations 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;

- *risks* 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.

Article 4.12.4.

Background: risk analysis – general principles

1. *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* (see Chapter 2.1.). 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.

2. For animal *diseases*, particularly those listed in the *Terrestrial Code*, there is broad agreement concerning the likely *risks* and *risks* can be qualitative or quantitative (see Chapter 2.1.). 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 descriptive (high/medium/low) terms.

3. 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.

4. 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.

5. 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 recommendations 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.

Article 4.12.5.

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 (see Chapter 4.8.). An analysis of SCNT methodology allows the procedural details to be categorised into:

a) 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.

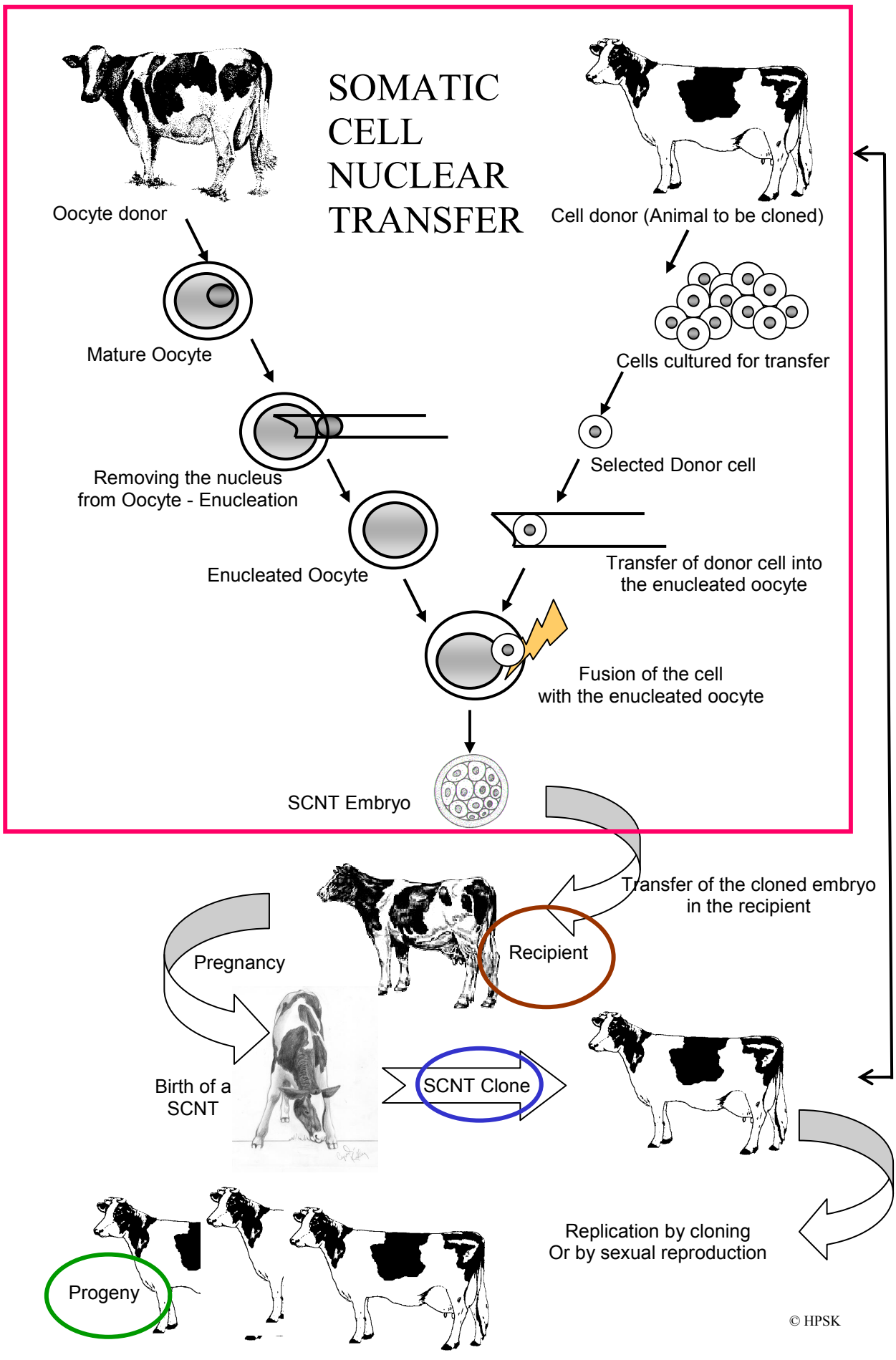
b) Donor cells (cells obtained from animals chosen to be cloned – by biopsy, harvesting at slaughter or after death)

   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.

c) *In vitro* culture of reconstructed embryos (procedure used to fuse the donor and recipient material and to culture the reconstructed embryo)

d) *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
Replication by cloning Or by sexual reproduction
Progeny
© HPSK

1. 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.

2. 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 (see Manual of the International Embryo Transfer Society [IETS]).

3. 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 (see Chapters 4.7. and 4.8.).

Article 4.12.6.

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.

Annex X (contd)

3. 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), probably in relation to ~~and~~ placental abnormalities rather than fetal abnormalities, have been ~~are~~ particularly observed in cloned cattle and sheep following suboptimal in vitro handling. These abnormalities are becoming less frequent in small ruminants.

- 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.

4. 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:

a) Characterisation of the health profile, including health status and data on *animal welfare*, would consolidate the knowledge of sexually reproduced progeny.

b) Monitoring the reproductive performance of sexually reproduced progeny of clones would be useful to assess their reproductive capacity in comparison with their conventional counterparts.

5. 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:

a) The health profile (health status and data on *animal welfare*) should be characterised to consolidate the knowledge.

b) 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.

Article 4.12.7.

Review

The goal of this Chapter 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 recommendations will focus initially on the scientific basis for the *risk assessment* aspects, prevention measures and guidance for production livestock and horses, derived from SCNT cloning and should be reviewed in light of new scientific information.

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Annex XI

CHAPTER 5.1.

GENERAL OBLIGATIONS RELATED TO CERTIFICATION

Community comments

The Community can accept the proposed change.

Article 5.1.1.

Safety of *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 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 for trade. To maximise harmonisation of the sanitary aspects of *international trade*, *Veterinary Authorities* of OIE Members should base their import requirements on the OIE standards.

These requirements should be included in the model certificates approved by the OIE which are included from Chapters 5.10. to 5.12. 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* 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 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 5.1.2.

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. *Importing countries* should restrict their requirements to those 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*.

2. The *international veterinary certificate* should not include requirements for the exclusion of pathogens or animal *diseases* which are present in the *importing country* and are not subject to any *official control programme*. 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 measures against pathogens or *diseases* which are not OIE listed, unless the *importing country* has demonstrated through import *risk analysis*, carried out in accordance with Section 2., 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 the responsibility of *Veterinary Authorities*. However, it can be issued by private sector *veterinarians* at the place of origin of the *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.

Article 5.1.3.

Responsibilities of the exporting country

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

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

   b) regular and prompt information on the occurrence of *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 3.1. and 3.2.;

   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~~ Authority* of the *exporting country* is ultimately accountable for veterinary certification used in *international trade*.

Article 5.1.4.

Responsibilities in case of an incident 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 this *Authority* to notify the *importing country*, so that the imported *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 *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 5.2.

CERTIFICATION PROCEDURES

Community comments

The Community thanks the TAHSC for this important proposed change and has a comment on the article 5.2.3. paragraph 7.

Article 5.2.1.

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 3.1. and 3.2.

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 5.1.1. is not only to inform the signing veterinarian but also to safeguard professional integrity.

Article 5.2.2.

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;

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 5.2.3.

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 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.

Community comments

The Community proposes to cut in two the point 7 above, after the first sentence. The new point 8 would concern the type of stamp, and would read :

"8. The signature and stamp must be in a colour different to that of the printing of the certificate. The stamp can instead be embossed."

This to include the possibility of a dry embossed stamp.

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 duplicates should be provided by the issuing authority and ~~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.

9. Only original certificates are acceptable.

Article 5.2.4.

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 may be in a different format but should carry the same information as conventional paper 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 XII

CHAPTER 6.1.

THE ROLE OF THE VETERINARY SERVICES IN FOOD SAFETY

Community comments

The Community can support the proposed change.

Article 6.1.1.

Purpose

The purpose of this Chapter is to provide guidance to OIE Members in regard to the role and responsibilities of the *Veterinary Services* in food safety, to assist them in meeting the food safety objectives laid down in national legislations and the requirements of *importing countries*.

Article 6.1.2.

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.

Article 6.1.3.

Approaches to food safety

1. 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.

Annex XII (contd)

2. 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 above. 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.

3. 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.

4. 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. Chapters 6.5. to 6.8. of the *Terrestrial Code* contain recommendations on the use of antimicrobials.

5. Meat inspection

Slaughterhouse inspection of live *animals* (ante-mortem) and their carcasses (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 standards 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) constitutes the primary international standard for *meat* hygiene and incorporates a risk-based approach to application of sanitary measures throughout the *meat* production chain. Chapter 6.2. of the *Terrestrial Code* contains recommendations 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 *Terrestrial Code* was on global animal health protection and transparency. Under its current mandate, the OIE also addresses animal production food safety risks. The *Terrestrial Code* includes several standards and recommendations aimed at protecting public health (such as Chapter 6.2. 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 the *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.

6. 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.

7. The 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.

8. 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 Chapter meets high standards and that there are national programmes for ongoing and comprehensive professional development. The *Veterinary Services* should comply with the OIE fundamental principles of quality given in Chapter 3.1. of the *Terrestrial Code*. Recommendations for the evaluation of *Veterinary Services* are provided in Chapter 3.2. of the *Terrestrial Code* and in the OIE *Tool for the Evaluation of Performance of Veterinary Services*.

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.

Annex XIII

CHAPTER X.X.

~~GUIDELINES ON~~ THE DETECTION, CONTROL AND PREVENTION OF NON-TYPHOID *SALMONELLA* ~~SPP.~~ IN ~~POULTRY~~ CHICKENS

Community comments

The Community recognises the usefulness of standards related to hygiene of production and prevention of Salmonella infection through detection and control measures, however it is still unsure what is this chapter made for: no reference is made to status, nor trade, so the Chapter is considered to be included in the first volume of the Code and as such, the detailed part should not be developed this way: the article x.x.4; should stop after its point c) and all the part under "sampling" should be deleted and possibly inserted in a guidance document not included in the Code.

This draft is thus not at all ready for vote and the Community wishes to participate in the coming ad hoc group that should revise it in depth.

The Community does not support the restriction to Phage Type 4 (PT4) of *Salmonella* Enteritidis. In 2003 61.9% of human *S.* Enteritidis cases were non-PT4, representing about half of all human cases. "PT4" should be deleted throughout the draft.

Moreover, the community has very substantial comments on the text itself, inserted below. The outcomes of the ad hoc group will be essential for comprehensive comments.

Article X.X.1.

Introduction

~~The aim of the *Code* is to assist Members in the management and control of significant animal diseases, including diseases with zoonotic potential, and in developing animal health measures applicable to trade in terrestrial animals and their products.~~ ~~These guidelines~~ This Chapter provides recommendations on the detection, control and prevention of non-typhoid *Salmonella* ~~spp.~~ in ~~poultry~~ chickens (*Gallus gallus domesticus*) used for the production of *meat* and eggs for human consumption.

In most food animal species, non-typhoid *Salmonella* ~~spp.~~ can establish a clinically inapparent *infection* of variable duration, which is significant as a potential *zoonosis*. Such animals may be important in relation to the spread of *infection* between *flocks* and as causes of human foodborne *infection*. In the latter case, this can occur when *meat* and eggs, or their products, enter the food chain thus producing contaminated food ~~products~~.

Salmonellosis is one of the most common foodborne bacterial *diseases* in the world. ~~It is estimated that over 90%~~ The great majority of *Salmonella infections* in humans are foodborne with *Salmonella* Enteritidis Phage Type 4 (PT4) and *Salmonella* Typhimurium serotypes accounting for a major part of the problem. *Salmonella* serotypes may vary considerable between localities, districts, regions and countries.

In the development and implementation of programmes to achieve control of *S.* Enteritidis PT4 and *S.* Typhimurium, an improvement in *flock* status for other *Salmonella* serotypes can be expected.

Article X.X.2.

Purpose and scope

~~These guidelines~~ This Chapter deals with methods for on farm detection, control and prevention of *Salmonella* ~~spp.~~ in ~~poultry~~ chickens, and ~~. These guidelines~~ complements the Codex Alimentarius Code of Hygiene Practice for Meat (CAC/RCP 58-2005) and Code of Hygienic Practice for Eggs and Egg Products (CAC/RCP 15-1976 Revision 2007). A pathogen reduction strategy at the farm level is seen as the first step in a continuum that will assist in minimizing the presence of foodborne pathogens in ~~producing~~ eggs and *meat* ~~that are safe to eat~~.

All hygiene and biosecurity procedures to be implemented in ~~poultry~~ chicken *flocks* and hatcheries are described in Chapter 6.3. ~~on~~ Hygiene and Biosecurity Procedures in Poultry Production.

The scope covers ~~breeding flocks,~~ chickens ~~and other domesticated birds~~ used for the production of eggs and *meat* for human consumption. The recommendations presented in ~~these guidelines~~ this Chapter are relevant to the control of all non-typhoid *Salmonella* ~~spp.~~ with special attention to *S.* Enteritidis PT4 and *S.* Typhimurium serotypes, as these are problems in many countries. It should be noted that the definition of the epidemiology of animal and human salmonellosis in a particular locality, district, region or country is important for effective control of salmonellosis.

Article X.X.3.

Definitions (for this chapter only)

Broilers
means birds of the species *Gallus gallus* selectively bred and reared for their *meat* rather than eggs.

Broken/ leaker egg
means an egg showing breaks of both the shell and the membrane, resulting in the exposure of its contents.

Competitive exclusion
means the administration of defined or undefined bacterial flora ~~to poultry to~~ or the administration of substrates which allow for the proliferation of beneficial bacteria and which prevent gut colonisation by enteropathogens, including non-typhoid *Salmonella*.

Cracked egg
means an egg with a damaged shell, but with intact membrane.

Culling
means the depopulation of a *flock* before the end of its normal production period.

Dirty egg
means an egg with foreign matter on the shell surface, including egg yolk, manure or soil.

Layer or laying flock
means a *flock* of ~~poultry~~ chickens during the period of laying eggs for human consumption.

Non-typhoid Salmonella
means those serotypes of *Salmonella enterica* for which the reservoir hosts are domestic and wild animals, as opposed to the serotypes *S.* Typhi and *S.* Paratyphi which cause typhoid fever in humans, which are the reservoir host.

Peak of lay
means the period of time in the laying cycle (normally expressed as age in weeks) when the production of the *flock* is highest.

~~*Poultry*~~
~~means members of the class Aves that are kept for the purpose of breeding or for the production of meat or eggs.~~

Pullet flock

means a *flock* of ~~poultry~~ chickens prior to the period of laying eggs for human consumption or hatching.

Article X.X.4.

Surveillance of ~~poultry~~ chickens flocks for *Salmonella* ~~spp~~ serotype

Where justified by *risk assessment*, *surveillance* should be performed to identify infected *flocks* in order to take measures that will reduce the prevalence in ~~poultry~~ chickens and the risk of transmission of *Salmonella* ~~spp.~~ serotypes to humans. Microbiological testing is preferred to serological testing because of its higher sensitivity in broilers and higher specificity in breeders and layers. In the framework of regulatory programmes for the control of ~~*Salmonella* spp.~~ salmonellosis, confirmatory testing may be appropriate to ensure that decisions are soundly based.

Results ~~of~~ from *surveillance* may lead to the implementation of ~~will allow~~ control measures ~~to be implemented~~ to reduce the risk of transmission of *Salmonella* ~~spp.~~ serotypes to humans:

a) In breeders, control measures may be ~~taken~~ implemented to ~~will~~ minimise ~~prevent~~ the transmission of *Salmonella* ~~spp.~~ serotypes to the next generation.

b) In layers control measures will reduce or eliminate ~~*Salmonella* spp.~~ contamination of eggs ~~for human consumption~~ with *Salmonella* serotypes.

c) In broilers, ~~this~~ control measures, such as logistic *slaughter* and channelling, may ~~will permit measures to~~ be ~~taken~~ implemented at *slaughter* ~~and~~ or further down the food chain ~~(logistic slaughter and channelling)~~.

Sampling

Community comment

The detailed should be avoided and the objective of surveillance should be highlighted, e.g. a certain degree of confidence.

A minimum amount of material (25g) is relevant for both drag swabs and boot swabs. In addition, there is clear evidence that the number of swabs is not relevant, but this minimum amount and the requirement that the sample should be representative of the whole house is essential. See the three proposed changes below.

1. Available methods for sampling

   Drag swabs: sampling is done by dragging swabs around the poultry building to collect samples of 10-25 g and to include faeces, and moist and dry litter.

Community comment

The words " to collect samples of 10-25 g and to include" should be replaced by the word "including".

Boot swabs: sampling is done by walking around the poultry building with absorbent material placed over the footwear of the sampler.

Faecal samples: multiple samples of fresh faeces collected from different areas in the poultry building.

Meconium, dead in shell and culled chicks at the hatchery.

Additional sampling of equipment and surfaces may be performed to increase sensitivity.

2. Number of samples to be taken according to the chosen method

Community comment

The words "Amount of material and" should be added before the word "number".

The sentence below "Recommendation is five pairs of boot swabs or 10 drag swabs" should be replaced by "The pair(s) of boot swabs or drag swabs should be representative for the whole surface of the house".

Recommendation is five pairs of boot swabs or 10 drag swabs. These swabs may be pooled into no less than two samples with each pool containing 10-25 g of material.

Community comment

The number 10 should be deleted.

The total number of faecal samples to be taken on each occasion is shown in Table I and is based on the random statistical sample required to give a probability of 95% to detect at least one positive sample given that *infection* is present in the population at a level of 5% or greater.

Table I

Number of birds in the flock	Number of faecal samples to be taken on each occasion
25-29	20
30-39	25
40-49	30
50-59	35
60-89	40
90-199	50
200-499	55
500 or more	60

3. Laboratory methods

Refer to the *Terrestrial Manual*.

4. ~~Time, frequency and type of samples to be tested~~ Testing of samples

Community comment

The original wording better covers the content of this section; a possible alternative wording could be: "Sampling frame".

Time, frequency and type of sample for each ~~poultry~~ category listed below are based on *risk assessment* and production methods:

Community comment

To be better applicable, the sentence above should read: "Time, frequency and type of sample for each poultry category listed below are given as guidance. They may be changed based on *risk assessment*."

a) Breeders and hatcheries

i) Breeder pullet flock

- At the end of the first week of life.

Community comment

The words "At the end" should be replaced by "Before the end". Firstly it is more applicable("at the end" is not clear, e.g. the seventh day?), and secondly, results need to be known as soon as possible.

- Within the four weeks before being moved to another house, or before going into production if the animals will remain in the same house for the production period.
- One or more times during the growing period if there is a culling policy in place. The frequency would be determined on commercial considerations.

ii) Breeding flocks in lay

- At least at monthly intervals during the laying period.
- The minimal frequency would be determined by the *Veterinary Services*.

iii) Hatcheries

- Testing in hatcheries complements on farm testing.

Community comment

The above point should read: "Testing in hatcheries may be used to survey flocks. If positive samples are found, this sampling should be complemented by surveillance at farm to identify the source of infection. Surveillance in hatcheries would also result in the detection of typical hatchery infections."

Indeed, surveillance in hatcheries may be used to survey flocks. Certain serotypes of Salmonella (Senftenberg, Virchow) may persist in hatcheries while breeding flocks may be free.

- The minimal frequency would be determined by the *Veterinary Services*.

b) ~~Poultry~~ Chickens for the production of eggs for human consumption

i) Layer pullet flocks

- At the end of the first week of life when the status of the breeding farm and the hatchery is not known or does not comply with ~~these guidelines~~ this Chapter.

Community comment

The words "At the end" should be replaced by "Before the end". Firstly it is more applicable("at the end" is not clear, e.g. the seventh day?), and secondly, results need to be known as soon as possible.

- Within the four weeks before being moved to another house, or before going into production if the animals will remain in the same house for the production period.
- One or more times during the growing period if there is a culling policy in place. The

frequency would be determined on commercial considerations.

ii) Layer or laying flocks

- At expected peak of lay for each production cycle.
- One or more times if there is a culling policy in place or if eggs are diverted to processing for the inactivation of the pathogen. The minimal frequency would be determined by the *Veterinary Services*.

c) Broilers

i) *Flocks* should be sampled at least once. On farms where there is a long period (2 weeks or more) between thinning and final depopulation further testing should be considered.

ii) *Flocks* should be sampled as late as possible before the first birds are transported to the slaughterhouse. However, this must be done at a time that ensures the results are available before *slaughter*.

d) Empty building testing

i) Bacteriological monitoring of the efficacy of *disinfection* procedures is recommended when any of the *Salmonella* ~~spp.~~ serotypes have been detected in the previous *flock*.

ii) As appropriate, s~~S~~ampling of equipment and surfaces as well as boot swabs or drag swabs of the empty building after depopulation, cleaning and *disinfection*.

Article X.X.5.

Control measures

Salmonella control can be achieved by adopting Good Agricultural Practices and Hazard Analysis Critical Control Point (HACCP) in combination with the following measures. No single measure used alone will achieve effective *Salmonella* control.

Community comment

For better clarity and applicability, the Community proposes the following wording of the first sentence:

"As a minimum *Salmonella* should be controlled by adopting Good Agricultural Practices and Hazard Analysis Critical Control Point (HACCP). Where possible and appropriate, these measures should be combined with the following additional measures."

Additional control measures currently available include: vaccination, *competitive exclusion*, *flock* culling and product diversion to processing.

Antimicrobials should not be used to control *infection* with *Salmonella* ~~spp.~~ serotypes in ~~poultry~~ chickens ~~for human consumption~~ because the effectiveness of the therapy is limited; it has the potential to produce residues in *meat* and eggs and can contribute to the development of antimicrobial resistance. Antimicrobials may also reduce normal flora in the gut and increase the likelihood of colonisation with *Salmonella* ~~spp.~~ In special circumstances antimicrobials may be used to salvage animals with high genetic value.

Community comment

At the end of the second sentence above, the following should be added: "They may as well mask the infection at sampling."

1. Day old chicks used to stock a poultry house should be obtained from breeding *flocks* and hatcheries that are certified as free from at least *S.* Enteritidis PT4 and *S.* Typhimurium and have been monitored according to ~~these guidelines~~ this Chapter.

2. Layer ~~or~~ and laying *flocks* ~~or~~ and breeder *flocks* should be stocked from pullet *flocks* that are certified as free from at least *S.* Enteritidis PT4 and *S.* Typhimurium and have been monitored according to ~~these guidelines~~ this Chapter.

Community comment

For consistency with point 6 second paragraph, the following should be added at the end of the sentence above:

"unless the flocks are intended for the egg production, not intended for direct human consumption but for processing for inactivation of Salmonella."

3. Feed ~~may be~~ contamination ~~contaminated~~ with *Salmonella* is known to be a source of *infection* for chickens. Therefore, it is recommended to monitor the *Salmonella* status of ~~poultry~~ chicken feed, and if found positive to take corrective measures. The use of ~~pelletised~~ heat treated feeds or feeds subjected to other bactericidal treatment is recommended. Feed should be stored in clean closed containers to prevent access by wild birds and rodents. Spilled feed should be cleaned up immediately to remove attractants for wild birds and rodents.

4. *Competitive exclusion* can be used in day old chicks to reduce colonisation by *Salmonella* ~~spp~~ serotypes.

5. As far as vaccination is concerned, many vaccines are used against *Salmonella infections* caused by different ~~serovars~~ serotypes in various ~~poultry~~ chicken species, including single or combined vaccines ~~against *S.* Enteritidis and *S.* Typhimurium~~. Vaccines produced according to the *Terrestrial Manual* should be used.

   If live vaccines are used it is important that field and vaccine strains ~~can~~ be easily ~~be~~ differentiated in the laboratory. If serology is used as the *surveillance* method, it may not be possible to distinguish between vaccination ~~or~~ and *infection* with a field strain.

   Vaccination can be used as part of an overall *Salmonella* control programme. ~~Vaccination should never be used as the sole control measure.~~ It is recommended that vaccination not be used as the sole control measure.

   When the status of the breeding farm and the hatchery from which the pullet *flock* originates is not known or does not comply with ~~these guidelines~~ this Chapter, vaccination of pullet *flocks*, starting with day-old chicks, against *S.* Enteritidis or *S.* Enteritidis/*S.* Typhimurium should be considered.

   Vaccination should be considered when moving day-old chicks to a previously contaminated shed so as to minimize the risk of the birds contracting *infection* with *S.* Enteritidis and *S.* Typhimurium.

   When used, vaccination should be performed according to the instructions provided by the manufacturer and in accordance with the instructions of the *Veterinary Services*.

   Vaccination against *S.* Enteritidis can cause a positive reaction in *Salmonella* Pullorum-Gallinarum serological tests and needs to be considered when implementing measures for these pathogens.

6. Depending on animal health, *risk assessment*, and public health policies, culling is an option to manage infected breeder and layer *flocks*. Infected *flocks* should be destroyed or slaughtered and processed in a manner that minimises human exposure to *Salmonella* ~~spp~~ serotypes.

If ~~poultry~~ chickens are not culled, eggs for human consumption should be diverted for processing for inactivation of *Salmonella* ~~spp~~.

7. As far as the veterinary involvement is concerned, the responsible veterinarian should monitor the results of *surveillance* testing for *Salmonella* ~~spp~~. This information should be available to the veterinarian before marketing if a certificate for *flock Salmonella* status is required prior to ~~in order to certify the flock for~~ the *flock* for *slaughter*. When required by the *Competent Authority*, ~~This~~ the veterinarian or other authorised person should notify the ~~*Veterinary*~~ *Competent Authority* if the presence of *Salmonella* ~~spp.~~ of the relevant serotypes is confirmed.

Article X.X.6.

Prevention of Salmonella spread

If a *flock* is found infected with non-typhoid *Salmonella* ~~spp.,~~ the following actions should be taken in addition to general measures detailed in the Chapter 6.3. ~~on~~ Hygiene and Biosecurity Procedures in Poultry Production:

Community comment

The words "which are submitted to a control programme" should be added after the word "Salmonella", in order to be clear that the measures are related to a control plan.

1. Epidemiological investigations should be carried out to determine the origin of the *infection* as appropriate to the epidemiological situation.
2. Movement of broilers, culled ~~poultry~~ chickens or layers at the end of the production cycle should only be allowed for *slaughter* or destruction. Special precautions should be taken in the transport, *slaughter* and processing of the birds, e.g. they could be sent to a separate slaughterhouse or processed at the end of a shift before cleaning and *disinfection* of the equipment.
3. Litter should not be reused. ~~Poultry~~ Chicken litter/faeces and other potentially contaminated farm waste should be disposed of in a safe manner to prevent the ~~spread of infections with~~ direct or indirect exposure of humans, livestock and wildlife to ~~with~~ *Salmonella* ~~spp.~~ Particular care needs to be taken in regard to ~~poultry~~ chicken litter/faeces used to fertilise plants intended for human consumption.
4. Particular care should be taken in cleaning and *disinfection* of the poultry house and equipment.

4~~5~~. Before restocking bacteriological examination should be carried out as detailed in ~~these guidelines~~ this Chapter.

Article X.X.7.

Special considerations for broiler flocks

1. The grow out phase of broiler production is short and therefore it is important to emphasize the *Salmonella* status of the source *flock*.
2. Broilers are susceptible to colonisation with non-typhoid *Salmonella* ~~spp.~~ because of high-level exposure ~~they are young and are grown~~ at the high stocking rates at which they are kept and because they are immunologically naive.
3. To reduce *Salmonella* ~~spp.~~ contamination in the abattoir it is helpful to reduce the amount of feed in the bird's gut at the time of *slaughter*. Feed transits the gut in about four hours; therefore, it is recommended to withdraw feed to the birds at an appropriate period before *slaughter* (8-10 hours).
4. *Slaughter* processing should be conducted in accordance with Chapter 6.2.

— text deleted

Annex XIV

CHAPTER 6.X.

INTRODUCTION TO THE RECOMMENDATIONS FOR CONTROLLING ANTIMICROBIAL RESISTANCE

Community comments

The Community welcomes the initiative of the OIE and understands that its intention is to propose an introduction chapter to the recommendations for the surveillance and control of use of antimicrobians and of antimicrobial resistance. This could be a good and helpful complement to Chapters 6.5 to 6.8. However, it should not be proposed for adoption before having been discussed in an appropriate expert group, in particular to discuss the Codex alimentarius "Proposed Draft Guidance for Risk Analysis of Foodborne Antimicrobial Resistance" document which is currently under discussion.

It would be therefore appropriate that the Working Group on Food Safety discuss this draft chapter at the light of the Codex work, which could be used and adapted or complemented while guaranteeing consistency between both drafts.

Article 6.X.1.

The purpose of this Chapter is to provide methodologies for OIE Members to appropriately address the emergence or spread of resistant bacteria from the use of antimicrobial agents in animal husbandry and to contain antimicrobial resistance through controlling the use of antimicrobial agents.

Antimicrobial agents are essential drugs for human and animal health and welfare. The OIE recognises the need for access to antimicrobial agents in veterinary medicine: antimicrobial agents are essential for treating, controlling and preventing infectious diseases in animals and this contributes to human health through the supply of animal protein without the risk of transmission of food-borne diseases. The OIE therefore considers that ensuring continued access to effective antimicrobial agents is a priority.

Community comments

The Community proposes to delete the following, as there is not enough clear relation and it does not add to the text:

"and this contributes to human health through the supply of animal protein without the risk of transmission of food-borne diseases"

The OIE recognises that antimicrobial resistance is a global public and animal health concern that is influenced by the usage of antimicrobial agents in humans, animals and elsewhere. Those working in the human, animal and plant sectors have a shared responsibility to prevent or minimise pressures for the selection of antimicrobial resistance factors in humans and animals. Arising from its mandate for the protection of animal health and food safety, the OIE developed these Chapters to provide guidance to Members in regard to risks in the animal sector.

The application of risk management measures should be based on risk assessment that is supported by sound data and information. The methodologies provided in these Chapters should be consulted as part of the standard approach to preventing antimicrobial resistance.

Community comments

In order to be in line with international standards on microbiological risk analysis, the words "risk assessment that is" should be replaced by "international standards on microbiological risk analysis and"; the Community reiterates its comments of the definition of risk, risk assessment and risk analysis.

In some situations where there is evidence of risk, provisional measures may be taken before all information is available, so the words ", when available" should be added after "sound data and information" at the end of the first sentence.

Antimicrobial resistance should also be reduced if present and not only prevented, so the words "prevent and reduce" should replace the word "preventing" in the second sentence.

Finally, a new paragraph should be added at the end in order to guarantee consistency with the ongoing work within the Codex alimentarius:

"Risk management options described in the next chapters should be implemented as a minimum. Following risk profiling and/or risk assessment national/regional Authorities might find a need for risk management activities additional to those outlined in the next chapters."

Annex XV

DRAFT GUIDELINES ON STRAY DOG POPULATION CONTROL

Community comments

The Community welcomes the positive improvements of the text and acknowledges that a number of Community comments previously submitted have been taken into account.

Nevertheless, the Community wishes to reiterate its previous comments:

1. For more clarity of the scope of these guidelines, the following sentence should be added at the beginning of the preamble: "The scope of these guidelines is to deal with problems caused by stray and feral dogs."

2. Methodological approach regarding the carrying capacity and the estimation of dog population size could be further expanded as well as methods of capture, transport, keeping and killing of dogs. Scientific information regarding the behaviour of stray dogs and their possible practical applications to control their population would be valuable to be added.

Preamble: Stray and feral dogs pose serious human health, socio-economic, political, religious and animal welfare problems in many countries. Whilst acknowledging human health is a priority including the prevention of zoonotic diseases notably rabies, the OIE recognises the importance of control dog populations without causing unnecessary or avoidable animal suffering. Veterinary Services should play a lead role in preventing zoonotic diseases and ensuring animal welfare and should be involved in dog population control.

Guiding principles

The following guidelines are based on those laid down in Chapter 7.1. of the OIE *Terrestrial Animal Health Code* (The *Terrestrial Code)*. Some additional principles are relevant to these guidelines:

1. The promotion of responsible dog ownership can significantly reduce the numbers of stray dogs and the incidence of zoonotic diseases.

2. Because dog ecology is linked with human activities, control of dog populations has to be accompanied by changes in human behaviour to be effective.

Article 1

Definitions

Stray dog: means any dog not under direct control by a person or not prevented from roaming.

Community comment

The Community reiterates its previous comment: the definition of "Stray dog" should be modified as follows: "Any dog which does not show physical evidence of identification or ownership and is not under direct control or prevented from roaming."

Justification: A hunting dog for example could be not under direct control although not being a stray dog.

Types of stray dog:

a) free roaming owned dog not under direct control or restriction at a particular time;

Community comment

The point a) should be replaced as follows: "free roaming owned dog not having physical evidence of ownership and not under direct control or restriction at a particular time".

Justification: An owned dog could be not under the direct control of its owner for a short period of time without being a stray dog if it can be easily recognised as owned.

b) free roaming dog with no owner;

c) feral dog: domestic dog that has reverted to the wild state and is no longer directly dependent upon humans for successful reproduction.

Owned dog: means a dog with a person that claims responsibility.

Community comment

In the above definition the words "with physical evidence of ownership or " should be included between the words "dog" and "with".

Justification: See previous comments.

Person: this can include more than one individual, and could comprise family/household members or an organisation.

Responsible dog ownership: means the situation whereby a person (as defined above) accepts and commits to perform various duties according to the legislation in place and focused on the satisfaction of the psychological, environmental and physical needs of a dog-and to the prevention of *risks* (aggression, *disease* transmission or injuries) that the dog may pose to the community, other animals or the environment.

Community comment

In the above definition, the word "*situation*" should be replaced by the word *"state"* and the word *"psychological"* should be replaced by the word "behavioural".

Justification:

1. More that a situation, responsible ownership means the condition in which a person accepts and commits to perform various duties.

2. The reference to the behavioural needs of dogs is in line with the Guiding principles for animal welfare as laid done in the Terrestrial Code as well as with the Community comments reiterated in Art 3.6 of these draft guidelines. Furthermore, scientifically the study of ethology of dogs is more clearly understood as it describes what dogs do than the psychology of dogs which purports to describe the motivations of animals to behave in particular ways.

Euthanasia: means the act of inducing death in a humane manner.

Dog population control programme: means a programme with the aim of reducing a stray dog population to a particular level and/or maintaining it at that level and/or managing it in order to meet a predetermined objective (see Article 2).

Carrying capacity: is the upper limit of the dog population density that could be supported by the habitat based on the availability of resources (food, water, shelter), and human acceptance.

Community comment

The notion of "carrying capacity" is very valuable but would need to be further developed as to be used more practically. Further references or examples of models to calculate or estimate the carrying capacity should be presented.

Article 2

Dog population control programme objectives

The objectives of a programme to control the dog population may include the following:

1. improve health and welfare of owned and stray dog population;
2. reduce numbers of stray dogs to an acceptable level;
3. promote responsible ownership;
4. assist in the creation and maintenance of a rabies immune or rabies free dog population;
5. reduce the risk of zoonotic diseases other than rabies;
6. manage other risks to human health e.g. parasites;
7. prevent harm to the environment and other animals;
8. prevent illegal trade and trafficking.

Article 3

Responsibilities and competencies

Community comment

In the title of Art 3 Point 1, the title "*Veterinary Authority*" should be replaced by "*Veterinary Authority* and *Competent Authority*".

Furthermore, the following text should be inserted as second sentence of the paragraph in Point 1 "In some cases animal welfare legislation is under the responsibility of other *Competent Authority* than the *Veterinary Authority*".

Justification: As defined in the Glossary of the Terrestrial Code, "Competent Authority" includes the Veterinary Authority as well as other Governmental Authority of an OIE Member having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures.

1. *Veterinary Authority*

   The *Veterinary Authority* is responsible for the implementation of animal health and animal welfare legislation. Control of endemic zoonotic diseases such as rabies and parasitic *infections* (e.g. *Echinococcus*

spp.) would require technical advice from the *Veterinary Authority*, as animal health and some aspects of public health are within this Authority's competence but organising and/or supervising dog control schemes can be the responsibility of non-governmental organisations and governmental agencies other than the *Veterinary Authority*.

2. Other *government* agencies

The responsibilities of other government agencies will depend on the risk being managed and the objective/nature of the dog population control measures employed.

The ministry or other agency responsible for public health would normally play a leadership role and may have legislative authority in dealing with zoonotic diseases. Control of stray dogs with regard to other human health risks (e.g. stray dogs on roads; dog attacks within communities) may fall within the responsibility of the public health agency but is more likely to be the responsibility of police or other agencies for public safety/security operating at the state/provincial or municipal level.

Environment protection agencies may take responsibility for control problems associated with stray dogs when they present a hazard to the environment (e.g. control of feral dogs in national parks; prevention of dog attacks on wildlife or transmission of *diseases* to wildlife) or where a lack of environmental controls is giving rise to stray dog populations that threaten human health or access to amenities. For example, environmental protection agencies may regulate and enforce measures to prevent dogs (and other wild animals) from accessing waste or human sewage.

3. Private sector veterinarians

The private sector veterinarian is responsible for providing advice to dog owners or handlers consulting the veterinarian for advice or treatment of a dog. The private sector veterinarian can play an important role in *disease* surveillance because he/she might be the first to see a dog suffering from a *notifiable disease* such as rabies. It is necessary that the private sector veterinarian follow the procedure established by the *Veterinary Authority* for responding to and reporting a suspected rabies case or a dog that is suffering from any other *notifiable disease*. Private sector veterinarians also play an important role (often in liaison with the police and/or local authorities) in dealing with cases of neglect that can lead to problems with stray and mismanaged dogs.

The private veterinarian has competence and will normally be involved in dog health programmes and population control measures, including health testing, vaccination, identification, kennelling during the absence of the owner, sterilisation and euthanasia. Two-way communication between the private sector veterinarian and *Veterinary Authority*, often via the medium of a veterinary professional organisation, is very important and the *Veterinary Authority* is responsible to set up appropriate mechanisms for this action.

4. Non governmental organisations (NGOs)

Non governmental organisations (NGOs) are potentially important partners of the *Veterinary Services* in contributing to public awareness and understanding and helping to obtain resources to contribute in a practical way to the design and successful implementation of dog control programmes. NGOs can supply local knowledge on dog populations and features of ownership, as well as expertise in handling and kennelling dogs and the implementation sterilisation programmes. NGOs can also contribute, together with veterinarians and the authorities in educating the public in responsible dog ownership.

5. Local government authorities

Local government authorities are responsible for many services and programmes that relate to health,

safety and public good within their jurisdiction. In many countries the legislative framework gives authority to local government agencies in regard to aspects of public health, environmental health/hygiene and inspection/compliance activities.

In many countries local government agencies are responsible for enforcement of legislation relating to dog ownership (e.g. microchipping, vaccination, leash laws, abandonment), the control of stray dogs (e.g. dog catching and shelters) and the alleviation of the problems stray dogs cause. This would normally be done with advice from a higher level (national or state/provincial) authority with specialised expertise in regard to public health and animal health. Collaboration with the private sector veterinarians (e.g. in programs to sterilise and vaccinate stray dogs) and NGOs is a common feature of dog control programmes. Regardless of the legislative basis, it is essential to have the co-operation of local government authorities in the control of stray dogs.

6. Dog owners

Community comment

The Community welcomes the identification of owners' responsibilities and competencies and suggests further expanding this part. In particular the owner should ensure that the welfare of the dog and the fulfilments of its needs are respected as well as its health.

Justification: Responsibility for the dog should include not only protection from infectious diseases and unwanted reproduction but also the respect of the behavioural needs of the dog

When a person takes on the ownership of a dog there should be an immediate acceptance of responsibility for that dog, and for any offspring it may produce, for the duration of its life or until a subsequent owner is found. The owner must ensure that the welfare of the dog, including behavioural needs, are respected and the dog is protected, as far as possible, from infectious *diseases* (e.g. through vaccination and parasite control) and from unwanted reproduction (e.g. through surgical sterilisation). Owners should ensure that the dog's ownership is clearly identified (preferably with permanent identification such as a tattoo or microchip) and, where required by legislation, registered on a centralised database. All reasonable steps should be taken to ensure that the dog does not roam out of control in a manner that would pose a problem to the community and/or the environment.

Article 4

Community comment

In the first sentence of the following paragraph, the words "*such as*" should be included between the bracket and the words *"local authorities"*.

Justification: Examples of stakeholders are being provided and not a prescriptive list.

In the development of a dog population control programme it is recommended that the authorities establish an advisory group, which should include veterinarians, experts in dog ecology, dog behaviour and zoonotic diseases, and representatives of relevant stakeholders (local authorities, human health services/authorities, environmental control services/authorities, NGOs and the public). The main purpose of this advisory group would be to analyse and quantify the problem, identify the causes, obtain public opinion on dogs and propose the most effective approaches to use in the short and long term.

Important considerations are as follows:

1. Identifying the sources of stray dogs

a) Owned animals that roam freely

b) Dogs that have been abandoned by their owner, including puppies resulting from uncontrolled breeding of owned dogs.

c) Unowned dogs that reproduce successfully.

2. Estimating the existing number, distribution and ecology

Practical tools that are available include registers of dogs, population estimates, surveys of dogs, owners, dog shelters and associated veterinarians. The important factors relevant to the dog carrying capacity of the environment include food, shelter, water and human attitudes and behaviour.

A methodology, could be established to make an estimate of the total dog population, an overview of appropriate methodologies may be found in Annex I. The same methodology could be used at appropriate intervals to assess population trends.

Community comment

The Community encourages further developments of appropriate methodologies for estimating the size of dog populations.

3. Legislation

Legislation that would help authorities establish successful dog control programmes could include the following key elements:

a) registration and identification of dogs and licensing of dog breeders~~;~~

b) vaccination against rabies and other preventive measures against zoonotic disease, as appropriate;

c) veterinary procedures (e.g. surgical procedures);

d) control of dog movement (national and international);

e) control of dangerous dogs;

f) regulations on the breeding and sale of dogs;

g) environmental controls (e.g. *abattoirs*, rubbish dumps, dead stock facilities);

h) regulations for dog shelters;

i) animal welfare obligations of owners and authorities.

4. Resources available to authorities

a) Human resources;

b) financial resources;

c) technical tools;

d) infrastructure;

e) cooperative activities;

f) public-private-NGO partnerships;

g) central-state or province-local partnerships.

Article 5

Control measures

The following control measures could be implemented according to the national context and local circumstances. Measures may be used in combination. Euthanasia of dogs, used alone, is not an effective control measure. If used, it should be done humanely (see Article 5.11) and in combination with other measures to achieve effective long term control. It is also important that authorities gain an understanding of people's attitudes towards dog ownership so that they can develop a cooperative approach to the control of dog populations.

1. Education and legislation for responsible ownership

   Encouraging dog owners to be more responsible will reduce the number of dogs allowed to roam, improve the health and welfare of dogs, and minimise the risk that dogs pose to the community. The promotion of responsible dog ownership through legislation and education is a necessary part of a dog population control programme. Collaboration with animal welfare NGOs, kennel clubs, private veterinarians and veterinary organisations will assist *Veterinary Authorities* in establishing and maintaining programmes.

   Education on responsible dog ownership (for the currently owned dog and any offspring it produces) should address the following elements:

   a) the importance of proper care to ensure the welfare of the dog and any offspring; this may include preparing the dog to cope with its environment through attention to socialisation and training;

   b) registration and identification of dogs (see Article 5. 2.);

   c) disease prevention, in particular zoonotic disease, e.g. through regular vaccination in rabies endemic areas;

   d) preventing negative impacts of dogs on the community, via pollution (e.g. faeces and noise), risks to human health through biting or traffic accidents and risks to wildlife, livestock and other companion animal species;

   e) control of dog reproduction.

   In order to achieve a shift towards responsible ownership, a combination of legislation, public awareness, education, and promotion of these elements will be required. It may also be necessary to improve access to resources supporting responsible ownership, such as veterinary care, identification and registration services and measures for control of zoonotic diseases.

2. Registration and identification of dogs (licensing)

   A core component of dog population control by the *Competent Authorities* is the registration and identification of owned dogs. This may include granting licences to owners and breeders. Registration and identification may be emphasized as part of responsible dog ownership and are often linked to animal health programs, for example, mandatory rabies vaccination and a dog traceability.

   Registration of animals in a centralised database can be used to support the enforcement of legislation and the reuniting of lost animals with owners. The control of dog reproduction by sterilisation can be encouraged through financial incentives presented by differential licensing fees.

3. Reproductive control

   Controlling reproduction in dogs prevents the birth of unwanted puppies and can help address the balance between demand for dogs and the size of the population. It is advisable to focus efforts to control reproduction on those individuals or groups in the dog population identified as the most productive and the most likely to be the sources of unwanted and stray dogs, to ensure best use of

resources. Methods of controlling reproduction will require direct veterinary input to individual animals, involvement of both private and public veterinary sectors may be required to meet demand. Subsidisation of sterilisation programmes by government may be considered to encourage uptake. The control of reproduction is essentially the responsibility of owners and can be incorporated into education on responsible ownership (section 5 a.). Methods for controlling reproduction in dogs include:

a) surgical sterilisation;

b) chemical sterilisation;

c) chemical contraception;

d) separation of female dogs during oestrus from unsterilised males.

Surgical sterilisation should be carried out by a veterinarian and include appropriate anaesthesia and pain relief.

Any chemicals or drugs used in controlling reproduction should be shown to have appropriate safety, quality and efficacy for the function required and used according to the manufacturer's and *Competent Authority*'s regulations. In the case of chemical sterilants and contraceptives, research and field trials may need to be completed before use.

2. Removal and handling

Community comment

This point should be n°4, not 2, and the two following should be 5 and 6, not 3 and 4.

The *Competent Authority* should collect dogs that are not under direct supervision and verify their ownership. Capture, transport, and holding of the animals should be done humanely. The *Competent Authority* should develop and implement appropriate legislation and training to regulate these activities. Capture should be achieved with the minimum force required and equipment should be used that supports humane handling. Uncovered wire loops should not be used for capture.

Community comment

Basic behaviour and needs of dogs should be defined in order to set up acceptable methods of capture, transport and keeping. Furthermore, more guidance would be needed here concerning acceptable methods of capture and transport of dogs taking into account their basic behaviour and needs. Emphasis should be given on the needs for animals' handlers to be aware of the different aspects of these tasks (e.g. human safe and animal welfare).

Justification: Acceptable methods of capture, transport and keeping of dogs depend on their basic behaviour and needs. Furthermore, the behaviour of animals' handlers can influence the effective implementation of such acceptable methods while respecting the welfare of the dogs.

3. Management of captured stray dogs

Competent Authorities have the responsibility to develop minimum standards for the housing (physical facilities) and care of these dogs. There should be provision for holding the dogs for a reasonable period of time to allow for reunion with the owner and, as appropriate, for rabies observation.

a) Minimum standards for housing should include the following provisions:

i) site selection: Access to drainage, water and electricity are essential and environmental factors such as noise and pollution should be taken into account;

ii) kennel size, design and occupancy taking exercise into account;

iii) *disease* control measures including isolation and quarantine facilities.

b) Management should address:

i) adequate fresh water and nutritious food;

ii) regular hygiene and cleaning;

iii) routine inspection of the dogs;

iv) monitoring of health and provision of required veterinary treatments;

v) policies and procedures for rehoming, sterilisation and euthanasia;

vi) Training of staff in safe and appropriate handling of dogs;

vii) record keeping and reporting to authorities.

Dogs that are removed from a community may be reunited with the owner or offered to new owners for adoption (rehoming). This provides an opportunity to promote responsible ownership and good animal health care (including rabies vaccination). Prior to adoption dogs should be sterilize. The suitability of new owners to adopt dogs should be assessed and owners matched with available animals. The effectiveness of rehoming may be limited due to the suitability and number of dogs.

Community comments:

In the third sentence of the above paragraph, the words "be sterilize" should be replaced by "be sterilized".

Dogs that are removed from a community may in some cases be provided with health care (including rabies vaccination), sterilised, and released to their local community at or near the place of capture. This method is more likely to be accepted in the situation where the presence of stray dogs is considered to be inevitable and is well tolerated by the local community.

This method is not applicable in all situations and may be illegal in countries or regions where legislation prohibits the abandonment of dogs. Problems caused by dogs, such as noise, faecal pollution and traffic accidents, would not be alleviated as dogs are returned to the local community and their movements are not restricted. If the local community has owned dogs, and sterilised dogs are released, consideration should be given to the risk that this could encourage abandonment of unwanted dogs. In the situation where many dogs are owned, a population control programme that focuses on neutering and responsible ownership may be more appropriate.

It is recommended that before adopting this approach, a cost-benefit analysis is conducted. Factors such as the monetary costs, impact on culture of ownership and public safety should be assessed as well as the benefits for *disease* control and animal welfare as well as any societal benefits.

c) If this method is adopted, the following factors should be addressed:

i) raising awareness of the programme within the local community to ensure understanding and support;

ii) use of humane methods for catching, transporting and holding dogs;

iii) correct surgical technique, anaesthesia and analgesia, followed by post-operative care;

iv) *disease* control may include blanket vaccination (e.g. rabies) and treatments and testing for *diseases* (e.g. leishmaniasis) followed, as appropriate by treatment or euthanasia of the dog;

v) behavioural observation may be used to assess if dogs are suitable for release; if not suitable for release or re-homing euthanasia should be considered;

vi) permanent marking (e.g. tattoo) to indicate that the animal has been sterilised; individual identification allows for tracking of vaccination status and treatment history; a visible identification (e.g. collar) may also be used to prevent unnecessary recapture; identification can also be taken to indicate a level of 'ownership' by the organisation/authority responsible for carrying out this intervention;

vii) the dog should be returned to a place that is as near as possible to the place of capture;

viii) the welfare of dogs after release should be monitored and action taken if required.

Dogs that are removed from a community may, be too numerous or may be unsuitable for any rehoming scheme. If euthanasia of these unwanted animals is the only option, the procedure should be conducted in accordance with the regulations of the *Competent Authority* (see Article 5.11).

4. Environmental controls

Steps should be taken to reduce the carrying capacity, such as excluding dogs from sources of food (e.g. rubbish dumps and *abattoirs*, and installing animal-proof rubbish containers).

This should be linked to a reduction in the animal population by other methods, to avoid animal welfare problems.

Community comment

Public policy toward better services for the collection of rubbish associated with stricter rules concerning the release of wastes in the environment should be emphasized here. Synergy of such policy with the fight against rodents and insects could be also stressed.

7. Control of dog movement – international (export/import)

Chapter 2.2.5 of the Terrestrial Animal Health Code provides recommendations on the international movement of dogs between rabies free countries and countries considered to be infected with rabies.

8. Control of dog movements – within country (e.g. leash laws, roaming restrictions)

Measures for the control of dog movement in a country are generally invoked for the following reasons:

a) for rabies control when the *disease* is present in a country;

b) for public safety reasons;

c) for the safety of "owned dogs" in an area or locality when a stray dog control programme is in place;

d) to protect wildlife and livestock.

It is necessary to have empowering legislation to give the necessary power is necessary and a national or local infrastructure comprising organization, administration, staff and resources to encourage the finders of a stray dog to report to the *Competent Authority*.

9. Regulation of commercial dog dealers

Dog breeders and dealers should be encouraged to form or join an appropriate association. Such associations should encourage a commitment to the raising and selling of physically and psychologically healthy dogs, as unhealthy dogs may be more likely to be abandoned to become part of the stray population. They should encourage breeders and dealers to provide advice on proper care to all new owners of dogs. Regulations covering commercial dog breeders and dealers should include specific requirements for accommodation, provision of suitable food, drink and bedding, adequate exercise, veterinary care and disease control and may require breeders and dealers to allow regular inspection, including veterinary inspection.

10. Reduction in dog bite incidence

The most effective means of reducing prevalence of dog bites are education and placing responsibility on the owner. Dog owners should be educated in principles of responsible dog ownership as described in Article 5.1. Legal mechanisms that enable the *Competent Authorities* to impose penalties or otherwise deal with irresponsible owners are necessary. Mandatory registration and identification schemes will facilitate the effective application of such mechanisms. Young children are the group at highest risk for dog bites. Education programmes focussed on appropriate dog-directed behaviour have been demonstrated to be effective in reducing dog bite prevalence and these programmes should be encouraged.

11. Euthanasia

When euthanasia is practised, the general principles in the *Code* should be followed, with the emphasis on using the most practical, rapid and humane methods and ensuring operator safety.

For practical reasons, different procedures may be used in rural and urban areas.

Community comment

The above sentence should be deleted, since in the table 1 it is not specified which methods should be used in rural or urban areas.

Table 1 shows a list of methods for the euthanasia of dogs.

Table 1: List of methods for the euthanasia of dogs

Community comments:

In the following chemical methods for the euthanasia of dogs, the section on barbiturates should also consider mixture of barbiturates with other chemical agents such as Secobarbital Sodium and Cinchocaine Hydrochloride, which should be given intravenously with the full dose over 10–15 seconds via a catheter in order to minimise premature cardiac arrest.
Additionally, an injection rate that is too slow may induce normal collapse, but prolong the period until death.

Justification:

Such mixtures do have some advantages over using barbiturates as cardiac arrest is not dependent on development of profound hypoxia and euthanasia with such mixtures is generally not accompanied with gasping which may occur with other agents.
Secobarbital Sodium is a hypnotic derivate of barbituric acid with a rapid onset of action, which profoundly depresses the central nervous system, including the respiratory centres. Cinchocaine has marked cardio-toxic effects at high doses.
When given in combination, the barbiturate produces rapid loss of consciousness and cessation of respiration while the Cinchocaine depresses the cardiac conduction resulting in early cardiac arrest.
Since cardiac arrest is not dependent on development of profound hypoxia, euthanasia with such mixtures is generally not accompanied with the gasping which may occur with other agents (see data sheet www.vmd.gov.uk/espcsite/Documents/110326.DOC*).*

Euthanasia method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements	Considerations relating to operator security	Advantages	Disadvantages
Chemical -via injection	Barbiturates	Correct restraint is needed. IP is slow and may be irritant. IC injection is a painful procedure.	Recommend to use IV injection. When using IP injection, the solution may be diluted or local anaesthetic agent used in conjunction. IC should only be performed on unconscious animal and by skilled operator.	Correct restraint is needed. Administered under veterinary supervision and requires trained personnel.	Speed of action generally depends on the dose, concentration, route and rate of injection. Barbiturates induce euthanasia smoothly, with minimal discomfort to the animal. Barbiturates are less expensive than many other euthanasia	These drugs persist in the carcass and may cause sedation or death in animals that consume the cadaver.

					agents.	
	Embutramide + Mebezonium + Tetracaine	Muscle paralysis may occur before lost of consciousness if injection given rapidly	Use slow IV injection with sedation to permit slow rate of injection.	Correct restraint is needed. To be administered under veterinary supervision and by trained personnel.	Quite low cost.	Unavailable/unlicensed in some countries
Chemical **-via** **injection (contd)**	Anaesthetic agent overdose (thiopentone or propofenol)	Underdosing may lead to recovery	IV injection of a sufficient dose	Correct restraint is needed. To be administered under veterinary supervision and by trained personnel.	Generally quick action and minimal discomfort to animal.	Large volume required (cost implications)
	Potassium chloride (KCl)	K^+ is cardiotoxic and very painful if used without anaesthetic agent.	Only use on anaesthetised animals, IV injection	Requires trained personnel.	Readily available without veterinary control.	Prior need for anaesthetic (cost and availability implications)

Annex XV (contd)

Table 1: List of methods for the euthanasia of dogs (contd)

Mechanical	Free bullet	Can be inhumane if shot is inaccurate and dog is only wounded; dog may also escape.	Skilled operator essential.	Risk of injury to operators and spectators.	Not necessary to handle or capture dog.	Brain tissue may be unavailable for rabies diagnosis. Risk of injury to bystanders. Legal constraints on use of firearms.
	Penetrating captive bolt followed by pithing where necessary to ensure death	Can be inhumane if shot is inaccurate and dog is only wounded.	Skilled operator essential.	Animal must be restrained. Skilled operator essential.	No risk to operator (cf free bullet) unless risk of dog infected with rabies, due to potential contact with brain tissue	Brain tissue may be unavailable for rabies diagnosis. Legal constraints on use of firearms. May raise aesthetic objections.
	Exsanguination	Onset of hypovolaemia may cause dog to become anxious.	Only use on unconscious animal	Danger to operator through use of sharp instrument.	Material requirements minimal.	Must be done on unconscious animal. Aesthetically objectionable

Table 1: List of methods for the euthanasia of dogs (contd)

Euthanasia method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements	Considerations relating to operator security	Advantages	Disadvantages
Gaseous	Carbon monoxide (CO)	Inadequate concentration of CO is not lethal and can cause suffering. Signs of distress (convulsions, vocalization and agitation) may occur.	Compressed CO in cylinders must be used to achieve and maintain adequate concentration, which must be monitored. Note: fumes from gasoline engines are irritant and this source of CO is not recommended.	Very hazardous for operator - gas is odourless and causes toxicity at both acute high levels and chronic low levels	Dog dies quite rapidly if concentration of 4 to 6% used. No odour (therefore no aversive effect). Gas is not flammable or explosive except at concentration greater than 10%.	

Annex XV (contd)

Table 1: List of methods for the euthanasia of dogs (contd)

Euthanasia method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements	Considerations relating to operator security	Advantages	Disadvantages
Gaseous	Carbon dioxide (CO_2)	Gas is aversive. Inadequate concentration of CO_2 is not lethal and can cause suffering. CO_2 is heavier than air, so when incomplete filling of the chamber occurs, dogs may raise their head and avoid exposure. Few studies on adequate concentration and animal welfare.	Compressed CO_2 gas chamber is the only recommended method because the concentration can be monitored and regulated.	Minimal hazard to operator when properly designed equipment used.	Gas is not flammable or explosive and causes quite rapid anaesthesia when correct concentrations used. Low cost. Readily available as compressed gas	Unconsciousness can occur in minutes, but death may take some time. Likelihood of suffering before unconsciousness.
	Inert gas (nitrogen, N_2 argon, Ar)	Loss of consciousness is preceded by hypoxemia and ventilatory stimulation, which may be distressing to the dog. Re-establishing a low concentration of O_2 (i.e. greater than or equal to 6%) in the chamber before death will allow immediate recovery.	Concentration above 98% must be achieved rapidly and maintained. Properly designed equipment must be used	Minimal hazard to operator when properly designed equipment used.	Gas is not flammable or explosive and is odourless. Readily available as compressed gas.	High cost. Little data on animal welfare implications in dogs.

Table 1: List of methods for the euthanasia of dogs (contd)

Euthanasia method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements	Considerations relating to operator security	Advantages	Disadvantages
Gaseous	Anaesthetic gas overdose (halothane or enflurane)	Animal may struggle and become anxious during induction. Vapours may be irritating and can induce excitement.	Supplementation with air or O_2 required to avoid hypoxemia during induction phase.	Some gases may be hazardous, especially for pregnant women. General recommendation: Avoid human exposure to greater than or equal to 2ppm to avoid narcosis.	Gas is not flammable or explosive. Valuable for use with small animals (<7kgs) and animals that are already anesthetised with gas.	High cost. Anaesthetic and euthanasia properties of the gas used must be known. Isoflurane has a pungent odour. Methoxyflurane's action is slow and dog may become agitated.
Electrical	Electrocution	Cardiac fibrillation occurs before onset of unconsciousness, causing severe pain if dog is conscious. Pain can also be caused by violent extension of the limbs, head and neck. Method may not be effective if insufficient current applied.	Dogs must be unconscious before being electrocuted. This can be accomplished by electrical stunning (current through the brain to produce an instantaneous stun) or anaesthesia. Electrodes should span the brain in order that the current passed through the brain in order to achieve an effective stun. Death would result from current passed through the heart of an unconscious animal. Proper equipment and trained operator is essential.	May be hazardous for operator, who should use protective equipment (boots and gloves).	Low cost.	Inhumane if performed on conscious dog. May raise aesthetic objections.

KEY to abbreviations used in Table 1:
IV: intravenous
IP: Intraperioneal
IC: Intracardiac

a) Comments on methods for the euthanasia of dogs:

i) Restraint

When a dog needs to be restrained for any procedure, including euthanasia, this should always be done with full regard for operator security and animal welfare. Some euthanasia methods must be used in association with sedation or anaesthesia in order to be considered humane.

ii) Special equipment

When special equipment is needed to perform euthanasia (eg. gas chamber) the system should be designed for the purpose and regularly maintained in order to achieve operator security and animal welfare.

iii) The following methods, procedures and practices are unacceptable on animal welfare grounds:

- Chemical methods:
  - § Embutramide + Mebezonium + Tetracaine without sedation or by other than IV injection
  - § Chloral hydrate
  - § Nitrous oxide: may be used with other inhalants to speed the onset of anaesthesia, but alone it does not induce anaesthesia in dogs
  - § Ether
  - § Chloroform
  - § Cyanide
  - § Strychnine
  - § Neuromuscular blocking agents (nicotine, magnesium sulphate, potassium chloride, all curariform agents) : when used alone, respiratory arrest occurs before lost of consciousness, so the dog may perceive pain
  - § Formalin
  - § Household products and solvents.
- Mechanical methods:
  - § Air embolism on conscious animal
  - § Burning
  - § Exsanguination of conscious animal
  - § Decompression: expansion of gas trapped in body cavities may be very painful
  - § Drowning
  - § Hypothermia, rapid freezing
  - § Stunning: stunning is not a euthanasia method, it should always be followed by a method which ensures death.
  - § Kill-trapping
  - § Electrocution of conscious animal.

Because neonatal animals and adults with impaired breathing or low blood pressure are resistant to hypoxia, methods that depend upon achieving a hypoxic state (eg CO_2, CO, N_2, Ar) should not be used. These methods should not be used in animals aged less than 2 months, except to produce loss of consciousness and should be followed by another method to cause death. Cervical dislocation and concussion may be used in very small neonatal dogs and only in cases of emergency. Operators must be well trained in the use of physical techniques to ensure that they are correctly and humanely carried out. The dog must be exsanguinated immediately after concussion or cervical dislocation.

iv) Confirmation of death

For all methods of euthanasia used, death must be confirmed before animals are disposed of or left unattended. If an animal is not dead, another method of euthanasia must be performed.

v) Carcass disposal

Carcasses should be disposed of in a manner that complies with legislation. Attention must be paid to the risk of residues occurring in the carcase. Incineration is generally the safest way of carcass disposal.

Article 6

Monitoring and evaluation of dog population control programmes

Monitoring and evaluation allows for comparison of important indicators against the baselines measured during initial assessment (Article 4). The three main reasons for carrying out monitoring and evaluation are:

1. to help improve performance, by highlighting both problems and successful elements of interventions;

2. for accountability, to demonstrate that the programme is achieving its aims;

3. assuming methods are standardised, to compare the success of strategies used in different locations and situations.

Monitoring is a continuous process that aims to check the programme progress against targets and allows for regular adjustments. Evaluation is a periodic assessment, usually carried out at particular milestones to check the programme is having the desired and stated impact. These procedures involve the measurement of 'indicators' that are chosen because they reflect important components of the programme at different stages. Selection of suitable indicators requires clear planning of what the programme is aiming to achieve, the best selection of indicators will be one that reflects the interest of all relevant stakeholders. Standardised methodology will facilitate comparison of data from subsequent evaluations and performance between different projects. Indicators can be direct measurements of an area targeted to change (e.g. population of free roaming dogs on public property) or indirect measures that reflect change in a targeted area (e.g. number of reported dog bites as a reflection of rabies prevalence).

4. Elements that should generally be monitored and evaluated include:

   a) dog population size, separated by into sub-populations according to ownership and restriction of movement (i.e. roaming unrestricted or restricted by an owner);

   b) dog welfare, in the target population (e.g. body condition score, skin conditions and injuries or lameness) and as a result of the programme (if interventions involve direct handling of dogs, the welfare of the dogs as result of this handling should be monitored);

   c) prevalence of zoonotic diseases, such as rabies, in both the animal and human population;

   d) responsible animal ownership, including measures of attitudes and understanding of responsible ownership and evidence that this is translating into responsible behaviour.

5. There are many sources of information for measuring indicators, including:

   a) feedback from the local community (e.g. through the use of structured questionnaires, focus groups or 'open format' consultation processes);

   b) records and opinions obtained from relevant professionals (e.g. veterinarians, medical doctors, law enforcement agencies, educators);

   c) animal based measurements (e.g. direct observation surveys of population size and welfare status).

The output of activities against budget should be carefully recorded in order to evaluate the effort (or cost) against the outcomes and impact (or benefit) that are reflected in the results of monitoring and evaluation.

Annex I:

An overview of appropriate methodologies for estimating the size of dog populations.

Population estimates are necessary for making realistic plans for dog population management and zoonosis control, and for monitoring the success of such interventions. However, for designing effective management plans, data on population sizes alone are insufficient. Additional information is required, such as degrees of supervision of owned dogs, the origin of ownerless dogs, accessibility, etc.

The term "owned" may be restricted to a dog that is registered with licensing authorities, or it may be expanded to unregistered animals that are somewhat supervised and receive shelter and some form of care in individual households. Owned dogs may be well supervised and restrained at all times, or they may be left without control for various time periods and activities. Dogs without owners that claim responsibility may still be accepted or tolerated in the neighbourhood, and individuals may provide food and protection. Such animals are sometimes called "community owned dogs" or "neighbourhood dogs". For an observer it is frequently impossible to decide if a free roaming dog belongs to someone or not.

The choice of methods for assessing the size of a dog population depends on the ratio of owned versus ownerless dogs, which may not always easy to judge. For populations with a large proportion of owned dogs it may be sufficient to consult dog registration records or to conduct household surveys. These surveys should establish the number of owned dogs and the dog to human ratio in the area. In addition, questions on dog reproduction and demographics, care provided, zoonosis prevention, dog bite incidence, etc. may be asked. Sample questionnaires can be found in the "Guidelines for Dog Population Management" (WHO/WSPA 1990). Standard polling principles must be applied.

If the proportion of ownerless dogs is high or difficult to asses, then one must resort to more experimental approaches. Methods borrowed from wildlife biology can be applied. These methods are described WHO/WSPA's "Guidelines for Dog Population Management" (1990), and in more detail in numerous professional publications and handbooks, such as Bookhout (1994) and Sutherland (2006). Being generally diurnal and tolerant to human proximity, dogs lend themselves to direct observation and the application of mark-recapture techniques. Nevertheless, a number of caveats and limitations have to be taken into account. The methods are relatively labour intensive, they require some understanding of statistics and population biology, and most importantly, they are difficult to apply to very large areas. One must take into account that dog distribution is non-random, that their populations are not static, and that individual dogs are fairly mobile.

Counting of dogs visible in a defined area is the simplest approach to getting information on population size. One has to take into account that the visibility of dogs depends on the physical environment, but also on dog and human activity patterns. The visibility of animals changes with the time of the day and with seasons as a function of food availability, shelter (shade), disturbance, etc. Repeated standardized counting of dogs visible within defined geographical localities (e.g. wards) and specific times will provide indications of population trends. Direct counting is most reliable if it is applied to small and relatively confined dog populations, e.g. in villages, where it might be possible to recognize individual dogs based on their physical appearance.

Annex I:

Methods using mark-recapture procedures are often considered more reliable. However, they also produce trustworthy results only when a number of preconditions are met. Mortality, emigration and recruitment into the population must be minimal during the census period. One may be able to incorporate corrective factors into the calculations.

It is therefore important that the recommended census procedures are applied at times of low dispersal and that one selects study plots of shape and size that minimize the effect of dog movements in and out of the observation area. Census surveys should be completed within a few days to a maximum of two weeks in order to reduce demographic changes. In addition, all individuals in the population must have an equal chance of being counted. This is a highly improbable condition for dogs, whose visibility depends on ownership status and degrees of supervision. It is therefore recommended that the investigator determines what fraction of the total population he/she might cover with an observational method and how much this part overlaps with the owned dog segment that he/she assesses with household surveys.

There are essentially two ways to obtain a population estimate if it is possible, in a defined area and within a few days, to tag a large number of dogs with a visible mark, e.g. a distinctive collar or a paint smudge. The first method requires that the capture (marking) effort remains reasonably constant for the whole length of the study. By plotting the daily number of dogs marked against the accumulated total of marked dogs for each day one can extrapolate the value representing the total number of dogs in the area. More commonly used in wildlife studies are mark recapture methods (Peterson-Jackson, Lincoln indices). Dogs are marked (tagged) and released back into the population. The population is subsequently sampled by direct observation. The number of marked and unmarked dogs is recorded. One multiplies the number of dogs that were initially marked and released by the number of subsequently observed dogs divided by the number of dogs seen as marked during the re-observation to obtain a total population estimate. Examples for the two methods are given in WHO/WSPA's "Guidelines for Dog Population Management" (1990).

Since the dog populations of entire countries, states, provinces or even cities are much too large for complete assessment, it is necessary to apply the methods summarized above to sample areas. These should be selected (using common sense) so that results can be extrapolated to larger areas.

Bookhout TA (ed), 1994: *Research and Management Techniques for Wildlife and Habitats*, 5th ed. The Wildlife Society, Bethesda, Maryland, 740p.

Sutherland WJ (ed), 2006: *Ecological Census Techniques* - A Handbook, 2nd ed. Cambridge University Press, Cambridge, 448 p.

WHO/WSPA, 1990: *Guidelines for Dog Population Management*. WHO/ZOON/90.165. WHO, Geneva, 116 p.

Annex XVI

CHAPTER 8.3.

BLUETONGUE

Community comments

The Community cannot accept the proposed changes.

- The reduction of the waiting period after vaccination from 60 to 30 days for inactivated vaccines cannot be accepted unless there is scientific evidence that is not provided by the TAHSC; a period of 60 days gives the assurance that there have been no infection just after the vaccination that might not have been prevented.

- The wording "were protected in a *quarantine station*" instead of the current "were protected from attack" is far too restrictive (see definition of Quarantine station in Chapter Glossary) and furthermore the wording is not correct because the word "attack" is now missing. The Community proposes the following wording "were protected from attack from Culicoides in an insect proof establishment".

- The need to test vaccinated animals to demonstrate that they have antibodies is too restrictive; indeed, if trade takes place, it is supposed that the Veterinary Authority of the exporting country correctly applies the conditions required, such as vaccination; the proposed new text says that the animals "were vaccinated" AND "demonstrated to have antibodies", it should read "the animals: "were vaccinated" OR "demonstrated to have antibodies".

- If the TAHSC proposes to delete North boundary for vectors and insert "a possible northern range" instead, the Community does not oppose, but then sees no reason why there should be a Southern one; the whole paragraph should be deleted, as there is no certainty about any such distribution limits for the disease and that adds nothing to the chapter.

- In the light of the OIE new concept of "commodity trade", and as for other chapters (such as CBPP, BSE, etc), this chapter should include a list of safe commodities after the first article.

- As BTV are diverse and each one provokes a distinct disease, a country or zone should be able to declare is status according to each specific virus, and for example be free from BTV8 while having BVT1; this should be reflected in the chapter.

Article 8.3.1.

General provisions

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

The global BTV distribution is currently ~~between the latitudes of approximately 53°N and~~ north of 34S with a possible northern range to the arctic (66.33°N) ~~but is known to be expanding in the northern hemisphere~~.

Community comment

If the TAHSC proposes to delete North boundary for vectors and insert "a possible

northern range" instead, the Community does not oppose, but then sees no reason why there should be a Southern one; the whole paragraph should be deleted, as there is no certainty about any such distribution limits for the disease and that adds nothing to the chapter.

In the absence of clinical *disease* in a country or *zone* within this part of the world, its BTV status should be determined by an ongoing *surveillance* programme (in accordance with Articles 8.3.16. to 8.3.21.). The programme may need to be adapted to target parts of the country or *zone* at a higher risk due to historical, geographical and climatic factors, ruminant population data and *Culicoides* ecology, or proximity to enzootic or incursional zones as described in Articles 8.3.16. to 8.3.21.

All countries or *zones* adjacent to a country or *zone* not having free status should be subjected to similar *surveillance*. The *surveillance* should be carried out over a distance of at least 100 kilometres from the border with that country or *zone*, but a lesser distance could be acceptable if there are relevant ecological or geographical features likely to interrupt the transmission of BTV or a bluetongue *surveillance* programme (in accordance with Articles 8.3.16. to 8.3.21.) in the country or *zone* not having free status supports a lesser distance.

Community comment

In the second sentence of the paragraph above, the words "demonstrable vaccinal protection," should be added after "if there are relevant". Indeed, such a situation would be considered as a barrier to infection progress and thus enable to limit the width of the surveillance zone.

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

Article 8.3.2.

BTV free country or zone

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

   a) the country or *zone* lies wholly ~~north of 53°N or~~ south of 34°S, and is not adjacent to a country or *zone* not having a free status; or

Community comment

If the TAHSC proposes to delete North boundary, the Community does not oppose, but then sees no reason why there should be a Southern one; the whole point should be deleted, as there is no certainty about any distribution limits for the disease.

   b) a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21. has demonstrated no evidence of BTV in the country or *zone* during the past 2 years; or

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

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

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

a) the animals have been vaccinated in accordance with the *Terrestrial Manual* at least ~~60~~ 30 days prior to dispatch with a vaccine which covers all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21., and ~~that~~ the animals are identified in the accompanying certification as having been vaccinated; where live attenuated vaccine has been used, vaccination has been carried out at least 60 days prior to shipment; or

Community comment

The reduction of the waiting period after vaccination from 60 to 30 days for inactivated vaccines cannot be accepted unless there is scientific evidence that is not provided by the TAHSC; a period of 60 days gives the assurance that there have been no infection just after the vaccination that might not have been prevented.

b) the animals are not vaccinated, and a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21. has been in place in the source population for a period of 60 days immediately prior to dispatch, and no evidence of BTV transmission has been detected.

4. A BTV free country or zone adjacent to an infected country or *infected zone* should include a *zone* as described in Article 8.3.1. in which *surveillance* is conducted in accordance with Articles 8.3.16. to 8.3.21. Animals within this *zone* must be subjected to continuing *surveillance*. The boundaries of this *zone* must be clearly defined, and must take account of geographical and epidemiological factors that are relevant to BTV transmission.

Article 8.3.3.

BTV seasonally free zone

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

For the application of Articles 8.3.6., 8.3.9. and 8.3.13., the seasonally free period is taken to commence the day following the last evidence of BTV transmission (as demonstrated by the *surveillance* programme), and of the cessation of activity of adult *Culicoides* likely to be competent BTV vectors.

For the application of Articles 8.3.6., 8.3.9. and 8.3.13., the seasonally free period is taken to conclude either:

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

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

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

Article 8.3.4.

BTV infected country or zone

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

Article 8.3.5.

Recommendations for importation from BTV free countries or zones

for ruminants and other BTV susceptible herbivores

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

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

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

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

4. the animals:

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

   b) were vaccinated in accordance with the *Terrestrial Manual* ~~60~~ at least 30 days before the introduction into the free country or zone against all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme as described in Articles 8.3.16. to 8.3.21.; where live attenuated vaccine has been used, vaccination has been carried out at least 60 days prior to shipment;

Community comment

The reduction of the waiting period after vaccination from 60 to 30 days for inactivated vaccines cannot be accepted unless there is scientific evidence that is not provided by the TAHSC; a period of 60 days gives the assurance that there have been no infection just after the vaccination that might not have been prevented.

   c) were identified as having been vaccinated; and

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

AND

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

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

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

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

Article 8.3.6.

Recommendations for importation from BTV seasonally free zones

for ruminants and other BTV susceptible herbivores

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

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

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

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

4. were kept during the seasonally free period in a BTV seasonally free zone, and were vaccinated in accordance with the *Terrestrial Manual* ~~60~~ at least 30 days before the introduction into the free country or zone against all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21. and were identified as having been vaccinated and remained in the BTV free country or zone until shipment; where live attenuated vaccine has been used, vaccination has been carried out at least 60 days prior to shipment;

Community comment

The reduction of the waiting period after vaccination from 60 to 30 days for inactivated vaccines cannot be accepted unless there is scientific evidence that is not provided by the TAHSC; a period of 60 days gives the assurance that there have been no infection just after the vaccination that might not have been prevented.

AND

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

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

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

   c) were vaccinated in accordance with point 4 above.

Article 8.3.7.

Recommendations for importation from BTV infected countries or zones

for ruminants and other BTV susceptible herbivores

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1. were protected in a *quarantine station* ~~from attack~~ from *Culicoides* likely to be competent BTV vectors ~~since birth or~~ for at least 60 days prior to shipment and during transportation to the *place of shipment*; or

Community comment

The wording "were protected in a *quarantine station*" instead of the current "were protected from attack" is far too restrictive. The Community proposes the following wording for point 1 to 3: "were protected from attack from Culicoides in an insect proof *establishment*".

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

Community comment

The wording "were protected in a *quarantine station*" instead of the current "were protected from attack" is far too restrictive. The Community proposes the following wording for point 1 to 3: "were protected from attack from Culicoides in an insect proof *establishment*". The last words of point 2, "*quarantine station*; or" should then be replaced by "insect proof *establishment*; or".

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

Community comment

The wording "were protected in a *quarantine station*" instead of the current "were protected from attack" is far too restrictive. The Community proposes the following wording for point 1 to 3: "were protected from attack from Culicoides in an insect proof *establishment*". The last words of point 3, "*quarantine station*; or" should then be replaced by "insect proof *establishment*; or".

4. were vaccinated in accordance with the *Terrestrial Manual* ~~60~~ at least 30 days before shipment, and demonstrated to have antibodies against all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21., and were identified in the accompanying certification as having been vaccinated; where live attenuated vaccine has been used, vaccination has been carried out at least 60 days prior to shipment; or

Community comment

The reduction of the waiting period after vaccination from 60 to 30 days for inactivated vaccines cannot be accepted unless there is scientific evidence that is not provided by the TAHSC; a period of 60 days gives the assurance that there have been no infection just after the vaccination that might not have been prevented.

5. are not vaccinated, a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21. has been in place in the source population for a period of 60 days immediately prior to shipment, and no evidence of BTV transmission has been detected and~~;~~

Community comment

This point 5 should be deleted;

The situation described is already taken into account in a seasonally free zone. There should not be any "60 days temporary free zones".

~~AND~~

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

~~7. were vaccinated in accordance with the *Terrestrial Manual* 60 days before shipment or had antibodies against all serotypes whose presence in the zones of transit has been demonstrated through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21.~~

Article 8.3.8.

Recommendations for importation from BTV free countries or zones

for semen of ruminants and other BTV susceptible herbivores

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:

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

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

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

2. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5.

Article 8.3.9.

Recommendations for importation from BTV seasonally free zones

for semen of ruminants and other BTV susceptible herbivores

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:

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

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

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

2. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5.

Article 8.3.10.

Recommendations for importation from BTV infected countries or zones

for semen of ruminants and other BTV susceptible herbivores

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:

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

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

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

2. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5.

Article 8.3.11.

Recommendations for the importation of *in vivo* derived bovine embryos/ oocytes

Regardless of the bluetongue status of the *exporting country*, *Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the embryos/oocytes were collected, processed and stored in conformity with the provisions of Chapter 4.7.

Article 8.3.12.

Recommendations for importation from BTV free countries or zones

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

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females:

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

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

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

2. the embryos were collected, processed and stored in conformity with the provisions of Chapter 4.7.

Article 8.3.13.

Recommendations for importation from BTV seasonally free zones

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

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females:

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

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

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

2. the embryos/oocytes were collected, processed and stored in conformity with the provisions of Chapter 4.7., Chapter 4.8. or Chapter 4.9., as relevant.

Article 8.3.14.

Recommendations for importation from BTV infected countries or zones

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

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females:

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

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

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

2. the embryos/oocytes were collected, processed and stored in conformity with the provisions of Chapter 4.7., Chapter 4.8. or Chapter 4.9., as relevant.

Article 8.3.15.

Protecting animals from *Culicoides* attack

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

Potential *risk management* strategies include:

1. treating animals with chemical repellents prior to and during transportation;

2. *loading*, transporting and *unloading* animals at times of low vector activity (i.e. bright sunshine, low temperature);

3. ensuring *vehicles* do not stop en route during dawn or dusk, or overnight, unless the animals are held behind insect proof netting;

4. darkening the interior of the *vehicle*, for example by covering the roof and/or sides of *vehicles* with shadecloth;

5. *surveillance* for vectors at common stopping and offloading points to gain information on seasonal variations;

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

Article 8.3.16.

Surveillance: introduction

Articles 8.3.16. to 8.3.21. define the principles and provide a guide on the *surveillance* for BT complementary to Chapter 1.4., applicable to Members seeking to determine their BT status. This may be for the entire country or *zone*. Guidance for Members seeking free status following an *outbreak* and for the maintenance of BT status is also provided.

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 recommendations for all situations. It is incumbent upon Members 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 to justify their infection status at an acceptable level of confidence.

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

Article 8.3.17.

Surveillance: 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 Articles 8.3.1. to 8.3.15. of this ~~*Terrestrial Code*~~ Chapter.

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

Article 8.3.18.

Surveillance: general conditions and methods

1. A *surveillance* system in accordance with Chapter 1.4. 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 *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 8.3.10. and 8.3.14.

Article 8.3.19.

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 Member should justify the *surveillance* strategy chosen as being adequate to detect the presence of BTV infection in accordance with Chapter 1.4. 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 Member must justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. 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, inputs from professionals competent and experienced in this field.

Annex XVI (contd)

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 recommendations and the requirements for a statistically valid survey for the presence of BTV infection should not be compromised.

Community comments

In the first sentence of the above paragraph, the Community suggests the following wording as the milk test or indeed other tissue test should be catered for: "It may be possible to use sera or other tissues collected for other survey purposes for BTV *surveillance*".

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*~~ *protection zone* within a free country or *zone* should separate it from a potentially infected country or *infected 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 *infected 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 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 *infective period*. 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 8.3.20.

Documentation of BTV infection free status

1. Members declaring freedom from BTV infection for the country or zone: additional surveillance procedures

   In addition to the general conditions described in the above-mentioned articles, 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 Chapter, 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 8.3.21.

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.

Fig. 1. Application of laboratory tests in serological surveillance

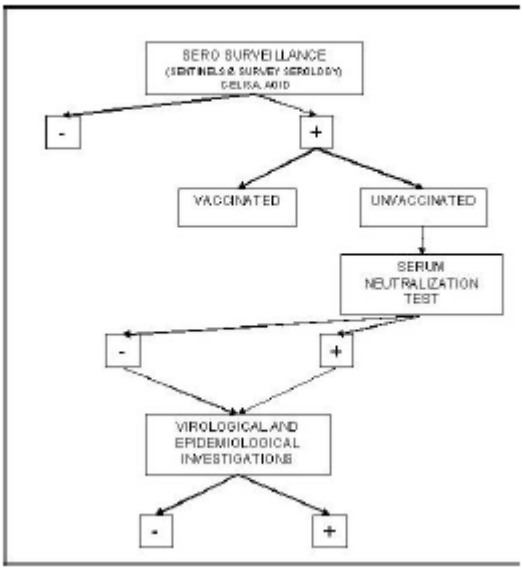
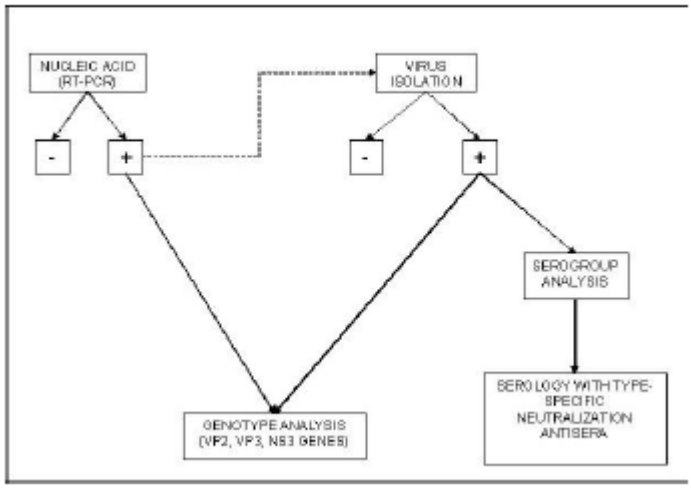


Fig. 2. Application of laboratory tests in virological surveillance



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Annex XVII

CHAPTER 8.5.

FOOT AND MOUTH DISEASE

Community comments

The Community can support the proposed changes. However, its former comments on articles 8.5.7 and 8.5.21 remain valid. Moreover, for the sake of clarity, the Articles 8.5.2 to 8.5.5 should be re-arranged so so as to have all the "FMD free without vaccination" together and then the same for the "FMD free with vaccination". The Community does not believe that compartmentalisation is a priority at this stage for FMD until practical experience has been gained in its application for avian influenza.

Article 8.5.1.

Introduction

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

For the purposes of this Chapter, ruminants include animals of the family of Camelidae (except *Camelus dromedarius*).

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 8.5.2.

FMD free country where vaccination is not practised

Susceptible animals in the FMD free country where vaccination is not practised ~~can~~ should be separated from neighbouring infected countries by ~~a *buffer zone*, or physical or geographical barriers, and~~ the application of animal health measures that effectively prevent the entry of the virus, taking into

consideration physical or geographical barriers. These measures may include a *protection zone* ~~should be implemented~~.

To qualify for inclusion in the existing list of FMD free countries where vaccination is not practised, a Member 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 Articles 8.5.40. to 8.5.46. is in operation;

   b) regulatory measures for the early detection, prevention and control of FMD have been implemented.

The Member 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 3b) above be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

Article 8.5.3.

FMD free country where vaccination is practised

Susceptible animals in the FMD free country where vaccination is practised ~~can~~ should be separated from neighbouring infected countries by ~~a *buffer zone*, or physical or geographical barriers, and~~ the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a *protection zone* ~~should be implemented~~.

To qualify for inclusion in the list of FMD free countries where vaccination is practised, a Member 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 Articles 8.5.40. to 8.5.46. 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 Member 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 to the OIE according to the requirements in Chapter 1.1.

If a Member that meets the requirements of a FMD free country where vaccination is practised wishes to change its status to FMD free country where vaccination is not practised, the status of this country remains unchanged for a period of at least 12 months after vaccination has ceased. Evidence should also be provided showing that FMDV infection has not occurred during that period.

Article 8.5.4.

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 4.3. should be followed. Susceptible animals in the FMD free zone ~~can~~ should be separated from the rest of the country and from neighbouring countries ~~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 *animal health status*~~, and~~ by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a *protection zone* ~~should be implemented~~.

A Member in which an FMD free zone where vaccination is not practised is to be established should:

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

2. send a declaration to the OIE stating that it wishes to establish an FMD free zone where vaccination is not practised, and that within the proposed FMD free zone:

   a) there has been no *outbreak* of FMD during the past 12 months;

   b) no evidence of FMDV infection has been found during the past 12 months;

   c) no vaccination against FMD has been carried out during the past 12 months;

   d) no vaccinated animal has been introduced into the zone since the cessation of vaccination, except in accordance with Article 8.5.9.;

   e) documented evidence shows that *surveillance* in accordance with Articles 8.5.40. to 8.5.46. 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*~~ *protection 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 8.5.9. 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 practised 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 and changes in the epidemiological situation or other significant events including those relevant to points 3a) and 3b) should be reported to the OIE according to the requirements in Chapter 1.1.

Article 8.5.5.

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 4.3. should be followed. Susceptible animals in the FMD free zone where vaccination is practised ~~can~~ should be separated from neighbouring countries or *zones* if they are infected 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 *animal health status*, and~~ the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a *protection zone* ~~should be implemented~~.

A Member 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 Articles 8.5.40. to 8.5.46. 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*~~ *protection 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 8.5.9. 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 and changes in the epidemiological situation or other significant events including those relevant to points 4a) and 4b) should be reported to the OIE according to the requirements in Chapter 1.1.

If a Member that has a *zone* which meets the requirements of a 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 period of at least 12 months after vaccination has ceased. Evidence should also be provided showing that FMDV infection has not occurred in the said *zone* during that period.

Article 8.5.6.

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 8.5.7.

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, including within a *protection 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*.

Community comments

The Community reiterates its former comment that the above paragraph should be in line with article 4.4.3 point é dealing with containment zone, and read "In the event of a limited number of *outbreaks*".

For this to be achieved, the *Veterinary Authority* should provide documented evidence that:

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

   a) immediately on suspicion, a rapid response including notification has been made;

   b) standstill of animal movements has been imposed, 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 8.5.1. after the stamping-out of the last detected *case* is completed;

2. a *stamping-out policy* 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 Articles 8.5.40. to 8.5.46. 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;

6. *containment zone* should be large enough to contain the *disease* and ~~comprise~~ include ~~both~~ a ~~restricted/~~*protection zone* ~~and larger *surveillance zone*~~.

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 8.5.8., 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 8.5.8.

Article 8.5.8.

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 Articles 8.5.40. to 8.5.46.; 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 Articles 8.5.40. to 8.5.46.; 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 Articles 8.5.40. to 8.5.46., provided that a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of *infection* in the remaining vaccinated population.

   Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.5.2. or 8.5.4. 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 Articles 8.5.40. to 8.5.46. 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 Articles 8.5.40. to 8.5.46. 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 8.5.9.

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*~~ *protection zone* directly to *slaughter*.

In the absence of an *abattoir* in the ~~*buffer*~~ *protection 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 Articles 8.5.32. to 8.5.39.

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 8.5.12.

Annex XVII (contd)

Article 8.5.10.

Recommendations for importation from FMD free countries where vaccination is not practised or FMD free zones where vaccination is not practised

for FMD susceptible animals

Veterinary Authorities should require 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 8.5.11.

Recommendations for importation from FMD free countries where vaccination is practised or from FMD free zones where vaccination is practised

for domestic ruminants and pigs

Veterinary Authorities should require 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 8.5.12.

Recommendations for importation from FMD infected countries or zones

for domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of FMD on the day of shipment;
2. were kept in the *establishment* of origin since birth, or
    a) for the past 30 days, if a *stamping-out policy* is in force in the *exporting country*, or

b) for the past 3 months, if a *stamping-out policy* is not in force in the *exporting country*, and that FMD has not occurred within a ten-kilometre radius of the *establishment* of origin for the relevant period as defined in points a) and b) above; and

3. were isolated in an *establishment* for the 30 days prior to shipment, and all animals in isolation were subjected to diagnostic tests (probang and serology) for evidence of FMDV *infection* with negative results at the end of that period, and that FMD did not occur within a ten-kilometre radius of the *establishment* during that period; or

4. were kept in a *quarantine station* for the 30 days prior to shipment, all animals in quarantine were subjected to diagnostic tests (probang and serology) for evidence of FMDV *infection* with negative results at the end of that period, and that FMD did not occur within a 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 8.5.13.

Recommendations for importation from FMD free countries where vaccination is not practised or FMD free zones where vaccination is not practised

for fresh semen of domestic ruminants and pigs

Veterinary Authorities should require 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 Chapter 4.5. or Chapter 4.6., as relevant.

Article 8.5.14.

Recommendations for importation from FMD free countries where vaccination is not practised or FMD free zones where vaccination is not practised

for frozen semen of domestic ruminants and pigs

Veterinary Authorities should require 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 Chapter 4.5. or Chapter 4.6., as relevant.

Article 8.5.15.

Recommendations for importation from FMD free countries where vaccination is practised or from FMD free zones where vaccination is practised

for semen of domestic ruminants and pigs

Veterinary Authorities should require 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 Chapter 4.5. or Chapter 4.6., 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 8.5.16.

Recommendations for importation from FMD infected countries or zones

for semen of domestic ruminants and pigs

Veterinary Authorities should require 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 Chapter 4.5. or Chapter 4.6., 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 8.5.17.

Recommendations for the importation of *in vivo* derived embryos of cattle

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 Chapter 4.7.or Chapter 4.9.

Article 8.5.18.

Recommendations for importation from FMD free countries where vaccination is not practised or FMD free zones where vaccination is not practised

for *in vitro* produced embryos of cattle

Veterinary Authorities should require 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 8.5.13., 8.5.14., 8.5.15. or 8.5.16., as relevant;

3. the oocytes were collected, and the embryos were processed and stored in conformity with the provisions of Chapter 4.8. or Chapter 4.9., as relevant.

Annex XVII (contd)

Article 8.5.19.

Recommendations for importation from FMD free countries where vaccination is practised or from FMD free zones where vaccination is practised

for *in vitro* produced embryos of cattle

Veterinary Authorities should require 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 8.5.13., 8.5.14., 8.5.15. or 8.5.16., as relevant;
4. the oocytes were collected, and the embryos were processed and stored in conformity with the provisions of Chapter 4.8. or Chapter 4.9., as relevant.

Article 8.5.20.

Recommendations for importation from FMD free countries where vaccination is not practised or FMD free zones where vaccination is not practised

for *fresh meat* of FMD susceptible animals

Veterinary Authorities should require 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 8.5.10., Article 8.5.11. or Article 8.5.12.;
2. have been slaughtered in an approved *abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results.

Article 8.5.21.

Recommendations for importation from FMD free countries where vaccination is practised or from FMD free zones where vaccination is practised

for *fresh meat* of cattle and buffaloes (*Bubalus bubalis*) (excluding feet, head and viscera)

Veterinary Authorities should require 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 8.5.10., Article 8.5.11. or Article 8.5.12.;

2. have been slaughtered in an approved *abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results.

Community comment

In the light of the principle of "commodity based trade", 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 an 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 8.5.22.

Recommendations for importation from FMD free countries where vaccination is practised or from FMD free zones where vaccination is practised

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

Veterinary Authorities should require 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 8.5.10., Article 8.5.11. or Article 8.5.12.;

2. have been slaughtered in an approved *abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results.

Community comment

In the light of the principle of "commodity based trade", 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)."

The Community would like to see ~~is interested in~~ any scientific information about the result of deboning and maturation in pig meat and meat from ruminant other than cattle and buffaloes on potential survival of FMD virus.

Article 8.5.23.

Recommendations for importation from FMD infected countries or zones, where an official control programme exists, involving compulsory systematic vaccination of cattle

for *fresh meat* of cattle and buffaloes (*Bubalus bubalis*) (excluding feet, head and viscera)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of meat:

1. comes from animals which:

   a) have remained in the *exporting country* for at least 3 months prior to *slaughter*;

   b) have remained, during this period, in a part of the country where cattle are regularly vaccinated against FMD and where official controls are in operation;

   c) have been vaccinated at least twice with the last vaccination not more than 12 months and not less than one month prior to *slaughter*;

   d) were kept for the past 30 days in an *establishment*, and that FMD has not occurred within a ten-kilometre radius of the *establishment* during that period;

   e) have been transported, in a *vehicle* which was cleansed and disinfected before the cattle were loaded, directly from the *establishment* of origin to the approved *abattoir* without coming into contact with other animals which do not fulfil the required conditions for export;

   f) have been slaughtered in an approved *abattoir*:

      i) which is officially designated for export;

      ii) in which no FMD has been detected during the period between the last *disinfection* carried out before *slaughter* and the shipment for export has been dispatched;

   g) have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results within 24 hours before and after *slaughter*;

2. comes from deboned carcasses:

   a) from which the major lymphatic nodes have been removed;

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

Article 8.5.24.

Recommendations for importation from FMD infected countries or zones

for *meat products* of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the entire consignment of *meat* comes from animals which have been slaughtered in an approved *abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results;

2. the *meat* has been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Article 8.5.32.;

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

Article 8.5.25.

Recommendations for importation from FMD free countries or zones (where vaccination either is or is not practised)

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

Veterinary Authorities should require 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 8.5.10., Article 8.5.11. or Article 8.5.12.

Article 8.5.26.

Recommendations for importation from FMD infected countries or zones where an official control programme exists

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

Veterinary Authorities should require 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 8.5.36. and in Article 8.5.37.;

2. the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMD virus.

Article 8.5.27.

Recommendations for importation from FMD infected countries

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

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

Article 8.5.28.

Recommendations for importation from FMD infected countries

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

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. these products have been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Articles 8.5.33., 8.5.34. and 8.5.35.;

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 8.5.29.

Recommendations for importation from FMD infected countries or zones

for straw and forage

Veterinary Authorities should require 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 8.5.30.

Recommendations for importation from FMD free countries or zones (where vaccination either is or is not practised)

for skins and trophies derived from FMD susceptible wild animals

Veterinary Authorities should require 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 8.5.31.

Recommendations for importation from FMD infected countries or zones

for skins and trophies derived from FMD susceptible wild animals

Veterinary Authorities should require 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 8.5.38.

Article 8.5.32.

Procedures for the inactivation of the FMD virus in 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 8.5.33.

Procedures for the inactivation of the FMD virus in 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 hydroxide (soda) or potassium 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 8.5.34.

Procedures for the inactivation of the FMD virus in 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 8.5.35.

Procedures for the inactivation of the FMD virus in 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 8.5.36.

Procedures for the inactivation of the FMD virus in 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 8.5.37.

Procedures for the inactivation of the FMD virus in 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 8.5.38.

Procedures for the inactivation of the FMD virus in skins and trophies from wild animals susceptible to the 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 8.5.39.

Procedures for the inactivation of the FMD virus in 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.

Article 8.5.40.

Surveillance: introduction

Articles 8.5.40. to 8.5.46. define the principles and provide a guide for the *surveillance* of FMD in accordance with Chapter 1.4. applicable to Members seeking ~~recognition from the OIE for~~ establishment of 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 is provided for Members seeking reestablishment of freedom from FMD for the ~~whole~~ entire country or for a *zone* ~~within the country,~~ either with or without vaccination, following an *outbreak* ~~, as well as recommendations~~ and for the maintenance of FMD status ~~are provided~~. 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 recommendations 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 Member 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 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 Chapter, virus circulation means transmission of FMDV as demonstrated by clinical signs, serological evidence or virus isolation.

Annex XVII (contd)

Article 8.5.41.

Surveillance: general conditions and methods

1. A *surveillance* system in accordance with Chapter 1.4. 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 a *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 *infected 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 8.5.42.

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 Member should justify the *surveillance* strategy chosen as adequate to detect the presence of FMDV *infection*/circulation in accordance with Chapter 1.4. 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 Member must justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. 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 Chapter 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 8.5.43.

Members applying for freedom from FMD for the whole country or a zone where vaccination is not practised: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, 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 Chapter, 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 8.5.44.

Members applying for freedom from FMD for the whole country or a zone where vaccination is practised: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, 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 Chapter. 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 8.5.45.

Members re-applying for freedom from FMD for the whole country or a zone where vaccination is either practised or not practised, following an outbreak: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, 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 8.5.8.

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 Chapter.

Article 8.5.46.

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. 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

   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. 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

   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.

Community comment

In the case of positive serology, all animals should be kept on the holding pending sampling results not just the animals being re-sampled. Thus, in the first sentence above, the words "as well as all the animals in direct or indirect contact" should be added after the words "The animals sampled".

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.

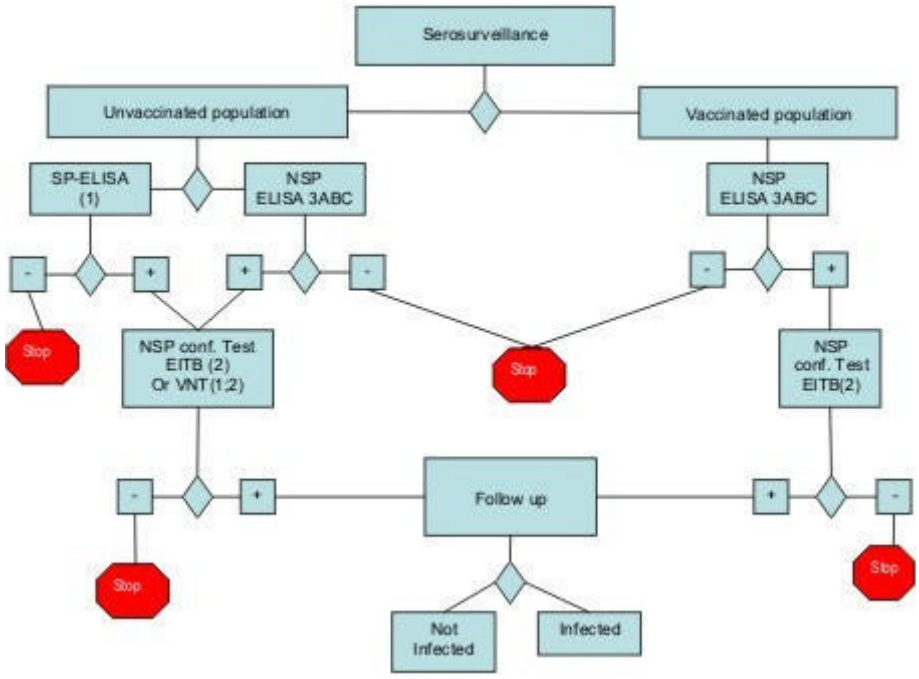
d) Sentinel animals can also be used. These can be young, unvaccinated animals or animals in which maternally conferred immunity has lapsed and belonging to the same species resident within the positive initial sampling units. They should be serologically negative if virus is not circulating. If other 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.

*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 XVIII

CHAPTER 8.11.

RABIES

Community comments

The Community can accept the proposed change but is concerned about Lyssavirus genotype one, responsible for around thirty thousand human death each year worldwideThe Commmunity supports the review of this Chapter by a working group and would like to participate.

Article 8.11.1.

General provisions

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 8.11.2.

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 B~~bat Lyssavirus;

5. no imported *case* in carnivores has been confirmed outside a *quarantine station* for the past 6 months.

Article 8.11.3.

Recommendations for importation from rabies free countries

for domestic mammals, and wild mammals reared under confined conditions

Veterinary Authorities should require 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 8.11.5., 8.11.6. or 8.11.7.

Annex XVIII (contd)

Article 8.11.4.

Recommendations for importation from rabies free countries

for wild mammals not reared under confined conditions

Veterinary Authorities should require 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 8.11.5.

Recommendations for importation from countries considered infected with rabies

for dogs and cats

Veterinary Authorities should require 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

3. 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

4. ere subjected not less than 3 months and not more than 24 months prior to shipment to an antibody test as prescribed in the *Terrestrial Manual* with a positive result equivalent to at least 0.5 IU/ml;

OR

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

Article 8.11.6.

Recommendations for importation from countries considered infected with rabies

for domestic ruminants, equines and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

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

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

Article 8.11.7.

Recommendations for importation from countries considered infected with rabies

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

Veterinary Authorities should require 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 8.11.8.

Recommendations for importation from countries considered infected with rabies

for wild mammals not belonging to the orders of primates or carnivores and not reared under confined conditions

Veterinary Authorities should require 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.

Annex XVIII (contd)

Article 8.11.9.

Recommendations for importation from countries considered infected with rabies

for frozen semen of dogs

Veterinary Authorities should require 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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1 *[Note: For non-human primates, reference should be made to Chapter 6.9.]*

Annex XIX

CHAPTER 8.13.

RINDERPEST

Community comments

The Community can support the proposed changes.

Article 8.13.1.

General provisions

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 8.13.2.

Rinderpest free country

To qualify for inclusion in the existing list of RP free countries, a Member 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 Articles 8.13.20. to 8.13.27. 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 Member 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 to the OIE according to the requirements in Chapter 1.1.

Article 8.13.3.

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 Articles 8.13.20. to 8.13.27.; 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 Articles 8.13.20. to 8.13.27.; 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 Articles 8.13.20. to 8.13.27.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply but Article 8.13.2. applies.

Article 8.13.4.

Infected country

When the requirements for acceptance as a RP free country are not fulfilled, a country shall be considered as RP infected.

Article 8.13.5.

Recommendations for importation from RP free countries

for RP susceptible animals

Veterinary Authorities should require 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 8.13.6.

Recommendations for importation from RP infected countries

for RP susceptible animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. RP is the subject of a national *surveillance* programme according to Articles 8.13.20. to 8.13.27.;

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 8.13.7.

Recommendations for importation from RP free countries

for semen of RP susceptible animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

Annex XIX (contd)

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 Chapter 4.5.

Article 8.13.8.

Recommendations for importation from RP infected countries

for semen of RP susceptible animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. RP is the subject of a national *surveillance* programme according to Articles 8.13.20. to 8.13.27.;

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 Chapter 4.5.

Article 8.13.9.

Recommendations for importation from RP free countries

for *in vivo* derived embryos of RP susceptible animals

Veterinary Authorities should require 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 Chapter 4.7.

Article 8.13.10.

Recommendations for importation from RP infected countries

for *in vivo* derived embryos of RP susceptible animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. RP is the subject of a national *surveillance* programme according to Articles 8.13.20. to 8.13.27.;

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 Chapter 4.7.

Article 8.13.11.

Recommendations for importation from RP free countries

for *fresh meat* or *meat products* of susceptible animals

Veterinary Authorities should require 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 8.13.12.

Recommendations for importation from RP infected countries

for *fresh meat* (excluding offal) of susceptible animals

Veterinary Authorities should require 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 Articles 8.13.20. to 8.13.27.;

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 *abattoir* and the date on which the shipment has been dispatched.

Article 8.13.13.

Recommendations for importation from RP infected countries

for *meat products* of susceptible animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. only *fresh meat* complying with the provisions of Article 8.13.12. 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 8.5.32.;

3. the necessary precautions were taken after processing to avoid contact of the *meat products* with any possible source of RPV.

Article 8.13.14.

Recommendations for importation from RP free countries

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

Veterinary Authorities should require 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 8.13.15.

Recommendations for importation from RP infected countries

for *milk* and cream

Veterinary Authorities should require 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 Articles 8.5.36. and 8.5.37.;

2. the necessary precautions were taken after processing to avoid contact of the products with any potential source of RPV.

Article 8.13.16.

Recommendations for importation from RP infected countries

for *milk products*

Veterinary Authorities should require 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 8.13.17.

Recommendations for importation from RP infected countries

for blood and meat-meals (from susceptible animals)

Veterinary Authorities should require 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 8.13.18.

Recommendations for importation from RP infected countries

for wool, hair, bristles, raw hides and skins (from susceptible animals)

Veterinary Authorities should require 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 Articles 8.5.33., 8.5.34. and 8.5.35.;

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 8.13.19.

Recommendations for importation from RP infected countries

for hooves, claws, bones and horns, hunting trophies and preparations destined for museums (from susceptible animals)

Veterinary Authorities should require 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.

Article 8.13.20.

Surveillance: introduction

~~In order to receive OIE recognition of rinderpest freedom, a country's national authority must present for consideration a dossier of information relating to its livestock production systems, rinderpest vaccination and eradication history and the functioning of its *Veterinary Services*. The dossier must contain convincing evidence derived from an animal disease *surveillance* system that sufficient evidence has accrued to demonstrate that the presence of rinderpest virus would have been disclosed were it to be present. Recommendations on the structure and the functioning of *Veterinary Services* and diagnostic support services are provided in Chapters 3.1. and 3.2. of the *Terrestrial Code*. A Member must also be in compliance with its OIE reporting obligations (Chapter 1.1. of the *Terrestrial Code*).~~

Articles 8.13.20. to 8.13.27. define the principles and provides a guide for the surveillance of rinderpest (RP) in accordance with Chapter 1.4. applicable to Members seeking establishment of freedom from RP. Guidance is provided for Members seeking reestablishment of freedom from RP, following an *outbreak* and for the maintenance of RP free status.

Surveillance strategies employed for demonstrating freedom from RP at an acceptable level of confidence will need to be adapted to the local situation. *Outbreaks* of rinderpest in cattle may be graded as per-acute, acute or sub-acute. Differing clinical presentations reflect variations in levels of innate host resistance (*Bos indicus* breeds being more resistant than *Bos taurus*), and variations in the virulence of the attacking strain. Experience has shown that syndromic surveillance strategies i.e. surveillance based on a predefined set of clinical signs (e.g. searching for "stomatitis-enteritis syndrome") are useful to increase the sensitivity of the system. It is generally accepted that unvaccinated populations of cattle are likely to promote the emergence of virulent strains and associated epidemics while partially vaccinated populations favour the emergence of mild strains associated with endemic situations. In the case of per-acute cases the presenting sign may be sudden death. In the case of sub-acute (mild) cases, clinical signs are irregularly displayed and difficult to detect.

In certain areas there are some key wildlife populations, especially African buffaloes, which act as sentinels for rinderpest infection. These subpopulations should be included in the design of the surveillance strategy.

Surveillance for RP should be in the form of a continuing programme designed to establish that the whole country is free from RP virus (RPV) infection.

Article 8.13.21.

Surveillance: ~~definitions~~ general conditions and methods

~~1. Rinderpest~~

~~For the purpose of this Chapter, rinderpest is defined as an *infection* of large ruminants (cattle, buffaloes, yaks, etc.), small ruminants, pigs and various wildlife species within the order Artiodactyla, caused by rinderpest virus. In small ruminants and various species of wildlife, particularly antelopes, *infection* generally passes without the development of frank clinical signs. Characteristic clinical signs and pathological lesions are described in Chapter 2.1.15. of the *Terrestrial Manual*.~~

~~*Outbreaks* of rinderpest in cattle may be graded as per-acute, acute or sub-acute. Differing clinical presentations reflect variations in levels of innate host resistance (*Bos indicus* breeds being more resistant than *Bos taurus*), and variations in the virulence of the attacking strain. It is generally accepted that unvaccinated populations of cattle are likely to promote the emergence of virulent strains and associated epidemics while partially vaccinated populations favour the emergence of mild strains associated with endemic situations. In the case of per-acute cases the presenting sign may be sudden death. In the case of sub-acute (mild) cases, clinical signs are irregularly displayed and difficult to detect.~~

~~Freedom from rinderpest means freedom from rinderpest virus infection.~~

1. A surveillance system in accordance with Chapter 1.4. 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 RP to a laboratory for RP diagnoses as described in the *Terrestrial Manual*.

~~2. Rinderpest vaccines~~

~~For the purpose of this Chapter and the *Terrestrial Code*, OIE-recognised rinderpest vaccines currently in use, or likely to become so in the forseeable future, are considered to be commercial modified live vaccines produced from attenuated rinderpest virus (referred to as 'rinderpest vaccine') produced in accordance with Chapter 2.1.15. of the *Terrestrial Manual*.~~

2. The RP 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 RP. 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 significant epidemiological events consistent with "stomatitis-enteritis syndrome" should be investigated immediately. Where suspicion cannot be resolved by epidemiological and clinical investigation, samples should be taken and submitted to a *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 RP 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~~ RP infected country.

An effective surveillance system will periodically identify suspicious cases compatible with the "stomatitis-enteritis syndrome" that require follow-up and investigation to confirm or exclude that the cause of the condition is RPV. 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 RPV infection should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of laboratory testing and the control measures to which the animals concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Annex XIX (contd)

Article 8.13.22.

Surveillance ~~activities~~ strategies

~~General recommendations on animal disease *surveillance* are outlined in Chapter 1.4. of the *Terrestrial Code*.~~

~~Rinderpest must be a *notifiable disease* i.e. notification of *outbreaks* of rinderpest as soon as detected or suspected must be brought to the attention of the *Veterinary Authority*.~~

~~The precise *surveillance* information required for establishing freedom will differ from country to country depending on factors such as the former rinderpest status of the country, the regional rinderpest situation and accreditation status, the time elapsing since the last occurrence of rinderpest, livestock husbandry systems (e.g. extensive pastoralism, nomadism and transhumance versus sedentary agropastoralism) and trading patterns.~~

~~Evidence of efficiency of the *surveillance* system can be provided by the use of performance indicators.~~

~~*Surveillance* results presented will be expected to have accrued from a combination of *surveillance* activities including some or all of the following:~~

~~1. A routine national animal disease reporting system supported by evidence of its efficiency and follow up - an on-going, statutory, centrally organised system of reporting~~

~~Ideally *disease* reports should be expressed in a Geographical Information System environment and analysed for clustering of observations and followed up.~~

1. Introduction

The target population for surveillance aimed at identifying *disease* and *infection* should cover all significant populations of susceptible species within the country to be recognised as free from RPV infection.

The strategy employed can be based on randomised sampling requiring surveillance consistent with demonstrating the absence of RPV infection 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) can be an appropriate strategy. The applicant Member should justify the surveillance strategy chosen as adequate to detect the presence of RPV infection in accordance with Chapter 1.4. and the epidemiological situation. It may, for example, be appropriate to target clinical surveillance at particular subpopulations likely to exhibit clear clinical signs. For targeted surveillance consideration should be given to the following:

i) historical disease patterns (risk mapping) – clinical, participatory and laboratory-based

ii) critical population size, structure and density

iii) livestock husbandry and farming systems

iv) movement and contact patterns – markets and other trade-related movements

v) transmission parameters (e.g. virulence of the strain, animal movements)

vi) wildlife and other species demography.

For random surveys, the design of the sampling strategy will need to take into account the expected disease 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 Member must justify the choice of design prevalence and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Chapter 1.4. Selection of the expected 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.

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 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 in Chapter 1.4. The design of surveillance programmes to prove the absence of RPV infection needs to be carefully followed to ensure the reliability of results. The design of any surveillance programme, therefore, requires inputs from professionals competent and experienced in this field.

~~2. Emergency disease reporting systems and investigation of epidemiologically significant events ('stomatitis-enteritis syndrome')~~

~~Emergency reporting systems can be devised to short-circuit normal passive reporting systems to bring suspicious events to the fore and lead to rapid investigation and tracing. All such investigations should be well documented for presentation as an outcome of the *surveillance* system.~~

2. Clinical surveillance

Clinical surveillance aims at detecting clinical signs of "stomatitis-enteritis syndrome" 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 sufficiently large numbers of clinically susceptible animals are examined. It is essential that clinical cases detected be followed by the collection of appropriate samples such as ocular and nasal swabs, blood or other tissues for virus isolation. Clinical surveillance and laboratory testing should always be applied in series to clarify the status of RP 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.

Active search for clinical disease can include participatory disease searching, tracing backwards and forwards, and follow-up investigations. Participatory disease surveillance is a form of targeted active surveillance based upon methods to capture livestock owners perceptions on the prevalence and patterns of disease.

The often underestimated labour intensity and the logistical difficulties involved in conducting clinical examinations should not be underestimated and should be taken into account.

It is essential that all RPV isolates are sent to an OIE reference laboratory to determine the biological characteristics of the causative virus as well as its genetic and antigenic characterization.

~~3. Detection and thorough investigation of epidemiologically significant events ('stomatitis enteritis syndrome') which raise suspicion of rinderpest supported by evidence of efficiency of the system~~

~~*Laboratory* examination undertaken to confirm or rule out rinderpest is given extra credibility if it is accompanied by the results of differential diagnostic examinations.~~

3. Virological surveillance

Given that RP is an acute infection with no known carrier state, virological surveillance using tests described in the *Terrestrial Manual* should be conducted to confirm clinically suspect cases. Applying virological methods in seropositive animals is not regarded as an efficient approach.

~~4. Searching for evidence of clinical rinderpest~~

~~Active search for *disease* might include participatory *disease* searching combined with village *disease* searching, tracing backwards and forwards, follow up and investigation.~~

~~5~~4. ~~Serosurveillance~~ Serological surveillance

Serological surveillance aims at detecting antibodies against RPV. Positive RPV antibody test results can have four possible causes:

a) natural infection with RPV;

b) vaccination against RP;

c) maternal antibodies derived from an immune dam (maternal antibodies in cattle can be found only up to 12 months of age);

d) heterophile (cross) and other non-specific reactions.

~~a) Randomised serosurveys~~

~~Statistically selected samples from relevant strata within the host populations are examined to detect serological evidence of possible virus circulation.~~

~~A sampling unit for the purposes of disease investigation and *surveillance* is defined as a group of animals in sufficiently close contact that individuals within the group are at approximately equal risk of coming in contact with the virus if there should be an infectious animal within the group. In most circumstances, the sampling unit will be a *herd* which is managed as a unit by an individual or a community, but it may also be other epidemiologically appropriate groupings which are subject to regular mixing, such as all animals belonging to residents of a village. In the areas where nomadic or transhumant movements exist, the sampling unit can be the permanent bore holes, wells or water points. Sampling units should normally be defined so that their size is generally between 50 and 1,000 animals.~~

i) Criteria for stratification of host populations

Strata are homogeneously mixing sub-populations of livestock. Any disease *surveillance* activities must be conducted on populations stratified according to the management system, and by *herd* size where this is variable. *Herds*, or other sampling units, should be selected by proper random statistical selection procedures from each stratum.

ii) Field procedures and sample sizes

Annual sample sizes shall be sufficient to provide 95% probability of detecting evidence of rinderpest if present at a prevalence of 1% of *herds* or other sampling units and 5% within *herds* or other sampling units. This can typically be achieved by examining 300 *herds* per stratum per year, but procedures for sampling should be in accordance with the "Guide to Epidemiological Surveillance for Rinderpest"[2], or another procedure that would achieve the same probability of detection.

Where the sampling frame of *herds* is known, *herds* shall be selected for examination by the use of random number tables. Otherwise, samples of *herds* can be selected by taking the nearest *herd* to a randomly selected map reference, provided that the *herds* are evenly distributed. Failing this, any *herd(s)* within a fixed radius of randomly selected map references should be sampled. It must be compulsory for any selected *herd* to be examined or tested as required.

In carrying out clinical *surveillance* for evidence of rinderpest, all animals in selected *herds* or sampling units will be examined by a *veterinarian* for signs of the *disease*, especially mouth lesions. Any positive result shall be evaluated using epidemiological and *laboratory* methods to confirm or refute the suspicion of rinderpest virus activity. All animals born after the cessation of vaccination and more than one year old will be eligible for serological testing.

Where operational considerations require it, the number of eligible animals tested within each sampled *herd* may be reduced. This will reduce the probability of within-herd detection and there must be at least a compensatory increase in the number of *herds* sampled, so that the required 95% probability of detecting 1% between-herd prevalence is maintained.

b) Risk-focussed serosurveillance

Risk-focussed serosurveillance differs from randomised serosurveillance in that it increases detection sensitivity by obtaining samples from areas/populations determined to be at higher risk of *infection*, so as to detect serological evidence of possible virus circulation. The operational modalities for risk-based focussing of *surveillance* require definition (randomisation within defined focus, high risk animals, etc.). The extent to which randomisation needs to be retained in the generation of risk-focussed serosurveillance data needs to be established.

Focussing can be achieved by reference to some or all of the following:

i) Historical disease patterns (prior probability mapping) — clinical, participatory and laboratory-based

ii) Critical population size, structure and density

iii) Livestock husbandry and farming systems

~~iv) Movement and contact patterns – markets and other trade-related movements~~

~~v) Transmission parameters (e.g. virulence of the strain, animal movements)~~

~~vi) Wildlife and other species demography.~~

Article 8.13.23.

Selection of cattle and buffaloes for serosurveillance

~~Ageing cattle and Asian buffaloes for the purpose of serosurveillance:~~

Mis-ageing of cattle selected for serosurveillance is the most common source of error. Colostral immunity can persist almost up to one year of age when measured by the H c-ELISA. Thus, it is essential to exclude from sampling buffaloes and cattle less than one year of age. In addition, it is frequently necessary to be able to exclude those which are older than a certain age, for example, to select only those born after cessation of vaccination.

~~Accounts of the ages for eruption of the incisor teeth vary markedly and are clearly dependent on species, breed, nutritional status and nature of the feed.~~

~~Pragmatically, and solely for the purposes of serosurveillance, it can be accepted that:~~

~~a) cattle having only one pair of erupted permanent central incisor teeth are aged between 21 and 36 months (Asian buffaloes 24-48 months);~~

~~b) cattle having only two pairs of erupted permanent central incisor teeth are aged between 30 and 48 months (Asian buffaloes 48-60 months).~~

~~Thus selecting a cohort of cattle possessing only one pair of permanent incisors will preclude any interference from maternal immunity derived from earlier vaccination or *infection* and ensure that vaccinated cattle are not included if vaccination ceased 3 years or more previously (for Asian buffaloes 4 years or more).~~

It is important to select a cohort of cattle possessing only one pair of permanent incisors to preclude any interference from maternal immunity derived from earlier vaccination or infection and ensure that vaccinated cattle are not included.

Although it is stressed here that animals with milk teeth only are not suitable for *surveillance* based on serology, they are of particular interest and importance in *surveillance* for clinical *disease*. After the loss of colostral immunity, by about one year of age, these are the animals which are most likely to suffer the more severe disease form and in which to look for lesions indicative of rinderpest.

It may be possible to use serum collected for other survey purposes for RP surveillance. However, the principles of survey design described in this Chapter and the requirement for a statistically valid survey for the presence of RPV 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.

The results of random or targeted serological surveys are important in providing reliable evidence that RPV infection is not present in a country. It is therefore essential that the survey be adequately ~~thoroughly~~ documented.

Article 8.13.24.

Wildlife surveillance where a significant susceptible wildlife population exists

There are some key wildlife populations, especially African buffaloes, which act as sentinels for rinderpest infection. Where a significant population of a susceptible wildlife species exists, serosurveillance data ~~are required~~ should be collected to support absence of *infection*. ~~These populations should be monitored purposively to support the dossiers to be submitted for freedom from rinderpest virus infection.~~ Detection of virus circulation in wildlife can be undertaken indirectly by sampling contiguous livestock populations.

Obtaining meaningful data from wildlife *surveillance* can be enhanced by close coordination of activities in the regions and countries. Both purposive and opportunistic samplings are used to obtain material for analysis in national and reference *laboratories*. The latter are required because ~~most~~ many countries ~~are unable~~ do not have adequate facilities to perform the full testing protocol for detecting ~~rinderpest~~ RP antibodies in wildlife sera.

~~Purposive~~ Targeted sampling is the preferred method to provide wildlife data to evaluate the status of rinderpest infection. In reality, the capacity to perform ~~purposive work~~ targeted surveillance in the majority of countries remains minimal. Opportunistic sampling (hunting) is feasible and it provides useful background information.

Wildlife form transboundary populations; therefore, any data from the population could be used to represent the result for the ecosystem and be submitted by more than one Member in ~~a dossier~~ an application to the OIE (even if the sampling was not obtained in the Member submitting the application). It is ~~therefore~~ recommended therefore that the Members represented in a particular ecosystem should coordinate their sampling programmes.

~~The standards for serosurveillance are different from that set for cattle because the serological tests are not fully validated for wildlife species and financial and logistic constraints of sampling prevent collection of large numbers of samples.~~

Where the serological history of the herd is known from previous work (as might be the case for a sentinel herd), repeat sampling need only focus on the untested age groups, born since the last known infection. The sample needs to be taken according to the known epidemiology of the disease in a given species. Opportunistic samples, which are positive, should not be interpreted without a targeted survey to confirm the validity of these results. Opportunistic sampling cannot follow a defined protocol and therefore can only provide background information.

~~From the collective experience of the *laboratories* and experts over the years, an appropriate test protocol is based on the high expected sero-prevalence in a previously infected buffalo *herd* (99% seroconversion of eligible animals within a *herd*), which is detected using a test, which is 100% sensitive. No single test can achieve this; however, combining H c-ELISA to VNT raises sensitivity close to 100%.~~

~~In the order of 1-2% of a *herd* of African buffaloes must be sampled to ensure that no positive case is missed. For example in a *herd* of 300 buffaloes, five animals should be sampled and the above multiple test protocol followed. Where the serological history of the *herd* is known from previous work (as might be the case for a sentinel *herd*), repeat sampling need only focus on the untested age groups, born since the last known *infection*. Appropriate sampling fraction for other wildlife species are less well-defined, as social organization (*herd* structure, likely contact rates, etc.) vary. The sample needs to be taken according to the known epidemiology of the *disease* in a given species. Opportunistic samples, which are positive, should not be interpreted without a purposive survey to confirm the validity of these results. Opportunistic sampling cannot follow a defined protocol and therefore can only provide background information.~~

~~Article 8.13.25.~~

~~Evaluation of applications for accreditation of~~ Members applying for recognition of freedom from ~~rinderpest~~ RP

~~Evaluation of applications for the status of freedom from rinderpest will be the responsibility of the OIE Scientific Commission for Animal Diseases which can request the Director General if the OIE to appoint an ad hoc group in order to assist in reaching an informed decision to present to the OIE International Committee for approval.~~

~~The composition and method of selection of the ad hoc group shall be such as to ensure both a high level of expertise in evaluating the evidence and total independence of the group in reaching conclusions concerning the disease status of a particular country.~~

In addition to the general conditions described in this Chapter, a Member applying for recognition of RP freedom for the country 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 Chapter, to demonstrate absence of RPV infection, during the preceding 24 months in susceptible populations. This requires the support of a national or other laboratory able to undertake identification of RPV infection through virus/antigen/genome detection and antibody tests described in the *Terrestrial Manual*.

~~Article 8.13.26.~~

~~Steps to be taken to declare a country to be free from rinderpest~~

~~Recognition of the status 'free from rinderpest' is given to a Member. Where traditionally managed livestock move freely across international borders, groups of Members may usefully associate themselves into a group for the purposes of obtaining data to be used for mutually supportive applications for individual country accreditation.~~

~~For the purpose of this Chapter, the following assumptions are made:~~

a) that within most previously infected countries, rinderpest vaccine will have been used to control the rate of *infection*;

b) that within an endemically infected population there will be a large number of immune hosts (both vaccinees and recovered animals);

c) that the presence of a proportion of immune hosts within a vaccinated population could have led to a slowing of the rate of virus transmission and possibly the concomitant emergence of strains of reduced virulence, difficult to detect clinically;

d) that the virulence of the virus (and therefore the ease of clinical detection) may or may not increase as the *herd* immunity declines following withdrawal of vaccination; however, continuing transmission will generate serological evidence of their persistence.

Before accreditation can be considered, countries which have the *disease* by the use of rinderpest vaccine must wait until an unvaccinated cohort is available to allow meaningful serological *surveillance* to be conducted.

The OIE has concluded that the majority of countries have stopped vaccinating for a sufficient length of time for it now to be feasible that a single submission of evidence gained over 2 years of appropriate *surveillance* shall be sufficient to gain rinderpest free accreditation.

A Member accredited as free from rinderpest must thereafter submit annual statements to the Director General of the OIE indicating that *surveillance* has failed to disclose the presence of rinderpest, and that all other criteria continue to be met.

A country previously infected with rinderpest which has not employed rinderpest vaccine for at least 25 years and has throughout that period detected no evidence of rinderpest virus *disease* or *infection* may be accredited as free from rinderpest by the OIE based on historical grounds, provided that the country:

- has had throughout at least the last 10 years and maintains permanently an adequate animal disease *surveillance* system along with the other requirements outlined in Article 8.13.25.;

- is in compliance with OIE reporting obligations (Chapter 1.1.).

The *Veterinary Authorities* of the Member must submit a dossier containing evidence supporting their claim to be free from rinderpest on a historical basis to the Director General of the OIE for evaluation by the OIE Scientific Commission for Animal Diseases and accreditation by the OIE International Committee. The dossier should contain at least the following information:

- a description of livestock populations, including wildlife;

- the history of rinderpest occurrence in the country and its control;

- an affirmation that rinderpest has not occurred for 25 years, that vaccine has not been used during that time, and that rinderpest is a *notifiable disease*;

- ~~evidence that in the last 10 years the disease situation throughout the Member has been constantly monitored by a competent and effective veterinary infrastructure that has operated a national animal disease reporting system submitting regular (monthly) disease occurrence reports to the *Veterinary Authority*;~~

- ~~the structure and functioning of the *Veterinary Services*;~~

- ~~the Member operates a reliable system of *risk analysis* based importation of livestock and livestock products.~~

~~Evidence in support of these criteria must accompany the Member's accreditation application dossier. In the event that satisfactory evidence is not forthcoming, the OIE may seek clarification or refer the dossier back to the originators, giving its reasons for so doing. Under such circumstances a fresh dossier would be entertained in due course.~~

~~OR~~

~~A Member having eradicated rinderpest within the last 25 years, wishing to be accredited free from rinderpest and having ended rinderpest vaccination must initiate a two year *surveillance* programme to demonstrate freedom from rinderpest whilst banning further use of rinderpest vaccine. The step of accreditation as free from rinderpest is subject to meeting stringent criteria with international verification under the auspices of the OIE.~~

~~A country historically infected with rinderpest but which has convincing evidence that the *disease* has been excluded for at least 2 years and is not likely to return, may apply to OIE to be accredited as free from rinderpest. The conditions which apply include that an adequate animal disease *surveillance* system has been maintained throughout at least that period.~~

~~The *Veterinary Authority* of the Member must submit a dossier containing evidence supporting their claim to be free from rinderpest to the Director General of the OIE for evaluation by the OIE Scientific Commission for Animal Diseases and accreditation by the OIE International Committee showing that they comply with:~~

- ~~the provisions outlined in this Chapter;~~

- ~~OIE reporting obligations outlined in Chapter 1.1. of the *Terrestrial Code*.~~

~~Other conditions that apply are:~~

- ~~The Member affirms that rinderpest has not occurred for at least 2 years, that vaccine has not been used during that time, and that rinderpest is a *notifiable disease*.~~

- ~~The *Veterinary Authority* has issued orders curtailing the distribution and use of rinderpest vaccine in livestock.~~

- ~~The *Veterinary Authority* has issued orders for the recall and destruction of rinderpest vaccine already issued.~~

- ~~The *Veterinary Authority* has issued orders restricting the importation of rinderpest vaccine into, or the further manufacture of rinderpest vaccine within, the territory under his jurisdiction. An exception can be made for establishing a safeguarded rinderpest emergency vaccine bank under the control of the Chief Veterinary Officer who can demonstrate that no calls have been made on that vaccine bank.~~

- ~~The *Veterinary Authority* has set in place a rinderpest contingency plan.~~

- ~~Over the previous 2 years at least, the disease situation throughout the Member has been constantly monitored by a competent and effective infrastructure that has operated a national animal disease reporting system submitting regular (monthly) disease occurrence reports to the *Veterinary Authority.*~~

- ~~All *outbreaks of disease* with a clinical resemblance to rinderpest have been thoroughly investigated and routinely subjected to *laboratory* testing by an OIE recognised rinderpest specific test within the national rinderpest *laboratory* or at a recognised reference *laboratory.*~~

~~The dossier shall contain:~~

- ~~the results of a continuous *surveillance* programme, including appropriate serological surveys conducted during at least the last 24 months, providing convincing evidence for the absence of rinderpest virus circulation;~~

- ~~a description of livestock populations including wildlife;~~

- ~~the history of rinderpest occurrence in the country and its control;~~

- ~~an affirmation that rinderpest has not occurred for at least 2 years, that vaccine has not been used during that time, and that rinderpest is a *notifiable disease*;~~

- ~~evidence that in the last 2 years the disease situation throughout the Member has been constantly monitored by a competent and effective veterinary infrastructure that has operated a national animal disease reporting system submitting regular (monthly) disease occurrence reports to the *Veterinary*~~

~~*Authority;*~~

- ~~the structure and functioning of the *Veterinary Services;*~~

- ~~the Member operates a reliable system of *risk analysis* based importation of livestock and livestock products.~~

~~In the event that satisfactory evidence in support of the application is not forthcoming, the OIE may seek clarification or refer the dossier back to the originators, giving its reasons for so doing. Under such circumstances a fresh dossier would be entertained in due course.~~

Article 8.13.~~27~~26.

~~Rinderpest outbreaks after accreditation and recovery of rinderpest free status~~ Members re-applying for recognition of freedom from RP following an outbreak

~~Should there be an *outbreak*, or *outbreaks,* of rinderpest in a Member at any time after recognition of rinderpest freedom, the origin of the virus strain must be thoroughly investigated. In particular it is important to determine if this is due to the re-introduction of virus or re-emergence from an undetected focus of *infection*. The virus must be isolated and compared with historical strains from the same area as well as those representatives of other possible sources. The *outbreak* itself must be contained with the utmost rapidity using the resources and methods outlined in the Contingency Plan.~~

Following an *outbreak*, or *outbreaks*, of rinderpest in a Member at any time after recognition of rinderpest freedom, the origin of the virus strain should be thoroughly investigated. In particular it is important to determine if this is due to the re-introduction of virus or re-emergence from an undetected focus of infection. Ideally, the virus should be isolated and compared with historical strains from the same area as well as those representatives of other possible sources.

After elimination of the *outbreak*, a Member wishing to regain the status 'free from rinderpest' ~~must~~ should undertake serosurveillance according to this Chapter to determine the extent of virus spread. In addition to the general conditions described in this Chapter, a Member re-applying for recognition of country freedom from RP should show evidence of an active surveillance programme for RP as well as absence of RPV infection.

If investigations show the *outbreak* virus originated from outside the country, provided the *outbreak* was localised, rapidly contained and speedily eliminated, and provided there was no serological evidence of virus spread outside the index infected area, accreditation of freedom could proceed rapidly. The Member must satisfy the OIE Scientific Commission for Animal Diseases that the *outbreaks* were contained, eliminated and did not represent endemic *infection*.

~~An application to regain the status free from rinderpest shall not generally be accepted until both clinical and serological evidence shows that there has been no virus transmission for at least 3 or 6 months, depending on whether or not stamping out or vaccination respectively has been applied.~~

Article 8.3.27.

The use and interpretation of serological tests for serosurveillance of RP

Serological testing is an appropriate tool to use for RP surveillance. The prescribed serological tests which should be used for RP surveillance are described in the *Terrestrial Manual*; these are of high diagnostic specificity and minimise the proportion of false positive reactions. Antibodies to virulent strains and the Kabete O vaccine strain of RPV can be detected in cattle from about 10 days post infection (approximately 7 days after the appearance of fever) and peak around 30 to 40 days post infection. Antibodies then persist for many years, possibly for life, although titres decline with time. In the case of less virulent strains the detection of the antibody response by ELISA may be delayed by as much as three weeks. There is only one serotype of virus and the tests will detect antibodies elicited by infection with all RP viruses but the tests cannot discriminate between antibodies to field infection and those from vaccination with attenuated vaccines. This fact compromises serosurveillance in vaccinated populations and realistically meaningful sero surveillance can only commence once vaccination has ceased for several years. In these circumstances, dental ageing of cattle and buffaloes is of great value to minimise the inclusion of animals seropositive by virtue of colostral immunity and historic vaccination or infection. The cohort of cattle with one single set of central incisors is the most appropriate to sample[2].

The test most amenable to the mass testing of sera as required to demonstrate freedom from infection is the H c-ELISA. Practical experience from well-controlled serological surveillance in non-vaccinated populations in Africa and Asia demonstrate that one can expect false positive reactions in 0.05 % or less of sera tested. The sensitivity of the test approaches 100 % (relative to the VNT) in Kabete O vaccinated cattle and infection with highly virulent viruses but is lower in the case of low virulence strains. Experience supported by experimental studies indicates that in all cases sensitivity exceeds 70 %.

Only tests approved by OIE as indicated in the *Terrestrial Manual* should be used to generate data presented in support of applications for accreditation of RP freedom. It is necessary to demonstrate that apparently positive serological results have been adequately investigated. The follow-up studies should use appropriate clinical, epidemiological, serological and virological investigations. By this means the investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the survey were not due to virus circulation.

The prescribed serological tests have not been fully validated for use in all wild species. From the collective experience of the reference laboratories and experts over the years, an appropriate test protocol for wildlife is based on the high expected sero-prevalence in a previously infected buffalo herd which is 99 % seroconversion of eligible animals within a herd as detected by use of a 100 % sensitive test. No single test can achieve this but combining the H c-ELISA with the VNT raises sensitivity close to 100 %.

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— text deleted

1. JAMES A.D. (1998). Guide to epidemiological surveillance for rinderpest. *Rev. Sci. Tech.* **17** (3), 796-824.

2. Pragmatically and solely for the purposes of serosurveillance, it can be accepted that:

   (a) Cattle having one pair of erupted permanent central incisor teeth are aged between 21 and 36 months (Asian buffaloes 24 to 48 months);

   (b) Cattle having only two pairs of erupted permanent central incisor teeth are aged between 30 and 48 months (Asian buffaloes 48-60 months)

Annex XX

CHAPTER 10.4.

AVIAN INFLUENZA

Community comments

The Community can only support the proposed changes, if article 10.4.6, 10.4.9 and 10.4.12 are modified.

The Community would be ready to give data to the OIE concerning the inactivation of the AI virus in feathers.

Article 10.4.1.

General provisions

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 Member 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 1.2.3. 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~~ immediately 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 Articles 10.4.27. to 10.4.33.

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 10.4.2.

Determination of the NAI status of a country, zone or compartment

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

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;

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 NAI *surveillance* programme in accordance with Articles 10.4.27. to 10.4.33.;

3. consideration of all epidemiological factors for NAI occurrence and their historical perspective.

Article 10.4.3.

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 Articles 10.4.27. to 10.4.33.

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 Articles 10.4.27. to 10.4.33. 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 Articles 10.4.20. or 10.4.21. 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 Articles 10.4.27. to 10.4.33. has been carried out during that three-month period.

Article 10.4.4.

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 Articles 10.4.27. to 10.4.33., 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 Articles 10.4.27. to 10.4.33. has been carried out during that three-month period.

Article 10.4.5.

Recommendations for importation from a NAI free country, zone or compartment

for live poultry (other than day-old poultry)

Veterinary Authorities should require 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 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 Articles 10.4.27. to 10.4.33., 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 rticles 10.4.27. to 10.4.33.; in that case, the nature of the vaccine used and the date of vaccination should be attached to the certificate.

Article 10.4.6.

Recommendations for the importation of live birds other than poultry

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Authorities* should require 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. a statistically valid sample of the birds ~~were~~ was subjected to a diagnostic test within 14 days prior to shipment to demonstrate freedom from *infection* with a virus which would be considered NAI in poultry;

Community comment

The Community cannot support the proposed article. It reiterates its previous comment that import from an NAI infected compartment should not be authorised: this is the case

for live poultry and it should be the same for birds other than poultry.

The word "compartment" should be deleted.

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 should be attached to the certificate.

Article 10.4.7.

Recommendations for importation from a NAI free country, zone or compartment

for day-old live poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the poultry were kept in a NAI free country, *zone* or *compartment* since they were hatched;

2. the poultry were derived from parent *flocks* which had been kept in a 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 articles 10.4.27. to 10.4.33.; in that case, the nature of the vaccine used and the date of vaccination should be attached to the certificate.

Community comment

The same should apply as in article 10.4.8 concerning the containers, and a point should be added:

3. the poultry are transported in new *containers*;

Article 10.4.8.

Recommendations for importation from a HPNAI free country, zone or compartment

for day-old live poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the poultry were kept in a HPNAI free country, *zone* or *compartment* since they were hatched;

2. the poultry were derived from parent *flocks* which had been kept in a NAI free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;

3. the poultry are transported in new *containers*;

4. if the poultry or the parent *flocks* were vaccinated, vaccination was carried out in accordance with articles 10.4.27. to 10.4.33.; in that case, the nature of the vaccine used and the date of vaccination should be attached to the certificate.

Article 10.4.9.

Recommendations for the importation of day-old live birds other than poultry

Regardless of the NAI status of the country, *zone* or *compartment*, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. the birds showed no clinical signs suggestive of NAI 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.

Community comment

The Community cannot support the proposed article. It reiterates its previous comment that import from an HPNAI infected compartment should not be authorised: this is the case for day old live poultry and it should be the same for day old birds other than poultry.

The word "compartment" should be deleted.

Article 10.4.10.

Recommendations for importation from a NAI free country, zone or compartment

for hatching eggs of poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the eggs came from a NAI free country, *zone* or *compartment*;

2. the eggs were derived from parent *flocks* which had been kept in a 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 Articles 10.4.27. to 10.4.33.; in that case, the nature of the vaccine used and the date of vaccination should be attached to the certificate;

4. the eggs are transported in new or appropriately sanitized *containers*.

Article 10.4.11.

Recommendations for importation from a HPNAI free country, zone or compartment

for hatching eggs of poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the eggs came from a HPNAI free country, *zone* or *compartment*;

2. the eggs were derived from parent *flocks* which had been kept in a NAI free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;

3. the eggs have had their surfaces sanitised (in accordance with Chapter 6.3.) and are transported in new packing material;

4. if the parent *flocks* were vaccinated, vaccination was carried out in accordance with articles 10.4.27. to 10.4.33.; in that case, the nature of the vaccine used and the date of vaccination should be attached to

the certificate.

Article 10.4.12.

Recommendations for the importation of hatching eggs from birds other than poultry

Regardless of the NAI status of the country, *zone* or *compartment* origin, *Veterinary Authorities* should require 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;

2. the eggs have had their surfaces sanitized (in accordance with Chapter 6.3.) 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.

Community comment

The Community cannot support the proposed article. It reiterates its previous comment that import from an HPNAI infected compartment should not be authorised: this is the case for hatching eggs of poultry and it should be the same for hatching eggs of birds other than poultry.

The word "compartment" should be deleted.

Article 10.4.13.

Recommendations for importation from a NAI free country, zone or compartment

<u>for eggs for human consumption</u>

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the eggs were produced and packed in a NAI free country, *zone* or *compartment*;

2. the eggs are transported in new or appropriately sanitized packaging material.

Article 10.4.14.

Recommendations for importation from a HPNAI free country, zone or compartment

<u>for eggs for human consumption</u>

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the eggs were produced and packed in a HPNAI free country, *zone* or *compartment*;

2. the eggs have had their surfaces sanitized (in accordance with Chapter 6.4.) and are transported in new or appropriately sanitized packing material.

Article 10.4.15.

Recommendations for importation from a NAI free country, zone or compartment

<u>for egg products</u>

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the egg products come from, and were processed in, a NAI free country, *zone* or *compartment*.

Article 10.4.16.

Recommendations for importation from a country, zone or compartment not considered free from NAI

for egg products

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the egg products are derived from eggs which meet the requirements of Articles 10.4.123. or 10.4.14.; or

2. the egg products were processed to ensure the destruction of NAI virus in accordance with Article 10.4.25.;

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.~~

Article 10.4.17.

Recommendations for importation from a NAI free country, zone or compartment

for poultry semen

Veterinary Authorities should require 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 NAI free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

Article 10.4.18.

Recommendations for the importation from a HPNAI free country, zone or compartment

for poultry semen

Veterinary Authorities should require 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 HPNAI free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

Article 10.4.19.

Recommendations for the importation of semen of birds other than poultry

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Authorities* should require 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 within 14 days prior to semen collection and shown to be free of NAI infection.

Article 10.4.20.

Recommendations for importation from a NAI free country, zone or compartment

for fresh meat of poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from poultry:

1. which have been kept in a 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 Chapter 6.3. and have been found free of any signs suggestive of NAI.

Article 10.4.21.

Recommendations for importation from a HPNAI free country, zone or compartment

for fresh meat of poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from poultry:

1. which have been kept in a 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 Chapter 6.2. and have been found free of any signs suggestive of NAI.

Article 10.4.22.

Recommendations for the importation of meat products of poultry

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. the *commodity* is derived from *fresh meat* which meet the requirements of Articles 10.4.20. or 10.4.21.; or

2. the *commodity* has been processed to ensure the destruction of avian influenza virus in accordance with Article 10.4.26.;

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 10.4.23.

Recommendations for the importation of products of poultry origin intended for use in animal feeding, or for agricultural or industrial use

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* were processed in a NAI free country, *zone* or *compartment* from poultry which were kept in a NAI free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; 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 10.4.24.

Recommendations for the importation of feathers and down of poultry

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* were processed in a NAI free country, *zone* or *compartment* from poultry which were kept in a NAI free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or

2. these *commodities* have been processed to ensure the destruction of avian influenza virus (under study);

Community comment

The Community requests that the OIE complete this work as soon as possible and would be ready to give data to the OIE concerning the inactivation of the AI virus in feathers.

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of avian influenza virus.

Article 10.4.24 bis.

Recommendations for the importation of feather meal

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* were processed in a NAI free country, *zone* or *compartment* from poultry which were kept in a NAI free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or

2. these *commodities* have been processed either;

   a at a minimum temperature of 118ºC for minimum of 40 minutes; or

   b) with a continuous hydrolysing process under at least 3.79 bar of pressure with steam at a minimum temperature of 122 ºC for a minimum of 15 minutes;

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of avian influenza virus.

Article 10.4.25.

Procedures for the inactivation of the AI virus in eggs and egg products

The following times for industry standard temperatures are suitable for the inactivation of 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~~ 20 hours
Dried egg white	54.4	~~21.38 days~~ 513 hours

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 10.4.26.

Procedures for the inactivation of the AI virus in 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

Article 10.4.27.

Surveillance: introduction

Articles 10.4.27. to 10.4.33. define the principles and provide a guide on the *surveillance* of NAI complementary to Chapter 1.4., applicable to Members seeking to determine their NAI status. This may be for the entire country, *zone* or *compartment*. Guidance for Members seeking free status following an *outbreak* and for the maintenance of NAI status is also provided.

The presence of avian influenza viruses in wild birds creates a particular problem. In essence, no Member can declare itself free from avian influenza (AI) in wild birds. However, the definition of NAI in this Chapter refers to the *infection* in poultry only, and Articles 10.4.27. to 10.4.33. were 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 recommendations 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 Member 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 10.4.28.

Surveillance: general conditions and methods

1. A *surveillance* system in accordance with Chapter 1.4. 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 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*. 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 *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;

Community comment

In the fifth sentence of point a) above, the word "always" should be inserted between "As suspicion cannot" and "be resolved".

   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 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.

Community comment

In the last sentence of point b) above, the word "potential" should be inserted between "or other" and "sources of NAIV".

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

Article 10.4.29.

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 Member should justify the *surveillance* strategy chosen as adequate to detect the presence of NAIV infection in accordance with Chapter 1.4. 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).

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 Member must justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. 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.

Community comment

In the last sentence of point 2 above, this is a too harsh approach to the confirmation of infected animals based on clinical suspicion. Restrictions until evidence to the contrary is produced is all right, classification as infected is not. The words: "be classified as infected" should be replaced by "have restrictions imposed upon it".

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 recommendations 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 10.4.33.

Article 10.4.30.

Documentation of NAI or HPNAI free status

1. Members declaring freedom from NAI or HPNAI for the country, zone or compartment: additional surveillance procedures

In addition to the general conditions described in above mentioned articles, a Member declaring freedom from NAI or 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 Chapter, 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 10.4.31.

Countries, zones or compartments declaring that they have regained freedom from NAI or HPNAI following an outbreak: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, a Member 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 recommendations. The *surveillance* should at least give the confidence that can be given by a randomized representative sample of the populations at risk.

Article 10.4.32.

NAI free establishments within HPNAI free compartments: additional surveillance procedures

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 recommendations. The frequency of testing should be based on the risk of *infection* and at a maximum interval of 21 days.

Article 10.4.33.

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 Chapter.

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. The follow-up procedure in case of positive test results if vaccination is used

   In case of vaccinated populations, one has to exclude the likelihood that positive test results are indicative of virus circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from *surveillance* conducted on NAI-vaccinated poultry. The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated, and the results should be collated in the final report.

   Knowledge of the type of vaccine used is crucial in developing a serological based strategy to differentiate infected from vaccinated animals.

   a) Inactivated whole AI virus vaccines can use either homologous or heterologous neuraminidase subtypes between the vaccine and field strains. If poultry in the population have antibodies to NP/M and were vaccinated with inactivated whole AI virus vaccine, the following strategies should be applied:

      i) sentinel birds should remain NP/M antibody negative. If positive for NP/M antibodies, indicating AI virus infection, specific HI tests should be performed to identify H5 or H7 AI virus infection;

      ii) if vaccinated with inactivated whole AI virus vaccine containing homologous NA to field virus, the presence of antibodies to NSP could be indicative of *infection*. Sampling should be initiated to exclude the presence of 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. The follow-up procedure in case of positive test results indicative of infection for determination of infection due to HPNAI or LPNAI virus

   The detection of antibodies indicative of a NAI virus infection as indicated in point a)i) above will result in the initiation of epidemiological and virological investigations to determine if the infections are due to HPNAI or LPNAI viruses.

Virological testing should be initiated in all antibody-positive and at risk populations. The samples should be evaluated for the presence of AI virus, by virus isolation and identification, and/or detection of influenza A specific proteins or nucleic acids (Figure 2). Virus isolation is the gold standard for detecting *infection* by AI virus and the method is described in the *Terrestrial Manual*. All AI virus isolates should be tested to determine HA and NA subtypes, and *in vivo* tested in chickens and/or sequencing of HA proteolytic cleavage site of H5 and H7 subtypes for determination of classification as HPNAI, LPNAI or LPAI (not notifiable) viruses. As an alternative, nucleic acid detection tests have been developed and validated; these tests have the sensitivity of virus isolation, but with the advantage of providing results within a few hours. Samples with detection of H5 and H7 HA subtypes by nucleic acid detection methods should either be submitted for virus isolation, identification, and *in vivo* testing in chickens, or sequencing of nucleic acids for determination of proteolytic cleavage site as HPNAI or LPNAI viruses. The antigen detection systems, because of low sensitivity, are best suited for screening clinical field cases for *infection* by Type A influenza virus looking for NP/M proteins. NP/M positive samples should be submitted for virus isolation, identification and pathogenicity determination.

Community comment

It is proposed to add "detection of specific genomic material".

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;

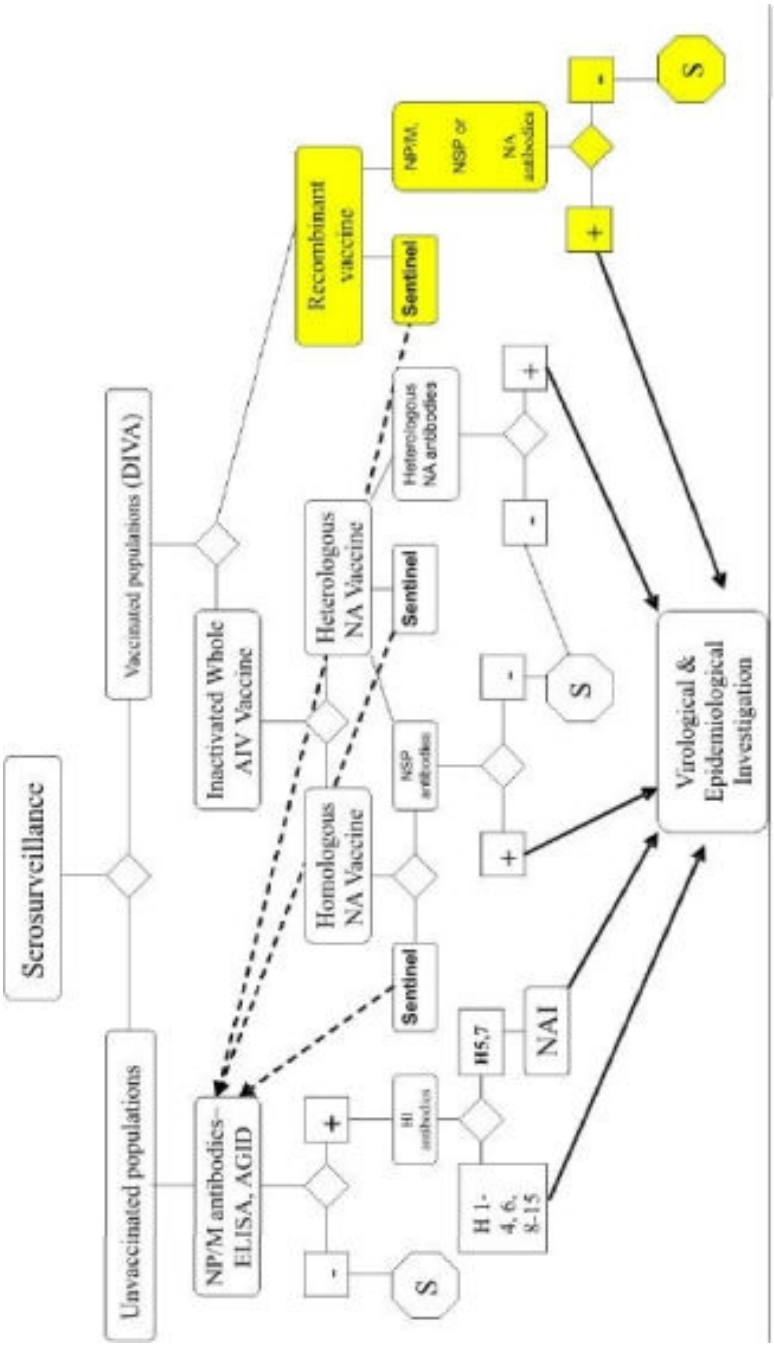
d) sanitary protocol and history of the affected *establishments*;

e) control of *animal identification* and movements;

f) other parameters of regional significance in historic NAIV transmission.

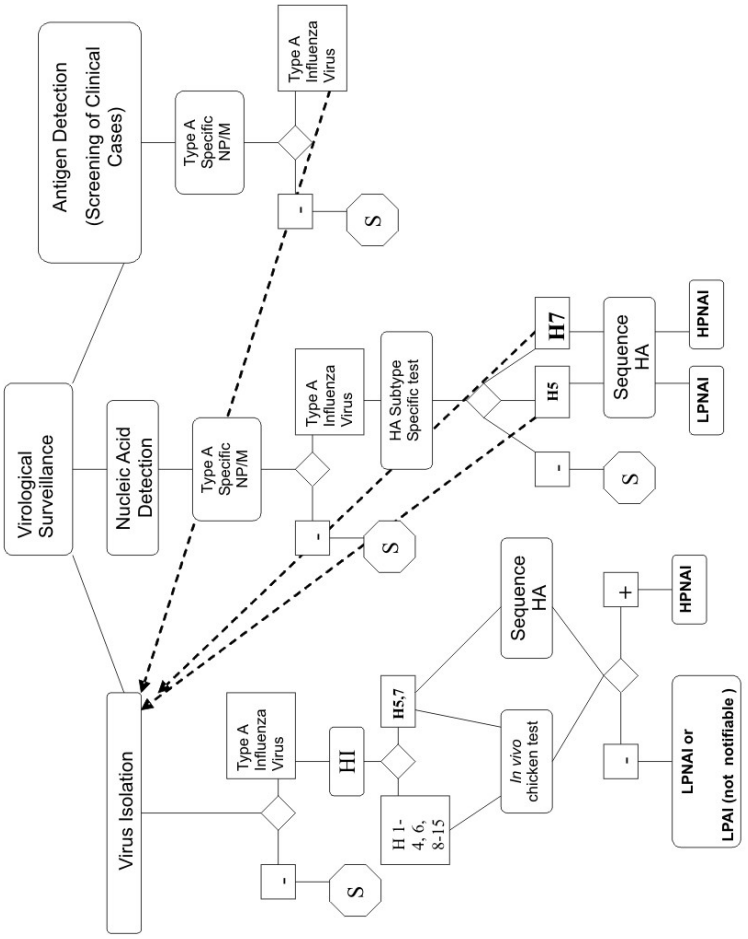
The entire investigative process should be documented as standard operating procedure within the epidemiological *surveillance* programme.

Fig. 1. ***Schematic representation of laboratory tests for determining evidence of NAI infection through or following serological surveys***



Annex XX (contd)

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

— text deleted

Annex XXI

CHAPTER 10.13.

NEWCASTLE DISEASE

Community comments

The Community can only support the proposed changes, if article 10.3.5, 10.3.7 and 10.3.9 are modified.

Moreover, the Community would appreciate to get detailed scientific evidence for the new article 19 bis.

Article 10.13.1.

General provisions

1. For the purposes of *international trade*, Newcastle disease (ND) is defined as an *infection* of poultry caused by a virus (NDV) of avian paramyxovirus serotype 1 (APMV-1) 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.'

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. This Chapter deals with NDV *infection* of poultry as defined in point 2 above, in the presence or absence of clinical signs. For the purposes of *international trade*, a Member should not impose immediate trade bans in response to reports of *infection* with NDV in birds other than poultry according to Article 1.2.3. of the *Terrestrial Code*.

4. The occurrence of *infection* with NDV is defined as the isolation and identification of NDV as such or the detection of viral RNA specific for NDV.

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

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 10.13.2.

Determination of the ND status of a country, zone or compartment

The ND status of a country, a *zone* or a *compartment* can be determined 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 NDV *infection* in the absence of clinical signs in poultry, this may be achieved through an ND *surveillance* programme in accordance with Articles 10.13.20. to 10.13.24.;

3. consideration of all epidemiological factors for ND occurrence and their historical perspective.

Article 10.13.3.

ND free country, zone or compartment

A country, *zone* or *compartment* may be considered free from ND when it has been shown that NDV *infection* has not been present in the country, *zone* or *compartment* for the past 12 months, based on *surveillance* in accordance with Articles 10.13.20. to 10.13.24.

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 Articles 10.13.20. to 10.13.24. has been carried out during that three-month period.

Article 10.13.4.

Recommendations for importation from an ND free country, zone or compartment as defined in Article 10.13.3.

<u>for live poultry (other than day-old poultry)</u>

Veterinary Authorities should require 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 poultry are transported in new or appropriately sanitized *containers*.

If the birds were vaccinated against ND, the nature of the vaccine used and the date of vaccination should be attached to the *certificate*.

Article 10.13.5.

Recommendations for the importation of live birds other than poultry

Regardless of the ND status of the country, *zone* or *compartment* of origin, *Veterinary Authorities* should require 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* during the isolation period;

3. a statistically valid sample of the birds ~~were~~ was subjected to a diagnostic test within 14 days prior to shipment to demonstrate freedom from *infection* with NDV;

Community comment

The Community cannot support the proposed article. Import from an ND infected compartment should not be authorised: this is the case for live poultry and it should be the same for birds other than poultry.

The word "compartment" should be deleted.

Moreover, in point 1 the word "ND" should be replaced by "infection with NDV".

4. the birds are transported in new or appropriately sanitized *containers*.

If the birds were vaccinated against ND, the nature of the vaccine used and the date of vaccination should also be attached to the *certificate*.

Article 10.13.6.

Recommendations for importation from an ND free country, zone or compartment as defined in Article 10.13.3.

for day-old live poultry

Veterinary Authorities should require 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 are transported in new or appropriately sanitized *containers*.

If poultry 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 10.13.7.

Recommendations for the importation of day-old live birds other than poultry

Regardless of the ND status of the country, *zone* or *compartment*, *Veterinary Authorities* should require 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*.

Community comment

The Community cannot support the proposed article. Import from an ND infected compartment should not be authorised: this is the case for day old live poultry and it should be the same for day old birds other than poultry.

The word "compartment" should be deleted.

Moreover, in point 1 the word "ND" should be replaced by "infection with NDV".

Article 10.13.8.

Recommendations for importation from an ND free country, zone or compartment as defined in Article 10.13.3.

for hatching eggs of poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the birds:

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 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 should also be attached to the *certificate*.

Article 10.13.9.

Recommendations for the importation of hatching eggs from birds other than poultry

Regardless of the ND status of the country, *zone* or *compartment* origin, *Veterinary Authorities* should require 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 NDV;
2. the eggs have had their surfaces sanitized (in accordance with Chapter 6.3.) and 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 should also be attached to the *certificate*.

Community comment

The Community cannot support the proposed article. Import from an ND infected compartment should not be authorised: this is the case for poultry hatching eggs and it should be the same for hatching eggs of birds other than poultry.

The word "compartment" should be deleted.

Article 10.13.10.

Recommendations for importation from an ND free country, zone or compartment as defined in Article 10.13.3.

for eggs for human consumption

Veterinary Authorities should require 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 10.13.11.

Recommendations for importation from an ND free country, zone or compartment as defined in Article 10.13.3.

for egg products

Veterinary Authorities should require 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 10.13.12.

Recommendations for importation from a country, zone or compartment not considered free from ND

for egg products

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the egg products are processed to ensure the destruction of NDV ~~(under study)~~ in accordance with Article 10.13.19.tris;
2. the necessary precautions were taken after processing to avoid contact of the egg products with any source of NDV;
3. ~~the egg products are transported in new or appropriately sanitized *containers*.~~

Article 10.13.13.

Recommendations for importation from an ND free country, zone or compartment as defined in Article 10.13.3.

for poultry semen

Veterinary Authorities should require 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 10.13.14.

Recommendations for the importation of semen of birds other than poultry

Regardless of the ND status of the country, *zone* or *compartment* of origin, *Veterinary Authorities* should require 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 NDV during the isolation period and on the day of semen collection;

3. were subjected to a diagnostic test within 14 days prior to semen collection to demonstrate freedom from *infection* with NDV.

Article 10.13.15.

Recommendations for importation from an ND free country, zone or compartment as defined in Article 10.13.3.

for fresh meat of poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of fresh meat comes from poultry:

1. which have been kept 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 Chapter 6.2. and have been found free of any sign suggestive of ND.

Article 10.13.16.

Recommendations for importation from an ND free country, zone or compartment

for meat products of poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the *commodity* is derived from *fresh meat* which meets the requirements of Article 10.13.15. 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 NDV.

Article 10.13.17.

Recommendations for importation from a country, zone or compartment not considered free from ND

for meat products of poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the entire consignment of meat comes from poultry which have been slaughtered in an approved *abattoir* and have been subjected to ante-mortem and post-mortem inspections in accordance with Chapter 6.2. and have been found free of any signs suggestive of ND;

2. the *commodity* has been processed to ensure the destruction of NDV ~~(under study)~~ in accordance with Article 10.13.19.quads;

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV.

Article 10.13.18.

Recommendations for the importation of products of poultry origin intended for use in animal feeding, or for agricultural or industrial use

Regardless of the ND status of the country, *zone* or *compartment* of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* were processed in a ND free country, *zone* or *compartment* from poultry which were kept in a ND free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or

2. these *commodities* have been processed to ensure the destruction of NDV (under study);

OR

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV.

Article 10.13.19.

Recommendations for the importation of feathers and down

Regardless of the ND status of the country, *zone* or *compartment* of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* were processed in a ND free country, *zone* or *compartment* from poultry which were kept in a ND free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or

2. these *commodities* have been processed to ensure the destruction of NDV (under study);

Community comment

The Community requests that the OIE complete this work as soon as possible and would be ready to give data to the OIE concerning the inactivation of the ND virus in feathers.

OR

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV.

Article 10.13.19 bis.

Recommendations for the importation of feather meal

Regardless of the ND status of the country, *zone* or *compartment* of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* were processed in a ND free country, *zone* or *compartment* from poultry which were kept in a ND free country, *zone* or *compartment* from the time they were hatched until the time of

slaughter or for at least the 21 days preceding *slaughter*; or

2. these *commodities* have been processed either;

   a) at a minimum temperature of 118ºC for minimum of 40 minutes; or

   b) with a continuous hydrolysing process under at least 3.79 bar of pressure with steam at a minimum temperature of 122ºC for a minimum of 15 minutes;

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of ND.

Article 10.13.19.tris

Procedures for the inactivation of the ND virus in eggs and egg products

The following times and temperatures are suitable for the inactivation of ND virus present in eggs and egg products:

	Temperature (°C)	**Time**
Whole egg	55	2521 seconds
Whole egg	57	1596 seconds
Whole egg	59	674 seconds
Liquid egg white	55	2278 seconds
Liquid egg white	57	986 seconds
Liquid egg white	59	301 seconds
10% salted yolk	55	176 seconds
Dried egg white	57	50.4 hours

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 10.13.19.quads

Procedures for the inactivation of the ND virus in meat

A procedure which produces a core temperature of 70ºC for 574 seconds is suitable for the inactivation of ND virus present in meat.

	Temperature (°C)	**Time**
Poultry meat	65.0	840 seconds
	70.0	574 seconds
	74.0	280 seconds
	80.0	203 seconds

Article 10.13.20.

Surveillance: introduction

Articles 10.13.20. to 10.13.24. define the principles and provide a guide on the *surveillance* for ND as

defined in Article 10.13.1. and is complementary to Chapter 1.4. It is applicable to Members seeking to determine their ND status. This may be for the entire country, *zone* or *compartment*. Guidance for Members seeking free status following an outbreak and for the maintenance of ND status is also provided.

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.

Community comment

The first part of the sentence seems to imply that the prevalence, a precise quantitative data, of the APMV-1 is known worldwide. It is suggested to replace "prevalence" by "occurrence/presence".

The impact and epidemiology of ND differ widely in different regions of the world and therefore it is not possible to provide specific recommendations 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 Member 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 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 NDV *infection*.

Article 10.13.21.

Surveillance: general conditions and methods

1. A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. In particular there should be in place:

   a) a formal and ongoing system for detecting and investigating outbreaks of *disease* or NDV *infection*;

   b) a procedure for the rapid collection and transport of samples from suspect cases of ND to a *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 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 *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

country, *zone*, *compartment*, places where birds and poultry of different origins are mixed, or other sources of NDV).

An effective *surveillance* system may identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is due to 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 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 10.13.22.

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 NDV *infection* / circulation needs to be carefully followed to avoid producing results that are either unreliable, or excessively costly and logistically complicated.

If a Member wishes to declare freedom from 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 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*. If alternative tests are used they must have been validated as fit-for-purpose in accordance with OIE standards. A Member should justify the *surveillance* strategy chosen as adequate to detect the presence of NDV *infection* in accordance with Chapter 1.4. and the prevailing epidemiological situation.

In surveys, the sample size selected for testing should be statistically justified to detect *infection* at a predetermined 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 Member should justify the choice of survey design and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4.

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 10.13.2.) 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 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 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 NDV.

A presumptive diagnosis of clinical ND in suspect infected populations should always be confirmed by virological testing in a *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 vaccination is carried out, serological *surveillance* is of limited value. Serological *surveillance* cannot be used to discriminate between NDV and other APMV-1. Test procedures and interpretations of results are as described in the *Terrestrial Manual*. Positive NDV antibody test results can have five possible causes:

a) natural *infection* with APMV-1;

b) vaccination against ND;

c) exposure to vaccine virus;

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;

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 recommendations 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 *infection*, virological methods should be used to confirm the presence of NDV in such populations. Until validated strategies and tools to differentiate vaccinated animals from those infected with field 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 to detect virus circulation. 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 be immunologically naïve and may be used in vaccinated *flocks*. In case of the use of sentinel poultry, the structure and organisation of the poultry sector, the 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 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 10.13.23.

Documentation of ND free status: additional surveillance procedures

The requirements for a country, *zone* or *compartment* to declare freedom from ND are given in Article 10.13.3.

A Member 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 recommendations.

1. Members 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 Chapter to demonstrate absence of NDV *infection* in poultry during the preceding 12 months.

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

   Vaccination against ND may be used as a component of a disease prevention and control programme. The vaccine used must comply with the provisions of the *Terrestrial Manual*.

   In vaccinated populations there is a need to perform *surveillance* ~~(Article x.x.x.x.)~~ to ensure the absence of 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 evidence to show the effectiveness of the vaccination programme is regularly provided.

Article 10.13.24.

Countries, zones or compartments regaining freedom from ND following an outbreak: additional surveillance procedures

A Member regaining country, zone or compartment freedom from ND should show evidence of an active surveillance programme depending on the epidemiological circumstances of the outbreak to demonstrate the absence of the infection.

A Member declaring freedom of a country, zone or compartment after an outbreak of ND (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 recommendations.

— text deleted

Annex XXII

CHAPTER 11.6.

BOVINE SPONGIFORM ENCEPHALOPATHY

Community comments

The Community can support the proposed changes, only if its comments are taken into consideration.

Article 11.6.1.

General provisions and safe commodities

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~~ tallow with ~~(~~maximum level of insoluble impurities of 0.15% in weight~~)~~ and derivatives made from this tallow;

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. the Community can only support the inclusion of protein-free tallow with a maximal 0,15% insoluble impurities to the list under Article 11.6.1, 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 11.6.14.;

Community comment

The Community took note of the proposal to remove the 30 months age limit on trade in deboned skeletal muscle meat between countries, irrespective of BSE status. In view of the unknown risk status of countries with an undetermined BSE risk status, the Community can not agree on the proposal to remove the 30 months age limit in point g) of Article 11.6.1.

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 11.6.2.

The BSE risk status of the cattle population of a country, zone or compartment

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 the provisions of the *Terrestrial Code*, identifying all potential factors for BSE occurrence and their historic perspective. Members 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 11.6.14. 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 proposes 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 sub-populations as defined in Articles 11.6.20. to 11.6.22.;

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 a *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 Member should conduct Type B *surveillance* in accordance with Articles 11.6.20. to 11.6.22.

When the *risk assessment* fails to demonstrate negligible risk, the Member should conduct Type A *surveillance* in accordance with Articles 11.6.20. to 11.6.22.

Article 11.6.3.

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 11.6.2., has been conducted in order to identify the historical and existing risk factors, and the Member has demonstrated that appropriate specific

measures have been taken for the relevant period of time defined below to manage each identified risk;

2. the Member has demonstrated that Type B *surveillance* in accordance with Articles 11.6.20. to 11.6.22. 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 11.6.2. 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 11.6.3., 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 11.6.3., point 3b) ii), Article 11.6.4, point 3a)(ii) and 3b), Article 11.6.7.,point 2), Article 11.6.8., point 3, Article 11.6.9., point 1) en 3b) and Article 11.6.10., 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 11.6.2. 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 Member 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 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 to the OIE according to the requirements in Chapter 1.1.

Community comment

The European 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 11.6.4.

The Community would like to draw the TAHSC attention on the letter that is being sent to the OIE to allow Members to provide their information in January or February so as to include the whole past calendar year.

Article 11.6.4.

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 11.6.2., has been conducted in order to identify the historical and existing risk factors, and the Member 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 Member has demonstrated that Type A *surveillance* in accordance with Articles 11.6.20. to 11.6.22. 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 11.6.2. 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 11.6.2. 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 11.6.2. 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;

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 11.6.2. are <u>being</u> 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 <u>is being</u> fed to ruminants."

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 Member 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 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 to the OIE according to the requirements in Chapter 1.1.

Article 11.6.5.

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 11.6.6.

Recommendations for the importation of bovine commodities from a country, zone or compartment posing a negligible BSE risk

<u>for all *commodities* from cattle not listed in point 1 of Article 11.6.1.</u>

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the country, *zone* or *compartment* complies with the conditions in Article 11.6.3.

Article 11.6.7.

Recommendations for the importation of cattle from a country, zone or compartment posing a negligible BSE risk but where there has been an indigenous case

<u>for cattle selected for export</u>

Veterinary Authorities should require 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 3b)iii) of Article 11.6.3.;

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 just after the implementation of the feed ban should also be considered and should not always, based on the situation and an assessment, constitute a reason to question the negligible risk status.

The Community proposes the following:

"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 11.6.8, point 3.

In addition the cattle selected for export should be born and continuously reared in an exporting country with a negligible risk 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 11.6.8.

Recommendations for the importation of cattle from a country, zone or compartment posing a controlled BSE risk

for cattle

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the country, *zone* or *compartment* complies with the conditions referred to in Article 11.6.4.;

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 3b) of Article 11.6.4.;

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 11.6.9.

Recommendations for the importation of cattle from a country, zone or compartment posing an undetermined BSE risk

for cattle

Veterinary Authorities should require 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.

Article 11.6.10.

Recommendations for the importation of meat and meat products from a country, zone or compartment posing a negligible BSE risk

for *fresh meat* and *meat products* from cattle (other than those listed in point 1 of Article 11.6.1.)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the country, *zone* or *compartment* complies with the conditions in Article 11.6.3.;

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 an exporting country with a 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 11.6.11.

Recommendations for the importation of meat and meat products from a country, zone or compartment posing a controlled BSE risk

for *fresh meat* and *meat products* from cattle (other than those listed in point 1 of Article 11.6.1.)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the country, *zone* or *compartment* complies with the conditions referred to in Article 11.6.4.;

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 11.6.14.,

   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 11.6.11 point 4 b) with:
'4) b) mechanically separated meat from all bones from cattle of all ages,'
This comment also applies to Article 11.6.12, point 2c).

Article 11.6.12.

Recommendations for the importation of meat and meat products from a country, zone or compartment posing an undetermined BSE risk

for *fresh meat* and *meat products* from cattle (other than those listed in point 1 of Article 11.6.1.)

Veterinary Authorities should require 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 11.6.14.,

   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 11.6.13.

Recommendations on ruminant-derived meat-and-bone meal or greaves

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 11.6.3., 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 11.6.4. and 11.6.5. should not be traded between countries.

Article 11.6.14.

Recommendations on commodities that should not be traded

1. From cattle of any age originating from a country, *zone* or *compartment* defined in Articles 11.6.4. and 11.6.5., 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.

The Community asks again the OIE to provide the scientific justification to consider only the distal ileum as specified risk material.

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 11.6.4., 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 11.6.5., 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 11.6.15.

Recommendations for the importation of gelatine and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

Veterinary Authorities of *importing countries* should require 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 or undetermined BSE risk and are derived from cattle which have passed ante-mortem and post-mortem inspections; and that

   a) skulls ~~and vertebral columns~~ 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 exclusion of the skull from bovine animals originating from controlled BSE risk countries for the production of gelatine.

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 only vertebral column from bovine animals below 30 months can be used for the production of gelatine.

Article 11.6.16.

Recommendations for the importation of tallow (other than as defined in Article 11.6.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1. the tallow 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 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 11.6.14.

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 11.6.14."

Article 11.6.17.

Recommendations for the importation of dicalcium phosphate (other than as defined in Article 11.6.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

Veterinary Authorities of *importing countries* should require 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 11.6.15.

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 originates 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 11.6.14.

3. it originates 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 11.6.14"

Article 11.6.18.

Recommendations for the importation of tallow derivatives (other than those made from protein-free tallow as defined in Article 11.6.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1. the tallow derivatives 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 11.6.16.; or

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

Article 11.6.19.

Procedures for the reduction of BSE infectivity in meat-and-bone meal

The following procedure should be used to reduce the infectivity of any transmissible spongiform encephalopathy agents which may be present during the production of *meat-and-bone meal* containing ruminant proteins.

1. The raw material should be reduced to a maximum particle size of 50 mm before heating.

2. The raw material should be heated under saturated steam conditions to a temperature of not less than 133°C for a minimum of 20 minutes at an absolute pressure of 3 bar.

Article 11.6.20.

Surveillance: 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 11.6.2. 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);

d) cattle over 36 months of age at routine slaughter.

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 <u>for human consumption</u> or <u>showing abnormal clinical signs</u> 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);"

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, *zone* or *compartment*. This approach is consistent with Articles 11.6.20. to 11.6.22.

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 11.6.21.

Surveillance: description of cattle subpopulations

1. <u>Cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects)</u>

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 Members 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 11.6.2.), 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 Members 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 Members 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 Members 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 11.6.22.

Surveillance activities

In order to implement efficiently a *surveillance* strategy for BSE, a Member 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 is determined 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 chapter 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 Chapter 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 Member 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.

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 11.6.3.) 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 11.6.4.), following the achievement of the relevant points target using Type A *surveillance*, to maintain confidence in the knowledge gained through Type A *surveillance*.

3. 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
25,000 -50,000	7,500	3,750

Community comment

The Community thanks the OIE Code for taking into account the comments related to countries with a small adult cattle population.

4. 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 Chapter 1.4. 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, Members should sample at least three of the four subpopulations.

Annex XXII (contd)

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
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

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.

Surveillance points remain valid for 7 years (the 95th percentile of the incubation period).

Article 11.6.23.

BSE risk assessment: introduction

The first step in determining the BSE risk status of the cattle population of a country or *zone* is to conduct a *risk assessment* (reviewed annually), based on Section 2. 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 BSE agent has been introduced via the importation of the following commodities potentially contaminated with a 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 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 recommendations 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. The recommendations are supported by greater detail in the questionnaire used for the submission of data for country assessment.

Article 11.6.24.

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

This point is irrelevant if the exposure assessment outlined below in Article 11.6.27. indicates that *meat-and-bone meal* or *greaves* has not been fed, either deliberately or accidentally, in the past 8 years.

Nevertheless, documentation should be provided on the control systems (including relevant legislation) in place to ensure that *meat-and-bone meal* or *greaves* has not been fed to ruminants.

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

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

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

Evidence required:

- Documentation to support claims that *meat-and-bone meal*, *greaves* or feedstuffs containing either *meat-and-bone meal* or *greaves* have not been imported, OR

- Where *meat-and-bone meal*, *greaves* or feedstuffs containing them have been imported, documentation of country of origin and, if different, the country of export.

- Documentation on annual volume, by country of origin, of *meat*, *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 BSE agent, should it be present.

- Documentation describing the fate of imported *meat-and-bone meal* and *greaves*.

Article 11.6.25.

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

Assumptions:

- Countries which have imported ruminants from countries infected with 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 2.2.3.).

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 11.6.26.

The potential for the release of the BSE agent through the importation of products of animal origin potentially infected with 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 BSEs are more likely to experience BSE.

- 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 2.2.3.).

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 11.6.14.);

- 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*.

Annex XXII (contd)

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

- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article 11.6.27.

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 (see Articles 11.6.3. and 11.6.4.)?

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 11.6.28.

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

Assumptions:

- BSE has a long *incubation period* and insidious onset of signs, so cases may escape detection.

- Pre-clinical BSE infectivity cannot reliably be detected by any method and may enter rendering, in particular if specified risk materials are not removed.

- Tissues most likely to contain high titres of BSE infectivity (brain, spinal cord, eyes) may not be harvested for human consumption and may be rendered.

- BSE may manifest in sudden death, chronic disease, or recumbency, and may be presented as fallen stock or materials condemned as unfit for human consumption.

- BSE agent survival in rendering is affected by the method of processing. Adequate rendering processes are described in Article 11.6.19.

- 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 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 11.6.29.

Conclusions of the risk assessment

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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1. See point 4) of Article 11.6.21.
2. See point 3) of Article 11.6.21.
3. See point 2) of Article 11.6.21.
4. See point 1) of Article 11.6.21.

— text deleted

Annex XXIII

CHAPTER 11.7.

BOVINE TUBERCULOSIS

Community comments

The Community cannot support the proposed changes. All the bovine tuberculosis surveillance and prophylaxis is based upon the notion of free herds, which cannot be deleted. Compartments are a notion far too new to directly replace herds. Moreover, it is a notion related to trade with specific approval and much too heavy to organise at a global level. And the current proposed article for bovine TB compartments lacks completely from any biosecurity measures, although the role of the herd environment and wildlife is not negligible. There should be a gradation between a free herd and a free compartment, this must be further studied.

Furthermore, the Community cannot accept the change in articles 11.7.2 point 3, nor the article 11.7.3 on compartments as proposed (see below in the text). This leads to a necessary adaptation of all following articles.

Lastly, the definition of Bovine tuberculosis (and this applies also for deer tuberculosis), should include the new M. caprae (formerly M. Bovis subspecies caprae). The Community suggests to refer to "any member of M. tuberculosis complex causing tuberculosis in bovines" or, as an alternative, to "Infection in cattle with any of the disease-causing mycobacterial species within the M. tuberculosis complex". This topic should be further addressed by the Scientific Commission.

Article 11.7.1.

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*).

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

Article 11.7.2.

Country or zone free from bovine tuberculosis

To qualify as free from bovine tuberculosis, a country or *zone* should satisfy the following requirements:

1. *M. bovis* infection in domestic (permanently captive and owned free-range) bovines including cattle, water buffalo and wood bison 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 bovine tuberculosis;

3. regular and periodic testing of ~~all~~ cattle, water buffalo, and wood bison *herds* ~~did not detect~~ demonstrated that *M. bovis* infection was not present 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 deletion of the word "all" is not acceptable. The surveillance of a disease like bovine TB cannot be performant on a random basis: it is not possible to certify that TB was absent from at least 99.8% of the herds if not all herds have been tested. Thus, all herds should be included, at least for the first years and until 3 consecutive years showed the required percentage of free herds.

4. a *surveillance* programme should be in place to detect bovine tuberculosis in the country or *zone* through ante-mortem and post-mortem inspection as described in Chapter 6.2.;

5. if the *surveillance* programme described in points 3 and 4 above has not detected infection with *M. bovis* for 5 consecutive years, *surveillance* may be maintained through ante-mortem and post-mortem inspection as described in Chapter 6.2.;

Community comment

The point 5 above could lead to misunderstanding, and should be written in the same way as point 3: "if the *surveillance* programme described in points 3 and 4 above demonstrated that *M. bovis* infection was not present in at least 99.8% of the *herds* and 99.9% of the animals in the country or *zone* for 5 consecutive years, *surveillance* may be maintained through ante-mortem and post-mortem inspection as described in Chapter 6.2"; alternatively, the first part could read: " if the *surveillance* programme described in points 3 and 4 above has been complied with for 5 consecutive years," etc.

6. cattle, water buffalo and wood bison introduced into a country or *zone* free from bovine tuberculosis should be accompanied by a certificate from an *Official Veterinarian* attesting that they come from a country or *zone* or ~~*herd*~~ *compartment* free from bovine tuberculosis or comply with the relevant provisions in Article 11.7.5. or in Article 11.7.6.

Community comment

The beginning of the third line of the paragraph above should read: "country, *zone* , *herd* or *compartment*".

Article 11.7.3.

Compartment free from bovine tuberculosis ~~(under study)~~

To qualify as a *compartment* free from bovine tuberculosis, ~~a *herd* or *herds* of~~ cattle, water buffalo or wood bison in a *compartment* should be certified by the *Veterinary Authority* as satisfying the following requirements:

Community comment

The word “all” should be included before the word “cattle”, both in the paragraph above and in point 1 below, as it should be clear that all animals (as listed above) in the compartment are included in the qualification regime.

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) met one of the following conditions:

i) showed a negative result to an annual tuberculin test to ensure the continuing absence of bovine tuberculosis; or

ii) 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

iii) 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~~iv) 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*~~ *compartment* 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.

Community comment

A paragraph 3 should be added:

3. cattle, water buffalo and wood bison of the compartment are managed under a common biosecurity plan protecting them from contamination with M. bovis, and the compartment has been approved by the *Veterinary Authority* in accordance with Chapter 4.4.

~~Article 11.7.4.~~

~~**Herd free from bovine tuberculosis**~~

~~To qualify as free from bovine tuberculosis, a *herd* of cattle, water buffalo, or wood bisons should satisfy the following requirements:~~

~~1. the *herd* is in a country or a *zone* free from bovine tuberculosis and is certified free by the *Veterinary Authority*, or~~

~~2. cattle, water buffalo and wood bison in the *herd*:~~

~~a) showed no signs 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 wood bison 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.~~

Community comment

This article should not be deleted.

Article 11.7.5.

Recommendations for the importation of cattle, water buffalo and wood bison for breeding or rearing

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no signs of bovine tuberculosis on the day of shipment;

2. originate from a ~~*herd*~~ *compartment* 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*~~ *compartment* free from bovine tuberculosis; or

Community comment

The points 2 and 3 do not make sense ("2. originate from a *compartment*… that is in a *compartment*"?) and there should be three points:

"2. originate from a *herd* free from bovine tuberculosis that is in a country or *zone* free from bovine tuberculosis; or

3. originate from a *compartment* free from bovine tuberculosis; or

4. 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 "

Point 4 would become point 5.

And in the new point 5 below, the word "and" should be added between "entry into the herd" and "were subjected".

4. have been isolated for at least 90 days prior to entry into the *herd* were subjected to at least two tuberculin tests carried out at a six-month interval with negative results with the second tuberculin test performed during the 30 days prior to entry into the herd.

Article 11.7.6.

Recommendations for the importation of cattle, water buffalo and wood bison for slaughter

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no signs of bovine tuberculosis on the day of shipment;

2. originated from a ~~*herd*~~ *compartment* free from bovine tuberculosis or were subjected to a tuberculin test for bovine tuberculosis with negative results during the 30 days prior to shipment;

Community comment

The point 2 above should read: "*herd* or *compartment*".

Animals for slaughter may come from a free herd, which is distinct from a free compartment as far as biosecurity measures are concerned. The test is required in case the status of the herd is not free.

3. were not being eliminated as part of an eradication programme against bovine tuberculosis.

Article 11.7.7.

Recommendations for the importation of semen of cattle, water buffalo and wood bison

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:

   a) showed no 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 a free ~~*herds*~~ *compartment* ~~in a free country, *zone* or *compartment*~~; or

Community comment

To be applicable and conform to reality, the point b) above should read: "from free *herds* in a free country or *zone*, or from a free *compartment*".

   c) showed negative results to tuberculin tests carried out annually and were kept in a ~~*herd*~~ *compartment* free from bovine tuberculosis;

2. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5.

Article 11.7.8.

Recommendations for the importation of embryos/ ova of cattle, water buffalo and wood bison

Veterinary Authorities of *importing countries* should require 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 signs of bovine tuberculosis during the 24 hours prior to embryo collection;

b) originated from a ~~*herd*~~ *compartment* free from bovine tuberculosis in a country, *zone* or *compartment* free from bovine tuberculosis; or

Community comment

The point b) above does not make sense ("from a *compartment*… in a *compartment*"?). And what the use of having a compartment if it is to originate from a free zone or to make tests? It should read: "from a herd free from bovine tuberculosis in a country or *zone* free from bovine tuberculosis, or from a free *compartment*".

c) were kept in a ~~*herd*~~ *compartment* 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 collection;

Community comment

The point c) above does not make sense: why should there be an additionnal test on a animal originating in a free compartment? The animals originating from a free compartment are covered by the point b); the word "herd" should be kept here.

2. the embryos/ova were collected, processed and stored in conformity with the provisions of Chapter 4.7., Chapter 4.8. or Chapter 4.9., as relevant.

Article 11.7.9.

Recommendations for the importation of fresh meat and meat products of cattle, water buffalo, and wood bison

Veterinary Authorities of *importing countries* should require 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 Chapter 6.2.

Article 11.7.10.

Recommendations for the importation of milk and milk products of cattle, water buffalo and wood bison

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the consignment:

1. has been derived from animals in a ~~*herd*~~ *compartment* free from bovine tuberculosis; or

Community comment

There also it should read "herd or compartment". The risk is not that high as to forbid the trade of raw milk from a free herd, and the approval of all free herds as free compartments is a total lack of common sens.

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.

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— text deleted

CHAPTER X.X.

BOVINE TUBERCULOSIS OF FARMED CERVIDAE

Community comments

Although it supports the split of bovine TB into 2 chapters the Community cannot support the proposed draft chapter as its the same as the Bovine TB Chapter which the Community does not support, unless its comments are taken into account. The same general comments apply here as noted in the previous Chapter, as well as all specific comments in the articles. The Community recommends that this Chapter is further reviewed before being proposed for adoption.

The bovine status should not be affected by the disease in Cervidae. This should be reflected in the text.

The definition of Bovine tuberculosis in farmed cervidae should include the new M. caprae (formerly M. Bovis subspecies caprae). The Community suggests to refer to "any member of M. tuberculosis complex causing tuberculosis in farmed cervidae " or, as an alternative, to "Infection in farmed cervidae with any of the disease-causing mycobacterial species within the M. tuberculosis complex". This topic should be addressed by the Scientific Commission.

Article 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) farmed cervidae (red deer, wapiti, sika, samba, rusa, fallow deer, white-tailed, black-tailed and mule deer [*Cervus elephus*, *C. canadensis*, *C. nippon*, *C. unicolor unicolor*, *C. timorensis*, *Dama dama dama*, *Odocoileus virginianus borealis*, *Odocoileus hemionus columbianus* and *Odocoileus hemionus hemionus*]). The Chapter does not address the management of tuberculosis in wild cervid populations.

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

Article 2.

Country or zone free from bovine tuberculosis of farmed cervidae

To qualify as free from bovine tuberculosis of farmed cervidae, a country or *zone* should satisfy the following requirements:

1. *M. bovis infection* in domestic bovines and in farmed cervidae as specified in Article 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 tuberculosis;

3. regular and periodic testing of *herds* of farmed cervidae has demonstrated that *M. bovis infection* was not present in at least 99.8% of the *herds* and 99.9% of the farmed cervidae in the country or *zone* for 3

consecutive years;

4. a *surveillance* programme should be in place to detect bovine tuberculosis in the country or *zone* through ante-mortem and post-mortem inspection as described in Chapter 6.2.;

5. if the *surveillance* programme described in points 3 and 4 above has not detected *infection* with *M. bovis* in farmed cervidae for 5 consecutive years, *surveillance* may be maintained through ante-mortem and post-mortem inspection as described in Chapter 6.2.;

6. farmed cervidae introduced into a country or *zone* 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* free from bovine tuberculosis or comply with the relevant provisions in Article 4.

Article 3.

Compartment free from bovine tuberculosis of farmed cervidae

To qualify as a *compartment* free from bovine tuberculosis of farmed cervidae, the *Veterinary Authority* should be able to certify that the following requirements are satisfied:

1. all farmed cervidae:

   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) met one of the following conditions:

      i) showed a negative result to an annual tuberculin test to ensure the continuing absence of bovine tuberculosis; or

      ii) 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

      iii) 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

      v) 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. farmed cervidae introduced into the *compartment* come from a *compartment* 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 4.

Recommendations for the importation of farmed cervidae for breeding or rearing

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no signs of bovine tuberculosis on the day of shipment;

2. originate from a *compartment* free from bovine tuberculosis of farmed cervidae that is in a country, *zone* or *compartment* free from bovine tuberculosis of farmed cervidae; 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 *compartment* free from bovine tuberculosis of farmed cervidae; or

4. have been isolated for at least 90 days prior to entry into the *herd* were subjected to at least two tuberculin tests carried out at a six-month interval with negative results with the second tuberculin test performed during the 30 days prior to entry into the *herd*.

Article 5.

Recommendations for the importation of farmed cervidae for slaughter

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no signs of bovine tuberculosis on the day of shipment;

2. originated from a *compartment* free from bovine tuberculosis of farmed cervidae or were subjected to a tuberculin test for bovine tuberculosis with negative results during the 30 days prior to shipment;

3. were not being eliminated as part of an eradication programme against bovine tuberculosis.

Article 6.

Recommendations for the importation of semen of farmed cervidae

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:

    a) showed no 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 any species, in a country, *zone* or *compartment* free from bovine tuberculosis of farmed cervidae, and which only accepts animals from a free *compartment*; or

    c) showed negative results to tuberculin tests carried out annually and were kept in a *compartment* free from bovine tuberculosis of farmed cervidae;

2. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5.

Article 7.

Recommendations for the importation of embryos/ ova of farmed cervidae

Veterinary Authorities of *importing countries* should require 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 signs of bovine tuberculosis during the 24 hours prior to embryo collection;

b) originated from a *compartment* free from bovine tuberculosis of farmed cervidae in a country, *zone* or *compartment* free from bovine tuberculosis; or

c) were kept in a *compartment* free from bovine tuberculosis of farmed cervidae, 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 collection;

2. the embryos/ova were collected, processed and stored in conformity with the provisions of Chapter 4.7., Chapter 4.8. or Chapter 4.9., as relevant.

Article 8.

Recommendations for the importation of fresh meat and meat products of farmed cervidae

Veterinary Authorities of *importing countries* should require 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 Chapter 6.2.

Annex XXIV

CHAPTER 11.8.

CONTAGIOUS BOVINE PLEUROPNEUMONIA

Community comments

The Community can support the proposed draft chapter.

Article 11.8.1.

General provisions

For the purposes of the *Terrestrial Code*, the *incubation period* for contagious bovine pleuropneumonia (CBPP) shall be 6 months.

For the purpose of this chapter, a *case* of CBPP means an animal infected with *Mycoplasma mycoides* subsp. *mycoides* SC (*Mmm*SC), and freedom from CBPP means freedom from *Mmm*SC infection.

For the purpose of this chapter, susceptible animals include domestic cattle (*Bos indicus* and *B. taurus*) and water buffalo (*Bubalus bubalis*).

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

The following defines the occurrence of *Mmm*SC infection:

1. *Mmm*SC has been isolated and identified as such from an animal, embryos, oocytes or semen; or

2. antibodies to *Mmm*SC antigens which are not the consequence of vaccination, or *Mmm*SC DNA, have been identified in one or more animals showing pathological lesions consistent with infection with *Mmm*SC with or without clinical signs, and epidemiological links to a confirmed *outbreak* of CBPP in susceptible animals.

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

Article 11.8.1.bis

Trade in commodities

When authorising import or transit of live ruminants, *Veterinary Authorities* should comply with recommendations of this Chapter as relevant to the CBPP status of the exporting country, *zone* or *compartment*.

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any CBPP related conditions, regardless of the CBPP risk status of the bovine population of the *exporting country* or *zone*:

1. *milk* and *milk products*;

[2. semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendation of the International Embryo Transfer Society;

3. hides and skins;

4. *meat* and *meat products*].

Article 11.8.2.

CBPP free country, zone or compartment

To qualify for inclusion in the existing list of CBPP free countries, a Member 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 CBPP during the past 24 months;

   b) no evidence of CBPP infection has been found during the past 24 months;

   c) no vaccination against CBPP has been carried out during the past 24 months,

   and supply documented evidence that surveillance for CBPP in accordance with this Chapter is in operation and that regulatory measures for the prevention and control of CBPP have been implemented;

3. not have imported since the cessation of vaccination any animals vaccinated against CBPP.

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 2a), 2b), 2c) and 3 above be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

Article 11.8.3.

Recovery of free status

When a CBPP *outbreak* occurs in a CBPP free country, *zone* or *compartment*, one of the following waiting periods is required to regain the status of CBPP free country, *zone* or *compartment*:

1. 12 months after the last *case* where a *stamping-out policy* and serological surveillance and strict movement control are applied in accordance with this Chapter;

2. if vaccination was used, 12 months after the slaughter of the last vaccinated animal.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply but Article 11.8.2. applies.

Article 11.8.4.

Infected country

When the requirements for acceptance as a CBPP free country, *zone* or *compartment* are not fulfilled, a country shall be considered as CBPP infected.

~~Article 11.8.5.~~

~~*Veterinary Authorities* of CBPP free countries, *zones* or *compartments* may prohibit importation or transit through their territory of domestic cattle and water buffalo, from countries and *zones* considered infected with CBPP.~~

Article 11.8.6.

Recommendations for importation from CBPP free countries, zones or compartments

for domestic cattle and water buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals showed no clinical sign of CBPP on the day of shipment.

Article 11.8.7.

Recommendations for importation from CBPP infected countries or zones

for domestic cattle and water buffaloes for slaughter

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

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

2. originate from an establishment where no *case* of CBPP was officially reported for the past 6 months, and

3. are transported directly to the *slaughterhouse* in sealed *vehicles*.

Article 11.8.8.

Surveillance: Introduction

The Articles 11.8.9. to 11.8.13. define the principles and provides a guide for the surveillance of contagious bovine pleuropneumonia (CBPP) in accordance with Chapter 1.4. applicable to Members seeking ~~recognition from the OIE for~~ establishment of freedom from CBPP. ~~This may be for the entire country, *zone* or *compartment* within the country.~~ Guidance is provided for Members seeking reestablishment of freedom from CBPP for the ~~whole~~ entire country~~,~~ or for a *zone* or *compartment* ~~within the country,~~ following an *outbreak*~~, as well as guidelines~~ and for the maintenance of CBPP free status ~~are provided. These guidelines are intended to expand on and explain the requirements of this Chapter.~~ Applications to the OIE for recognition of freedom should follow the format and answer all the questions posed by the "Questionnaire on CBPP" available from the OIE *Central Bureau*.

The impact and epidemiology of CBPP 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 s~~Surveillance strategies employed for demonstrating freedom from CBPP at an acceptable level of confidence will need to be adapted to the local situation. It is incumbent upon the applicant Member to submit a dossier to the OIE in support of its application that not only explains the epidemiology of CBPP 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 OIE Members to provide a well-reasoned argument to prove that the absence of CBPP infection is assured at an acceptable level of confidence.

Surveillance for CBPP should be in the form of a continuing programme designed to establish that the whole territory or part of it is free from CBPP infection.

Annex XXIV (contd)

Article 11.8.9.

Surveillance: general conditions and methods

1. A surveillance system in accordance with Chapter 1.4. 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 CBPP to a laboratory for CBPP diagnoses as described in the *Terrestrial Manual.*

2. The CBPP surveillance programme should:

   a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers (such as community animal health workers) who have day-to-day contact with livestock, meat inspectors as well as laboratory diagnosticians, should report promptly any suspicion of CBPP. They should be integrated directly or indirectly (e.g. through private veterinarians or *veterinary para-professionals)* into the surveillance system. All suspect cases of CBPP should be investigated immediately. Where suspicion cannot be resolved by epidemiological and clinical investigation, samples should be taken and submitted to an *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 CBPP diagnosis and control;

   b) implement, when relevant, regular and frequent clinical inspection and testing of high-risk groups of animals, such as those adjacent to a CBPP infected country or *zone* (for example, areas of transhumant production systems);

   c) take into consideration additional factors such as animal movement, different production systems, geographical and socio-economic factors that may influence the risk of disease occurrence.

   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 CBPP. 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 CBPP infection should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of laboratory testing and the control measures to which the animals concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 11.8.10.

Surveillance strategies

1. Introduction

   The target population for surveillance aimed at identifying *disease* and *infection* should cover all the susceptible species (*Bos taurus*, *B. indicus* and *Bubalus bubalis*) within the country, *zone* or *compartment* ~~to be recognised as free from CBPP infection~~.

   Given the limitations of the diagnostic tools available, the interpretation of surveillance results should be at the herd level rather than at the individual animal level.

Randomised surveillance may not be the preferred approach given the epidemiology of the disease (usually uneven distribution and potential for occult foci of infection in small populations) and the limited sensitivity and specificity of currently available tests. Targeted surveillance (e.g. based on the increased likelihood of *infection* in particular localities or species, focusing on slaughter findings, and active clinical surveillance) may be the most appropriate strategy. The applicant Member should justify the surveillance strategy chosen as adequate to detect the presence of CBPP infection in accordance with Chapter 1.4. and the epidemiological situation.

Targeted surveillance may involve testing of the entire target subpopulation or a sample from it. In the latter case 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 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 Member must justify the choice of design prevalence and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Chapter 1.4. 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.

Irrespective of the surveillance system employed, the 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 follow-up with supplementary tests, clinical investigation and post-mortem examination in the original sampling unit as well as herds which may be epidemiologically linked to it.

2. Clinical surveillance

Clinical surveillance aims at detecting clinical signs of CBPP in a herd by close physical examination of susceptible animals. Clinical inspection will be an important component of CBPP surveillance contributing to reach the desired 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 CBPP suspects detected by either of these complementary diagnostic approaches. Laboratory testing and post-mortem examination may contribute to 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.

3. Pathological surveillance

Systematic pathological surveillance for CBPP is the most effective approach and should be conducted at *slaughterhouses* and other slaughter facilities. Suspect pathological findings should be confirmed by agent identification. Training courses for slaughter personnel and meat inspectors are recommended.

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4. Serological testing

Serological surveillance is not the preferred strategy for CBPP. However, in the framework of epidemiologic investigations, serological testing may be used.

The limitations of available serological tests for CBPP will make the interpretation of results difficult and useful only at the herd level. Positive findings should be followed-up by clinical and pathological investigations and agent identification.

Clustering of seropositive reactions should be expected in CBPP infections and will be usually accompanied by clinical signs. As clustering may signal field strain infection, the investigation of all instances must be incorporated in the surveillance strategy.

Following the identification of a CBPP infected herd, contact herds need to be tested serologically. Repeated testing may be necessary to reach an acceptable level of confidence in herd classification.

5. Agent surveillance

Agent surveillance using tests described in the *Terrestrial Manual* should be conducted to follow-up and confirm or exclude suspect cases. Isolates should be typed to confirm *Mmm*SC.

Article 11.8.11.

Countries or zones applying for recognition of freedom from CBPP

In addition to the general conditions described in this Chapter, an OIE Member applying for recognition of CBPP freedom for the 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 will be planned and implemented according to general conditions and methods in this Chapter, to demonstrate absence of CBPP infection, during the preceding 24 months in susceptible populations. This requires the support of a national or other laboratory able to undertake identification of CBPP infection using methods described in the *Terrestrial Manual*.

Article 11.8.12.

Compartments seeking recognition of freedom from CBPP

The bilateral recognition of CBPP free *compartments* should follow the principles laid in this Chapter, Chapter 4.3. and Chapter 4.4.

Article 11.8.13.

Countries or zones re-applying for recognition of freedom from CBPP following an outbreak

In addition to the general conditions described in this Chapter, a Member re-applying for recognition of country or *zone* freedom from CBPP should show evidence of an active surveillance programme for CBPP, following the recommendations of this Chapter.

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

1. slaughter of all clinically affected and in-contact susceptible animals;

2. vaccination used without subsequent slaughter of vaccinated animals.

The time periods before which an application can be made for re-instatement of freedom from CBPP depends on which of these alternatives is followed. The time periods are prescribed in Article 11.8.3.

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Annex XXV

CHAPTER 12.1.

AFRICAN HORSE SICKNESS

Community comments

The Community can support the proposed changes.

Article 12.1.1.

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 Chapter 1.4.

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

Article 12.1.2.

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 and their semen and oocytes or embryos are carried out in accordance with this Chapter, and either:

   a) historical freedom as described in Chapter 1.4. 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 and includes a complete season of vector activity; 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 and their semen, oocytes or embryos from infected countries or infected zones, provided these imports are carried out in accordance with this Chapter.

Article 12.1.3.

AHSV seasonally free zone

1. An AHSV seasonally free zone is a part of an infected country or an infected zone ~~for~~ in which for part of a year, ongoing surveillance and *monitoring* consistently demonstrated ~~no~~ neither evidence of

AHSV transmission ~~and~~ nor the evidence of the presence of adult Culicoides likely to be competent AHSV vectors.

2. For the application of Articles 12.1.6., 12.1.8. and 12.1.9., 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 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 and their semen, oocytes or embryos from infected countries or infected zones, provided these imports are carried out in accordance with this Chapter.

Article 12.1.4.

AHSV infected country or zone

An AHSV infected country or infected zone is one in which the conditions of Article 12.1.2. or Article 12.1.3. do not apply.

Article 12.1.5.

Recommendations for importation from AHSV free countries that are neither neighbouring nor considered to be at risk from an AHSV infected country or infected zone

for equidae

Veterinary Authorities should require 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 attacks by Culicoides at all times when transiting through an infected country or infected zone.

Article 12.1.6.

Recommendations for importation 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

for equidae

Veterinary Authorities should require 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 attacks by Culicoides; 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 antibodies against AHSV 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 attacks by Culicoides at all times during transportation (including to and at the place of shipment).

Article 12.1.7.

Recommendations for importation from AHSV infected countries or zones

for equidae

Veterinary Authorities should require 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 attacks by Culicoides; 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 antibodies against AHSV 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. protected from attacks by Culicoides at all times during transportation (including during transportation to and at the place of shipment).

Article 12.1.8.

Recommendations for the importation of equid semen

Veterinary Authorities of *importing countries* should require 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~~ immunised against AHS with a live attenuated vaccine within 40 days prior to the day of collection;

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 12.1.9.

Recommendations for the importation of in vivo derived equid embryos/ oocytes

Veterinary Authorities of *importing countries* should require 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 embryos/oocytes and for the following 40 days;

   b) had not been ~~vaccinated~~ immunised against AHS with a live attenuated vaccine within 40 days prior to the day of collection;

   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 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 embryos/oocytes collection for this consignment;

2. the embryos were collected, processed and stored in conformity with the provisions of Chapter 4.7.;

3. semen used to fertilize the oocytes, complies at least with the requirements in Article 12.1.8.

Article 12.1.10.

Protecting animals from Culicoides attack

When transporting equines through AHSV infected countries or AHSV infected zones, *Veterinary Authorities* should require strategies to protect animals from attacks by Culicoides 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 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.

Article 12.1.11.

Surveillance: introduction

Articles 12.1.11. to 12.1.13. define the principles and provides a guide on the surveillance for AHS, complementary to Chapter 1.4., applicable to Members seeking to determine their AHSV status. This may be for the entire country or zone. Guidance for Members 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.

According to this Chapter, a Member 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 Chapter. 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.

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.

Article 12.1.12.

Surveillance: general conditions and methods

1. A surveillance system should be under the responsibility of the Veterinary Authority. In particular the following should be in place:

   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 a 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 Chapter 1.4.

Annex XXV (contd)

Article 12.1.13.

Surveillance strategies

The target population for surveillance aimed at identification of disease and/or infection should cover susceptible 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 Member should justify the surveillance strategy chosen as appropriate to detect the presence of AHSV infection in accordance with Chapter 1.4. 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 Member must justify the choice of design prevalence and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Chapter 1.4. 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 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 recommendations 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*~~ *protection 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 that are not vaccinated and are managed at fixed locations and observed and sampled regularly to detect new AHSV infections.

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.

— text deleted

CHAPTER 12.7.

EQUINE INFLUENZA

Community comments

The Community can support the proposed changes.

Article 12.7.1.

General provisions

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 12.7.1.bis

Recommendations on safe commodities

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 Chapter 4.7. (under study).

Article 12.7.2.

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.

Annex XXV (contd)

Article 12.7.3.

Equine influenza free country, zone or compartment

A country or a *zone* or a *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 Chapter 1.4. 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, a *zone* or a *compartment* seeking freedom from EI, in which vaccination is practised, should also demonstrate that EIV has not been circulating in the population of domestic ~~horse~~ equidae ~~population~~ during the past 12 months, through *surveillance*, in accordance with Chapter 1.4. 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.

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 in accordance with Chapter 1.4.

~~Article 12.7.4.~~

~~**Recommendations on safe commodities**~~

~~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 Chapter 4.7. (under study).~~

Article 12.7.5.

Recommendations for the importation of horses for immediate slaughter

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 12.7.6.

Recommendations for the importation of 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 according to the manufacturer's instructions with a vaccine complying with the standards described in the *Terrestrial Manual* beween 21 and 90 days before shipment either with a primary course or a booster.

Article 12.7.7.

Recommendations for the importation of horses which will be kept in isolation (see Article 12.7.1.)

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 according to the manufacturer's instructions with a vaccine complying with the standards described in the *Terrestrial Manual*.

Article 12.7.8.

Recommendations for the importation of 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 Chapter 6.2.

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— text deleted

CHAPTER 12.9.

EQUINE RHINOPNEUMONITIS

Community comments

The Community can support the proposed changes, but has a comment on the proposed Article 1.

Article 12.9.1.

General provisions

Equine rhinopneumonitis (ER) is a collective term for any one of several highly contagious, clinical disease entities of equids that may occur as a result of *infection* by either of two closely related herpesviruses, equid herpesvirus-1 and -4 (EHV-1 and EHV-4).

Infection by either EHV-1 or EHV-4 is characterised by a primary respiratory tract *disease* of varying severity that is related to the age and immunological status of the infected animal. *Infections* by EHV-1 in particular are capable of progression beyond the respiratory mucosa to cause the more serious disease manifestations of abortion, perinatal foal death, or neurological dysfunction.

Community comment

The word "usually" should be added between "*Infection* by either EHV-1 or EHV-4 is" and "characterised by a primary respiratory tract *disease*".

EHV associated abortion and neurological disease are not always preceded by primary respiratory diseases. It is important that this is clarified to prevent EHV being disregarded as a cause of abortion or neurological disease due to lack of history of preceding respiratory disease. Numerous peer-reviewed scientific papers are available which support the proposed change.

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

Article 12.9.2.

Recommendations for the importation of equines

Veterinary Authorities of *importing countries* should require 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.

CHAPTER 12.10.

EQUINE VIRAL ARTERITIS

Community comments

The Community congratulate the TAHSC for the proposed changes as the chapter is now much more consistent and applicable.

However, some changes must still be made to the text to be fully in line with the reality of the disease and its control related to trade. These changes are given in the appropriate Articles below.

Article 12.10.1.

General provisions

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 12.10.2.

Recommendations for the importation of uncastrated male equines

Veterinary Authorities of *importing countries* should require 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 and met one of the following requirements;

~~2~~1. were isolated for the 28 days prior to shipment and were 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~~ 21 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

The Community specifically supports the deletion of this paragraph that appeared to allow introduction of possible virus shedders.

~~3~~2. were ~~isolated for the 28 days prior to shipment and were~~ subjected between 6 and 9 months of age to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out on two blood samples collected at least 14 days apart with stable or decreasing titre, immediately vaccinated for EVA and regularly revaccinated according to the manufacturer's instructions; or

43. ~~were isolated for the 28 days prior to shipment and 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~~ met the following requirements:

a) were isolated for the 28 days prior to shipment; and

b) were tested, with negative results, with a test for EVA as prescribed in the *Terrestrial Manual;* and

Community comment

The Community reiterates its comment that the isolation has nothing to do with the shipment but with the vaccination procedure. What is needed is a valid vaccination carried out on a seronegative and/or semen negative stallion of any age kept in isolation during primary vaccination. Thus, the words "prior to shipment" in point a) should be deleted and the words "not earlier than 7 days of commencing isolation" should be added at the beginning of point b)

Point a) and b) should then read:

a) were isolated for at least 28 days ; and

b) not earlier than 7 days of commencing isolation were tested, with negative results, with a test for EVA as prescribed in the *Terrestrial Manual*; and

c) were then immediately vaccinated; and

d) were kept separated from other equidae to 21 days following vaccinaton; and

e) were revaccinated regularly according to the manufacturer's instructions; or

54. 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

The *Terrestrial Manual* does not attribute a particular preference to either test mating or laboratory test for virus isolation, for this reason both methods of semen testing should be considered equivalent to demonstrate absence of virus in the semen of a seropositive animal, and point a) and b) above should not differ regarding the period of the tests.

Furthermore, as the origin of the seropositivity cannot be ascertained in all cases, and therefore vaccination cannot be ruled out, and following changes made by manufacturers to the technical specification of their vaccines, it is advisable to limit the period of protective immunity derived from possible vaccination to 6 months.

Thus in point a) above the words "12 months" should be replaced by "6 months", and in point b) the words "28 days" should be replaced by "6 months".

Article 12.10.3.

Recommendations for the importation of equines other than uncastrated males

Veterinary Authorities of *importing countries* should require 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 were 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 were subjected, between 6 and 9 months of age, to a diagnostic test for EVA, as prescribed in the *Terrestrial Manual*, carried out on two 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

In case of equidae other than uncastrated males, the risk of carriers state is negligible. To prevent acute clinical disease accompanied by virus shedding through secretions and excretions, it is sufficient to guaranty either isolation of seronegative animals form possible infection or to have the animals protected by immunity whether after infection or after vaccination. If import conditions were nevertheless to be formulated they should take account of the infective period and in case of seropositive animals the humoral protection that allows to prove absence of acute infection without pre-export isolation on an establishment free of clinical disease.

These conditions should be then read:

***Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the animals showed no clinical sign of EVA on the day of shipment and**

1. either were kept in an *establishment* where no animals have shown any signs of EVA for the 28 days prior to shipment; and

a) either the animals were subjected to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out 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

b) were vaccinated and revaccinated regularly according to the manufacturer's instructions;

OR

2. were isolated for the 28 days prior to shipment and during this period of isolation no animals have shown any signs of EVA and the animals were 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 results

Article 12.10.4.

Recommendations for the importation of semen

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the animal donors:

Community comment

The conditions for a virus free stallion as laid down in Article 12.10.2. must be reflected in this paragraph, see below proposal for point 4.

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

Community comment

To reflect Article 12.10.2, the point 4 should read:

4. were prior to first vaccination isolated for at least 28 days ; and not earlier than 7 days of commencing isolation 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 until the end of semen collection; or

Community comment

The Community suggests to add the following to point 5 above:

- the word "physically" before "separated from other equidae" and

- the words "not of an equivalent EVA status" after.

Indeed it is assumed that the accommodation of more than one donor stallion and where necessary of a teaser mare is allowed on a semen collection centre.

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

This point must be aligned to Article 12.10.2: "12 months" and "28 days" respectively in points a) and b) should be replaced by "6 months".

7. were, for frozen semen, subjected with negative results either;

a) 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 semen collected immediately prior to processing.

Community comment

The Community welcomes the inclusion of post-collection testing and suggests:

- in line with the comment to article 12.10.2, to replace "12 months" by "6 months";

- to add the following at the end of point b): "of that semen, or on an aliquot of semen collected within 14 to 30 days after the collection of the semen to be exported", in order to add possibility to use an aliquot of semen that was collected shortly after the export semen was collected as a reference basis for certifying absence of virus in the semen intended for export.

Annex XXVI

CHAPTER 14.9.

SCRAPIE

Community comments

The Community opposes the adoption of this Chapter 14.9 in its present form and regrets that the discussion on the review of the Scrapie Chapter has been stopped.

The Community opposes to the recognition of historical freedom without any requirements related to surveillance. It is suggested that a basis for the minimum level of active surveillance necessary to detect a low prevalence of disease, particularly in large sheep populations, should be laid down. The Chapter on Animal Health Surveillance also states that historical freedom is related to some kind of surveillance.

In addition reference is made to small ruminants or to sheep and goats.The community proposes, in order to be consistent, to refer to sheep and goats all through the text, as indicated under.

Moreover, the Community rejects the simple exchange of herds or establishments by compartments. As in the Chapter on TB, scrapie surveillance and prophylaxis is based upon the notion of free herds, which cannot be deleted. Compartment as defined in the Glossary and described in the chapter 4.3 is a notion far too new to directly replace herds. Moreover, it is a notion related to trade with specific approval and much too heavy to organise at a global level. There should be a gradation between a free herd and a free compartment, and acceptance that compartments are not needed in every chapters like a copy-and-paste of herds. If not, that would surely jeopardize the whole concept of compartmentalisation.

Article 14.9.1.

General provisions

Scrapie is a neurodegenerative *disease* of sheep and goats. The main mode of transmission is from mother to offspring immediately after birth and to other susceptible neonates exposed to the birth fluids and tissues of an infected animal. Transmission occurs at a much lower frequency to adults exposed to the birth fluids and tissues of an infected animal. A variation in genetic susceptibility of sheep has been recognised. The *incubation period* of the *disease* is variable; however, it is usually measured in years. The duration in *incubation period* can be influenced by a number of factors including host genetics and strain of agent.

~~The recommendations in the present Chapter are not intended, or sufficient, to manage the *risks* associated with the potential presence of the bovine spongiform encephalopathy agent in small ruminants.~~

Scrapie is not considered to pose a risk to human health. The recommendations in this Chapter are intended to manage the animal health risks associated with the presence of the scrapie agent in sheep and goats. The Chapter does not cover so-called 'atypical' scrapie which is clinically, pathologically, biochemically and epidemiologically unrelated to 'classical' scrapie, may not be contagious and may, in fact, be a spontaneous degenerative condition of older sheep.

Community comment to be discussed at Council level: Since the paragraph clearly indicates that the recommendations are intended to manage the animal health risks

associated with the presence of the scrapie agent in sheep and goats, the statement related to human health (the first sentence of the paragraph above) should be deleted, as not relevant. If yes, question on milk for human consumption as a "safe commodity".

1. When authorising import or transit of the following *commodities* and any products made from these *commodities* and containing no other tissues from small ruminants, *Veterinary Authorities* should not require any scrapie-related conditions, regardless of the scrapie risk status of the small ruminant populations of the *exporting country, zone* or *compartment*:

   a) *meat* (excluding materials as referred to in Article 14.9.11.);

   b) semen;

Community comment

The Community reserves its position on the inclusion of semen and in vivo derived embryos to the list of products which do not require any scrapie-related measures. This should at least be put "under study".

   c) hides and skins;

   d) gelatine;

   e) collagen prepared from hides or skins;

   f) tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;

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

   h) wool or fibre.

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 scrapie risk status of the small ruminant populations of the *exporting country, zone* or *compartment*.

Community comment

In point 1 and 2 the words "small ruminant" should be replaced by "sheep and goat" to be consistent with the article 1.

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

Article 14.9.2.

The scrapie status of the sheep and goat populations of a country, a *zone* or ~~an~~ ~~*establishment*~~ *compartment* ~~can~~ should be determined on the basis of the following criteria:

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

   ~~a) epidemiological situation concerning all animal transmissible spongiform encephalopathies (TSE) in the country, *zone* or *establishment*;~~

   ~~b~~a) importation or introduction of ~~small ruminants~~ sheep and goats or their embryos/oocytes potentially infected with scrapie;

   ~~c~~b) extent of knowledge of the population structure and husbandry practices of sheep and goats in

the country ~~or~~, *zone* or *compartment*;

~~d~~c) feeding practices, including consumption of *meat-and-bone meal* or *greaves* derived from ruminants;

Community comment

This point should include milk and milk products for feed, to reflect article 9 bis, see detailed Community comments at this new article.

~~e) importation of *meat and bone meal* or *greaves* potentially contaminated with an animal TSE or feedstuffs containing either;~~

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

2. an on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and *slaughter* of sheep and goats to facilitate recognition and encourage reporting of all animals with clinical signs compatible with scrapie;

3. a *surveillance* and monitoring system including the following:

   a) official veterinary *surveillance*, reporting and regulatory control in accordance with the provisions of Chapter 1.4.;

   b) a *Veterinary Authority* with current knowledge of, and authority over, all *establishments* which contain sheep and goats in the whole country;

   c) compulsory notification and clinical investigation of ~~all~~ sheep and goats showing clinical signs compatible with scrapie;

   d) examination, in accordance with the *Terrestrial Manual*, in an ~~approved~~ *laboratory* of appropriate material from sheep and goats older than 18 months displaying clinical signs compatible with scrapie ~~taking into account the recommendations in Chapter X.X. (under study)~~;

   e) maintenance of records including the number and results of all investigations for at least 7 years.

Article 14.9.3.

Scrapie free country or zone

Countries or *zones* may be considered free from scrapie if within the said territory:

1. a *risk assessment*, as described in point 1 of Article 14.9.2., has been conducted, and it has been demonstrated that appropriate measures have been taken for the relevant period of time to manage any *risk* identified;

AND ~~EITHER~~

2. one of the following conditions should be met:

   a) the country or the *zone* have demonstrated historical freedom taking into account the recommendations in Articles 14.9.13. and 14.9.14.;or,

Community comment

Article 14.9.3 point 2 above allows for a country or zone to be considered scrapie free on the basis of a favourable risk assessment and demonstration of historical freedom.

While historical freedom should be one factor in the determination of scrapie freedom for a country or zone, if it is to be used to determine status in this way then the appendix should define a minimum level of targeted active surveillance using rapid tests. Experience in the Community has shown that scrapie infection can escape detection despite compulsory notification and a low level of active surveillance for many years, but be quickly uncovered by more extensive active surveillance. This comment applies to Articles 14.9.13. and 14.9.14, which should be modified.

In addition, the Community has approved the use of rapid tests for the monitoring of TSEs in sheep. Addition of these tests to the manual of standards for the diagnosis of scrapie would open up the possibility of testing larger and more significant sample sizes.

~~OR~~

~~3. for at least 7 years, a *surveillance* and monitoring system as referred to in Article 14.9.2. has been in place, and no *case* of scrapie has been reported during this period;~~

~~OR~~

~~4.~~b) for at least 7 years, a sufficient number of investigations has been carried out annually, to provide a 95% level of confidence of detecting scrapie if it is present at a prevalence rate exceeding 0.1% out of the total number of all chronic wasting conditions in the population of sheep and goats older than 18 months of age ~~(under study)~~ and no *case* of scrapie has been reported during this period; it is assumed that the occurrence rate of chronic wasting conditions within the population of sheep and goats older than 18 months of age is at least 1%; or,

Community comment

Under points 2(a) and 2(c) there are requirements for scrapie to be compulsorily notifiable. It is suggested to add this requirement under this point as well.

It should also be included a reference to article 13 and 14, as in point a).

~~OR~~

~~5.~~c) all ~~*establishments*~~ *compartments* containing sheep or goats have been accredited free as described in Article 14.9.4.;

Community comment

Same comment as for BV TB: herd should not be systematically replaced by compartments.

AND

~~6~~3. the feeding to sheep and goats of *meat-and-bone meal* or *greaves* ~~potentially contaminated with an animal TSE~~ of ruminant origin has been banned and effectively enforced in the whole country for at least 7 years;

AND

~~7~~4. introductions of sheep and goats, ~~semen and~~ embryos/oocytes from countries or *zones* not free from scrapie are carried out in accordance with Articles 14.9.6., 14.9.7., 14.9.8. or 14.9.9., as relevant.

~~For maintenance of country or *zone* free status, the investigations referred to in point 4 above should be repeated every 7 years.~~

Article 14.9.4.

Scrapie free ~~establishment~~ compartment

Community comment

Same comment as for BV TB: herd should not be systematically replaced by compartments.

An *establishment* may be considered eligible for accreditation as a scrapie free ~~*establishment*~~ *compartment* if:

1. in the country or *zone* where the *establishment* is situated, the following conditions are fulfilled:

   a) the *disease* is compulsorily notifiable;

   b) a *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;

   c) affected sheep and goats are slaughtered and completely destroyed;

   d) the feeding to sheep and goats of *meat-and-bone meal* or *greaves* of ruminant origin ~~potentially contaminated with an animal TSE~~ has been banned and effectively enforced in the whole country;

   e) an official accreditation scheme is in operation under the supervision of the *Veterinary Authority*, including the measures described in point 2 below;

2. in the *establishment* the following conditions have been complied with for at least 7 years:

   a) sheep and goats should be permanently identified and records maintained, to enable trace back to their *establishment* of birth;

   b) records of movements of sheep and goats in and out of the *establishment* are ~~established and~~ maintained;

   c) introductions of ~~animals~~ sheep and goats are allowed only from ~~*establishments*~~ free country, *zone* or *compartment* ~~of an equal or higher stage in the process of accreditation; however, rams and bucks complying with the provisions in point 2 of Article 14.9.8. may also be introduced~~;

   d) an *Official Veterinarian* inspects sheep and goats in the *establishment* and audits the records at least once a year;

   e) no *case* of scrapie has been reported;

   f) sheep and goats of the *establishment* should have no direct or indirect contact, including shared grazing, with sheep or goats from *establishments* of a lower status;

   g) all culled ~~animals~~ sheep and goats over 18 months of age are inspected by an *Official Veterinarian*, and a proportion of those exhibiting neurological or wasting signs are tested in a *laboratory* for scrapie. The selection of the ~~animals~~ sheep and goats to be tested should be made by the *Official Veterinarian*. ~~Animals~~ Sheep and goats over 18 months of age that have died or have been killed for reasons other than routine *slaughter* should also be tested (including 'fallen' stock and those sent for emergency *slaughter*).

~~Article 14.9.5.~~

~~**Recommendations on safe commodities**~~

~~Regardless of the scrapie status of the *exporting country, Veterinary Authorities* should authorise without restriction the import or transit through their territory of *meat* (excluding materials as referred to in Article~~

~~14.9.11.), *milk*, *milk products*, wool and its derivatives, hides and skins, tallow, derivatives made from this tallow and dicalcium phosphate originating from sheep and goats.~~

Article 14.9.6.

Recommendations for importation from countries <u>or zones</u> not considered free from scrapie

<u>for sheep and goats for breeding or rearing</u>

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals come from a ~~*zone* or~~<u>,</u> ~~an *establishment*~~ <u>*compartment*</u> free from scrapie as described in ~~Article 14.9.3. and in~~ Article 14.9.4.

Community comment

Same comment as for BV TB: herd should not be systematically replaced by compartments.

Article 14.9.7.

Recommendations for importation from countries or zones not considered free from scrapie

<u>for sheep and goats for slaughter</u>

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. in the country or *zone*:
    a) the *disease* is compulsorily notifiable;
    b) a *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;
    c) affected sheep and goats are slaughtered and completely destroyed;
2. the sheep and goats selected for export showed no clinical sign of scrapie on the day of shipment.

~~Article 14.9.8.~~

~~**Recommendations for importation from countries or zones not considered free from scrapie**~~

~~for semen of sheep and goats~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:~~

~~1. in the country or *zone*:~~
    ~~a) the *disease* is compulsorily notifiable;~~
    ~~b) a *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;~~
    ~~c) affected sheep and goats are slaughtered and completely destroyed;~~
    ~~d) the feeding of sheep and goats with *meat and bone meal* or *greaves* potentially contaminated with an animal TSE has been banned and effectively enforced in the whole country;~~
~~2. the donor animals:~~
    ~~a) are permanently identified, to enable trace back to their *establishment* of origin;~~

~~b) have been kept since birth in *establishments* in which no *case* of scrapie had been confirmed during their residency;~~

~~c) showed no clinical sign of scrapie at the time of semen collection;~~

~~3. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5.~~

Article 14.9.9.

Recommendations for importation from countries or zones not considered free from scrapie

for embryos/oocytes of sheep and goats

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. in the country or *zone*:

   a) the *disease* is compulsorily notifiable;

   b) a *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;

   c) affected sheep and goats are slaughtered and completely destroyed;

   d) the feeding to sheep and goats of *meat-and-bone meal* or *greaves* of ruminant origin ~~potentially contaminated with animal TSE~~ has been banned and effectively enforced in the whole country;

2. the donor animals either have been kept since birth in a free *compartment*, or meet the following conditions:

   a) are permanently identified, to enable trace back to their *establishment* of origin;

   b) have been kept since birth in *establishments* in which no *case* of scrapie had been confirmed during their residency;

   c) showed no clinical sign of scrapie at the time of embryo/oocyte collection;

3. the embryos/oocytes were collected, processed and stored in conformity with the provisions of Chapter 4.7.

Article 14.9.9.bis

Recommendations for importation from countries or zones not considered free from scrapie

for milk and milk products intended for use in feeding of sheep and goats

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the milk and milk products come from scrapie free *compartments*.

Community comment

Same comment as for BV TB: herd should not be systematically replaced by compartments and should remain here.

Morevoer, on 6 November 2008 the European Food Safety Authority (EFSA) published an opinion on the exposure risk related to transmissible spongiform encephalopathies from milk and milk products derived from small ruminants. In that opinion, EFSA concluded that classical scrapie can be transmitted from ewe to lamb via milk or

colostrums. EFSA also stated that the use of milk and milk products from a flock with classical scrapie may carry a TSE exposure risk for humans and animals. Another conclusion of EFSA was that the breeding programmes for scrapie resistance in sheep can be expected to reduce human and animal exposure associated with small ruminants dairy products.

In view of those new scientific elements and in particular the proven transmissibility of classical scrapie through milk from ewe to lamb, protective measures in relation to milk and milk products coming from classical scrapie infected flocks should be adopted in due time in order to prevent the spread of classical scrapie to other ruminant flocks through feeding.

The Community proposes the following wording:

"Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the milk and milk products are derived from ovine and caprine animals which have been kept continuously since birth or for the last three years on a holding where no official movement restriction is imposed due to a suspicion of TSE and which has satisfied the following requirements for the last three years:

(i) it has been subject to regular official veterinary checks;

(ii) no classical scrapie case has been diagnosed or, following the confirmation of a classical scrapie case:

– all animals in which classical scrapie was confirmed have been killed and destroyed, and

– all goats and sheep on the holding have been killed and destroyed, except for breeding rams of the ARR/ARR genotype and breeding ewes carrying at least one ARR allele and no VRQ allele."

Article 14.9.10.

Recommendations on meat-and-bone meal

Meat-and-bone meal containing any sheep or goat protein, or any feedstuffs containing that type of *meat-and-bone meal*, which originate from countries not considered free of scrapie should not be traded between countries for ruminant feeding.

Article 14.9.11.

Recommendations for importation from countries or zones not considered free from scrapie

for skulls including brains, ganglia and eyes, vertebral column including ganglia and spinal cord, tonsils, thymus, spleen, intestine, adrenal gland, pancreas, or liver, and protein products derived therefrom, from sheep and goats

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. in the country or *zone*:

   a) the *disease* is compulsorily notifiable;

   b) a *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;

   c) affected sheep and goats are slaughtered and completely destroyed;

2. the materials come from sheep and goats that showed no clinical sign of scrapie on the day of *slaughter*.

Community comment

As stated in the introductory part of this Chapter, the recommendations in this Chapter are intended to manage the animal health risks associated with the presence of the scrapie agent in sheep and goats. In order to reduce the potential risk for animals resulting from the exposure to infected animal products, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of feed, fertilisers, or veterinary pharmaceuticals including biologicals: spleen and ileum. Protein products intended for animal use, feed, fertilisers or veterinary pharmaceuticals prepared using these commodities should also not be traded.

From sheep and goats that were at the time of slaughter over 12 months of age or which have a permanent incisor erupted through the gum, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of feed, fertilisers, or veterinary pharmaceuticals including biologicals: skull, brain, eyes, spinal cord, tonsils. Protein products intended for animal use, feed, fertilisers or veterinary pharmaceuticals prepared using these commodities should also not be traded.

Article 14.9.12.

Recommendations for the importation of ovine and caprine materials destined for the preparation of biologicals

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products originate from sheep and goats born and raised in a scrapie free country, *zone* or ~~*establishment*~~ *compartment*.

Community comment

Same comment as for BV TB: herd should not be systematically replaced by compartments.

Article 14.9.13.

Principles for declaring a country or zone historically free from scrapie

Articles 14.9.13. and 14.9.14. outline principles for declaring a country or *zone* free from scrapie.

An essential prerequisite to provide the guarantees required for the recognition of freedom from *disease/infection* is that the *Veterinary Services* of the Member comply with the provisions of Chapter 3.1. on evaluation of *Veterinary Services*, and, if relevant, with the provisions of Chapter 4.3. on zoning and compartmentalisation.

The provisions of the above-mentioned articles are based on the principles developed in Chapter 1.4. and the following premises:

1. the sheep population of the country or *zone* includes a range of genotypes known to be susceptible to scrapie;

2. the *Veterinary Services* have the competence, capacity and mandate to investigate, diagnose and report scrapie, if present;

3. the absence of scrapie over a long period of time can be substantiated by effective *disease* investigation and reporting by the *Veterinary Services* of an OIE Member.

Article 14.9.14.

Requirements to declare a country or zone historically free from scrapie

A country or *zone* may be recognised free from scrapie without having applied the requirements of Article 14.9.3. when:

a) scrapie has been notifiable for at least 25 years; and

b) a formal programme of targeted *surveillance* and monitoring can be documented as having been in place for at least 10 years; and

Following the comment in article 14.9.3 point 2, before the status of historical freedom can be granted, the country has to perform a certain level of monitoring for a period of at least 7 years. The below proposed level of monitoring is based on the experience in the European Community:

Monitoring in sheep and goats slaughtered for human consumption

Countries in which the population of ewes and ewe lambs put to the ram exceeds 750 000 animals shall test in accordance with the sampling rules set out in point 4 a minimum annual sample of 10 000 ovine animals slaughtered for human consumption;

Countries in which the population of goats which have already kidded and goats mated exceeds 750 000 animals shall test in accordance with the sampling rules set out in point 4 a minimum annual sample of 10 000 caprine animals slaughtered for human consumption;

Monitoring in sheep and goats not slaughtered for human consumption

Table A

Country population of ewes and ewe lambs put to the ram	**Minimum sample size of dead ovine animals (1)**
> 750 000	**10 000**
100 000-750 000	**1 500**
40 000-100 000	**100 % up to 500**
< 40 000	**100 % up to 100**

(1) Minimum sample sizes are set to take account of the size of the ovine populations in the individual countries and are intended to provide achievable targets.

Table B

Member State population of goats which have already kidded and goats mated	**Minimum sample size of dead caprine animals (1)**
> 750 000	**10 000**
100 000-750 000	**1 500**
40 000-100 000	**100 % up to 500**
< 40 000	**100 % up to 100**

(1) Minimum sample sizes are set to take account of the size of the ovine populations in the individual countries and are intended to provide achievable targets.

c) the presence of a range of scrapie susceptible genotypes in this sheep population can be documented; and

d) appropriate measures to prevent scrapie introduction can be documented as having been in place for at least 25 years; and

i) either scrapie has never been reported; or

ii) no *case* of scrapie has been reported for at least 25 years.

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— text deleted

Annex XXVII

CHAPTER 15.3.

CLASSICAL SWINE FEVER

Community comments

The Community can support the proposed changes, for which the TAHSC must be congratulated as the chapter is now much more consistent and practical.

There are still some technical comments which should be taken into consideration and furthermore, article 15.3.23 should either be deleted or adapted and included in article 24.

After adoption of this new chapter, WAHIS needs to be adapted to ensure notification of CSF in domestic pigs and information concerning CSF in wild boars.

Article 15.3.1.

General provisions

For the purposes of *international trade*, classical swine fever (CSF) is defined as an *infection* of domestic pigs.

Domestic pig is defined as 'all domesticated pigs, permanently captive or farmed free range, used for the production of meat for consumption, for the production of other commercial products or for breeding these categories of pigs.

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) populations.

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*.

Community comment

The most recent data on CSF set the incubation period from 5 to 12 days, it should be updated in the above paragraph to replace "7-10 days".

Furthermore, the words "when showing clinical signs" should be added after the words "days 5 and 14" in order to be clearer.

For the purposes of *international trade*, a Member should not impose immediate trade bans in response to a notification of *infection* with classical swine fever virus in wild pigs according to Article 1.2.3 of the *Terrestrial Code*.

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

Article 15.3.2.

Determination of the CSF status of a country, zone or compartment

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~~1. CSF should be notifiable in the whole territory, and all clinical signs suggestive of CSF should be subjected to appropriate field and~~/or~~ *laboratory* investigations;

~~3~~2. an on-going awareness programme should be in place to encourage reporting of all *cases* suggestive of CSF;

~~4~~3. the *Veterinary Authority* should have current knowledge of, and authority over, all domestic pigs in the country, *zone* or *compartment;*

~~5~~4. the *Veterinary Authority* should have current knowledge about the population and habitat of wild pigs in the country or *zone.*

5. for domestic pigs, appropriate *surveillance* is in place to capable of detecting the presence of *infection* in the absence of clinical signs, and the risk posed by wild pigs; this may be achieved through a *surveillance* programme in accordance with Articles 15.3.20 to 15.3.26.

Community comment

It is very difficult to assert here that the surveillance programme is actually capable of detecting CSF in the absence of clinical signs. The surveillance programme should at least comply with the present chapter articles 20 to 26 and the words "in the absence of clinical signs" should be deleted.

6. for wild pigs, if present in the country, a *surveillance* programme is in place according to Article 15.3.26, taking into account the presence of natural boundaries, the ecology of the wild pig population, and an assessment of the risks of disease spread; additionally taking measures to limit the spread of CSF within the wild pig population.

Community comment

The words "or zone" should be added after "if present in the country". The word “disease” should be replced by the words “infection/disease”.

7. Based on the assessed risk of spread within the wild pig population, and according to Article 15.3.24, the domestic pig population should be separated from the wild pig population by appropriate biosecurity measures to prevent transmission of CSF from wild to domestic pigs.

Article 15.3.3.

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 15.3.2. but without formally applying a specific surveillance programme, if the provisions of Article 1.4.6. 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 15.3.2. has been conducted, surveillance in accordance with Articles 15.3.26. to 15.3.31. has been in place for at least 12 months, and when no *outbreak* has been observed for at least 12 months.~~

A country, *zone* or *compartment* may be considered free from CSF when *surveillance* in accordance with Articles 15.3.20. to 15.3.26. has been in place for at least 12 months, and when:

2. ~~CSF free status following an outbreak~~ ~~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 Articles 15.3.26. to 15.3.31. has been in place and after a *risk assessment* as referred to in Article 15.3.2. 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 Articles 15.3.26. to 15.3.31. 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*.~~

a) there has been no *outbreak* of CSF in domestic pigs during the past 12 months;

b) no evidence of CSFV *infection* has been found in domestic pigs during the past 12 months;

c) no vaccination against CSF has been carried out in domestic pigs during the past 12 months;

~~d) surveillance in accordance with Articles 15.3.20. to 15.3.25. has been in place in domestic pigs for the past 12 months;~~

~~e~~d) imported domestic pigs comply with the requirements in Articles 15.3.5. or Articles 15.3.6.

~~AND~~

~~Based on surveillance in accordance with Articles 15.3.20. to 15.3.25., CSFV infection has been demonstrated not to be present in any wild pig population in the country or zone, and:~~

~~f) there has been no clinical evidence or virological evidence of CSF in wild pigs during the past 12 months;~~

~~g) no seropositive wild pigs have been detected in the age class 6–12 months during the past 12 months;~~

~~h) there has been no vaccination in wild pigs for the past 12 months;~~

~~i) imported wild pigs comply with the requirements in Article 15.3.7.~~

~~Article 15.3.4.~~

~~**Country free of CSF in domestic pigs but with a wild pig population**~~

~~Requirements in points 2a to 2c of Article 15.3.3., 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 to prevent transmission of CSF from wild pigs to domestic pigs.~~

Article 15.3.~~5~~4.

Recovery of free status

Should a CSF *outbreak* occur in a ~~previously~~ 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 Articles 15.3.~~26~~20. to 15.3.~~31~~25. 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;

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 means, validated to OIE standards (Chapter 2.8.3. 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 15.3.3. should be followed;

~~AND~~

~~Based on surveillance in accordance with Articles 15.3.20 to 15.3.25., CSFV *infection* has been demonstrated not to be present in any wild pig population in the country or zone.~~

~~Article 15.3.6.~~

~~**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 Articles 15.3.26. to 15.3.31. 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 15.3.24.;~~

~~5. imported wild pigs comply with the relevant requirements set forth in the present chapter.~~

Article 15.3.~~7~~5.

Recommendations for importation from countries, zones or compartments free of CSF

for domestic pigs

Veterinary Authorities should require 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 means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs.

~~Article 15.3.8.~~

~~**Recommendations for importation from countries free of CSF in domestic pigs but with a wild pig population**~~

~~for domestic pigs~~

~~*Veterinary Authorities* should require 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;~~

Article 15.3.~~9~~6.

Recommendations for importation from CSF infected countries or zones ~~with CSF infection in domestic pigs~~

for domestic pigs

Veterinary Authorities should require 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 means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs.

Article 15.3.~~10~~7.

Recommendations for importation ~~from countries or zones free of CSF~~ of wild pigs

~~for wild pigs~~

Regardless of the CSF status of the country, *zone* or *compartment* of origin, *Veterinary Authorities* should require 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~~ 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;

3. have not been vaccinated against CSF, unless there are ~~validate~~ means, validated to OIE standards (Chapter 2.8.3. 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 15.3.~~11~~8.

Recommendations for importation from countries, zones or compartments free of CSF

for semen of domestic pigs

Veterinary Authorities should require 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 Chapter 4.6.

~~Article 15.3.12.~~

~~**Recommendations for importation from countries free of CSF in domestic pigs but with a wild pig population**~~

~~for semen of domestic pigs~~

~~*Veterinary Authorities* should require 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 Chapter 4.6.~~

Article 15.3.~~13~~9.

Recommendations for importation from CSF infected countries or zones ~~considered infected with CSF in domestic pigs~~

for semen of domestic pigs

Veterinary Authorities should require 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 2.8.3. of the *Terrestrial Manual*), that any antibody is due to the vaccine;

Community comment

The Community propose to add another alternative:

"e) have been vaccinated against CSF and were subjected to a virological test performed on a blood sample taken on the day of collection and it has been conclusively demonstrated by means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), that the boar is negative for virus genome"

2. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.6.

Article 15.3.~~14~~10.

Recommendations for importation from countries, zones or compartments free of CSF

for *in vivo* derived embryos of domestic pigs

Veterinary Authorities should require 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 Chapter 4.7.

~~Article 15.3.15.~~

~~**Recommendations for importation from countries free of CSF in domestic pigs but with a wild pig population**~~

~~for *in vivo* derived embryos of pigs~~

~~*Veterinary Authorities* should require 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 Chapter 4.7.~~

Article 15.3.~~16~~11.

Recommendations for importation from CSF infected countries or zones ~~considered infected with CSF in domestic pigs~~

for *in vivo* derived embryos of domestic pigs

Veterinary Authorities should require 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 2.8.3. 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 Chapter 4.7.

Article 15.3.~~17~~12.

Recommendations for importation from countries, zones or compartments free of CSF

for *fresh meat* of domestic pigs

Veterinary Authorities should require 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 15.3.5. or Article 15.3.6.;

Community comment

The point 1 above, added to point 1 of article 15.3.4, means that no fresh meat of domestic pigs can be exported from a country or zone at least 6 months after the last case of CSF, without epidemiological justification. The conditions to recover the free status are sufficient and 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 Chapter 6.2. and have been found free of any sign suggestive of CSF.

~~Article 15.3.18.~~

~~**Recommendations for importation from countries or zones free of CSF in domestic pigs but with a wild pig population**~~

~~*for fresh meat* of domestic pigs~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from animals which:~~

~~1. were kept in a country, zone or compartment free of CSF in domestic pigs since birth or for at least the past 3 months;~~

~~2. have been slaughtered in an *approved abattoir,* have been subjected to ante-mortem and post-mortem inspections as described in the Codex Alimentarius Code of Hygienic Practice for Meat and have been found free of any sign suggestive of CSF.~~

Article 15.3.~~19~~13.

Recommendations for importation ~~from countries or zones free of CSF~~ of fresh meat of wild pigs

~~for *fresh meat* of wild pigs~~

Regardless of the CSF status of the country, *zone* or *compartment* of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that~~:~~

Community comment

The word "compartment" should be deleted here as it's not possible to have a wild boar compartment.

~~1.~~ the entire consignment of meat comes from animals ~~which~~:

~~a) have been killed in a CSF-free country or *zone*;~~

~~b)~~1. which have been subjected to a post-mortem inspection ~~as described in the Codex Alimentarius Code of Hygienic Practice for Meat~~ in accordance with Chapter 6.2. in an approved examination centre, and have been found free of any sign suggestive of CSF;

2. from each of which a sample has been collected and has been subjected to a virological test and a serological test for CSF, with negative results.

~~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 15.3.~~20~~14.

Recommendations for the importation of 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

Veterinary Authorities of *importing countries* should require 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 15.3.~~17~~12.~~, 15.3.18~~. or 15.3.~~19~~13., as relevant;

   b) in a processing establishment:

      i) approved by the *Veterinary Authority* for export purposes;

      ii) processing only meat meeting the conditions laid down in Articles 15.3.~~17~~12.~~, 15.3.18.~~ or 15.3.~~19~~13., as relevant;

OR

2. have been processed in an establishment approved by the *Veterinary 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 15.3.~~25~~19. and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 15.3.~~21~~15.

Recommendations for the importation of products of animal origin (from pigs, but not derived from fresh meat) intended for use in animal feeding and for agricultural or industrial use

Veterinary Authorities of *importing countries* should require 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 15.3.~~17~~12.~~, 15.3.18.~~ or 15.3.~~19~~13., as relevant;

   b) in a processing establishment:

      i) approved by the *Veterinary 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 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 15.3.~~25~~19. and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article15.3.~~22~~16.

Recommendations for the importation of bristles (from pigs)

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1. ~~come from~~ originate from domestic pigs in a CSF 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 CSF virus and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 15.3.~~23~~17.

Recommendations for the importation of litter and manure (from pigs)

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1. ~~come from~~ originate from domestic pigs in a country, *zone* or *compartment* free of CSF; or

2. have been processed in an establishment approved by the *Veterinary 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 15.3.~~24~~18.

Procedures for the inactivation of the CSF virus in swill

For the inactivation of classical swine fever (CSF) viruses likely to be present in swill, one of the following procedures should be used:

1. the swill should be maintained at a temperature of at least 90°C for at least 60 minutes, with continuous stirring; or

2. the swill should be maintained at a temperature of at least 121°C for at least 10 minutes at an absolute pressure of 3 bar.

Article 15.3.~~25~~19.

Procedures for the inactivation of the CSF virus in meat

For the inactivation of viruses present in *meat*, one of the following procedures should be used:

1. Heat treatment

   Meat shall be subjected to one of the following treatments:

   a) heat treatment in a hermetically sealed container with a Fo value of 3.00 or more;

   b) heat treatment at a minimum temperature of 70°C, which must be reached throughout the meat.

2. Natural fermentation and maturation

   The *meat* should be subjected to a treatment consisting of natural fermentation and maturation having the following characteristics:

   a) an aw value of not more than 0.93, or

   b) a pH value of not more than 6.0.

   Hams should be subjected to a natural fermentation and maturation process for at least 190 days and loins for 140 days.

3. Dry cured pork meat

   a) Italian style hams with bone-in should be cured with salt and dried for a minimum of 313 days.

   b) Spanish style pork meat with bone-in should be cured with salt and dried for a minimum of 252 days for Iberian hams, 140 days for Iberian shoulders, 126 days for Iberian loin, and 140 days for Serrano hams.

Article 15.3.~~26~~20.

Surveillance: introduction

Articles 15.3.~~26~~20. to 15.3.~~31~~25. define the principles and provide a guide on the *surveillance* for CSF, complementary to Chapter 1.4., applicable to Members seeking to determine their CSF status. This may be for the entire country or a *zone*. Guidance for Members seeking free status following an *outbreak* and for the maintenance of CSF status is also provided.

The impact and epidemiology of CSF differ widely in different regions of the world, and it is, therefore, impossible to provide specific recommendations for all situations. 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 establish that a

population in a country, *zone* or *compartment* is free from CSFV infection 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 Chapter, 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 15.3.~~27~~21.

Surveillance: general conditions and methods

1. A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary 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 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 15.3.~~28~~22.

Surveillance strategies

1. Introduction

There are two basic strategies that can be employed for CSF *surveillance* depending on the purpose of the Member 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 population covered by *surveillance* aimed at 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*.

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 Member 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 Member should justify the *surveillance* strategy chosen as adequate to detect the presence of CSFV infection in accordance with Chapter 1.4. 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 Member must justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. 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 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* - 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.

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 *diseases* 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.

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 Chapter 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 15.3.~~29~~23.

Country or zone historically free of CSF: ~~additional~~ surveillance procedures

Community comment

The word "historically" should be deleted to be coherent with article 15.3.3.

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:

1. an emergence or an increase in the prevalence of CSF in countries or *zones* from which live pigs or products are imported;

2. an increase in the volume of imports or a change in their country or *zone* of origin;

3. an increase in the prevalence of CSF in the domestic or wild pigs of adjacent countries or *zones*;

4. an increased entry from, or exposure to, infected wild pig populations of adjacent countries or *zones*.

Article 15.3.~~30~~24.

Countries, zones or compartments declaring freedom from CSF: additional surveillance procedures

1. Country or zone free of CSF

   In addition to the general conditions described in the above-mentioned articles, 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 Chapter, 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* is to demonstrate the absence of CSFV infection in the *compartment*. The provisions of Chapter 4.3. should be followed. The effective separation of the two subpopulations should be demonstrated. To this end, a *biosecurity plan* that includes but is not limited to the following provisions should be implemented:

a) proper containment of domestic pigs;

b) control of movement of *vehicles* with cleaning and *disinfection* as appropriate;

c) control of personnel entering into the *establishments* and awareness of risk of fomite spread;

d) prohibition of introduction to the *establishments* of wild caught animals and their products;

e) record of animal movements into and out of *establishments*;

f) information and training programmes for farmers, processors, veterinarians, etc.

The *biosecurity plan* implemented also requires internal and external monitoring by the *Veterinary Authority*. This monitoring should include:

a) periodic clinical and serological monitoring of *herds* in the country or *zone*, and adjacent wild pig populations following these recommendations;

b) *herd* registration;

c) official accreditation of *biosecurity plans*;

d) periodic monitoring and review.

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 *compartment*. The design of a monitoring system 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 should justify its choice of design prevalence and level of confidence based on Chapter 1.4.

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 15.3.~~31~~25.

Recovery of free status: additional surveillance procedures

~~1. Countries or zones seeking re-establishment of freedom from CSF following an outbreak~~

In addition to the general conditions described in the above-mentioned articles, a Member seeking reestablishment of country or *zone* freedom from CSF should show evidence of an active *surveillance*

programme to demonstrate absence of CSFV infection.

Populations under this *surveillance* programme should include:

a) *establishments* in the 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 recommendations. The *surveillance* should be based on a statistically representative sample of the populations at risk.

Article 15.3.26.

Surveillance for CSF in wild pigs

~~2. 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 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 if a given *disease* is present, and if so, at what prevalence.

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* 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) interface between wild and domestic pig populations;

e) picnic and camping areas;

f) farms with free-ranging pigs;

g) garbage dumps;

h) other risk areas determined by the *Veterinary Authority*.

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— text deleted

Annex XXVIII

CHAPTER 8.XX.

WEST NILE FEVER

Community comments

The Community feels that this Chapter is not mature enough to be voted next May as it needs more scientific input and specifically :

- Article 1 defines the "occurrence" of WNF while referring in this definition to WNF "outbreak", which is not defined;

- Whereas article 2 states that "Member should not impose trade restrictions on dead-end hosts such as horses", the articles on trade conditions refer to the "susceptible species", which include horses; it should be clearer that trade restrictions should apply only to the susceptible species and not to dead end hosts

- Article 9 should be deleted, it does not bring more than article 8.

Article 8.XX.1.

General provisions

West Nile fever (WNF) is a zoonotic *disease* caused by certain strains of the mosquito-borne West Nile virus (WNV).

For the purpose of this Chapter, the susceptible species are equidae, geese, ducks (under study) and chicken and turkey chicks less than 12 days old and birds other than poultry.

Community comment

Either turkeys are susceptible or not, so the words “less than 12 days” should be deleted.

Second and fourth paragraph shoud be clearer that we don’t consider dead end hosts for trade purposes and this chapter only relate to susceptible species.

WNV is maintained in a mosquito–bird–mosquito transmission cycle, whereas humans and equidae are considered dead-end hosts. Most human *infections* occur by natural transmission from mosquitoes.

In relation to domestic animal trade, geese and ducks pose a risk for the spread of the WNV as some species have been documented to develop a viraemia sufficient to infect mosquitoes.

Surveillance for WNF will be carried out according to Chapter X.X.

The following criteria define the occurrence of WNF:

1. WNV has been isolated from an animal; or

2. viral antigen or viral ribonucleic acid (RNA) specific to WNV has been identified in samples from one or more animals that show clinical signs consistent with WNF, or that is epidemiologically linked to a confirmed or suspected *outbreak* of WNF; or

3. antibodies to WNV that are not a consequence of vaccination, have been identified in an animal, that shows clinical signs consistent with WNF, or that is epidemiologically linked to a confirmed or suspected *outbreak* of WNF.

For the purposes of the *Terrestrial Code*, the *incubation period* for WNF shall be 15 days.

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

Article 8.XX.~~1~~2.

Trade in commodities

Member should not impose trade restrictions on dead-end hosts such as horses.

When authorising import or transit of the following *commodities* and any products made from these, *Veterinary Authorities* should not require any West Nile virus (WNV) related conditions, regardless of the WNF risk status of the animal population of the *exporting country* or *zone*:

a) *hatching eggs;*

b) eggs for human consumption;

c) egg products;

d) poultry semen;

e) *fresh meat* and *meat products* of poultry;

f) products of poultry origin intended for use in animal feeding, or for agricultural or industrial use;

g) feathers and down from poultry;

h) semen of horses;

i) *fresh meat* and *meat products* of horses.

~~Article 8.XX.21.~~

~~West Nile fever (WNF) is a zoonotic *disease* caused by certain strains of the mosquito-borne West Nile virus (WNV).~~

~~For the purpose of this Chapter, the susceptible species are equidae, geese, ducks (under study) and chicken and turkey chicks less than 12 days old and birds other than poultry.~~

~~Although most avian species are susceptible to infection, the outcome of the infection is highly variable according to the species. Chickens and turkeys, are usually resistant to disease and do not develop viremia sufficient to infect mosquitoes, with the exception of chicks less than 12 days old.~~

~~Birds are responsible for virus dispersal, including reintroduction of WNV from endemic areas into regions that may subsequently experience sporadic outbreaks.~~

~~WNV is maintained in a mosquito-bird-mosquito transmission cycle, whereas humans and equidae are considered dead-end hosts. Most human *infections* occur by natural transmission from mosquitoes.~~

~~Many animal species are known to be susceptible to WNV infection and outbreaks of a fatal neurological disease have been reported in humans, equidae, geese and wild birds.~~

~~In relation to domestic animal trade, geese and ducks might represent pose a risk for the spread of the WNV the WNF as some species have been documented to develop a viraemia sufficient to infect mosquitoes.~~

~~WNV has been reported to date in a wide geographical range that includes portions of Europe, Asia, Africa, Australia and the Americas. Although competent vectors and susceptible bird species are nearly ubiquitous, WNV circulation in sylvatic cycles may spill over occasionally in domestic population.~~

~~Surveillance for WNF will be carried out according to Chapter X.X.~~

~~The following~~ criteria ~~defines the occurrence of WNF case~~:

1. ~~WNV has been isolated and identified as such from an animal, including human; or~~

2. ~~viral antigen or viral ribonucleic acid (RNA) specific to WNV has been identified in samples from one or more animals including human~~ that ~~showing clinical signs consistent with WNF, or~~ that is ~~epidemiologically linked to a confirmed or suspected *outbreak* of WNF; or~~

3. ~~antibodies to WNV that are not a consequence of vaccination, have been identified in an animal, that including human showings clinical signs consistent with WNF, or that is epidemiologically linked to a confirmed or suspected *outbreak* of WNF.~~

~~For the purposes of the *Terrestrial Code*, the *incubation period* for WNF shall be 3-15 days.~~

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

~~Article 2.2.XX.2.~~

~~WNF infected country,~~ or ~~zone or compartment~~

~~A WNF infected country ,~~ or ~~*zone* or compartment is a country, zone or compartment clearly defined where one in which a case of WNF has been reported during the past 2 years~~

Article 8.XX.3.

WNF free country~~,~~ or zone ~~or compartment~~

1. A country~~,~~ or *zone ~~or compartment~~* may be considered free from WNF when WNF is notifiable in the whole country and either:

   a) no ~~clinical~~ occurrence of indigenous WNF *cases* have been recorded for the past 2 years; or

   b) a surveillance programme in accordance with Chapter X.X. has demonstrated no evidence of WNF~~F~~V in the country or *zone* ~~or compartment~~ during the past 2 years; or

   c) a surveillance programme has demonstrated no evidence of ~~*Culex*~~ mosquitoes likely to be competent WNV vectors in the country~~,~~ or *zone ~~or compartment~~*.

2. A WNF free country~~,~~ or *zone* ~~or compartment~~ will not lose its free status through the importation from WNF infected countries or *infected zones* ~~or compartment~~ of:

   a) seropositive animals;

   b) semen, embryo or ova;

   c) animals vaccinated in accordance with the *Terrestrial Manual* at least 30 days prior to dispatch, and ~~that the animals~~ are identified in the accompanying certification as having been vaccinated; or

   d) animals not vaccinated if a surveillance programme in accordance with Chapter X.X. has been in place in the source population for a period of 30 days immediately prior to dispatch, and no evidence of WNV transmission has been detected.

Article 8.XX.4.

WNF seasonally free country or zone

1. A WNF seasonally free country or *zone* is ~~a country or a zone for~~ one in which for part of a year, surveillance demonstrates no evidence either of WNV transmission or presence of ~~adult *Culex*~~ mosquitoes ~~likely to be competent WNV vectors~~.

2. For the application of Article 8.XX.7., the seasonally free period is taken to commence 21 days following the last evidence of WNV transmission (as demonstrated by the surveillance programme), or the cessation of activity of ~~adult *Culex*~~ mosquitoes likely to be competent WNV vectors.

3. For the application of Article 8.XX.7., the seasonally free period is taken to conclude either:

   a) at least 21 days before the earliest date that historical data show WNV transmission cycle has recommenced; or

   b) immediately if current climatic data or data from a surveillance programme indicate an earlier resurgence of activity of ~~adult *Culex*~~ mosquitoes likely to be competent WNV vectors.

4. A WNF seasonally free country or *zone* will not lose its free status through the importation ~~of animals or semen or embryo and ova~~ from infected countries or *zones* of:~~.~~

   a) seropositive animals;

   b) semen, embryo or ova;

   c) animals vaccinated in accordance with the *Terrestrial Manual* at least 30 days prior to dispatch, and are identified in the accompanying certification as having been vaccinated; or

   d) animals not vaccinated if a surveillance programme in accordance with Chapter X.X. has been in place in the source population for a period of 30 days immediately prior to dispatch, and no evidence of WNV transmission has been detected.

~~Article 8.XX.5.~~

~~**WNF infected country or zone**~~

~~A WNF infected country or *zone* is one in which a *case* of WNF has been reported during the past 2 years~~

Article 8.XX.6.

Recommendations for importation from WNF free countries~~,~~ or *zones*, ~~or compartment~~

for susceptible species

Community comment

To be coherent with article 1, the words "except dead end hosts" should be added above.

Veterinary ~~Administrations~~ Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the animals were kept in a WNF free country~~,~~ or *zone* ~~or compartment~~ since birth or for at least 30 days prior to shipment; or

2. the animals were kept in a WNF free country~~,~~ or *zone* ~~or compartment~~ for at least ~~7~~ 15 days, were subjected, ~~with negative results,~~ to an agent identification test according to the *Terrestrial Manual*, with

negative results, carried out on a sample collected at least 3 days after the commencement of the residence period and remained in the WNF free country~~,~~ or *zone* ~~or compartment~~ until shipment; or

3. the animals:

   a) were vaccinated in accordance with the *Terrestrial Manual* 30 days before introduction into the free country~~,~~ or *zone* ~~or compartment~~; and

   b) were identified as having been vaccinated; and

   c) were kept in a WNF free country or *zone* for at least ~~7~~ 15 days; and

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

AND

4. if the animals were exported from a WNF free *zone*, either:

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

   b) were protected from attack from ~~WNV~~ mosquito ~~vectors~~ at all times when transiting through an *infected zone*; or

   c) had been vaccinated in accordance with point 3 above.

Article 8.XX.7.

Recommendations for importation from WNF seasonally free countries or *zones*

for susceptible species

Community comment

To be coherent with article 1, the words "except dead end hosts" should be added above.

Veterinary ~~Administrations~~ Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1. were kept during the seasonally free period in a WNF seasonally free country or *zone* for at least 30 days prior to shipment; or

2. were kept during the WNF seasonally free period in a WNF seasonally free country or *zone* for at least ~~7~~ 15 days prior to shipment, and were subjected during the residence period in the country or *zone* to an agent identification test according to the *Terrestrial Manual*, with negative results, carried out ~~at carried out~~ on a sample collected at least 3 days after the commencement of the residence period and remained in the WNF seasonally free country~~,~~ or *zone* until shipment; or

3. were kept during the seasonally free period in a WNF seasonally free country or *zone*, and were vaccinated in accordance with the *Terrestrial Manual* 30 days before introduction into the free country or *zone* against WNF, were identified as having been vaccinated and remained in the WNF seasonally free country or *zone* until shipment;

AND

4. if the animals were exported from a WNF free country or *zone*, either:

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

b) were protected from attack from ~~WNV~~ mosquito ~~vectors~~ at all times when transiting through an infected country or *infected zone*; or

c) were vaccinated in accordance with point 3 above.

Article 8.XX.8.

Recommendations for importation from WNF infected countries or infected zones

for susceptible species

Community comment

To be coherent with article 1, the words "except dead end hosts" should be added above.

Veterinary ~~Administrations~~ Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1. were protected from attack from ~~WNV~~ mosquito ~~vectors~~ for at least 30 days prior to shipment; or

2. were subjected to a serological test according to the *Terrestrial Manual* to detect WNV neutralizing antibodies with positive results; or

3. were protected from attack from ~~WNV~~ mosquito ~~vectors~~ for at least 15 days prior to shipment, and were subjected during that period to an agent identification test according to the *Terrestrial Manual*, with negative results, carried out on a sample collected at least 3 days after being introduced in the mosquito free *zone*; or

4. were vaccinated in accordance with the *Terrestrial Manual* at least 30 days before shipment, against WNV, and were identified in the accompanying certification as having been vaccinated; or

5. are not vaccinated and a surveillance programme in accordance with Chapter X.X. has been in place in the source population for a period of 30 days immediately prior to shipment, and no evidence of WNV transmission has been detected;

AND

6. were protected from attack from ~~WNV~~ mosquito ~~vectors~~ during transportation to the *place of shipment*; ~~or~~

7. ~~were vaccinated 30 days before shipment or had antibodies against WNV.~~

Article 8.XX.9.

Recommendations for the importation of birds

Veterinary ~~Administrations~~ Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the birds showed no clinical sign of WNF on the day of shipment; and

2. the birds were kept in a *quarantine station* in a mosquito-free environment for 30 days prior to shipment and a statistically valid sample was ~~they were~~ subjected, with negative results, to an agent identification test ~~according to the *Terrestrial Manual* carried out on samples collected~~ at least 3 days after the commencement of the residence period.

Community comment

The article 9 above should be deleted and its points added to article 8.

Article 8.XX.10.

Protecting animals from WNV mosquito vectors

When transporting animals through WNF infected countries or *infected zones*, *Veterinary ~~Administrations~~ Authorities* should require strategies to protect animals from attack from WNV mosquito vectors during transport, taking into account the local ecology of the vectors.

Potential *risk management* strategies include:

1. treating animals with chemical repellents prior to and during transportation;

2. ensuring *vehicles* do not stop en route unless the animals are held behind insect proof netting;

3. surveillance for vectors at common stopping and offloading points to gain information on seasonal variations;

4. integrated pest management practices at holding, common stopping and offloading points;

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

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— text deleted

Annex XXIX

CHAPTER 9.1.

ACARAPISOSIS OF HONEY BEES

Community comment
The Community can support the proposed changes.

Article 9.1.1.

General provisions

For the purposes of this Chapter, acarapisosis, acarine disease or tracheal mite infestation is a *disease* of the adult honey bee *Apis mellifera L.*, and possibly of other *Apis* species (such as *Apis cerana*). It is caused by the Tarsonemid mite *Acarapis woodi* (Rennie). The mite is an internal obligate parasite of the respiratory system, living and reproducing mainly in the large prothoracic trachea of the bee. Early signs of *infection* normally go unnoticed, and only when *infection* is heavy does it become apparent; this is generally in the early spring. The *infection* spreads by direct contact from adult bee to adult bee, with newly emerged bees under 10 days old being the most susceptible. The mortality rate may range from moderate to high.

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

Article 9.1.2.

Determination of the acarapisosis status of a country or zone/ compartment

The acarapisosis status of a country or *zone/compartment* (under study) can only be determined after considering the following criteria:

1. a *risk assessment* has been conducted, identifying all potential factors for acarapisosis occurrence and their historic perspective;

2. acarapisosis should be notifiable in the whole country or *zone/compartment* (under study) and all clinical signs suggestive of acarapisosis should be subjected to field and laboratory investigations;

3. an on-going awareness programme should be in place to encourage reporting of all *cases* suggestive of acarapisosis;

4. the *Veterinary Authority* or other *Competent Authority* with responsibility for ~~the health~~ reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the whole country.

Article 9.1.3.

Country or zone/ compartment (under study) free from acarapisosis

1. Historically free status

   A country or *zone /compartment* (under study) may be considered free from acarapisosis after conducting a *risk assessment* as referred to in Article 9.1.2. but without formally applying a specific *surveillance* programme if the country or *zone/compartment* (under study) complies with the provisions of Chapter 1.4.

Annex XXIX (contd)

2. Free status as a result of an eradication programme

A country or *zone/compartment* (under study) which does not meet the conditions of point 1 above may be considered free from acarapisosis after conducting a *risk assessment* as referred to in Article 9.1.2. and when:

a) the *Veterinary Authority* or other *Competent Authority* with responsibility for ~~the health~~ reporting and control of diseases of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or *zone/compartment* (under study);

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

c) for the 3 years following the last reported *case* of acarapisosis, annual surveys supervised by the *Veterinary Authority*, with negative results, have been carried out on a representative sample of *apiaries* in the country or *zone/compartment* (under study) to provide a confidence level of at least 95% of detecting acarapisosis if at least 1% of the *apiaries* were infected at a within-*apiary* prevalence rate of at least 5% of the hives; such surveys may be targeted towards *apiaries*, areas and seasons with a higher likelihood of *disease*;

d) to maintain free status, an annual survey supervised by the *Veterinary Authority*, with negative results, is carried out on a representative sample of *apiaries* in the country or *zone/compartment* (under study) to indicate that there has been no new *cases*; such surveys may be targeted towards areas with a higher likelihood of *disease*;

e) (under study) there is no self-sustaining feral population of *A. mellifera* or other possible host species in the country or *zone/compartment* (under study);

f) the importation of the *commodities* listed in this Chapter into the country or *zone/compartment* (under study) is carried out in conformity with the recommendations of this Chapter.

Article 9.1.4.

Recommendations on safe commodities

Regardless of the acarapisosis status of the *exporting country*, *Veterinary 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. used equipment associated with beekeeping;

3. honey, beeswax, honey bee-collected pollen, propolis and royal jelly.

Article 9.1.5.

Recommendations for the importation of live queen honey bees, worker bees and drones with or without associated brood combs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the bees come from a country or *zone/compartment* (under study) free from acarapisosis.

Article 9.1.6.

Recommendations for the importation of eggs, larvae and pupae of honey bees

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1. were sourced from an officially free country or *zone/compartment* (under study); or

2. were examined by an official *laboratory* and declared free of all life stages of *A. woodi;* or

3. have originated from queens in a *quarantine station* and were examined microscopically and found free of all life stages of *A. woodi*.

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— text deleted

CHAPTER 9.2.

AMERICAN FOUL BROOD OF HONEY BEES

Community comment

The Community can support the proposed changes.

However, all bacteria causing American Foulbrood should be called *Paenibacillus larvae*. So the words "*subsp. larvae*" should be deleted. Justification can be found in "Elke Genersch, et al. (2006) Reclassification of Paenibacillus larvae subsp. pulvifaciens and Paenibacillus larvae subsp. Larvae as Paenibacillus larvae without subspecies differentiation." International Journal of Systematic and Evolutionary Microbiology (2006), 56, 501–511.

Article 9.2.1.

General provisions

For the purposes of this Chapter, American foulbrood is a *disease* of the larval and pupal stages of the honey bee *Apis mellifera* and other *Apis* spp., and occurs in most countries where such bees are kept. *Paenibacillus larvae subsp. larvae*, the causative organism, is a bacterium that can produce over one billion spores in each infected larva. The spores are very long-living and extremely resistant to heat and chemical agents, and only the spores are capable of inducing the *disease*.

Combs of infected *apiaries* may show distinctive clinical signs which can allow the *disease* to be diagnosed in the field. However, subclinical *infections* are common and require *laboratory* diagnosis.

For the purposes of the *Terrestrial Code*, the *incubation period* for American foulbrood shall be 15 days (not including the wintering period which may vary according to country).

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

Article 9.2.2.

Determination of the American foulbrood status of a country or zone/ compartment

The American foulbrood status of a country or *zone/compartment* (under study) can only be determined after considering the following criteria:

1. a *risk assessment* has been conducted, identifying all potential factors for American foulbrood occurrence and their historic perspective;

2. American foulbrood should be notifiable in the whole country or *zone/compartment* (under study) and all clinical signs suggestive of American foulbrood should be subjected to field and/or laboratory investigations;

3. an on-going awareness programme should be in place to encourage reporting of all cases suggestive of American foulbrood;

4. the *Veterinary Authority* or other *Competent Authority* with responsibility for ~~the health~~ reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the country.

Annex XXIX (contd)

Article 9.2.3.

Country or zone/ compartment (under study) free from American foulbrood

1. Historically free status

A country or *zone/compartment* (under study) may be considered free from the *disease* after conducting a *risk assessment* as referred to in Article 9.2.2. but without formally applying a specific *surveillance* programme if the country or *zone/compartment* (under study) complies with the provisions of Chapter 1.4.

2. Free status as a result of an eradication programme

A country or *zone/compartment* (under study) which does not meet the conditions of point 1 above may be considered free from American foulbrood after conducting a *risk assessment* as referred to in Article 9.2.2. and when:

a) the *Veterinary Authority* or other *Competent Authority* with responsibility for ~~the health~~ reporting and control of *diseases* of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or *zone/compartment* (under study);

b) American foulbrood is notifiable in the whole country or *zone /compartment* (under study), and any clinical cases suggestive of American foulbrood are subjected to field and/or *laboratory* investigations;

c) for the 5 years following the last reported isolation of the American foulbrood agent, annual surveys supervised by the *Veterinary Authority*, with negative results, have been carried out on a representative sample of *apiaries* in the country or *zone/compartment* (under study) to provide a confidence level of at least 95% of detecting American foulbrood if at least 1% of the *apiaries* were infected at a within-*apiary* prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with the last reported isolation of the American foulbrood agent;

d) to maintain free status, an annual survey supervised by the *Veterinary Authority*, with negative results, is carried out on a representative sample of hives in the country or *zone/compartment* (under study) to indicate that there has been no new isolations; such surveys may be targeted towards areas with a higher likelihood of isolation;

e) (under study) there is no self-sustaining feral population of *A. mellifera* or other possible host species in the country or *zone/compartment* (under study);

f) all equipment associated with previously infected *apiaries* has been sterilised or destroyed;

g) the importation of the *commodities* listed in this Chapter into the country or *zone/compartment* (under study) is carried out in conformity with the recommendations of this Chapter.

Article 9.2.4.

Recommendations on safe commodities

Regardless of the American foulbrood status of the *exporting country*, *Veterinary Authorities* should authorise without restriction the import or transit through their territory of honey bee semen and honey bee venom.

Article 9.2.5.

Recommendations for the importation of live queen honey bees, worker bees and drones with or without associated brood combs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the bees come from a country or *zone/compartment* (under study) officially free from American foulbrood.

Article 9.2.6.

Recommendations for the importation of eggs, larvae and pupae of honey bees

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1. were sourced from a free country or *zone/compartment* (under study); or

2. have been isolated from queens in a *quarantine station*.

Article 9.2.7.

Recommendations for the importation of used equipment associated with beekeeping

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the equipment was sterilised under the supervision of the *Veterinary Authority* by either immersion in 1% sodium hypochlorite for at least 30 minutes (suitable only for non-porous materials such as plastic and metal), gamma irradiation using a cobalt-60 source at a dose rate of 10 kGy, or processing to ensure the destruction of both bacillary and spore forms of *P. larvae larvae*, in conformity with one of the procedures referred to in Chapter X.X. (under study).

Article 9.2.8.

Recommendations for the importation of honey, honey bee-collected pollen, beeswax, propolis and royal jelly

Veterinary Authorities of *importing countries* officially free from American foulbrood should require the presentation of an *international veterinary certificate* attesting that the products:

1. were collected in a country or *zone/compartment* (under study) free from American foulbrood; or

2. have been processed to ensure the destruction of both bacillary and spore forms of *P. larvae larvae*, in conformity with one of the procedures referred to in Chapter X.X. (under study).

— text deleted

CHAPTER 9.3.

EUROPEAN FOULBROOD OF HONEY BEES

Community comment

The Community can support the proposed changes. However, *Melissococcus pluton* should be replaced by *Melissococcus plutonius*, its actual name. Justification in "Bailey and Collins (1983) Validation of the publication of new names and new combinations previously effectively published outside the IJSB. Int. J. Syst. Bacteriol. 33:672-674".

Article 9.3.1.

General provisions

For the purposes of this Chapter, European foulbrood is a *disease* of the larval and pupal stages of the honey bee *Apis mellifera* and other *Apis* spp., and occurs in most countries where such bees are kept. The causative agent is the non-sporulating bacterium *Melissococcus pluton*. Subclinical *infections* are common and require *laboratory* diagnosis. *Infection* remains enzootic because of mechanical contamination of the honeycombs. Recurrences of *disease* can therefore be expected in subsequent years.

For the purposes of the *Terrestrial Code*, the *incubation period* for European foulbrood shall be 15 days (not including the wintering period which may vary according to country).

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

Article 9.3.2.

Determination of the European foulbrood status of a country or zone/ compartment

The European foulbrood status of a country or *zone/compartment* (under study) can only be determined after considering the following criteria:

1. a *risk assessment* has been conducted, identifying all potential factors for European foulbrood occurrence and their historic perspective;

2. European foulbrood should be notifiable in the whole country or *zone/compartment* (under study) and all clinical signs suggestive of European foulbrood should be subjected to field and *laboratory* investigations;

3. an on-going awareness programme should be in place to encourage reporting of all cases suggestive of European foulbrood;

4. the *Veterinary Authority* or other *Competent Authority* with responsibility for ~~the health~~ reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all *apiaries* in the whole country.

Article 9.3.3.

Country or zone/ compartment (under study) free from European foulbrood

1. Historically free status

A country or *zone /compartment* (under study) may be considered free from the *disease* after conducting a *risk assessment* as referred to in Article 9.3.2. but without formally applying a specific *surveillance* programme if the country or *zone/compartment* (under study) complies with the provisions of Chapter 1.4.

2. Free status as a result of an eradication programme

A country or *zone/compartment* (under study) which does not meet the conditions of point 1 above may be considered free from European foulbrood after conducting a *risk assessment* as referred to in Article 9.3.2. and when:

a) the *Veterinary Authority* or other *Competent Authority* with responsibility for ~~the health~~ reporting and control of *diseases* of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or *zone/compartment* (under study);

b) European foulbrood is notifiable in the whole country or *zone/compartment* (under study), and any clinical cases suggestive of European foulbrood are subjected to field and *laboratory* investigations;

c) for the 3 years following the last reported isolation of the European foulbrood agent, an annual survey supervised by the *Veterinary Authority*, with negative results, have been carried out on a representative sample of *apiaries* in the country or *zone/compartment* (under study) to provide a confidence level of at least 95% of detecting European foulbrood if at least 1% of the *apiaries* were infected at a within-*apiary* prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with the last reported isolation of the European foulbrood agent;

d) to maintain free status, an annual survey supervised by the *Veterinary Authority*, with negative results, is carried out on a representative sample of hives in the country or *zone/compartment* (under study) to indicate that there has been no new isolations; such surveys may be targeted towards areas with a higher likelihood of isolation;

e) (under study) there is no self-sustaining feral population of *A. mellifera* or other possible host species in the country or *zone/compartment* (under study);

f) the importation of the *commodities* listed in this Chapter into the country or *zone/compartment* (under study) is carried out in conformity with the recommendations of this Chapter.

Article 9.3.4.

Recommendations on safe commodities

Regardless of the European foulbrood status of the *exporting country*, *Veterinary Authorities* should authorise without restriction the import or transit through their territory of honey bee semen and honey bee venom.

Article 9.3.5.

Recommendations for the importation of live queen honey bees, worker bees and drones with or without associated brood combs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the bees come from a country or *zone/compartment* (under study) free from European foulbrood.

Article 9.3.6.

Recommendations for the importation of eggs, larvae and pupae of honey bees

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1. were sourced from a free country or *zone/compartment* (under study); or

2. have been isolated from queens in a *quarantine station*, and all workers which accompanied the queen or a representative sample of eggs or larvae were examined for the presence of *Melissococcus pluton* by bacterial culture or PCR.

Article 9.3.7.

Recommendations for the importation of used equipment associated with beekeeping

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the equipment was sterilised under the supervision of the *Veterinary Authority* by either immersion in 0.5% sodium hypochlorite for at least 20 minutes (suitable only for non-porous materials such as plastic and metal), gamma irradiation using a cobalt-60 source at a dose rate of 10 kGy, or processing to ensure the destruction of *Melissococcus pluton*, in conformity with one of the procedures referred to in Chapter X.X. (under study).

Article 9.3.8.

Recommendations for the importation of honey, honey bee-collected pollen, beeswax, propolis and royal jelly

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1. were collected in a country or *zone/compartment* (under study) free from European foulbrood; or

2. have been processed to ensure the destruction of *Melissococcus pluton*, in conformity with one of the procedures referred to in Chapter X.X. (under study).

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— text deleted

CHAPTER 9.4.

SMALL HIVE BEETLE INFESTATION
(*Aethina tumida*)

Community comments

The Community can support the proposed changes. However, for better clarity in the fifth paragraph of the article 9.4.1 below, the word "bee" should be added between "leading to high" and "mortality in the hive". And there is a comment in article 9.4.10.

Article 9.4.1.

General provisions

For the purposes of this Chapter, small hive beetle (SHB) is an infestation of bee colonies by the beetle *Aethina tumida*, which is 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 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. tumida* begins with the adult beetle laying eggs within infested hives. These are usually laid in irregular masses in crevices or brood combs. After 2-6 days, the eggs hatch and the emerging larvae begin to feed 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 4 to 6 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.

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 2 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. tumida* can be found and can thrive within the natural environment, and can fly up to 6-13 km from its nest site, it is capable of dispersing rapidly and directly colonising hives. Dispersal includes following or accompanying swarms. 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 9.4.2.

Determination of the *A. tumida* status of a country or zone

The *A. tumida* status of a country or *zone* can only be determined after considering the following criteria:

1. *A. tumida* infestation should be notifiable in the whole country, and all signs suggestive of *A. tumida* infestation should be subjected to field and *laboratory* investigations;

2. on-going awareness and training programmes should be in place to encourage reporting of all cases suggestive of *A. tumida* infestation;

3. the *Veterinary Authority* or other *Competent Authority* with responsibility for ~~the health~~ reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the country.

Article 9.4.3.

Country or zone free from *A. tumida*

1. Historically free status

   A country or *zone* may be considered free from the pest after conducting a *risk assessment* as referred to in Article 9.4.2. but without formally applying a specific *surveillance* programme if the country or *zone* complies with the provisions of Chapter 1.4.

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 *A. tumida* infestation after conducting a *risk assessment* as referred to in Article 9.4.2. and when:

   a) the *Veterinary Authority* or other *Competent Authority* with responsibility for ~~the health~~ reporting and control of *diseases* of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or *zone*;

   b) *A. tumida* infestation is notifiable in the whole country or *zone*, and any clinical cases suggestive of *A. 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 *A. tumida* infestation, an annual survey supervised by the ~~*Competent*~~ *Veterinary Authority*, with negative results, 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 *A. 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 ~~*Competent*~~ *Veterinary Authority*, with negative results, is carried out on a representative sample of *apiaries* to indicate that there 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 *A. tumida* spp., in conformity with one of the procedures referred to in Chapter 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 *A .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 9.4.4.

Recommendations on safe commodities

Regardless of the status of the *exporting country* with regard to *A. tumida* infestation, ~~*Competent*~~ *Veterinary 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 9.4.5.

Recommendations for the importation of individual consignments containing a single live queen honey bee or queen bumble bee, accompanied by a small number of associated attendants (a maximum of 20 attendants per queen)

~~*Competent*~~ *Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the bees come from a country or *zone* officially free from *A. tumida* infestation.

OR

~~*Competent*~~ *Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* including an attestation from the ~~*Competent*~~ *Veterinary Authority* 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 signs or suspicion of the presence of *A. tumida* or its eggs, larvae or pupae; and

2. the bees come from an area of at least 100 km radius where no *apiary* has been subject to any restrictions associated with the occurrence of *A. 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 *A. 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.

Article 9.4.6.

Recommendations for the importation of live worker bees, drone bees or bee colonies with or without associated brood combs or for live bumble bees

~~*Competent*~~ *Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1. the bees come from a country or *zone* officially free from *A. tumida* infestation; and

2. the bees and accompanying packaging presented for export have been inspected and do not contain *A. tumida* or its eggs, larvae or pupae; and

3. the consignment of bees is covered with fine mesh through which a live beetle cannot enter.

Annex XXIX (contd)

Article 9.4.7.

Recommendations for the importation of eggs, larvae and pupae of honey bees or bumble bees

~~Competent~~ *Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1. the products were sourced from a free country or *zone* free from *A. tumida* infestation ~~(under study)~~;

OR

~~2. have been isolated from queens in a *quarantine station*; and~~

2. the products have been bred and kept under a controlled environment within a recognised establishment which is supervised and controlled by the *Veterinary Authority*;

~~3. are from hives or come from hives or colonies which were inspected immediately prior to entry into the *quarantine station* and show no signs or suspicion of the presence of *A. tumida* or its eggs or larvae or pupae then and during the quarantine period.~~

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 *A. 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 *A. tumida* or its eggs, larvae or pupae.

Article 9.4.8.

Recommendations for the importation of used equipment associated with beekeeping

~~Competent~~ *Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1. the equipment:

   EITHER

   a) comes from a country or *zone* free from *A. 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. tumida* spp., in conformity with one of the procedures referred to in Chapter X.X. (under study);

AND

2. all precautions have been taken to prevent infestation/contamination.

Article 9.4.9.

Recommendations for the importation of honey-bee collected pollen and beeswax (in the form of honeycomb)

~~*Competent*~~ *Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1. the products:

   EITHER

   a) comes from a country or *zone* free from *A. 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. tumida* spp., in conformity with one of the procedures referred to in Chapter X.X. (under study);

AND

2. all precautions have been taken to prevent infestation/contamination.

Article 9.4.10.

Recommendations for the importation of comb honey

~~*Competent*~~ *Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1. comes from a country or *zone* free from *A. tumida* infestation; and

2. contains no live honey bees or bee brood.

Community comment

In the light of the OIE commodity based trade approach, there should be an alternative with risk mitigation measures, which would read:

3. or were subjected to a treatment at a temperature of -12°C or lower in the core of the product during at least 24 hours.

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— text deleted

CHAPTER 9.5.

TROPILAELAPS INFESTATION OF HONEY BEES

Community comment

The Community can support the proposed changes. However in article 9.5.1 below the word "mite" should read "mites", and there are two new species recognised, T. thaii and T. mercedesae. Justification in "Denis L. Anderson & Mathew J. Morgan (2007) Genetic and morphological variation of bee-parasitic Tropilaelaps mites (Acari: Laelapiae): new and re-defined species. Exp. Appl. Acarol. (2007) 43:1–24".

Article 9.5.1.

General provisions

For the purposes of this Chapter, *Tropilaelaps* infestation of the honey bee *Apis mellifera* L. is caused by the mite *Tropilaelaps dareae* and *T. koenigerum*. The mite is an ectoparasite of brood of *Apis mellifera* L., *Apis laboriosa* and *Apis dorsata*, and cannot survive for periods of more than 7 days away from bee brood.

Early signs of *infection* normally go unnoticed, but the growth in the mite population is rapid leading to high hive mortality. The *infection* spreads by direct contact from adult bee to adult bee, and by the movement of infested bees and bee brood. The mite can also act as a vector for viruses of the honey bee.

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

Article 9.5.2.

Determination of the Tropilaelaps **status of a country or zone/ compartment**

The *Tropilaelaps* status of a country or *zone/compartment* (under study) can only be determined after considering the following criteria:

1. a *risk assessment* has been conducted, identifying all potential factors for *Tropilaelaps* occurrence and their historic perspective;

2. *Tropilaelaps* infestation should be notifiable in the whole country or *zone/compartment* (under study) and all clinical signs suggestive of *Tropilaelaps* infestation should be subjected to field and *laboratory* investigations;

3. an on-going awareness programme should be in place to encourage reporting of all cases suggestive of *Tropilaelaps* infestation;

4. the *Veterinary Authority* or other *Competent Authority* with responsibility for ~~the health~~ reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the country.

Article 9.5.3.

Country or zone/ compartment (under study) free from *Tropilaelaps* spp

1. Historically free status

A country or *zone/compartment* (under study) may be considered free from the *disease* after conducting a *risk assessment* as referred to in Article 9.5.2. but without formally applying a specific *surveillance* programme if the country or *zone/compartment* (under study) complies with the provisions of Chapter 1.4.

2. Free status as a result of an eradication programme

A country or *zone/compartment* (under study) which does not meet the conditions of point 1 above may be considered free from *Tropilaelaps* infestation after conducting a *risk assessment* as referred to in Article 9.5.2. and when:

a) the *Veterinary Authority* or other *Competent Authority* with responsibility for ~~the health~~ reporting and control of *diseases* of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or *zone/compartment* (under study);

b) *Tropilaelaps* infestation is notifiable in the whole country or *zone/compartment* (under study), and any clinical cases suggestive of *Tropilaelaps* infestation are subjected to field and *laboratory* investigations;

c) for the 3 years following the last reported *case* of *Tropilaelaps* infestation, an annual survey supervised by the *Veterinary Authority*, with negative results, have been carried out on a representative sample of *apiaries* in the country or *zone/compartment* (under study) to provide a confidence level of at least 95% of detecting *Tropilaelaps* infestation if at least 1% of the *apiaries* were infected at a within-*apiary* prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with a higher likelihood of infestation;

d) to maintain free status, an annual survey supervised by the *Veterinary Authority*, with negative results, is carried out on a representative sample of *apiaries* in the country or *zone/compartment* (under study) to indicate that there has been no new *cases*; such surveys may be targeted towards areas with a higher likelihood of *disease*;

e) (under study) there is no self-sustaining feral population of *A. mellifera*, *A. dorsata* or *A. laboriosa*, or other possible host species in the country or *zone/compartment* (under study);

f) the importation of the *commodities* listed in this Chapter into the country or *zone/compartment* (under study) is carried out, in conformity with the recommendations of this Chapter.

Article 9.5.4.

Recommendations on safe commodities

Regardless of the status of the *exporting country* with regard to *Tropilaelaps* infestation, *Veterinary Authorities* should authorise without restriction the import or transit through their territory of the following *commodities*:

1. honey bee semen, honey bee eggs and honey bee venom;

2. extracted honey and beeswax (not in the form of honeycomb).

Article 9.5.5.

Recommendations for the importation of live queen honey bees, worker bees and drones with associated brood combs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the bees come from a country or *zone/compartment* (under study) officially free from *Tropilaelaps* infestation.

Article 9.5.6.

Recommendations for the importation of live queen honey bees, worker bees and drones without associated brood combs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the bees have been held in isolation from brood and bees with access to brood, for a period of at least 7 days.

Article 9.5.7.

Recommendations for the importation of used equipment associated with beekeeping

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the equipment:

1. comes from a country or *zone/compartment* (under study) free from *Tropilaelaps* infestation; or

2. contains no live honey bees or bee brood and has been held away from contact with live honey bees for at least 7 days prior to shipment; or

3. has been treated to ensure the destruction of *Tropilaelaps* spp., in conformity with one of the procedures referred to in Chapter X.X. (under study).

Article 9.5.8.

Recommendations for the importation of honey-bee collected pollen, beeswax (in the form of honeycomb), comb honey and propolis

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1. come from a country or *zone/compartment* (under study) free from *Tropilaelaps* infestation; or

2. contain no live honey bees or bee brood and has been held away from contact with live honey bees for at least 7 days prior to shipment; or

3. have been treated to ensure the destruction of *Tropilaelaps* spp., in conformity with one of the procedures referred to in Chapter X.X. (under study).

— text deleted

CHAPTER 9.6.

VARROOSIS OF HONEY BEES

Community comment
The Community can support the proposed changes.

Article 9.6.1.

General provisions

For the purposes of this Chapter, varroosis is a *disease* of the honey bee *Apis mellifera* L. It is caused by the Korea and Japan haplotypes of the mite *Varroa destructor*, the original hosts of which are the Korea and Japan haplotypes of *Apis cerana* (under study). The mite is an ectoparasite of adults and brood of *Apis mellifera* L. Early signs of *infection* normally go unnoticed, and only when *infection* is heavy does it become apparent. The *infection* spreads by direct contact from adult bee to adult bee, and by the movement of infested bees and bee brood. The mite can also act as a vector for viruses of the honey bee.

The number of parasites steadily increases with increasing brood activity and the growth of the bee population, especially late in the season when clinical signs of infestation can first be recognised. The life span of the mite depends on temperature and humidity but, in practice, it can be said to last from some days to a few months.

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

Article 9.6.2.

Determination of the varroosis status of a country or zone/ compartment

The varroosis status of a country or *zone/compartment* (under study) can only be determined after considering the following criteria:

1. a *risk assessment* has been conducted, identifying all potential factors for varroosis occurrence and their historic perspective;

2. varroosis should be notifiable in the whole country or *zone/compartment* (under study) and all clinical signs suggestive of varroosis should be subjected to field and *laboratory* investigations;

3. an on-going awareness programme should be in place to encourage reporting of all cases suggestive of varroosis;

4. the *Veterinary Authority* or other *Competent Authority* with responsibility for ~~the health~~ reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the country.

Article 9.6.3.

Country or zone/ compartment (under study) free from varroosis

1. Historically free status

   A country or *zone/compartment* (under study) may be considered free from the *disease* after conducting

a *risk assessment* as referred to in Article 9.6.2. but without formally applying a specific *surveillance* programme (historical freedom) if the country or *zone/compartment* (under study) complies with the provisions of Chapter 1.4.

2. Free status as a result of an eradication programme

A country or *zone/compartment* (under study) which does not meet the conditions of point 1 above may be considered free from varroosis after conducting a *risk assessment* as referred to in Article 9.6.2. and when:

a) the *Veterinary Authority* or other *Competent Authority* with responsibility for ~~the health~~ reporting and control of *diseases* of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or *zone/compartment* (under study);

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

c) for the 3 years following the last reported *case* of varroosis, an annual survey supervised by the *Veterinary Authority*, with negative results, have been carried out on a representative sample of *apiaries* in the country or *zone/compartment* (under study) to provide a confidence level of at least 95% of detecting varroosis if at least 1% of the *apiaries* were infected at a within-*apiary* prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with a higher likelihood of *disease*;

d) to maintain free status, an annual survey supervised by the *Veterinary Authority*, with negative results, is carried out on a representative sample of *apiaries* in the country or *zone/compartment* (under study) to indicate that there has been no new *cases*; such surveys may be targeted towards areas with a higher likelihood of *disease*;

e) (under study) there is no self-sustaining feral population of *A. mellifera*, the Korea and Japan haplotypes of *Apis cerana* or other possible host species in the country or *zone/compartment* (under study);

f) the importation of the *commodities* listed in this Chapter into the country or *zone/compartment* (under study) is carried out in conformity with the recommendations of this Chapter.

Article 9.6.4.

Recommendations on safe commodities

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

1. honey bee semen, honey bee eggs and honey bee venom;

2. extracted honey and beeswax (not in the form of honeycomb).

Article 9.6.5.

Recommendations for the importation of live queen honey bees, worker bees and drones with or without associated brood combs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the bees come from a country or *zone/compartment* (under study) officially free from varroosis.

Article 9.6.6.

Recommendations for the importation of larvae and pupae of honey bees

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1. were sourced from a free country or *zone/compartment* (under study); or

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

Article 9.6.7.

Recommendations for the importation of used equipment associated with beekeeping

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the equipment:

1. comes from a country or *zone/compartment* (under study) free from varroosis; or

2. contains no live honey bees or bee brood and has been held away from contact with live honey bees for at least 7 days prior to shipment; or

3. has been treated to ensure the destruction of *Varroa destructor*, in conformity with one of the procedures referred to in Chapter X.X. (under study).

Article 9.6.8.

Recommendations for the importation of honey-bee collected pollen, beeswax (in the form of honeycomb), comb honey and propolis

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1. come from a country or *zone/compartment* (under study) free from varroosis; or

2. contain no live honey bees or bee brood and has been held away from contact with live honey bees for at least 7 days prior to shipment; or

3. have been treated to ensure the destruction of *Varroa destructor*, in conformity with one of the procedures referred to in Chapter X.X. (under study).

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Annex XXX

~~GUIDELINES FOR~~ THE CONTROL OF HAZARDS OF ANIMAL HEALTH AND PUBLIC HEALTH IMPORTANCE IN ANIMAL FEED

Community comments

Apart from some comments hereunder included, the Community would like to stress that it is important to avoid any confusion or contradictory overlap with the relevant Codex Alimentarius standards dealing with animal feeding, in particular the Code of Good Animal Feeding (CAC/RCP 54-2004) but also others.

Article 1

Introduction

Animal feed is a critical component of the food-chain that has a direct impact on animal health and welfare and also on food safety and public health.

Historically, the OIE primarily addressed animal feed as an important pathway for the entry and spread of contagious epidemic *diseases*, such as foot and mouth disease, swine vesicular disease and avian influenza. In recent years, the role of feed as a vector for *disease* agents, including zoonotic organisms, was a focus of standards development in regards to bovine spongiform encephalopathy. Animal feed and feed ingredients are widely traded internationally and trade disruptions have the potential to impact economies in both developed and developing countries. Since 2002 the OIE has expanded its zoonotic disease mandate to encompass animal production food safety, working in collaboration with the Codex Alimentarius Commission (CAC) and other international organisations. In 2006 the International Committee resolved that the OIE should develop guidance on foodborne zoonoses and animal feeding, complementing relevant CAC texts.

Article 2

~~purpose~~ Objective and scope

The ~~purpose~~ objective of this ~~OIE guideline~~ Chapter is to provide guidance on animal feeding in relation to animal health and to complement the guidance provided by the Codex Code of Practice on Good Animal Feeding (CAC/RCP 54-2004) which deals primarily with food safety.

Community comment

The word "alimentarius" should be inserted between "Codex" and "Code".

The following should be added at the end: ", and related other Codex texts covering animal feeding, e.g. Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals (CAC/RCP 49-2001)".

~~This guideline~~ Chapter aims at ensuring the control of animal and public health hazards through adherence to recommended practices during the production (procurement, handling, storage, processing and distribution) and use of both commercial and on-farm produced animal feed and feed ingredients for ~~food producing~~ terrestrial animals.

~~Scope~~

This ~~guideline~~ Chapter applies to the production and use of all products destined for animal feed and feed ingredients at all levels whether produced commercially or on farm. It also includes grazing or free-range feeding, forage crop production and water for drinking. Swill feeding is a particular aspect of on-farm practice that is specifically addressed because of its recognised role in *disease* transmission.

~~This~~ These ~~gG~~uidelines This Chapter deals with ~~food or~~ feed for terrestrial ~~food producing~~ animals ~~other than aquatic animals~~ (i.e. livestock and poultry).

Article 3

Definitions

~~*Hazard*~~

~~means a biological, chemical or physical agent in, or a condition of, feed or a feed ingredient an *animal* or animal product with the potential to cause an adverse effect on animal or public health~~.

Feed

means any material (single or multiple), whether processed, semi-processed or raw, which is intended to be fed directly to terrestrial ~~food producing~~ animals (except bees).

Feed additives

means any intentionally added ingredient not normally consumed as feed by itself, whether or not it has nutritional value, which affects the characteristics of feed, ~~or~~ health of the animal or ~~and~~ the characteristics of products of the animal. Microorganisms, enzymes, acidity regulators, trace elements, vitamins and other products fall within the scope of this definition depending on the purpose of use and method of administration. This excludes veterinary drugs.

Community comment

For consistency with the Codex Alimentarius and for better clarity, the Community proposes the following wording for the first sentence:

"means any intentionally added ingredient not normally consumed as feed by itself, whether or not it has nutritional value or other effect on the animal, which affects the characteristics of feed or animal products."

~~*Medicated feed*~~

~~means any feed which contains a veterinary drug administered to food producing animals, for therapeutic or prophylactic purposes or for modification of physiological functions.~~

Feed ingredient

means a component part or constituent of any combination or mixture making up a feed, whether or not it has a nutritional value in the animal's diet, including feed additives. Ingredients are of plant~~,~~ (including aquatic plants)~~,~~ or animal ~~or aquatic~~ or aquatic origin, or other organic or inorganic substances.

Community comment

This definition should be placed right after that of food, as the definition of feed ingredient includes that of feed additives.

~~*Undesirable substance*~~

~~means a contaminant or other substance material which is present in and/or on feed and feed ingredients and which constitute a risk whose presence is potentially harmful to animal or public health and/or is restricted under current regulations~~.

~~*Commercial feed*~~

~~means all materials that are sold and distributed as feed, or to be mixed with feed, for animals except: unmixed seed, whole, processed, or unprocessed; straw, stover, silage, cobs, husks, and hulls; or individual chemical compounds not mixed with other ingredients.~~

~~*Cross c*~~*Contamination*

means ~~contamination~~ the presence of a material or product ~~with another material or product containing a component that~~ in a feed or feed ingredient ~~additive and~~ whose presence in that feed or feed ingredient ~~additive~~ is potentially harmful for animal or public health or is restricted under ~~the regulatory framework~~ current regulations.

Community comment

If the words "the presence" are added at the beginning of the above definition, then the words "whose presence in that feed or feed ingredient is" should be deleted and replaced by a simple comma ","; the second "is" should be deleted too.

Article 4

General principles

1. Roles and responsibilities

The *Competent Authority* has the legal power to set and enforce regulatory animal feeding requirements, and has final responsibility for verifying that these requirements are met. The *Competent Authority* may establish regulatory requirements for relevant parties to provide it with information and assistance. Refer to Chapters 3.1. and 3.2. of the ~~OIE~~ *Terrestrial Code*.

Those involved in the production and use of animal feed and feed ingredients have the responsibility to ensure that these products meet regulatory requirements. Appropriate contingency plans should be in place to enable tracing and recall of non-compliant products. All personnel involved in the manufacture, storage and handling of feed and feed ingredients should be adequately trained and aware of their role and responsibility in preventing the introduction or spread of ~~animal health and public health~~ hazards. ~~Appropriate contingency plans should be developed.~~ ~~E~~quipment Manufacturing equipment, storage and transport facilities should be maintained in good working order and in a sanitary condition.

Community comment

In the last sentence above, the words "be adequate and" should be inserted before "be maintained".

~~It is a particular responsibility of *Veterinary Services* to set and enforce the regulatory requirements pertaining to the use of veterinary drugs, animal *disease* control and the food safety aspects that relate to the management of live animals on farm.~~

Those providing specialist services to producers and to the feed industry (e.g. private veterinarians, nutritionists and laboratories) may be required to meet specific regulatory requirements pertaining to the services they provide (e.g. *disease* reporting, quality standards, transparency).

Community comment

The words "and" should be deleted between "nutritionists" and "laboratories", are they are a list of examples and it may not be limited to them.

2. Regulatory safety standards

All feed and feed ingredients should meet regulatory safety standards. In defining limits and tolerances for hazards, scientific evidence, including the sensitivity of analytical methods and on the characterisation of risks, should be taken into account.

3. Risk analysis (risk assessment, risk management and risk communication)

Internationally accepted principles and practices on risk analysis (Section 1.3. of the ~~OIE~~ *Terrestrial Code*~~;~~ and relevant Codex texts) should be used in developing and applying the regulatory framework.

Application of a generic framework should provide a systematic and consistent process for managing all biosecurity risks, while recognising the different risk assessment methodologies used in animal and public health.

4. Good practices

Where national guidelines exist, good agricultural practices and good manufacturing practices (including good hygienic practices) should be followed. Countries without such guidelines are encouraged to develop them.

Where appropriate, Hazard Analysis and Critical Control Point[1] (HACCP) principles should be followed to control hazards that may occur in the manufacture, distribution and feeding of feed and feed additives and feed ingredients.

Community comments

Distribution includes various activities that can represent a risk: after the word "distribution" should be added the words "including transport and storage".

As feed ingredients include feed additives, the paragraph above should read: "… feed and feed ingredients including feed additives".

5. Geographic and environmental considerations

~~Land and facilities used for production of animal feed and feed ingredients and water sources should not be located in close proximity to~~ Epidemiological links between potential sources of hazards for animal health or food safety should be considered when assessing water sources, land or facilities for suitability for the production of animal feed and feed ingredients. Animal health considerations include factors such as *disease* status, location of quarantined premises and existence of *zones/compartments* of specified health status. Food safety considerations include factors such as industrial operations that generate pollutants and waste treatment plants.

6. Zoning and compartmentalisation

Feed is an important component of biosecurity and needs to be considered when defining a compartment or zone in accordance with Chapter 4.3. of the ~~OIE~~ *Terrestrial Code*.

7. Sampling and analysis

Sampling and analytical protocols should be based on scientifically recognized principles and procedures.

Community comment

The words "analytical protocols" should be replaced by "analyses".

8. Labelling

[1]Hazard Analysis and Critical Control Point, as defined in the Annex to the Recommended International Code of Practice ~~on~~ - General Principles of Food Hygiene (CAC/RCP 1-1969).

Labelling on how the feed or feed ingredients should be handled, stored and used should be ~~clear and~~ informative ~~as to how the feed and feed ingredients should be handled, stored and used~~ unambiguous, legible and conspicuously placed on the package if sold in package ~~bagged~~ form and on the waybill and other sales documents if sold in bulk, un-packaged ~~bagged~~ form, and should comply with regulatory requirements.

See Codex Code of Ppractice on Ggood Aanimal Ffeeding (CAC/RCP 54-2004).

9. Design and management of inspection programmes

In meeting animal and public health objectives prescribed in national legislation or required by *importing countries*, *Competent Authorities* contribute through the ~~direct performance of some tasks~~ inspection or through the auditing of animal and public health activities conducted by other agencies or the private sector.

Feed and feed ingredients business operators and other relevant parts of industry should practice self-regulation to secure compliance with required standards for procurement, handling, storage, processing, distribution and use. Operators have the primary responsibility for implementing systems for process control. ~~Where such systems are applied, t~~The *Competent Authority* should verify that ~~they~~ process control systems and safety standards achieve all regulatory requirements.

10. Assurance and certification

Feed business operators are responsible for demonstrating the safety of the establishments under their control. *Competent Authorities* are responsible for providing assurances domestically and to trading partners that regulatory ~~requirements~~ safety standards have been met. For international trade in animal product based feeds, *Veterinary Services* are required to provide international veterinary certificates.

11. Hazards associated with animal feed

a) Biological hazards

Biological hazards that may occur in feed and feed ingredients include agents such as bacteria, viruses, prions, fungi and parasites.

b) Chemical hazards

Chemical hazards that may occur in feed and feed ingredients include naturally occurring chemicals (such as mycotoxins and gossypol), industrial and environmental contaminants (such as dioxins and PCBs), residues of veterinary drugs and pesticides and also radionuclides.

Community comment

Botanical impurities may also carry chemical hazards mentioned above, so the words "and biocides" should be added after "pesticides".

In addition the Community believes that naturally occurring substances (instead of chemicals as proposed) should be included in biological hazards in point a) above.

c) Physical hazards

Physical hazards that may occur in feed and feed ingredients include foreign objects (such as pieces of glass, metal, plastic or wood).

12. ~~Cross-c~~Contamination

It is important to avoid ~~cross-~~contamination during the manufacture, storage, distribution (including transport) and use of feed and feed ingredients and relevant provisions should be included in current regulations ~~the regulatory framework~~. Scientific evidence, including the sensitivity of analytical methods and on the characterisation of risks, should be drawn upon in developing this framework.

Procedures, such as flushing, sequencing and physical clean-out, should be used to avoid ~~cross-~~contamination between batches of feed or feed ingredients.

13. Antimicrobial resistance

Concerning the use of antimicrobials in animal feed refer to Section 3.9. of the ~~OIE~~ *Terrestrial Code*.

14. Management of information

The Competent Authority should establish clear requirements for the provision of information by the private sector as this relates to regulatory requirements.

Records should be maintained in a readily accessible form regarding the production, distribution and use of feed and feed ingredients. These records are required to facilitate the prompt trace-back of feed and feed ingredients to the immediate previous source, and trace-forward to the next subsequent recipients, to address identified animal health or public health concerns.

Animal identification and *animal traceability* are tools for addressing animal health (including zoonoses), and food safety risks arising from animal feed (see Section 3.5. of the ~~OIE~~ *Terrestrial Code*; Section 4.3. of CAC/RCP 54-2004).

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Annex XXXI

CHAPTER 8.12.

RIFT VALLEY FEVER

Community comments

The Community can support the proposed changes.

Article 8.12.1.

General provisions

For the purposes of the *Terrestrial Code*, the *infective period* for Rift Valley fever (RVF) shall be 30 days.

For the purposes of this Chapter, ruminants include camels.

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

The historic distribution of RVF is the sub-Saharian African continent, Madagascar and the Arabian Peninsula.

Countries or *zones* within the historic distribution of RVF or adjacent to those that are historically infected should be subjected to *surveillance*.

Epidemics of RVF may occur in infected areas after flooding. They are separated by inter-epidemic periods that may last for several decades in arid areas and, during these periods, the prevalence of *infection* in humans, animals and mosquitoes can be difficult to detect.

In the absence of clinical *disease*, the RVF status of a country or *zone* within the historically infected regions of the world should be determined by a *surveillance* programme (carried out in accordance with Chapter 1.4.) focusing on mosquitoes and serology of susceptible mammals. The programme should concentrate on parts of the country or *zone* at high risk because of historical, geographic and climatic factors, ruminant and mosquito population distribution, and proximity to areas where epidemics have recently occurred.

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

Article 8.12.1.bis

Trade in commodities

Commodities other than those listed below are not considered to have the potential to spread RVF when they are the subject of *international trade*.

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should comply with recommendations of this Chapter as relevant to the RVF status of the exporting country or *zone*:

1. live ruminants;

2. *meat* and *meat products* of domestic and wild ruminants.

3. *milk* and *milk products*. (under study)

Annex XXXI (contd)

Article 8.12.2.

RVF infection free country or zone

A country or a *zone* may be considered free from RVF infection when the *disease* is notifiable in animals throughout the country and either:

1. the country or *zone* lies outside the historically infected regions, and not adjacent to historically infections; or

2. a *surveillance* programme as described in Article 8.12.1. has demonstrated no evidence of RVF infection in humans, animals or mosquitoes in the country or *zone* during the past 4 years following a RVF epidemic.

The provisions of the last paragraph of Article 8.12.1. may need to be complied with on a continuous basis in order to maintain freedom from *infection*, depending on the geographical location of the country or *zone*.

A RVF infection free country or zone in which *surveillance* and monitoring has found no evidence that RVF infection is present will not lose its free status through the importation of permanently marked seropositive animals or those destined for direct *slaughter*.

Article 8.12.3.

RVF infected country or zone without disease

A RVF disease free country or zone is a country or *zone* that is not *infection* free (see Article 8.12.2.) but in which *disease* has not occurred in humans or animals in the past 6 months provided that climatic changes predisposing to *outbreaks* of RVF have not occurred during this time.

Article 8.12.4.

RVF infected country or zone with disease

A RVF infected country or zone with *disease* is one in which clinical *disease* in humans or animals has occurred within the past 6 months.

~~Article 8.12.5.~~

~~**Trade in commodities**~~

~~*Commodities* other than those listed below are not considered to have the potential to spread RVF when they are the subject of *international trade*.~~

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

~~1. live ruminants;~~

~~2. *meat* and *meat products* of domestic and wild ruminants.~~

Article 8.12.6.

Recommendations for importation from RVF infection free countries or zones

for ruminants

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1. were kept in a RVF free country or zone since birth or for at least 30 days prior to shipment; and

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

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

   b) were protected from mosquito attack at all times when transiting through an *infected zone*.

Article 8.12.7.

Recommendations for importation from RVF infection free countries or zones

for *meat* and *meat products* of domestic and wild ruminants

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the products are derived from animals which remained in the RVF infection free country/free zone since birth or for the last 30 days.

Article 8.12.8.

Recommendations for importation from RVF infected countries/ zones without disease

for ruminants

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no evidence of RFV on the day of shipment;

2. met one of the following conditions;

   a) were kept in a RVF infected country/zone free of *disease* since birth or for the last 6 months providing that climatic changes predisposing to *outbreaks* of RVF have not occurred during this time; or

~~OR~~

   ~~3.~~b) were vaccinated against RVF at least 21 days prior to shipment with a modified live virus vaccine; or

~~OR~~

   ~~4.~~ c) were held in a mosquito-proof *quarantine station* for at least 30 days prior to shipment during which the animals showed no clinical signs of RVF and were protected from mosquitoes between quarantine and the *place of shipment* as well as at the *place of shipment*;

Annex XXXI (contd)

AND

~~5~~3. did not transit through an *infected zone* with *disease* during transportation of the *place of shipment*.

Article 8.12.9.

Recommendations for importation from RVF infected countries or zones without disease

for *meat* and *meat products* of domestic and wild ruminants

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the products are derived from animals which:

   a) remained in the RVF ~~disease free country/zone~~ infected country or zone without disease since birth or for the last 30 days;

   b) were slaughtered in an approved *abattoir* and were subjected to ante-mortem and post-mortem inspections for RVF with favourable results;

2. the carcasses from which the products were derived were submitted to maturation at a temperature above +2°C for a minimum period of 24 hours following *slaughter*.

Article 8.12.10. (under study)

Recommendations for importation from RVF infected countries / zones with or without disease

for milk and milk products

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the consignment:

1. was subjected to pasteurization; or

2. 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.

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CHAPTER 11.4.

BOVINE CYSTICERCOSIS

Community comments

The Community can support the proposed changes.

Article 11.4.1.

General provisions

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

Article 11.4.2.

Recommendations for the importation of fresh meat of cattle

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of meat:

1. comes from animals which have been slaughtered in an approved *abattoir* and have been subjected to ante-mortem and post-mortem inspections for bovine cysticercosis with favourable results;

~~2. has been recognised as being free from bovine cysticercosis;~~ or

32. in cases of moderate infestation, has been processed using one of the methods provided in the "Recommended International Code of Practice for *ante-mortem* and *post-mortem* judgement of slaughter animals and meat", namely: freezing or heat treatment at 60°C (140°F) (FAO/WHO - Codex Alimentarius Commission CAC/RCP 34-1985).

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CHAPTER 15.6.

TESCHOVIRUS ENCEPHALOMYELITIS
(previously enterovirus encephalomyelitis, Teschen disease, Talfan disease)

Community comments

Although the Community could support the proposed changes it requests the OIE to delete this Chapter as there were extensive reasons given by the OIE when this disease was removed from the list of OIE notifiable diseases in 2005.

Article 15.6.1.

General provisions

For the purposes of the *Terrestrial Code*, the *incubation period* for Teschovirus encephalomyelitis shall be 40 days.

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

Article 11.8.1.bis

Trade in commodities

Commodities other than those listed below are not considered to have the potential to spread Teschovirus encephalomyelitis when they are the subject of *international trade*.

When authorising import or transit, *Veterinary Authorities* should comply with recommendations of this Chapter as relevant to the Teschovirus encephalomyelitis status of the exporting country, *zone* or *compartment*.

1. domestic and wild pigs;
2. semen of domestic and wild pigs;
3. *fresh meat* of domestic and wild pigs;
4. *meat products* of domestic and wild pigs which have not been processed to ensure the destruction of Teschovirus encephalomyelitis virus;
5. products of animal origin (from pigs) intended for use in animal feeding or for agricultural or industrial use;
6. products of animal origin (from pigs) intended for pharmaceutical or surgical use.

Article 15.6.2.

Teschovirus encephalomyelitis free country

A country may be considered free from Teschovirus encephalomyelitis when it has been shown that Teschovirus encephalomyelitis has not been present for at least the past 3 years.

This period shall be 6 months after the *slaughter* of the last affected animal for countries in which a *stamping-out policy* is practised with or without vaccination against Teschovirus encephalomyelitis.

Article 15.6.3.

Teschovirus encephalomyelitis infected zone

A zone shall be considered as infected with Teschovirus encephalomyelitis until:

1. at least 40 days have elapsed after the confirmation of the last *case* and the completion of a *stamping-out policy* and *disinfection* procedures, or

2. 6 months have elapsed after the clinical recovery or death of the last affected animal if a *stamping-out policy* was not practised.

~~Article 15.6.4.~~

~~**Trade in commodities**~~

~~*Veterinary Authorities* of Teschovirus encephalomyelitis free countries may prohibit importation or transit through their territory, from countries considered infected with Teschovirus encephalomyelitis, of the following *commodities*:~~

~~1. domestic and wild pigs;~~

~~2. semen of domestic and wild pigs;~~

~~3. *fresh meat* of domestic and wild pigs;~~

~~4. *meat products* of domestic and wild pigs which have not been processed to ensure the destruction of Teschovirus encephalomyelitis virus;~~

~~5. products of animal origin (from pigs) intended for use in animal feeding or for agricultural or industrial use;~~

~~6. products of animal origin (from pigs) intended for pharmaceutical or surgical use.~~

Article 15.6.5.

Recommendations for importation from Teschovirus encephalomyelitis free countries

<u>for domestic pigs</u>

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

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

2. were kept in a country free from Teschovirus encephalomyelitis since birth or for at least the past 40 days.

Article 15.6.6.

Recommendations for importation from Teschovirus encephalomyelitis free countries

<u>for wild pigs</u>

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

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

2. come from a country free from Teschovirus encephalomyelitis;

if the country of origin has a common border with a country considered infected with Teschovirus encephalomyelitis:

3. were kept in a *quarantine station* for the 40 days prior to shipment.

Article 15.6.7.

Recommendations for importation from countries considered infected with Teschovirus encephalomyelitis

for domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

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

2. were kept since birth, or for the past 40 days, in an *establishment* where no *case* of Teschovirus encephalomyelitis was officially reported during that period, and that the *establishment* of origin was not situated in an Teschovirus encephalomyelitis *infected zone*; or

3. were kept in a *quarantine station* for the 40 days prior to shipment;

4. have not been vaccinated against Teschovirus encephalomyelitis; or

5. were vaccinated against Teschovirus encephalomyelitis, not less than 30 days and not more than one year prior to shipment (the nature of the vaccine used, whether inactivated or modified live virus, and the virus types and strains included shall also be stated in the certificate).

Article 15.6.8.

Recommendations for importation from countries considered infected with Teschovirus encephalomyelitis

for wild pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

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

2. were kept in a *quarantine station* for the 40 days prior to shipment;

3. have not been vaccinated against Teschovirus encephalomyelitis; or

4. were vaccinated against Teschovirus encephalomyelitis, not less than 30 days and not more than one year prior to shipment (the nature of the vaccine used, whether inactivated or modified live virus, and the virus types and strains included shall also be stated in the certificate).

Article 15.6.9.

Recommendations for importation from Teschovirus encephalomyelitis free countries

for semen of pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the donor animals:

1. showed no clinical sign of Teschovirus encephalomyelitis on the day of collection of the semen;

2. were kept in a country free from Teschovirus encephalomyelitis for not less than 40 days prior to collection.

Article 15.6.10.

Recommendations for importation from countries considered infected with Teschovirus encephalomyelitis

for semen of pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the donor animals:

1. showed no clinical sign of Teschovirus encephalomyelitis on the day of collection of the semen;

2. were kept in the *exporting country*, for the 40 days prior to collection, in an *establishment* or *artificial insemination centre* where no *case* of Teschovirus encephalomyelitis was officially reported during that period, and that the *establishment* or *artificial insemination centre* was not situated in an Teschovirus encephalomyelitis *infected zone*.

Article 15.6.11.

Recommendations for importation from Teschovirus encephalomyelitis free countries

for *fresh meat* of pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from animals:

1. which have been kept in a country free from Teschovirus encephalomyelitis since birth or for at least the past 40 days;

2. which have been slaughtered in an approved *abattoir* and have been subjected to ante-mortem and post-mortem inspections for Teschovirus encephalomyelitis with favourable results.

Article 15.6.12.

Recommendations for importation from countries considered infected with Teschovirus encephalomyelitis

for *fresh meat* of pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from animals:

1. which have not been kept in an Teschovirus encephalomyelitis *infected zone*;

2. which have been slaughtered in an approved *abattoir* not situated in an Teschovirus encephalomyelitis *infected zone* and have been subjected to ante-mortem and post-mortem inspections for Teschovirus encephalomyelitis with favourable results.

Article 15.6.13.

Recommendations for importation from countries considered infected with Teschovirus encephalomyelitis

for *meat products* of pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the entire consignment of *meat products* comes from animals which have been slaughtered in an approved *abattoir* and have been subjected to ante-mortem and post-mortem inspections for Teschovirus encephalomyelitis with favourable results;

2. the *meat products* have been processed to ensure the destruction of the Teschovirus encephalomyelitis virus;

3. the necessary precautions were taken after processing to avoid contact of the meat with any source of Teschovirus encephalomyelitis virus.

Article 15.6.14.

Recommendations for importation from Teschovirus encephalomyelitis free countries

for products of animal origin (from pigs) intended for use in animal feeding or for agricultural or industrial use *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that these products come from animals which have been kept in a country free from Teschovirus encephalomyelitis since birth or for at least the past 40 days.

Article 15.6.15.

Recommendations for importation from countries considered infected with Teschovirus encephalomyelitis

for meal and flour from blood, meat, defatted bones, hooves and claws (from pigs)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed using heat treatment to ensure the destruction of Teschovirus encephalomyelitis virus.

Annex XXXI (contd)

Article 15.6.16.

Recommendations for importation from countries considered infected with Teschovirus encephalomyelitis

for bristles

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of Teschovirus encephalomyelitis virus, in premises controlled and approved by the *Veterinary Authority* of the *exporting country*.

Annex XXXII

QUESTIONNAIRE FOR BSE-STATUS RECOGNITION

REVISED VERSION- SEPTEMBER 2008

(including 2008 *Terrestrial Code* and 2008 *Manual* numbering)

Community comment

The Community can support the inclusion of the BSE questionnaire in the Terrestrial Code.

General introduction

Acceptance of this submission is based on the compliance of the Veterinary Service of the applicant country, *zone* or *compartment* with the provisions of Chapters 3.1. of the *Terrestrial Code* and the compliance of BSE diagnostic laboratories with the provisions of Chapter 1.1.3. of the *Terrestrial Manual*. Documentary evidence should be provided to support this based on Chapter 3.2. of the *Terrestrial Code*.

The OIE *Terrestrial Code* Chapter on BSE, Article 11.6.2. prescribes the criteria to determine the BSE risk status of a the cattle population of a country, *zone* or *compartment*. This document is the means whereby a claim for negligible risk (Article 11.6.3.) or controlled risk (Article 11.6.4.) can be made to the OIE.

The document comprises the following:

Section 1 – Risk assessment (Article 11.6.2. § 1)

Section 2 – Other requirements of Article 11.6.2. §2-4

- Ongoing awareness program
- Compulsory notification and investigation
- Diagnostic capability

Section 3 – Surveillance (Article 11.6.2. and Articles 11.6.20. to 11.6.22.)

Section 4 – BSE history of the country, *zone* or *compartment* (Article 11.6.3. and 11.6.4.)

N.B. Where, during the completion of this questionnaire, the submitting *Veterinary Service* provides documentation regarding the legislation under which it is mandated, it should provide the content of any legal act described (in one of the three official languages of OIE), as well as the dates of official publication and implementation. Submitting countries are encouraged to follow the format and numbering used in this document.

Annex XXXII (contd)

SECTION 1
RISK ASSESSMENT (11.6.2.§1)

Introduction

The first step in determining the bovine spongiform encephalopathy (BSE) risk status of the cattle population of a country, *zone* or *compartment* is to conduct a *risk assessment* (reviewed annually), based on Section 2. and 3. and Chapter 4.3. of the *Terrestrial Code*, identifying all potential factors for BSE occurrence and their historic perspective.

Documentation guidelines

This section provides guidance on the data gathering and presentation of information required to support the risk release and exposure assessments in respect of:

Release assessment

1. The potential for the release of the BSE agent through importation of meat-and-bone meal or greaves
2. The potential for the release of the BSE agent through the importation of potentially infected live cattle
3. The potential for the release of the BSE agent through the importation of potentially infected products of bovine origin

Exposure assessment

1. The origin of bovine carcasses, by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of cattle feed production
2. The potential for the exposure of cattle to the BSE agent through consumption of meat-and-bone meal or greaves of bovine origin

In each of the five areas of release and exposure assessment that follow, the contributor is guided in terms of the question, the rationale and the evidence required to support the country, *zone* or *compartment* status claim.

Release assessment

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

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

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

This point is irrelevant if the exposure assessment outlined below in Article 11.6.27. 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 cattle.

Evidence required:

1.1.1. 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

1.1.2. Documentation on annual volume, by country of origin, of *meat-and-bone meal*, *greaves* or feedstuffs containing them imported during the past 8 years.

1.1.3. Documentation describing the species composition of the imported *meat-and-bone meal*, *greaves* or feedstuffs containing them.

1.1.4. Documentation, from the *Veterinary Service* of 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 BSE agent, should it be present.

1.2. The potential for the release of the BSE agent through the importation of potentially infected live cattle

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

Rationale: The release risks are dependent on:

- country*, zone* or *compartment* 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 imported cattle in the country, *zone* or *compartment* 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 cattle 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;
- dairy versus meat breeds, where there are differences in exposure in the country, *zone* or *compartment* of origin because feeding practices result in greater exposure of one category;
- age at slaughter.

Evidence required:

1.2.1. Documentation including tables on the country, *zone* or *compartment* of origin of imports. This should identify the country, *zone* or *compartment* of origin of the cattle, the length of time they lived in that country, *zone* or *compartment* and of any other country in which they have resided during their lifetime.

1.2.2. Documentation including tables describing origin and volume of imports.

1.2.3. Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country, *zone* or *compartment* of origin.

1.3. The potential for the release of the BSE agent through the importation of potentially infected products of bovine origin

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

Rationale: The release risks are dependent on:

- the origin of the cattle products and whether these products contain tissues known to contain BSE infectivity (Article 11.6.13.);
- country, *zone* or *compartment* 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 cattle in the country, *zone* or *compartment* 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 cattle 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;
- dairy versus meat breeds, where there are differences in exposure in the country, *zone* or *compartment* of origin because feeding practices result in greater exposure of one category;
- age at slaughter.

Evidence required:

1.3.1. Documentation on the country, *zone* or *compartment* of origin of imports. This should identify the country, *zone* or *compartment* of origin of cattle from which the products were derived, the length of time they lived in that country, *zone* or *compartment* and of any other country in which they have resided during their lifetime.

1.3.2. Documentation describing origin and volume of imports

1.3.3. Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country, *zone* or *compartment* of origin.

Exposure assessment

1.4. The origin of bovine carcasses, by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of cattle feed production

Question to be answered: How have bovine carcasses, by-products and slaughterhouse waste been processed over the past 8 years?

Rationale: The overall risk of BSE in the cattle population of a country, *zone* or *compartment* 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, *zone* or *compartment* is of negligible or controlled BSE risk, it must have demonstrated that appropriate measures have been taken to manage any risks identified. If potentially infected cattle or contaminated materials are rendered, there is a risk that the resulting *meat-and-bone meal* could retain BSE infectivity. Where *meat-and-bone meal* is utilized in the production of any cattle feed, the risk of cross-contamination exists.

Evidence required:

1.4.1. Documentation describing the collection and disposal of fallen stock and materials condemned as unfit for human consumption.

1.4.2. Documentation including tables describing the fate of imported cattle, including their age at slaughter or death.

1.4.3. Documentation describing the definition and disposal of specified risk material, if any.

1.4.4. Documentation describing the rendering process and parameters used to produce *meat-and-bone meal* and *greaves*.

1.4.5. 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.

1.4.6. Documentation describing the end use of imported cattle products and the disposal of waste.

1.4.7. Documentation describing monitoring and enforcement of the above.

1.5. The potential for the exposure of cattle to the BSE agent through consumption of *meat-and-bone meal* or *greaves* of bovine origin

Question to be answered: Has *meat-and-bone meal* or *greaves* of bovine origin been fed to cattle within the past 8 years (Articles 11.6.3. and 11.6.4. in the *Terrestrial Code*)?

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

In the case of countries applying for negligible risk status, it will be required to demonstrate that the ruminant feed ban has been effective for at least 8 years following the birth of the youngest case.

Evidence required:

1.5.1. Documentation describing the use of imported *meat-and-bone meal* and *greaves*, including the feeding of any animal species.

1.5.2. Documentation describing the use made of *meat-and-bone meal* and *greaves* produced from domestic cattle, including the feeding of any animal species.

1.5.3. Documentation on the measures taken to control cross-contamination of cattle feedstuffs with the *meat-and-bone meal* and *greaves* including the risk of cross-contamination during production, transport, storage and feeding.

1.5.4a) Documentation, in the form of the following table, on the audit findings in rendering plants and feed mills processing ruminant material or mixed species containing ruminant material, related to the prohibition of the feeding to ruminants of *meat-and-bone meal* and *greaves*.

Year (information should be provided for each of the 8 years for effectiveness is claimed)	**Type of plant (renderer or feed mill)**	**Number of plants processing ruminant material**	**Number of plants in (A) inspected**	**Total number of visual inspections in (B)**	**Total number of plants in (B) with infractions**	**Total number of inspected plants in (B) with sampling**	**Total number of plants in (C) with positive test results**
		(A)	**(B)**				**(C)**
Year 1	Renderer						
	Feed mill						
Year 2 etc.	Renderer						
	Feed mill						

1.5.4b) Documentation, in the form of the following table, on the audit findings in rendering plants and feed mills processing non-ruminant material, related to the prohibition of the feeding of *meat-and-bone meal* and *greaves* to ruminants.

Year (information should be provided for each of the 8 years for effectiveness is claimed)	**Type of plant (renderer or feed mill)**	**Number of plants processing non-ruminant material**	**Number of plants in (A) inspected**	**Total number of visual inspections in (B)**	**Total number of plants in (B) with infractions**	**Total number of inspected plants in (B) with sampling**	**Total number of plants in (C) with positive test results**
		(A)	**(B)**				**(C)**
Year 1	Renderer						
	Feed mill						
Year 2 etc.	Renderer						

Feed mill

1.5.5a) Documentation, in the form of the following table, on each plant above processing ruminant material or mixed species containing ruminant material with infractions, specifying the type of infraction and the method of resolution.

Year (information should be provided for each of the 8 years for effectiveness is claimed) (renderer or feed mill)	Plant ID	Nature of infraction	Method of resolution	Follow up results	Type of plant
Year 1	Renderer	ID 1			
		ID 2			
		ID 3 etc.			
	Feed mill	ID 1			
		ID 2			
		ID 3 etc.			
Year 2 etc.	Renderer				
	Feed mill				

1.5.5b) Documentation, in the form of the following table, on each plant above processing non-ruminant material with infractions, specifying the type of infraction and the method of resolution.

Year (information should be provided for each of the 8 years for effectiveness is claimed) (renderer or feed mill)	Plant ID	Nature of infraction	Method of resolution	Follow up results	Type of plant
Year 1	Renderer	ID 1			
		ID 2			
		ID 3 etc.			
	Feed mill	ID 1			
		ID 2			
		ID 3 etc.			
Year 2 etc.	Renderer				
	Feed mill				

1.5.6. Documentation explaining why, in light of the findings displayed in the preceding four tables, it is considered that there has been no significant exposure of cattle to the BSE agent through consumption of *meat-and-bone meal* or *greaves* of bovine origin.

1.5.7. Documentation of husbandry practices (multiple species farms) which could lend themselves to cross-contamination of cattle feed with *meat-and-bone meal* and *greaves* destined to other species.

SECTION 2

OTHER REQUIREMENTS (11.6.2. § 2-4)

2.1. Awareness program (Article 11.6.2. § 2)

Questions to be answered:

- Is there an awareness programme?
- What is the target audience?
- What is the curriculum and how long has it been in place?
- Is there a contingency and/or preparedness plan that deals with BSE?

Rationale

An awareness program is essential to ensure detection and reporting of BSE, especially in countries of low prevalence and competing differential diagnoses.

Evidence required

2.1.1. Documentation indicating when the awareness program was instituted and its continuous application and geographical coverage.

2.1.2. Documentation on the number and occupation of persons who have participated in the awareness program (veterinarians, producers, workers at auctions, slaughterhouses, etc.)

2.1.3. Documentation of materials used in the awareness program (the manual, supportive documents, or other teaching materials).

2.1.4. Documentation on the contingency plan

2.2. Compulsory notification and investigation (Article 11.6.2. § 3)

Questions to be answered:

- What guidance is given to veterinarians, producers, workers at auctions, slaughterhouses, etc.) in terms of the criteria that would initiate the investigation of an animal as a BSE suspect? Have these criteria evolved?
- What were the date and content of the legal act making notification of BSE suspects compulsory?
- What are the measures in place to stimulate notification, such as compensation payments or penalties for not notifying a suspect?

Rationale

The socio-economic implications associated with BSE require that there be incentives and/or obligations to notify and investigate suspect cases.

Evidence required

2.2.1. Documentation on the date of official publication and implementation of compulsory notification. Including a brief description of incentives and penalties.

2.2.2. Documentation on the manual of procedures for investigation of suspect animals and follow-up of positive findings.

Annex XXXII (contd)

2.3. Examination in an approved laboratory of brain or other tissues collected within the framework of the aforementioned surveillance system (Article 11.6.2. § 5)

Questions to be answered:

- Are the diagnostic procedures and methods those described in Chapter 2.4.6. of the Manual?

- Have these diagnostic procedures and methods been applied through the entire surveillance period?

Rationale

The OIE only recognizes for the purpose of this submission samples that have been tested in accordance with the Manual.

Evidence required

2.3.1. Documentation as to the approved laboratories where samples of cattle tissues from the country, *zone* or *compartment* are examined for BSE. (If this is located outside the country, information should be provided on the cooperation agreement).

2.3.2. Documentation of the diagnostic procedures and methods used.

2.3.3. Documentation that the diagnostic procedures and methods have been applied through the entire surveillance period.

Annex XXXII (contd)

SECTION 3

BSE SURVEILLANCE AND MONITORING SYSTEM (11.6.2. § 4)

Questions to be answered:

- Does the BSE surveillance programme comply with the guidelines in Articles 11.6.20. to 11.6.22. of the *Terrestrial Code*?
- What were the results of the investigations?

Rationale

Article 11.6.2.§.4 and Articles 11.6.20. to 11.6.22. prescribe the number of cattle, by subpopulation, that need to be tested in order to ensure the detection of BSE at or above a minimal threshold prevalence.

Evidence required

3.1. Documentation that the samples collected are representative of the distribution of cattle population in the country, *zone* or *compartment*.

3.2. Documentation of the methods applied to assess the ages of animals sampled and the proportions for each method (individual identification, dentition, other methods to be specified)

3.3. Documentation of the means and procedures whereby samples were assigned to the cattle subpopulations described in 11.6.21., including the specific provisions applied to ensure that animals described as clinical met the conditions of 11.6.21§1.

3.4. Documentation of the number of animals meeting 11.6.21§1 as compared to the numbers of clinical samples submitted in previous years in accordance to the former provisions in the *Code*, and explanation of possible differences.

3.5. Documentation, based on the following table, of all clinically suspect cases notified complying with the definition in 11.6.21§1

Laboratory identification number	**Age**	**Clinical signs**	**Point of detection (farm, market channels, slaughterhouse)**

Documentation according to the following table, that the number of target points applicable to the country, *zone* or *compartment* and its BSE surveillance requirements (Type A or type B surveillance as a result of the risk assessment of section 1) are met as described in 11.6.21 and 11.6.22.

SUMMARY TABLE FOR BSE SURVEILLANCE

Year: (complete a separate table for each year of surveillance)

	Surveillance subpopulations							
	Routine slaughter		**Fallen stock**		**Casualty slaughter**		**Clinical suspect**	
	Samples	Points	Samples	Points	Samples	Points	Samples	Points
>1 and <2 years								
≥2 and <4 years								
≥4 and <7 years								
≥7 and <9 years								
≥9 years								
Subtotals								
Total points								

Indicate the number of adult cattle (over 24 month of age) in the country, *zone* or *compartment*

Annex XXXII (contd)

SECTION 4

BSE HISTORY OF THE COUNTRY, *ZONE* OR *COMPARTMENT* (11.6.3. and 11.6.4.)

Questions to be answered

Has BSE occurred in the country, *zone* or *compartment*?

How has it been dealt with?

Rationale

The categorization of a country, *zone* or *compartment* in either negligible or controlled risk is dependent upon, the outcome of the risk assessment described in section 1, compliance with the provisions described in section 2, the results of surveillance described in section 3, and the history of BSE in the country, *zone* or *compartment*. This section provides the opportunity to describe the BSE history in the country, *zone* or *compartment*.

Evidence required

4.1. Documentation of whether a case of BSE has ever been diagnosed in the country, *zone* or *compartment*.

In the case of positive BSE findings:

4.2. Documentation on the origin of each BSE case in respect to the country, *zone* or *compartment*. Indicate the birth date and place of birth.

4.3. Indicate the most recent year of birth in relation to all BSE cases

4.4. Documentation that:

the case(s) and all the progeny of female cases, born within 2 years prior to or after clinical onset of the disease, and

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.

Annex XXXIII

FMD FREE COUNTRY WHERE VACCINATION IS NOT PRACTISED

Report of Country which applies for recognition of status, under Chapter 8.5.
of the *Terrestrial Animal Health Code* 2008, as a FMD free country not practising vaccination

Community comment

The Community can support the inclusion of the FMD questionnaire in the Terrestrial Code.

Please address concisely the following topics. National regulations laws and *Veterinary Administration* directives may be referred to and annexed as appropriate in one of the OIE official languages

1. Introduction

1.1. Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to FMD dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of disease. Provide a map identifying the factors above.

1.2. Livestock industry. Provide a general description of the livestock industry in the country.

2. Veterinary system

2.1. Legislation. Provide a list and summary of all relevant veterinary legislation in relation to FMD.

2.2. *Veterinary Services.* Provide documentation on the compliance of the Veterinary Service of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how the veterinary services supervise and control all FMD related activities. Provide maps and tables wherever possible.

2.3. Role of farmers, industry and other relevant groups in FMD surveillance and control (include a description of training and awareness programs on FMD)

2.4. Role of private veterinary profession in FMD surveillance and control

3. FMD eradication

3.1. History. Provide a description of the FMD history in the country, date of first detection, origin of infection, date of eradication (date of last case), types and subtypes present.

3.2. Strategy. Describe how FMD was controlled and eradicated (e.g. stamping-out, modified stamping-out, zoning), provide timeframe for eradication

3.3. Vaccines and vaccination. Was FMD vaccine ever used? If so, when was the last vaccination carried out? What species were vaccinated?

3.4. Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.

3.5. Animal identification and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of animal identification, herd registration and traceability. How are animal movements controlled in the country? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and related paths of movement.

4. FMD diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3., and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

4.1. Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow up procedures and the time frame for obtaining results.

4.2. Provide an overview of the FMD approved laboratories, in particular to address the following points:

4.2.1. Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO etc. that exist in, or planned for, the laboratory system.

4.2.2. Give details of participation in inter-laboratory validation tests (ring tests).

4.2.3. Is live virus handled?

4.2.4. Biosecurity measures applied

4.2.5. Details of the type of tests undertaken

5. FMD surveillance

Provide documentary evidence that surveillance for FMD in the country complies with the provisions of Articles 8.5.40. to 8.5.46. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

5.1. Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspect cases, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis).

5.2. Serological surveillance. Are serological surveys conducted? If so, provide detailed information on the survey design (confidence level, sample size, stratification) How frequently are they conducted? Are wildlife susceptible species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted surveillance and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the surveillance system including indicators.

5.3. Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many herds, flocks, etc., of each susceptible species are in the country? How are they distributed (e.g., herd density, etc.)? Provide tables and maps as appropriate.

5.4. Wildlife demographics. What susceptible species are present in the country? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?

5.5. Slaughterhouses and markets. Where are the major livestock marketing or collection centers? What are the patterns of livestock movement within the country? How are the animals transported and handled during these transactions.

6. FMD prevention

6.1. Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries or zones that should be taken into account (e.g., size, distance from adjacent border to affected herds or animals)? Describe coordination, collaboration and information sharing activities with neighboring countries.

6.2. Import control procedures

From what countries or zones does the country authorize the import of susceptible animals or their products? What criteria are applied to approve such countries or zones? What controls are applied on entry of such animals and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported animals of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible animals and their products for the past two years, specifying country or zone of origin, species and volume.

6.2.1. Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central veterinary services. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

6.2.2. Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of.

6.2.3. Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow up of the following:

a) Animals
b) genetic material (semen and embryos)
c) animal products
d) veterinary medicinal products (i.e. biologics)

6.2.4. Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

7.1. Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed outbreaks of FMD.

7.2. Is quarantine imposed on premises with suspicious cases, pending final diagnosis? What other procedures are followed regarding suspicious cases?

7.3. In the event of an FMD outbreak:

7.3.1. indicate the sampling and testing procedures used to identify and confirm presence of the causative agent.

7.3.2. describe the actions taken to control the disease situation in and around any holdings found to be infected with FMD.

7.3.3. indicate the control and/or eradication procedures (e.g. vaccination, stamping out, partial slaughter/vaccination etc) that would be taken. Include details on antigen and vaccine banks.

7.3.4. describe the procedures used to confirm that an outbreak has been successfully controlled/eradicated, including any restrictions on restocking.

7.3.5. give details of any compensation payments made available to farmers etc when animals are slaughtered for disease control/eradication purposes and their prescribed timetable.

8. Compliance with the *Terrestrial Code*

8.1 In addition to the documentary evidence that the provisions of Article 8.5.2. are properly implemented and supervised, the Delegate of the country must submit a declaration indicating:

8.1.1. there has been no *outbreak* of FMD during the past 12 months;

8.1.2. no evidence of FMDV infection has been found during the past 12 months;

8.1.3. no vaccination against FMD has been carried out during the past 12 months,

8.2. and should confirm that since the cessation of vaccination no animals vaccinated against FMD have been imported.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 8.5.8. of the *Terrestrial Code* and provide detailed information as specified in sections 3.1., 3.2., 3.3. and 5.2. of this report. Information in relation to other sections need only be supplied if relevant.

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Annex XXXIII (contd)

FMD FREE COUNTRY WHERE VACCINATION IS PRACTISED

Report of Country which applies for recognition of status, under Chapter 8.5.
of the *Terrestrial Animal Health Code* 2008, as a FMD free country practising vaccination

Please address concisely the following topics. National regulations laws and *Veterinary Administration* directives may be referred to and annexed as appropriate in one of the OIE official languages

1. Introduction

1.1. Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to FMD dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of disease. Provide a map identifying the factors above.

1.2. Livestock industry. Provide a general description of the livestock industry in the country.

2. Veterinary system

2.1. Legislation. Provide a list and summary of all relevant veterinary legislation in relation to FMD.

2.2. *Veterinary Services.* Provide documentation on the compliance of the Veterinary Service of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how the veterinary services supervise and control all FMD related activities. Provide maps and tables wherever possible.

2.3. Role of farmers, industry and other relevant groups in FMD surveillance and control (include a description of training and awareness programs on FMD)

2.4. Role of private veterinary profession in FMD surveillance and control

3. FMD eradication

3.1. History. Provide a description of the FMD history in the country, date of first detection, origin of infection, date of eradication (date of last case), types and subtypes present.

3.2. Strategy. Describe how FMD was controlled and eradicated (e.g. stamping-out, modified stamping-out, zoning), provide timeframe for eradication

3.3. Vaccines and vaccination. What type of vaccine is used? What species are vaccinated? Provide evidence that the vaccine used complies with Chapter 2.1.5. of the OIE *Terrestrial Manual*. Describe the vaccination program, including records kept, and provide evidence to show its effectiveness (e.g. vaccination coverage, serosurveillance, etc.).

3.4. Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.

3.5. Animal identification and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of animal identification, herd registration and traceability, including vaccination data. How are animal movements controlled in the country? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and related paths of movement.

Annex XXXIII (contd)

4. FMD diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the *Manual* are applied. In particular, the following points should be addressed:

4.1. Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory (ies) samples are sent to, the follow-up procedures and the time frame for obtaining results.

4.2. Provide an overview of the FMD approved laboratories, in particular to address the following points:

4.2.1. Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO etc. that exist in, or planned for, the laboratory system.

4.2.2. Give details of participation in inter-laboratory validation tests (ring tests).

4.2.3. Is live virus handled?

4.2.4. Biosecurity measures applied

4.2.5. Details of the type of tests undertaken

5. FMD surveillance

Provide documentary evidence that surveillance for FMD in the country complies with the provisions of Articles 8.5.40. to 8.5.46. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

5.1. Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspect cases, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis).

5.2. Surveillance. Are serological and virological surveys conducted, in particular applying the provisions of Article 8.5.44.? If so, provide detailed information on the survey design (confidence level, sample size, stratification). How frequently are they conducted? Are wildlife susceptible species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMD and FMDV, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted surveillance and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the surveillance system including indicators.

5.3. Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many herds, flocks, etc., of each susceptible species are in the country? How are they distributed (e.g., herd density, etc.)? Provide tables and maps as appropriate.

5.4. Wildlife demographics. What susceptible species are present in the country? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?

5.5. Slaughterhouses and markets. Where are the major livestock marketing or collection centers? What are the patterns of livestock movement within the country? How are the animals transported and handled during these transactions.

6. FMD prevention

6.1. Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries or zones that should be taken into account (e.g., size, distance from adjacent border to affected herds or animals)? Describe coordination, collaboration and information sharing activities with neighbouring countries.

6.2. Import control procedures

From what countries or zones does the country authorize the import of susceptible animals or their products? What criteria are applied to approve such countries or zones? What controls are applied on entry of such animals and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported animals of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible animals and their products for the past two years, specifying country or zone of origin, species and volume.

6.2.1. Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central veterinary services. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

6.2.2. Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of.

6.2.3. Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:

a) animals

b) genetic material (semen and embryos)

c) animal products

d) veterinary medicinal products (i.e. biologics)

6.2.4. Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

7.1. Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed outbreaks of FMD.

7.2. Is quarantine imposed on premises with suspicious cases, pending final diagnosis? What other procedures are followed regarding suspicious cases?

7.3. In the event of an FMD outbreak:

7.3.1. indicate the sampling and testing procedures used to identify and confirm presence of the causative agent.

7.3.2. describe the actions taken to control the disease situation in and around any holdings found to be infected with FMD.

7.3.3. indicate the control and/or eradication procedures (e.g. vaccination, stamping out, partial slaughter/vaccination etc) that would be taken. Include details on antigen and vaccine banks.

7.3.4. describe the procedures used to confirm that an outbreak has been successfully controlled/eradicated, including any restrictions on restocking.

7.3.5. give details of any compensation payments made available to farmers etc when animals are slaughtered for disease control/eradication purposes and their prescribed timetable.

8. Compliance with the *Terrestrial Code*

8.1. In addition to the documentary evidence that the provisions of Article 8.5.3. are properly implemented and supervised, the Delegate of the country must submit a declaration indicating.

8.2. 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:

8.2.1. surveillance for FMD and FMDV circulation in accordance with Articles 8.5.40. to 8.5.46. is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;

8.2.2. routine vaccination is carried out for the purpose of the prevention of FMD;

8.2.3. the vaccine used complies with the standards described in the *Terrestrial Manual*.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 8.5.8. of the *Terrestrial Code* and provide detailed information as specified in sections 3.1., 3.2., 3.3. and 5.2. of this report. Information in relation to other sections need only be supplied if relevant.

FMD FREE ZONE WHERE VACCINATION IS NOT PRACTISED

Report of Country which applies for recognition of status, under Chapter 8.5.
of the *Terrestrial Animal Health Code* 2008, for a FMD free zone not practising vaccination

Please address concisely the following topics. National regulations laws and *Veterinary Administration* directives may be referred to and annexed as appropriate in one of the OIE official languages

1. Introduction

1.1. Geographical factors. Provide a general description of the country and the zone including physical, geographical and other factors that are relevant to FMD dissemination, countries or zones sharing common borders and other countries or zones that although may not be adjacent share a link for the potential introduction of disease. The boundaries of the zone must be clearly defined, including a buffer zone if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the zone.

1.2. Livestock industry. Provide a general description of the livestock industry in the country and the zone.

2. Veterinary system

2.1. Legislation. Provide a list and summary of all relevant veterinary legislation in relation to FMD.

2.2. *Veterinary Services.* Provide documentation on the compliance of the Veterinary Service of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how the veterinary services supervise and control all FMD related activities in the country and in the zone. Provide maps and tables wherever possible.

2.3. Role of farmers, industry and other relevant groups in FMD surveillance and control (include a description of training and awareness programs on FMD)

2.4. Role of private veterinary profession in FMD surveillance and control

3. FMD eradication

3.1. History. Provide a description of the FMD history in the country and zone, provide date of first detection, origin of infection, date of eradication in the zone (date of last case), types and subtypes present.

3.2. Strategy. Describe how FMD was controlled and eradicated in the zone (e.g. stamping-out, modified stamping-out), provide timeframe for eradication

3.3. Vaccines and vaccination. If vaccination is used in the rest of the country, what type of vaccine is used? What species are vaccinated? Provide evidence that the vaccine used complies with Chapter 2.1.5. of the OIE *Terrestrial Manual*. Describe the vaccination program, including records kept, and provide evidence to show its effectiveness (e.g. vaccination coverage, serosurveillance, etc.).

3.4. Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.

3.5. Animal identification and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of animal identification, herd registration and traceability. How are animal movements controlled in and between zones of the same or different status, in particular if the provisions of the *Terrestrial Code* in 8.5.9. are applied? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and the related paths of movement.

4. FMD diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

4.1. Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory (ies) samples are sent to. Indicate the laboratory (ies) where samples originating from the zone are diagnosed, the follow-up procedures and the time frame for obtaining results.

4.2. Provide an overview of the FMD approved laboratories, in particular to address the following points:

4.2.1. Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO etc. that exist in, or planned for, the laboratory system.

4.2.2. Give details of participation in inter-laboratory validation tests (ring tests).

4.2.3. Is live virus handled?

4.2.4. Biosecurity measures applied

4.2.5. Details of the type of tests undertaken

5. FMD surveillance

Provide documentary evidence that surveillance for FMD in the zone complies with the provisions of Articles 8.5.40. to 8.5.46. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

5.1. Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspect cases, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis).

5.2. Serological surveillance. Are serological surveys conducted? If so, provide detailed information on the survey design (confidence level, sample size, stratification). How frequently are they conducted? Are wildlife susceptible species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted surveillance and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the surveillance system including indicators.

5.3. Livestock demographics and economics. What is the susceptible animal population by species and production systems in the country and the zone? How many herds, flocks, etc., of each susceptible species are in the country? How are they distributed (e.g., herd density, etc.)? Provide tables and maps as appropriate.

5.4. Wildlife demographics. What susceptible species are present in the country and the zone? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?

5.5. Slaughterhouses and markets. Where are the major livestock marketing or collection centers? What are the patterns of livestock movement within the country? How are the animals transported and handled during these transactions.

6. FMD prevention

6.1. Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries and zones that should be taken into account (e.g. size, distance from adjacent border to affected herds or animals)? Describe coordination, collaboration and information sharing activities with neighbouring countries and zones.

If the FMD free zone without vaccination is situated in an FMD infected country or borders and infected country or zone, describe the animal health measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers.

6.2. Import control procedures

From what countries or zones does the country authorize the import of susceptible animals or their products into free zone? What criteria are applied to approve such countries or zones? What controls are applied on entry of such animals and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported animals of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible animals and their products for the past two years, specifying country or zone of origin, species and volume.

6.2.1. Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central veterinary services. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

6.2.2. Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of.

6.2.3. Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow up of the following:

a) animals

b) genetic material (semen and embryos)

c) animal products

d) veterinary medicinal products (i.e. biologics)

6.2.4. Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

Annex XXXIII (contd)

7. Control measures and contingency planning

7.1. Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed outbreaks of FMD.

7.2. Is quarantine imposed on premises with suspicious cases, pending final diagnosis? What other procedures are followed regarding suspicious cases?

7.3. In the event of an FMD outbreak:

7.3.1. indicate the sampling and testing procedures used to identify and confirm presence of the causative agent.

7.3.2. describe the actions taken to control the disease situation in and around any holdings found to be infected with FMD.

7.3.3. indicate the control and/or eradication procedures (eg. vaccination, stamping out, partial slaughter/vaccination etc) that would be taken. Include details on antigen and vaccine banks.

7.3.4. describe the procedures used to confirm that an outbreak has been successfully controlled/eradicated, including any restrictions on restocking.

7.3.5. Give details of any compensation payments made available to farmers etc when animals are slaughtered for disease control/eradication purposes and their prescribed timetable.

8. Compliance with the *Terrestrial Code*

8.1. In addition to the documentary evidence that the provisions of Article 8.5.4. are properly implemented and supervised, the Delegate of the country must submit a declaration indicating:

8.1.1. there has been no *outbreak* of FMD during the past 12 months;

8.1.2. no evidence of FMDV infection has been found during the past 12 months;

8.1.3. no vaccination against FMD has been carried out during the past 12 months;

8.1.4. no vaccinated animal has been introduced into the zone since the cessation of vaccination, except in accordance with Article 8.5.9.,

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 8.5.8. of the *Terrestrial Code* and provide detailed information as specified in sections 3.1., 3.2., 3.3. and 5.2. of this report. Information in relation to other sections need only be supplied if relevant.

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Annex XXXIII (contd)

FMD FREE ZONE WHERE VACCINATION IS PRACTISED

Report of Country which applies for recognition of status, under Chapter 8.5.
of the *Terrestrial Animal Health Code* 2008, for a FMD free zone practising vaccination

Please address concisely the following topics. National regulations laws and *Veterinary Administration* directives may be referred to and annexed as appropriate in one of the OIE official languages

1. Introduction

1.1. Geographical factors. Provide a general description of the country and the zone including physical, geographical and other factors that are relevant to FMD dissemination, countries or zones sharing common borders and other countries or zones that although may not be adjacent share a link for the potential introduction of disease. The boundaries of the zone must be clearly defined, including a buffer zone if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the zone.

1.2. Livestock industry. Provide a general description of the livestock industry in the country and the zone.

2. Veterinary system

2.1. Legislation. Provide a list and summary of all relevant veterinary legislation in relation to FMD.

2.2. *Veterinary Services.* Provide documentation on the compliance of the Veterinary Service of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how the veterinary services supervise and control all FMD related activities in the country and in the zone. Provide maps and tables wherever possible.

2.3. Role of farmers, industry and other relevant groups in FMD surveillance and control (include a description of training and awareness programs on FMD)

2.4. Role of private veterinary profession in FMD surveillance and control

3. FMD eradication

3.1. History. Provide a description of the FMD history in the country and zone, provide date of first detection, origin of infection, date of eradication in the zone (date of last case), types and subtypes present.

3.2. Strategy. Describe how FMD was controlled and eradicated in the zone (e.g. stamping-out, modified stamping-out), provide timeframe for eradication

3.3. Vaccines and vaccination. What type of vaccine is used? What species are vaccinated? Provide evidence that the vaccine used complies with Chapter 2.1.5. of the OIE *Terrestrial Manual*. Describe the vaccination program in the country and in the zone, including records kept, and provide evidence to show its effectiveness (e.g. vaccination coverage, serosurveillance, etc.).

3.4. Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.

3.5. Animal identification and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of animal identification, herd registration and traceability, including vaccination data. How are animal movements controlled in and between zones of the same or different status, in particular if the provisions of the *Terrestrial Code* in 8.5.9. are applied? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and the related paths of movement.

4. FMD diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

4.1. Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory (ies) samples are sent to, the follow up procedures and the time frame for obtaining results.. Indicate the laboratory (ies) where samples originating from the zone are diagnosed.

4.2. Provide an overview of the FMD approved laboratories, in particular to address the following points:

4.2.1. Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO etc. that exist in, or planned for, the laboratory system.

4.2.2. Give details of participation in inter-laboratory validation tests (ring tests).

4.2.3. Is live virus handled?

4.2.4. Biosecurity measures applied

4.2.5. Details of the type of tests undertaken

5. FMD surveillance

Provide documentary evidence that surveillance for FMD in the zone complies with the provisions of Articles 8.5.40. to 8.5.46. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

5.1 Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspect cases, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis).

5.2 Surveillance. Are serological and virological surveys conducted, in particular applying the provisions of Article 8.5.44.? If so, provide detailed information on the survey design (confidence level, sample size, stratification). How frequently are they conducted? Are wildlife susceptible species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMD and FMDV, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted surveillance and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the surveillance system including indicators.

5.3 Livestock demographics and economics. What is the susceptible animal population by species and production systems in the country and the zone? How many herds, flocks, etc., of each susceptible species are in the country? How are they distributed (e.g., herd density, etc.)? Provide tables and maps as appropriate.

5.4 Wildlife demographics. What susceptible species are present in the country and in the zone? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?

5.5 Slaughterhouses and markets. Where are the major livestock marketing or collection centers? What are the patterns of livestock movement within the country? How are the animals transported and handled during these transactions.

6. FMD prevention

6.1. Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries and zones that should be taken into account (e.g. size, distance from adjacent border to affected herds or animals)? Describe coordination, collaboration and information sharing activities with neighbouring countries and zones.

If the FMD free zone with vaccination is situated in an FMD infected country or borders and infected country or zone, describe the animal health measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers.

6.2. Import control procedures

From what countries or zones does the country authorize the import of susceptible animals or their products into free zone? What criteria are applied to approve such countries or zones? What controls are applied on entry of such animals and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported animals of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible animals and their products for the past two years, specifying country or zone of origin, species and volume.

6.2.1. Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central veterinary services. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

6.2.2. Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of.

6.2.3. Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow up of the following:

a) animals

b) genetic material (semen and embryos)

c) animal products

d) veterinary medicinal products (i.e. biologics)

6.2.4. Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

Annex XXXIII (contd)

7. Control measures and contingency planning

7.1. Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed outbreaks of FMD.

7.2. Is quarantine imposed on premises with suspicious cases, pending final diagnosis? What other procedures are followed regarding suspicious cases?

7.3. In the event of an FMD outbreak:

7.3.1. indicate the sampling and testing procedures used to identify and confirm presence of the causative agent.

7.3.2. describe the actions taken to control the disease situation in and around any holdings found to be infected with FMD.

7.3.3. indicate the control and/or eradication procedures (e.g. vaccination, stamping-out, partial slaughter/vaccination etc) that would be taken. Include details on antigen and vaccine banks.

7.3.4. describe the procedures used to confirm that an outbreak has been successfully controlled/eradicated, including any restrictions on restocking.

7.3.5. Give details of any compensation payments made available to farmers etc when animals are slaughtered for disease control/eradication purposes and their prescribed timetable.

8. Compliance with the *Terrestrial Code*

8.1. In addition to the documentary evidence that the provisions of Article 8.5.5. are properly implemented and supervised, the Delegate of the country must submit a declaration indicating:

8.1.1. that there has been no *outbreak* of FMD for the past 2 years,

8.1.2. no evidence of FMDV circulation for the past 12 months,

8.1.3. surveillance for FMD and FMDV circulation in accordance with Articles 8.5.40. to 8.5.46. is in operation.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 8.5.8. of the *Terrestrial Code* and provide detailed information as specified in sections 3.1., 3.2., 3.3. and 5.2. of this report. Information in relation to other sections need only be supplied if relevant.

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Annex XXXIV

RINDERPEST INFECTION FREE COUNTRY

Report of Country which applies for recognition of status, under Chapter 8.13. of the *Terrestrial Animal Health Code* 2008, as a rinderpest infection free country

Community comment

The Community can support the inclusion of the rinderpest questionnaire in the Terrestrial Code.

Please address concisely the following topics. National regulations laws and *Veterinary Administration* directives may be referred to and annexed as appropriate in one of the OIE official languages

1. Introduction

1.1. Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to rinderpest dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of disease. Provide a map identifying the factors above.

1.2. Livestock industry. Provide a general description of the livestock industry in the country.

2. Veterinary system

2.1. Legislation. Provide a list and summary of all relevant veterinary legislation in relation to rinderpest.

2.2. *Veterinary Services.* Provide documentation on the compliance of the Veterinary Service of the country with the provisions of chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how the veterinary services supervise and control all rinderpest related activities. Provide maps and tables wherever possible.

2.3. Role of farmers, industry and other relevant groups in rinderpest surveillance and control (include a description of training and awareness programs on rinderpest)

2.4. Role of private veterinary profession in rinderpest surveillance and control

3. Rinderpest eradication

3.1. History. Provide a description of the rinderpest history in the country, date of first detection, origin of infection, date of eradication (date of last case), lineage(s) present.

3.2. Strategy. Describe how rinderpest was controlled and eradicated (e.g. stamping-out, modified stamping-out, zoning), provide timeframe for eradication

3.3. Vaccines and vaccination. Was rinderpest vaccine ever used? If so, when was the last vaccination carried out? What species were vaccinated? Has heterologous vaccine been used in cattle, buffalo or yak?

3.4. Legislation, organisation and implementation of the rinderpest eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.

3.5. Animal identification and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of animal identification, herd registration and traceability. How are animal movements controlled in the country? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and related paths of movement.

4. Rinderpest diagnosis

Provide evidence that a system is in place for the rapid confirmation of a suspected outbreak i.e. that the provisions in chapters 1.1.3. and 2.1.15. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

4.1. Is rinderpest laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow up procedures and the time frame for obtaining results.

4.2. Provide an overview of the rinderpest approved laboratories, in particular to address the following points:

4.2.1. Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO etc. that exist in, or planned for, the laboratory system.

4.2.2. Give details of participation in inter-laboratory validation tests (ring tests).

4.2.3. Is live virus handled?

4.2.4. Biosecurity measures applied

4.2.5. Details of the type of tests undertaken

5. Rinderpest surveillance

Provide documentary evidence that surveillance for rinderpest in the country complies with the provisions of Articles 8.13.20. to 8.13.27. of the *Terrestrial Code* and chapter 2.1.15. of the *Terrestrial Manual*. In particular, the following points should be addressed:

5.1. Clinical suspicion. What are the criteria for raising a suspicion of rinderpest? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspect cases, the number of samples tested for rinderpest virus, species, type of sample, testing method(s) and results (including differential diagnosis). In particular, provide evidence of compliance with the provisions of Articles 8.13.20. to 8.13.27. of the *Terrestrial Code*.

5.2. Serological surveillance. Are serological surveys conducted? If so, provide detailed information on the survey design in accordance with Articles 8.13.20. to 8.13.27. of the *Terrestrial Code*[2]. Are wildlife susceptible species included in serological surveys? If not, explain the rationale. Provide a summary table indicating, for the past two years, the number of samples tested for rinderpest virus, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted surveillance and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the surveillance system including indicators.

5.3. Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many herds, flocks, etc., of each susceptible species are in the country? How are they distributed (e.g., herd density, etc.)? Provide tables and maps as appropriate.

5.4. Wildlife demographics. What susceptible species are present in the country? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?

5.5. Slaughterhouses and markets. Where are the major livestock marketing or collection centers? What are the patterns of livestock movement within the country? How are the animals transported and handled during these transactions.

6. Rinderpest prevention

6.1. Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries that should be taken into account (e.g., size, distance from adjacent border to affected herds or animals)? Describe coordination, collaboration and information sharing activities with neighbouring countries.

6.2. Import control procedures

From what countries or zones does the country authorize the import of susceptible animals or their products? What criteria are applied to approve such countries or zones? What controls are applied on entry of such animals and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported animals of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible animals and their products for the past two years, specifying country or zone of origin, species and volume.

6.2.1. Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central veterinary services. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

[2] Accounts of the ages for eruption of the incisor teeth vary markedly and are clearly dependent on species, breed, nutritional status and nature of the feed.
Therefore, for the purposes of serosurveillance, it should be noted that:
a) cattle having only one pair of erupted permanent central incisor teeth are aged between 21 and 36 months (Asian buffalos 24-48 months);
b) cattle having only two pairs of erupted permanent central incisor teeth are aged between 30 and 48 months (Asian buffalos 48-60 months).

6.2.2. Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow up of the following:

a) animals

b) genetic material (semen and embryos)

c) animal products

d) veterinary medicinal products (i.e. biologics)

6.2.3. Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

7.1. Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed outbreaks of rinderpest.

7.2. Is quarantine imposed on premises with suspicious cases, pending final diagnosis? What other procedures are followed regarding suspicious cases?

7.3. In the event of a rinderpest outbreak:

7.3.1 indicate the sampling and testing procedures used to identify and confirm presence of the causative agent.

7.3.2 describe the actions taken to control the disease situation in and around any holdings found to be infected with rinderpest,

7.3.3 indicate the control and/or eradication procedures (e.g. vaccination, stamping out, partial slaughter/vaccination etc) that would be taken,

7.3.4 describe the procedures used to confirm that an outbreak has been successfully controlled/eradicated, including any restrictions on restocking,

7.3.5 Give details of any compensation payments made available to farmers etc when animals are slaughtered for disease control/eradication purposes and their prescribed timetable.

8. Compliance with the *Terrestrial Code*

8.1. The Delegate of the country must submit documentary evidence that the provisions of Article 8.13.2. or 1.4.6.1. (historical freedom) of the *Terrestrial Code* have been properly implemented and supervised.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 8.13.3. of the *Terrestrial Code* and provide detailed information as specified in sections 3.1., 3.2., 3.3. and 5.2. of this questionnaire. Information in relation to other sections need only be supplied if relevant.

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CBPP FREE COUNTRY

Report of Country which applies for recognition of status, under Chapter 2.3.15 and Appendix 3.8.3 of the *Terrestrial Animal Health Code*, as a CBPP free country

Community comment

The Community can support the inclusion of the CBPP questionnaire in the Terrestrial Code.

Please address concisely the following topics. National regulations laws and *Veterinary Administration* directives may be referred to and annexed as appropriate in one of the OIE official languages

1. Introduction

1.1. Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to CBPP dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of disease. Provide a map identifying the factors above.

1.2. Livestock industry. Provide a general description of the livestock industry in the country.

2. Veterinary system

2.1. Legislation. Provide a list and summary of all relevant veterinary legislation in relation to CBPP.

2.2. *Veterinary Services.* Provide documentation on the compliance of the Veterinary Service of the country with the provisions of Chapters 1.3.3. and 1.3.4. of the *Terrestrial Code* and I.1.2 of the *Terrestrial Manual* and describe how the veterinary services supervise and control all CBPP related activities. Provide maps and tables wherever possible.

2.3. Role of farmers, industry and other relevant groups in CBPP surveillance and control (include a description of training and awareness programs on CBPP)

2.4. Role of private veterinary profession in CBPP surveillance and control

3. CBPP eradication

3.1. History. Provide a description of the CBPP history in the country, date of first detection, origin of infection, date of eradication (date of last case).

3.2. Strategy. Describe how CBPP was controlled and eradicated (e.g. stamping-out, modified stamping-out, zoning), provide timeframe for eradication

3.3. Vaccines and vaccination. Was CBPP vaccine ever used? If so, when was the last vaccination carried out?

3.4. Legislation, organisation and implementation of the CBPP eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.

3.5. Animal identification and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of animal identification, herd registration and traceability. How are animal movements controlled in the country? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and the related paths of movement.

4. CBPP diagnosis

Provide documentary evidence that the provisions in Chapters I.1.2 and 2.1.6. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

4.1. Is CBPP laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow up procedures and the time frame for obtaining results.

4.2. Provide an overview of the CBPP approved laboratories, in particular to address the following points:

4.2.1. Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO etc. that exist in, or planned for, the laboratory system

4.2.2. Give details of participation in inter-laboratory validation tests (ring tests).

4.2.3. Biosecurity measures applied

4.2.4. Details of the type of tests undertaken including procedures to isolate and identify *M. mycoides* subsp. *mycoides* SC as opposed to *M. mycoides* subsp. *mycoides* LC

5. CBPP surveillance

Provide documentary evidence that surveillance for CBPP in the country complies with the provisions of Appendix 3.8.3. of the *Terrestrial Code* and Chapter 2.1.6 of the *Terrestrial Manual*. In particular, the following points should be addressed:

5.1. Clinical surveillance. What are the criteria for raising a suspicion of CBPP? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspect cases, the number of samples tested for CBPP agent, species, type of sample, testing method(s) and results (including differential diagnosis).

5.2. Slaughterhouses, slaughter slabs, abattoirs. What are the criteria for raising a suspicion of CBPP lesion? What is the procedure to notify (by whom and to whom)? Provide a summary table indicating, for the past two years, the number of suspect cases, the number of samples tested for CBPP agent, species, type of sample, testing method(s) and results (including differential diagnosis).

5.3. Provide details on training programs for personnel involved in clinical and slaughter facilities surveillance, and the approaches used to increase community involvement in CBPP surveillance programs.

5.4. For countries where a significant proportion of animals are not slaughtered in controlled abattoirs, what are the alternative surveillance measures applied to detect CBPP (e.g. active clinical surveillance programs, laboratory follow up)

5.5. Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many herds of each susceptible species are in the country? How are they distributed (e.g., herd density, etc.)? Provide tables and maps as appropriate.

5.6. Slaughterhouses and markets. Where are the major livestock marketing or collection centers? What are the patterns of livestock movement within the country? How are the animals transported and handled during these transactions.

5.7. Provide a description of the means employed during the two years preceding this application to rule out the presence of any *Mmm*SC strain in the susceptible population. Provide criteria for selection of populations for targeted surveillance and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the surveillance system including indicators.

6. CBPP prevention

6.1. Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries that should be taken into account (e.g., size, distance from adjacent border to affected herds or animals)? Describe coordination, collaboration and information sharing activities with neighboring countries.

6.2. Import control procedures

From what countries or zones does the country authorize the import of susceptible animals? What criteria are applied to approve such countries or zones? What controls are applied on entry of such animals, and subsequent internal movement? What import conditions and test procedures are required? Are imported animals of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible animals for the past two years, specifying country or zone of origin, species and volume.

6.2.1. Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central veterinary services. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

6.2.2. Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow up of the following:

a) animals

b) veterinary medicinal products (i.e. biologics)

6.2.3. Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

7.1. Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed outbreaks of CBPP.

7.2. Is quarantine imposed on premises with suspicious cases, pending final diagnosis? What other procedures are followed regarding suspicious cases?

7.3. In the event of a CBPP outbreak:

7.3.1. indicate the sampling and testing procedures used to identify and confirm presence of the causative agent.

7.3.2. describe the actions taken to control the disease situation in and around any holdings found to be infected with CBPP,

7.3.3. indicate the control and/or eradication procedures (e.g. vaccination, stamping out, partial slaughter/vaccination etc.) that would be taken,

7.3.4. describe the procedures used to confirm that an outbreak has been successfully controlled/eradicated, including any restrictions on restocking,

7.3.5. give details of any compensation payments made available to farmers etc when animals are slaughtered for disease control/eradication purposes and their prescribed timetable.

8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of appendix 3.8.3 are properly implemented and supervised, the Delegate of the country must submit a declaration indicating:

8.1. no clinical CBPP has been detected for at least 2 years;

8.2. no CBPP vaccines have been used for at least 2 years in any susceptible species,

8.3. the country operates both clinical surveillance and disease reporting systems for CBPP adequate to detect clinical disease if it were present;

8.4. all clinical and pathological evidence suggestive of CBPP is investigated by field and laboratory methods (including serological assessment) to refute a possible diagnosis of CBPP;

8.5. there are effective measures in force to prevent the re-introduction of the disease.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 2.3.15.3 of the *Terrestrial Code* and provide detailed information as specified in sections 3.1, 3.2, 3.3, 5.2, 5.3 and 5.4 of this report. Information in relation to other sections need only be supplied if relevant.

CBPP FREE ZONE

Report of a Country which applies for recognition of status, under Chapter 2.3.15.~~3~~ and Appendix 3.8.3 of the *Terrestrial Animal Health Code*, for a CBPP free zone

Please address concisely the following topics. National regulations laws and *Veterinary Administration* directives may be referred to and annexed as appropriate in one of the OIE official languages

1. Introduction

1.1. Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to CBPP dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of disease. Provide a map identifying the factors above. The boundaries of the zone must be clearly defined. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the zone.

1.2. Livestock industry. Provide a general description of the livestock industry in the country.

2. Veterinary system

2.1. Legislation. Provide a list and summary of all relevant veterinary legislation in relation to CBPP.

2.2. *Veterinary Services.* Provide documentation on the compliance of the Veterinary Service of the country with the provisions of Chapters 1.3.3. and 1.3.4. of the *Terrestrial Code* and I.1.2 of the *Terrestrial Manual* and describe how the veterinary services supervise and control all CBPP related activities. Provide maps and tables wherever possible.

2.3. Role of farmers, industry and other relevant groups in CBPP surveillance and control (include a description of training and awareness programs on CBPP)

2.4. Role of private veterinary profession in CBPP surveillance and control

3. CBPP eradication

3.1. History. Provide a description of the CBPP history in the country, date of first detection, origin of infection, date of eradication (date of last case).

3.2. Strategy. Describe how CBPP was controlled and eradicated in the zone (e.g. stamping-out, modified stamping-out, zoning), provide timeframe for eradication

3.3. Vaccines and vaccination. Was CBPP vaccine ever used? In the entire country? If vaccination was used, when was the last vaccination carried out? Where in the country?

3.4. Legislation, organisation and implementation of the CBPP eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.

3.5. Animal identification and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of animal identification, herd registration and traceability. How are animal movements controlled in the zone? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and the related paths of movement.

4. CBPP diagnosis

Provide documentary evidence that the provisions in Chapters I.1.2 and 2.1.6. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

4.1. Is CBPP laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow up procedures and the time frame for obtaining results.

4.2. Provide an overview of the CBPP approved laboratories, in particular to address the following points:

4.2.1. Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO etc. that exist in, or planned for, the laboratory system

4.2.2. Give details of participation in inter-laboratory validation tests (ring tests). .

4.2.3. Biosecurity measures applied

4.2.4. Details of the type of tests undertaken including procedures to isolate and identify *M. mycoides* subsp. *mycoides* SC as opposed to *M. mycoides* subsp. *mycoides* LC

5. CBPP surveillance

Provide documentary evidence that surveillance for CBPP in the country complies with the provisions of Appendix 3.8.3. of the *Terrestrial Code* and Chapter 2.1.6 of the *Terrestrial Manual*. In particular, the following points should be addressed:

5.1. Clinical surveillance. What are the criteria for raising a suspicion of CBPP? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspect cases, the number of samples tested for CBPP agent, species, type of sample, testing method(s) and results (including differential diagnosis).

5.2. Slaughterhouses, slaughter slabs, abattoirs. What are the criteria for raising a suspicion of CBPP lesion? What is the procedure to notify (by whom and to whom)? Provide a summary table indicating, for the past two years, the number of suspect cases, the number of samples tested for CBPP agent, species, type of sample, testing method(s) and results (including differential diagnosis).

5.3. Provide details on training programs for personnel involved in clinical and slaughter facilities surveillance, and the approaches used to increase community involvement in CBPP surveillance programs.

5.4. For countries where a significant proportion of animals in the zone are not slaughtered in controlled abattoirs, what are the alternative surveillance measures applied to detect CBPP (e.g. active clinical surveillance program, laboratory follow up)

5.5. Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many herds of each susceptible species are in the zone? How are they distributed (e.g., herd density, etc.)? Provide tables and maps as appropriate.

5.6. Slaughterhouses and markets. Where are the major livestock marketing or collection centers? What are the patterns of livestock movement within the country and the zone? How are the animals transported and handled during these transactions.

5.7. Provide a description of the means employed during the two years preceding this application to rule out the presence of any *Mmm*SC strain in the susceptible population of the zone. Provide criteria for selection of populations for targeted surveillance and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the surveillance system including indicators.

6. CBPP prevention

6.1. Coordination with neighbouring countries and zones. Are there any relevant factors about the adjacent countries and zones that should be taken into account (e.g., size, distance from adjacent border to affected herds or animals)? Describe coordination, collaboration and information sharing activities with neighboring countries and zones. If the CBPP free zone is situated in a CBPP infected country or borders an infected country or zone, describe the animal health measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers.

6.2. Import control procedures

From what countries or zones does the country authorize the import of susceptible animals? What criteria are applied to approve such countries or zones? What controls are applied on entry of such animals, and subsequent internal movement? What import conditions and test procedures are required? Are imported animals of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible animals for the past two years, specifying country or zone of origin, species and volume.

6.2.1. Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central veterinary services. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

6.2.2. Describe the regulations, procedures, type and frequency of checks at the point of entry into the zone and/or their final destination, concerning the import and follow up of the following:

a) animals

b) veterinary medicinal products (i.e. biologics)

6.2.3. Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

Annex XXXV (contd)

7. Control measures and contingency planning

7.1. Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed outbreaks of CBPP.

7.2. Is quarantine imposed on premises with suspicious cases, pending final diagnosis? What other procedures are followed regarding suspicious cases?

7.3. In the event of a CBPP outbreak:

7.3.1. indicate the sampling and testing procedures used to identify and confirm presence of the causative agent,

7.3.2. describe the actions taken to control the disease situation in and around any holdings found to be infected with CBPP,

7.3.3. indicate the control and/or eradication procedures (e.g. vaccination, stamping out, partial slaughter/vaccination etc.) that would be taken,

7.3.4. describe the procedures used to confirm that an outbreak has been successfully controlled/eradicated, including any restrictions on restocking,

7.3.5. give details of any compensation payments made available to farmers etc when animals are slaughtered for disease control/eradication purposes.

8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of appendix 3.8.3 are properly implemented and supervised, the Delegate of the country must submit a declaration indicating that in the zone:

8.1. no clinical CBPP has been detected for at least 2 years;

8.2. no CBPP vaccines have been used for at least 2 years in any susceptible species,

8.3. the country operates both clinical surveillance and disease reporting systems for CBPP adequate to detect clinical disease if it were present in the zone;

8.4. all clinical and pathological suggestive of CBPP is investigated by field and laboratory methods (including serological assessment) to refute a possible diagnosis of CBPP;

8.5. there are effective measures in force to prevent the re-introduction of the disease.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 2.3.15.3 of the *Terrestrial Code* and provide detailed information as specified in sections 3.1, 3.2, 3.3, 5.2, 5.3 and 5.4 of this report. Information in relation to other sections need only be supplied if relevant.